This document is scheduled to be published in the Federal Register on 08/03/2023 and available online at **federalregister.gov/d/2023-15945**, and on **govinfo.gov**

DEPAR

Internal Revenue Service

26 CFR Part 54

[REG-120727-21]

RIN 1545-BQ29

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AC11

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146 and 147

[CMS-9902-P]

RIN 0938-AU93

Requirements Related to the Mental Health Parity and Addiction Equity Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Proposed rules.

SUMMARY: This document proposes amendments to regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and proposes new regulations implementing the nonquantitative treatment limitation (NQTL) comparative analyses requirements under MHPAEA, as amended by the Consolidated Appropriations Act, 2021 (CAA, 2021). Specifically, these proposed rules would amend the existing NQTL standard to prevent plans and issuers from using NQTLs to place greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As part of these changes, these proposed rules would require plans and issuers to collect

and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits, and would set forth a special rule with regard to network composition. These proposed rules would also amend existing examples and add new examples on the application of the rules for NQTLs to clarify and illustrate the protections of MHPAEA. Additionally, these proposed rules would set forth the content requirements for NQTL comparative analyses and specify how plans and issuers must make these comparative analyses available to the Department of the Treasury (Treasury), the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, the Departments), as well as to an applicable State authority, and participants, beneficiaries, and enrollees. The Departments also solicit comments on whether there are ways to improve the coverage of mental health and substance use disorder benefits through other provisions of Federal law. Finally, HHS proposes regulatory amendments to implement the sunset provision for self-funded, non-Federal governmental plan elections to opt out of compliance with MHPAEA, as adopted in the Consolidated Appropriations Act, 2023 (CAA, 2023).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to the address specified below. Any comment that is submitted will be shared with Treasury, Internal Revenue Service (IRS), and HHS. Please do not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions,

modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code 1210-AC11. Because of staff and resource limitations, the Departments cannot accept comments by facsimile (FAX) transmission.

Comments must be submitted in one of the following two ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to https://www.regulations.gov. Follow the "Submit a comment" instructions.

2. By mail. You may mail written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* 1210-AC11.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The comments are posted on the following website as soon as possible after they have been received: https://www.regulations.gov. Follow the search instructions on that website to view public comments.

FOR FURTHER INFORMATION CONTACT: Shira McKinlay, Internal Revenue Service, Department of the Treasury, at 202-317-5500; Beth Baum or David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; David Mlawsky, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 410-786-6851.

Customer Service Information:

Individuals interested in obtaining information from DOL concerning private employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website (www.dol.gov/agencies/ebsa).

In addition, information from HHS on private health insurance coverage and coverage provided by self-funded, non-Federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (www.cms.gov/cciio), and information on health care reform can be found at www.Healthcare.gov or https://www.hhs.gov/healthcare/index.html. In addition, information about mental and behavioral health and addiction is available at https://www.samhsa.gov/mental-health and https://www.samhsa.gov/find-support.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Mental health is essential to personal and societal wellbeing. America is experiencing a mental health and substance use disorder crisis[1] that worsened during the COVID-19 pandemic.[2] This crisis impacts both children and adults across various demographics nationwide and disproportionately affects marginalized and underserved communities. Recent data from the Centers for Disease Control and Prevention (CDC) indicate that, between August 2020 and February 2021, the percentage of adults exhibiting symptoms of an anxiety or depressive disorder increased significantly, from 36.4 percent to 41.5 percent.[3]

---

[1] Department of Health and Human Services (2023). SAMHSA Announces National Survey on Drug Use and Health (NSDUH) Results Detailing Mental Illness and Substance Use Levels in 2021. Retrieved from https://www.hhs.gov/about/news/2023/01/04/samhsa-announces-national-survey-drug-use-health-results-detailing-mental-illness-substance-use-levels-2021.html.

[2] Vahratian, A., Blumberg, S. J., Terlizzi, E. P., Schiller, J. S. (2021). Symptoms of Anxiety or Depressive Disorder and Use of Mental Health Care Among Adults During the COVID-19 Pandemic — United States, August 2020–February 2021. MMWR Morb Mortal Wkly Rep 2021;70:490–494. DOI: http://dx.doi.org/10.15585/mmwr.mm7013e2.

[3] *Id*.

Similarly, the overdose and substance use disorder epidemic has worsened in recent years. Overdose death numbers have risen substantially since 2015, reaching a then-historic high of 70,630 deaths nationally in 2019 and growing to a reported value of 107,421 overdose deaths in the 12-month period ending in July 2022.[4] Additionally, from 1999 through 2019, the rate of drug overdose deaths increased from 4.0 per 100,000 to 19.6 in rural counties,[5] and in 2020, the age-adjusted rate of drug overdose deaths increased to 26.2 per 100,000 in rural counties.[6] The number of people who died from drug overdoses in 2021 increased by approximately 36,000 over the prior 2 years.[7] During the first year of the COVID-19 pandemic, the overdose death rates were highest for American Indians and Alaska Natives and Black or African Americans, exceeding the overdose death rate for White people by about 30 and 16 percent, respectively.[8] While Hispanic and Latino people saw the lowest overdose death rates, those rates still increased in 2020.[9]

As noted above, both children and adolescents are also impacted by this mental health and substance use disorder crisis. Prior to the COVID-19 public health emergency (PHE), millions of children ages 12 to 17 reported experiencing at least one major depressive episode or severe major depression.[10] Suicidal behavior among children has increased sharply; known suicide attempts by ingestion alone in children ages 10 to 12 increased by about 450 percent

---

[4] Hedegaard, H., Miniño, A. M., Wagner, M. (2020). Drug Overdose Deaths in the United States, 1999-2019. NCHS Data Brief No. 304 (December 2020) https://www.cdc.gov/nchs/data/databriefs/db394-H.pdf; Centers for Disease Control and Prevention, National Center for Health Statistics. Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts. Available at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm. Accessed on July 14, 2023.

[5] Hedegaard H, Spencer MR. Urban–rural differences in drug overdose death rates, 1999–2019. NCHS Data Brief, no 403. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: https://dx.doi.org/10.15620/cdc:102891.

[6] Spencer MR, Garnett MF, Miniño AM. Urban–rural differences in drug overdose death rates, 2020. NCHS Data Brief, no 440. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: https://dx.doi.org/10.15620/cdc:118601.

[7] National Vital Statistics System. Provisional Drug Overdose Death Counts. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.

[8] Friedman, Joseph R, and Helena Hansen (2022). Research Letter: Evaluation of Increases in Drug Overdose Mortality Rates in the US by Race and Ethnicity Before and During the COVID-19 Pandemic. JAMA Psychiatry. https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2789697?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamapsychiatry.2022.0004.

[9] *Id.*

[10] Mental Health America (2022). Youth Ranking 2022. https://mhanational.org/issues/2022/mental-health-america-youth-data.

from 2010 to 2020.[11] Suicide rates among Black or African American children below age 13 increased rapidly from 2001 to 2015, and those children are nearly twice as likely to die by suicide than White children of the same age.[12] Additionally, one survey, conducted from September 20 to December 31, 2021, notes that 45 percent of Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) youth respondents ages 13 to 24 seriously considered attempting suicide in the past year,[13] including nearly half of multiracial LGBTQ youth respondents.[14] A sharp rise in eating disorders throughout the COVID-19 PHE also demonstrates the extent of this crisis for young people.[15] Emergency department visits for adolescent girls ages 12-17 with eating disorders doubled in January 2022 as compared to 2019,[16] and children are beginning to experience eating disorders at younger ages.[17] In addition, in 2021, nearly 3 in 5 teen girls felt persistently sad or hopeless, the highest level reported over the past decade.[18]

Americans are too frequently discouraged from and forgo seeking mental health and substance use disorders care because of barriers, both inside and outside of the health care

---

[11] Sheridan D, Grusing S, Marshall R. (2022) Changes in Suicidal Ingestion Among Preadolescent Children from 2000 to 2020. JAMA Pediatrics. https://jamanetwork.com/journals/jamapediatrics/article-abstract/2789948; *see also* CDC, Youth Risk Behavior Survey, available at https://www.cdc.gov/healthyyouth/data/yrbs/pdf/YRBS_Data-Summary-Trends_Report2023_508.pdf.

[12] Bridge JA, Horowitz LM, Fontanella CA, et al. (2018). Age-Related Racial Disparity in Suicide Rates Among US Youths From 2001 Through 2015. JAMA Pediatrics. https://jamanetwork.com/journals/jamapediatrics/fullarticle/2680952.

[13] The Trevor Project (2022). 2022 National Survey on LGBTQ Youth Mental Health. https://www.thetrevorproject.org/survey-2022/.

[14] The Trevor Project (2022). The Mental Health and Well-Being of Multiracial LGBTQ Youth. https://www.thetrevorproject.org/research-briefs/the-mental-health-and-well-being-of-multiracial-lgbtq-youth-aug-2022/.

[15] Radhakrishnan L, Leeb R, Bitsko R, Carey K, Gates A, Holland K, Hartnett K, Kite-Powell A, DeVies J, Smith A, van Santen K, Crossen S, Sheppard M, Wotiz S, Lane R, Njai R, Johnson A, Winn A, Kirking H, Rodgers L, Thomas C, Soetebier K, Adjemian J, Anderson K. (2022) Pediatric Emergency Department Visits Associated with Mental Health Conditions Before and During the COVID-19 Pandemic — United States, January 2019–January 2022. MMWR Morb Mortal Wkly Rep 2022; 71(8);319-324. https://www.cdc.gov/mmwr/volumes/71/wr/mm7108e2.htm.

[16] *Id.*

[17] Stuart B. Murray, Aaron J. Blashill, and Jerel P. Calzo (2022). Prevalence of Disordered Eating and Associations With Sex, Pubertal Maturation, and Weight in Children in the US, available at https://jamanetwork.com/journals/jamapediatrics/article-abstract/2794847.

[18] Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, U.S. Teen Girls Experiencing Increased Sadness and Violence (Feb. 13, 2023), available at https://www.cdc.gov/nchhstp/newsroom/2023/increased-sadness-and-violence-press-release.html.

system, such as discrimination, stigmatization,[19] inability to find an in-network provider accepting new patients,[20] cost, and geography. These barriers are particularly problematic for young adults ages 18-34, who are less likely to believe their mental health symptoms are well-managed than older adults,[21] and for people seeking substance use disorder treatment.[22] One survey reports that less than seven percent of people in need of substance use disorder treatment received care at a specialty facility and less than 10 percent received "any treatment,"[23] while only about 19 percent of people with opioid use disorder in 2021 received life-saving medications.[24] Sixty percent of rural Americans live in mental health professional shortage areas.[25] Additionally, non-metropolitan adults were more likely than metropolitan adults (43.7% vs. 34.5%) to see a general practitioner or family doctor, as opposed to a mental health specialist, for depressive symptoms, and among non-metropolitan adults with depression, fewer than 20 percent received treatment from a mental health professional.[26]

Moreover, against the backdrop of this mental health and substance use disorder crisis, when patients seek benefits under their health plan or coverage, they often find that coverage for treatment of mental health conditions or substance use disorders operates in a separate—and too

---

[19] Van Boekel, L. C., Brouwers, E. P., van Weeghel, J., & Garretsen, H. F. (2013). Stigma among health professionals towards patients with substance use disorders and its consequences for healthcare delivery: systematic review. Drug and Alcohol Dependence, 131(1-2), 23–35. DOI: 10.1016/j.drugalcdep.2013.02.018, available at https://pubmed.ncbi.nlm.nih.gov/23490450/.

[20] *Cf.* Jack Turbin. Ghost networks of psychiatrists make money for insurance companies but hinder patients' access to care. Stat News, June 17, 2019, https://www.statnews.com/2019/06/17/ghost-networks-psychiatrists-hinder-patient-care/

[21] National Alliance on Mental Illness (2021). Mood Disorder Survey Report. https://nami.org/NAMI/media/NAMI-Media/Research/NAMI-Mood-Disorder-Survey-White-Paper.pdf.

[22] Esther Adeniran, Megan Quinn, Richard Wallace, Rachel R. Walden, Titilola Labisi, Afolakemi Olaniyan, Billy Brooks, Robert Pack (2023). A scoping review of barriers and facilitators to the integration of substance use treatment services into US mainstream health care, Drug and Alcohol Dependence Reports; Volume 7, 100152 https://www.sciencedirect.com/science/article/pii/S2772724623000227.

[23] Center for Behavioral Health Statistics and Quality (2022), Results from the 2021 National Survey on Drug Use and Health: Detailed Tables, Substance Abuse and Mental Health Services Administration, available at https://www.samhsa.gov/data/report/2021-nsduh-detailed-tables. For this purpose, "any treatment" includes having participated in a mutual aid group, such as Alcoholics Anonymous, Narcotics Anonymous, or SMART Recovery, and receiving services in a hospital through primary care.

[24] *Id.*

[25] Health Resources and Services Administration, Designated Health Professional Shortage Areas Statistics (data updated through June 30, 2023), available at https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport (last accessed July 18, 2023).

[26] Borders, TF. Major Depression, Treatment Receipt, and Treatment Sources among Non-Metropolitan and Metropolitan Adults. Lexington, KY: Rural and Underserved Health Research Center; 2020. Available at https://www.ruralhealthresearch.org/publications/1348.

often disparate—system than their health plan's coverage for treatment of medical/surgical conditions.[27] These disparities exacerbate the hardships faced by people living with mental health conditions and substance use disorders. The disparities also can magnify the challenges faced by the parents, children, and loved ones of people living with mental health conditions or substance use disorders as well as those who care for them, who are profoundly affected by the person's illness and their difficulties in getting, or inability to get, coverage for needed care.[28]

Ensuring meaningful access to mental health and substance use disorder care is vital to addressing the Nation's mental health and substance use disorder crisis. A key component of access is the availability of an adequate number of appropriate providers within a plan's network. A survey of adults with private health coverage found that plan participants were more likely to perceive their mental health provider networks as inadequate when compared to medical provider networks.[29] Furthermore, another survey noted that most plan participants reported choosing mental health services from out-of-network mental health providers based on provider quality issues.[30]

A 2019 Milliman report found a growing disparity in the utilization of out-of-network behavioral health care (which the report uses to refer to care for mental health conditions and substance use disorders) providers relative to out-of-network medical/surgical care providers.[31]

---

[27] *See, generally*, Commonwealth Fund, Behavioral Health Care in the United States: How It Works and Where It Falls Short, available at https://www.commonwealthfund.org/publications/explainer/2022/sep/behavioral-health-care-us-how-it-works-where-it-falls-short.

[28] *See* National Alliance on Mental Illness, Mental Health By the Numbers, available at https://www.nami.org/mhstats (showing 8.4 million people in the U.S. provide care to an adult with a mental or emotional health issue); KFF, KFF/CNN Mental Health In America Survey, available at https://www.kff.org/other/report/kff-cnn-mental-health-in-america-survey/ (showing half of adults say they have had a severe mental health crisis in their family); California Health Care Foundation, In Their Own Words: How Fragmented Care Harms People with Both Mental Illness and Substance Use Disorder, available at https://www.chcf.org/publication/fragmented-care-harms-people-mental-illness-substance-use-disorder/.

[29] *See* Busch, Susan H. and Kelly Kyanko, Assessment of Perception of Mental Health vs. Medical Health Plan Networks Among US Adults with Private Insurance, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8536951/.

[30] *See* Kelly A. Kyanko, Leslie A. Curry, and Susan H. Busch, Out-of-Network Providers Use More Likely in Mental Health than General Health Care Among Privately Insured, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4707657/.

[31] Melek, S., Davenport, S., Gray, T. J. (2019). Addiction and mental health vs. physical health: Widening disparities in network use and provider reimbursement (p. 6). Milliman. https://assets.milliman.com/ektron/Addiction_and_mental_health_vs_physical_health_Widening_disparities_in_network_use_and_provider_reimbursement.pdf.

The same report found that the disparity between how often out-of-network behavioral health inpatient facilities were used relative to out-of-network medical/surgical inpatient facilities had increased 85 percent between 2013 and 2017 for people with commercial preferred provider organization (PPO) health plans. Over the same period, there were also increasing disparities in the use of out-of-network outpatient facilities and office visits for mental health and substance use disorder treatment relative to the use of out-of-network outpatient facilities and office visits for medical/surgical care.[32] The report additionally noted a growing disparity in reimbursement rates (as a percentage of Medicare-allowed amounts) between in-network mental health and substance use disorder providers and medical/surgical providers. Primary care reimbursements were, on average, 23.8 percent higher than behavioral health office visit reimbursements relative to Medicare allowed amounts in 2017—up from a 20.8 percent difference in 2015.[33] Low reimbursement rates for behavioral health providers and high demand for services, among other factors, contribute to this difficulty finding in-network providers,[34] which can stifle efforts to receive necessary care for mental health conditions or substance use disorders.

MHPAEA's fundamental purpose is to ensure that individuals in group health plans or with group or individual health insurance coverage who seek treatment for covered mental health conditions or substance use disorders do not face greater barriers to accessing benefits for such mental health conditions or substance use disorders than they would face when seeking coverage for the treatment of a medical condition or for a surgical procedure.[35] Such barriers are particularly problematic when they effectively result in the loss of benefits that the plan or issuer

---

[32] *Id.*

[33] *Id.* at pp. 6-7.

[34] *See* Busch, Susan H. and Kelly Kyanko, Assessment of Perception of Mental Health vs. Medical Health Plan Networks Among US Adults with Private Insurance, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8536951/.

[35] In a floor statement, Representative Patrick Kennedy (D-RI), one of the chief architects of MHPAEA, made the case for its passage on the grounds that "access to mental health services is one of the most important and most neglected civil rights issues facing the Nation. For too long, persons living with mental disorders have suffered from discriminatory treatment at all levels of society" 153 Cong. Rec. S1864-5 (daily ed. Feb. 12, 2007). Cf. H. Rept. 110-374, Part 3, available at https://www.congress.gov/congressional-report/110th-congress/house-report/374. ("The purpose of H.R. 1424, the 'Paul Wellstone Mental Health and Addiction Equity Act of 2007' is to have fairness and equity in the coverage of mental health and substance-related disorders vis-a-vis coverage for medical and surgical disorders.")

purports to make available and that individuals reasonably expect to be covered, and they contravene MHPAEA's clear mandate that the financial requirements and treatment limitations applicable to mental health benefits or substance use disorder benefits be "no more restrictive" than the predominant requirements and limitations applicable to substantially all medical/surgical benefits.[36]

MHPAEA was enacted as bipartisan legislation reflecting what Congress saw as a shared public concern: that it is wrong to place greater burdens on people in need of mental health and substance use disorder treatment than people in need of medical/surgical treatment under the same health coverage. However, almost 15 years after MHPAEA's enactment, disparities persist, as people face greater barriers when accessing benefits for mental health and substance use disorders under their plan or coverage than they do when accessing medical/surgical benefits. The Departments' experience since the MHPAEA final regulations were issued in 2013 (2013 final regulations) (78 FR 68240 (Nov. 13, 2013)) has shown that too often, group health plans and health insurance issuers offering group or individual health insurance coverage are not operating in compliance with MHPAEA, which can have devastating consequences for individuals with mental health conditions and substance use disorders and their families. The Departments continue to receive and investigate complaints that plans and issuers fail to comply with MHPAEA, by continuing to restrict access to benefits for mental health conditions and substance use disorders in ways that are more onerous and limiting than for medical or surgical care. As reflected in recent reports to Congress on MHPAEA compliance, the Departments found nearly all plans or issuers audited for MHPAEA compliance could not demonstrate compliance with the law's obligations in response to an initial request for NQTL comparative analyses.[37] As a result of these failures, participants and beneficiaries routinely encounter

---

[36] Internal Revenue Code (Code) section 9812(a)(3)(A), Employee Retirement Income Security Act of 1974 (ERISA) section 712(a)(3)(A), and Public Health Service Act (PHS Act) section 2726(a)(3)(A).

[37] 2022 MHPAEA Report to Congress, p. 4, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf and https://www.cms.gov/files/document/2022-mhpaea-report-congress.pdf; 2023 MHPAEA

additional barriers to access and are denied needed and potentially lifesaving care for opioid use disorder, eating disorders, autism spectrum disorder (ASD), anxiety, depression, and other mental health conditions and substance use disorders. The harm to these participants and beneficiaries, and to their families, friends, co-workers, and others, is incalculable.

In the last 2 years, the Departments have made an unprecedented commitment to advance parity for mental health and substance use disorder care by making it a top enforcement priority, especially with respect to NQTLs.[38] Specifically, EBSA, which has primary enforcement jurisdiction over MHPAEA for approximately 2.5 million private, employment-based group health plans covering approximately 133 million individuals, is taking extraordinary steps to enforce mental health and substance use disorder parity requirements and ensure that it is using its full authority to help participants and beneficiaries receive equitable coverage for mental health and substance use disorder treatment. Similarly, CMS continues to prioritize its MHPAEA enforcement activities with respect to non-Federal governmental plans nationwide[39] and health insurance issuers offering group and individual health insurance coverage in States where CMS is the direct enforcer of MHPAEA with respect to issuers.[40, 41]

In addition to using their enforcement authority, the Departments continue to work to reduce the stigma and discrimination that individuals with mental health conditions and substance use disorders face, raise awareness so these individuals can receive the treatment they need and the benefits to which they are entitled, and engage consumer advocates, members of the

---

Comparative Analysis Report to Congress, July 2023 (2023 MHPAEA Report to Congress), available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf and https://www.cms.gov/cciio/resources/forms-reports-and-other-resources#mental-health-parity.

[38] As discussed in more detail later in this preamble, NQTLs are generally non-numerical requirements that limit the scope or duration of benefits, such as prior authorization requirements, step therapy, and standards for provider admission to participate in a network, including methodologies for determining reimbursement rates.

[39] PHS Act section 2723(b).

[40] PHS Act section 2723(a).

[41] CMS currently enforces MHPAEA with respect to issuers in Texas and Wyoming. In addition, CMS has collaborative enforcement agreements with Alabama, Florida, Louisiana, Montana, and Wisconsin. These States with collaborative enforcement agreements with CMS perform State regulatory and oversight functions with respect to some or all of the applicable provisions of title XXVII of the PHS Act, including MHPAEA. However, if the State finds a potential violation and is unable to obtain compliance by an issuer, the State will refer the matter to CMS for possible enforcement action.

regulated community, State regulators, and other interested parties to inform the Departments' efforts in addressing the nation's mental illness and substance use disorder epidemic. These efforts have helped to deepen the Departments' understanding of the barriers to mental health and substance use disorder treatment Americans face, inform DOL's and HHS's MHPAEA enforcement approach, and connect advocacy groups to government resources.

The Departments have also continued to help plans, issuers, consumers, providers, States, and other interested parties understand and comply with MHPAEA's requirements, including the NQTL comparative analysis requirements. Additionally, the Departments have worked to help families, caregivers, and individuals understand the law and benefit from it, as Congress intended.

Since the promulgation of the 2013 final regulations on November 13, 2013,[42] the Departments have provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties to facilitate the implementation and enforcement of MHPAEA, as discussed later in this preamble, including

[42] 78 FR 68240 (Nov. 13, 2013).

numerous sets of Frequently Asked Questions (FAQs),[43] fact sheets,[44] compliance assistance tools,[45] templates,[46] reports,[47] and publications.[48] Despite this unprecedented outreach, plans and

---

[43] *See, e.g.*, FAQs About Affordable Care Act Implementation Part V and Mental Health Parity Implementation (Dec. 22, 2010), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-v.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-5; FAQs About Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation (Nov. 17, 2011), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-vii.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-7; Understanding Implementation of the Mental Health Parity and Addiction Equity Act of 2008 (May 9, 2012), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/understanding-implementation-of-mhpaea.pdf; FAQs for Employees about the Mental Health Parity and Addiction Equity Act (May 18, 2012), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/mhpaea-2.pdf; FAQs About Affordable Care Act Implementation (Part XVII) and Mental Health Parity Implementation (Nov. 8, 2013), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xvii.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-17; FAQs About Affordable Care Act Implementation (Part XVIII) and Mental Health Parity Implementation (Jan. 9, 2014), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xviii.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-18; FAQs About Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation (Oct. 23, 2015), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxix.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-29 (FAQs Part XXIX); FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (Apr. 20, 2016), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-31; FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation (Oct. 27, 2016), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-34 (FAQs Part 34); FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 38 (June 16, 2017), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-38.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-38 (FAQs Part 38); Proposed FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-proposed.pdf (Proposed FAQs Part 39); Final FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39 (Sept. 5, 2019), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf and https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-final-set-39 (FAQs Part 39); FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43 (June 23, 2020), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf and https://www.hhs.gov/guidance/document/faqs-about-families-first-coronavirus-response-act-and-coronavirus-aid-relief-and-0 (FAQs part 43); FAQs About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-FAQs-Part-45.pdf (FAQs Part 45); and Mental Health Parity and Addiction Equity Act (MHPAEA) FAQs, available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/mhpaea-1#.

[44] *See, e.g.*, The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) Fact Sheet (Jan. 2010), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea.pdf; MHPAEA Enforcement Fact Sheet (Jan. 2016), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement.pdf; FY 2016 MHPAEA Enforcement Fact Sheet, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2016.pdf; FY 2017 MHPAEA Enforcement Fact Sheet, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2017.pdf; FY 2018 MHPAEA Enforcement Fact Sheet, available at

https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/fact-sheets/mhpaea-enforcement-2018.pdf; FY 2019 MHPAEA Enforcement Fact Sheet, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/mhpaea-enforcement-2019.pdf and https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/mhpaea-enforcement-2019.pdf; FY 2020 MHPAEA Enforcement Fact Sheet, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/mhpaea-enforcement-2020.pdf and https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/mhpaea-enforcement-2020.pdf; FY 2021 MHPAEA Enforcement Fact Sheet, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/mhpaea-enforcement-2021.pdf; and FY 2022 MHPAEA Enforcement Fact Sheet, available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/mhpaea-enforcement-2022.pdf.

[45] *See* Self-Compliance Tool for Part 7 of ERISA: Health Care-Related Provisions, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-appendix-a.pdf; 2018 Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA), available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool-2018.pdf; and 2020 Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA), available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.

[46] *See* Form to Request Documentation from an Employer-Sponsored Health Plan or a Group or Individual Market Insurer Concerning Treatment Limitations, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/mhpaea-disclosure-template.pdf.

[47] *See, e.g.*, DOL 2012 Report to Congress: Compliance With the Mental Health Parity and Addiction Equity Act of 2008 (Jan. 1, 2012), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/mhpaea-report-to-congress-2012.pdf; DOL 2014 Report to Congress: Compliance of Group Health Plans (and Health Insurance Coverage Offered in Connection with Such Plans With the Requirements of the Mental Health Parity and Addiction Equity Act of 2008 (Sept. 2014), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/mhpaea-report-to-congress-2014.pdf; DOL 2016 Report to Congress: Improving Health Coverage for Mental Health and Substance Use Disorder Patients Including Compliance with the Federal Mental Health and Substance Use Disorder Parity Provisions (Jan. 2016), available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/improving-health-coverage-for-mental-health-and-substance-use-disorder-patients.pdf; HHS Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) Enforcement Report (Dec. 12, 2017), available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HHS-2008-MHPAEA-Enforcement-Period.pdf; DOL 2018 Report to Congress: Pathway to Full Parity, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/dol-report-to-congress-2018-pathway-to-full-parity.pdf; 21st Century Cures Act: Section 13002 Action Plan for Enhanced Enforcement of Mental Health and Substance Use Disorder Coverage, available at https://www.hhs.gov/sites/default/files/parity-action-plan-b.pdf; HHS Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) Enforcement Report for the 2018 Federal Fiscal Year, available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/FY2018-MHPAEA-Enforcement-Report.pdf; DOL 2020 Report to Congress: Parity Partnerships: Working Together, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/dol-report-to-congress-parity-partnerships-working-together.pdf; 2022 Report to Congress: Realizing Parity, Reducing Stigma, and Raising Awareness, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf and https://www.cms.gov/files/document/2022-mhpaea-report-congress.pdf; MHPAEA Comparative Analysis Report to Congress, July 2023, available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf and https://www.cms.gov/cciio/resources/forms-reports-and-other-resources#mental-health-parity.

[48] *See* Consumer Guide to Disclosure Rights: Making the Most of Your Mental Health and Substance Use Disorder Benefits, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/disclosure-guide-making-the-most-of-your-mental-health-and-substance-use-disorder-benefits.pdf; Know Your Rights: Parity for Mental Health and Substance Use Disorder Benefits, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/know-your-rights-parity-for-mental-health-and-substance-use-disorder-benefits.pdf; Parity of Mental Health and Substance Use Benefits with Other Benefits: Using Your Employer-Sponsored Health Plan to Cover Services, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/parity-of-mental-health-and-substance-use-benefits-with-other-benefits.pdf; Understanding Parity: A Guide to Resources for Families and Caregivers, available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/understanding-parity-a-guide-to-resources-for-families-and-caregivers.pdf; Warning Signs – Plan or Policy

issuers continue to fall short of MHPAEA's central mandate to ensure that participants, beneficiaries, and enrollees do not face greater barriers and restrictions to accessing benefits for mental health conditions or substance use disorders than they face when accessing benefits for a medical condition or surgical procedure. This noncompliance is especially evident with respect to the design and application of NQTLs that apply to mental health and substance use disorder benefits. Accordingly, Congress amended MHPAEA in the CAA, 2021, as described later in this preamble.

The Departments are proposing these revised rules to reinforce MHPAEA's fundamental objective, to ensure that limitations on mental health and substance use disorder benefits are no more restrictive than the limitations applicable to medical/surgical benefits. These proposed rules also would implement important requirements that Congress enacted in the CAA, 2021 to ensure that plans and issuers perform and document their NQTL comparative analyses and provide them to the Departments or an applicable State authority upon request for evaluation of compliance with MHPAEA. The aim of these proposed rules is to ensure that individuals benefit from the full protections afforded to them under MHPAEA, while providing clear standards for plans and issuers on how to comply with MHPAEA.

Specifically, the proposed regulations would:

- Make clear that MHPAEA requires that individuals can access their mental health and substance use disorder benefits in parity with medical/surgical benefits.

Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/warning-signs-plan-or-policy-nqtls-that-require-additional-analysis-to-determine-mhpaea-compliance.pdf; Mental Health Parity Provisions Questions and Answers, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-mhpaea.pdf; Mental Health and Substance use Disorder Parity: Compliance Assistance Materials Index, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/compliance-assistance-materials-index.pdf; The Essential Aspects of Parity: A Training Tool for Policymakers, available at https://store.samhsa.gov/product/essential-aspects-of-parity-training-tool-for-policymakers/pep21-05-00-001; and Approaches in Implementing the Mental Health Parity and Addiction Equity Act: Best Practices from the States, available at https://store.samhsa.gov/product/Approaches-in-Implementing-the-Mental-Health-Parity-and-Addiction-Equity-Act-Best-Practices-from-the-States/SMA16-4983.

- Provide specific examples that make clear that plans and issuers cannot use more restrictive prior authorization and other medical management techniques for mental health and substance use disorder benefits; standards related to network composition for mental health and substance use disorder benefits; and factors to determine out-of-network reimbursement rates for mental health and substance use disorder providers.
- Require plans and issuers to collect and evaluate outcomes data and take action to address material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, with a specific focus on ensuring that there are not any material differences in access as a result of the application of their network composition standards.
- Codify the requirement that plans and issuers conduct meaningful comparative analyses to measure the impact of NQTLs. This includes evaluating standards related to network composition, out-of-network reimbursement rates, and prior authorization NQTLs.
- Implement the sunset provision for self-funded, non-Federal governmental plan elections to opt out of compliance with MHPAEA, adopted in the CAA, 2023.

As a result of these proposals, the Departments anticipate changes in network composition and medical management techniques that would result in more robust mental health and substance use disorder provider networks and fewer and less restrictive prior authorization requirements for individuals seeking mental health and substance use disorder treatment.

Under a regulatory regime in which MHPAEA's promise of parity is realized, participants, beneficiaries, and enrollees would experience financial requirements and treatment limitations for mental health and substance use disorder benefits that are in parity with those applied to their medical/surgical benefits. These proposed rules are designed to achieve MHPAEA's purpose to ensure that participants, beneficiaries, and enrollees will not face greater

restrictions on access to obtaining mental health and substance use disorder benefits than those for medical/surgical benefits. At the same time, the proposed rules also aim to ensure that benefit structures that apply limitations that reflect independent professional medical or clinical standards or guard against indicators of fraud, waste, and abuse (while minimizing the negative impact on access to appropriate benefits) would continue to be permitted, as the Departments are of the view that such limitations are premised on standards that generally provide an independent and less suspect basis for determining access to mental health and substance use disorder treatment. These proposed rules also aim to ensure that plans and issuers that offer mental health and substance use disorder benefits strive to attain and maintain mental health and substance use disorder treatment provider networks that are as robust as their medical/surgical provider networks in terms of available in-network providers and facilities–not just as shown by a list of names in a provider directory, but as measured by actual provider participation and as evidenced by participant usage.

In evaluating their compliance with these proposed rules, plans and issuers would be required to consider whether an NQTL is inhibiting access to treatment for mental health conditions and substance use disorders by examining whether the NQTL that applies to mental health or substance use disorder benefits is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits within a classification of benefits set forth under the regulations.[49] A plan or issuer would also be required to consider whether the processes, strategies, evidentiary standards, or other factors that it uses to design or apply an NQTL to mental health or substance use disorder benefits in a classification are comparable to, and applied no more stringently than, those used in designing and applying the NQTL to medical/surgical benefits in the same classification. Under these proposed rules, plans and issuers would be required to consider data relevant to an NQTL's impact on participants' or

[49] The required classifications of benefits (and permissible sub-classifications) used to apply the MHPAEA regulations are addressed at 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii).

beneficiaries'[50] abilities to obtain mental health and substance use disorder benefits under the plan or coverage relative to its impact on access to medical/surgical benefits, and to take action to address the potential causes of material differences in access identified through the data as necessary to ensure compliance. As the proposal makes clear, ensuring that people seeking mental health and substance use disorder treatment do not face greater barriers to access to benefits for such treatment is central to the fundamental purpose of MHPAEA. These proposed rules would ensure that NQTLs that apply to mental health and substance use disorder benefits are "no more restrictive," and that processes, strategies, evidentiary standards, and other factors are "comparable to, and applied no more stringently," than those applicable to medical/surgical benefits. These proposed rules' focus on access to mental health and substance use disorder benefits and constraints on obtaining such benefits would add needed clarity to the statutory requirements for the regulated community and other interested parties.

Under the current rules, plans and issuers are generally permitted to prepare NQTL comparative analyses without regard to the overall impact of NQTLs on participants and beneficiaries. This has contributed to plans and issuers looking for ways to characterize the processes, strategies, evidentiary standards, and other factors associated with an NQTL as being "comparable" and "applied no more stringently" through careful word choice, without regard to how, in operation, the limitation burdens participants and beneficiaries by limiting access to, or by limiting the scope and duration of, the plan's or issuer's mental health and substance use disorder benefits relative to medical/surgical benefits. Such limitations on mental health and

---

[50] These proposed rules would apply directly to group health plans or health insurance coverage offered by an issuer in connection with a group health plan, and would apply to individual health insurance coverage by cross-reference through 45 CFR 147.160, which currently provides that the requirements of 45 CFR 146.136 apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market. As noted below, HHS also proposes an amendment to 45 CFR 147.160 to also include a cross-reference to proposed 45 CFR 146.137 to similarly extend the new proposed comparative analysis requirements to individual health insurance coverage in the same manner and to the same extent as group health insurance coverage. For simplicity, this preamble generally refers only to the applicability on group health plans and health insurance coverage offered in connection with a group health plan and to participants and beneficiaries enrolled in such a plan or coverage, but references to participants and beneficiaries should also be considered to include enrollees in the individual market, unless otherwise specified.

substance use disorder benefits under the plan or coverage must be analyzed in terms of the comparative burden on access they place (that is, whether they are more restrictive) on individuals.

These proposed rules set forth a number of standards that are intended to reinforce the proper application of the statutory and regulatory requirements; promote compliance with the NQTL comparative analysis requirements; explain how the various components of the regulation work together; and ensure that the purpose of MHPAEA, to remove greater barriers to access to mental health and substance use disorder benefits, is fulfilled. The Departments recognize the value of input from interested parties and welcome feedback on all aspects of the approach set forth in these proposed rules, as well as alternative approaches that would enable the Departments to more effectively implement MHPAEA.

B. The Mental Health Parity Act, The Mental Health Parity and Addiction Equity Act, and the Affordable Care Act

In 1996, Congress enacted the Mental Health Parity Act of 1996 (MHPA 1996), which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical/surgical benefits. These mental health parity provisions were codified in Employee Retirement Income Security Act of 1974 (ERISA) section 712, PHS Act section 2705, and Internal Revenue Code (Code) section 9812, and applied to group health plans and health insurance coverage offered in connection with a group health plan.[51]

MHPAEA was enacted on October 3, 2008, as sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Pub. L. 110-343, 122 Stat. 3765), to amend ERISA section 712, PHS Act section 2705, and Code section 9812 to add new requirements, including provisions to apply the mental health parity requirements to substance

[51] Pub. L. 104–204, 110 Stat. 2874 (Sept. 26, 1996). The Departments published interim final rules implementing MHPA 1996 at 62 FR 66932 (Dec. 22, 1997).

use disorder benefits, and make further amendments to the existing mental health parity provisions.

MHPAEA, as enacted, generally requires that group health plans and health insurance issuers offering group health insurance coverage ensure that the financial requirements and treatment limitations applicable to mental health or substance use disorder benefits be no more restrictive than those applicable to medical/surgical benefits and that there be no separate financial requirements and treatment limitations applicable only with respect to mental health or substance use disorder benefits. Together with the existing requirements for parity in aggregate lifetime and annual dollar limits, this is referred to as providing mental health and substance use disorder benefits "in parity" with medical/surgical benefits.

The Patient Protection and Affordable Care Act (Pub. L. 111-148, 123 Stat. 3028) was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, 124 Stat. 1029) was enacted on March 30, 2010 (collectively, the Affordable Care Act). The Affordable Care Act reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by these references are sections 2701 through 2728.

The Affordable Care Act extended MHPAEA to apply to individual health insurance coverage and redesignated MHPAEA in the PHS Act as section 2726.[52] Additionally, section

---

[52] The requirements of MHPAEA generally apply to both grandfathered and non-grandfathered health plans. *See* section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815-1251, 29 CFR 2590.715-1251, and 45 CFR 147.140. Under section 1251 of the Affordable Care Act, grandfathered health plans are exempted only from certain Affordable Care Act requirements enacted in Subtitles A and C of Title I of the Affordable Care Act. The provisions extending MHPAEA requirements to individual health insurance coverage and requiring that qualified health plans comply with MHPAEA are not included in these sections. However, because MHPAEA requirements apply to health insurance coverage offered in the small group market only through the

1311(j) of the Affordable Care Act applies PHS Act section 2726 to qualified health plans (QHPs)[53] in the same manner and to the same extent as to health insurance issuers and group health plans. Furthermore, HHS' regulations regarding essential health benefits (EHBs)[54] require health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets to comply with MHPAEA and its implementing regulations in order to satisfy the requirement to cover "mental health and substance use disorder services, including behavioral health treatment," as part of EHBs.[55]

On April 28, 2009, the Departments published a request for information soliciting comments on issues under MHPAEA (2009 RFI).[56] Over the next few years, the Departments considered comments regarding MHPAEA and issued further clarifications and guidance. On February 2, 2010, the Departments published interim final regulations implementing MHPAEA (interim final regulations).[57] After considering the comments and other feedback received from interested parties, the Departments published the 2013 final regulations.[58]

The 2013 final regulations established an exhaustive list of six classifications of benefits (not counting the exhaustive list of permissible sub-classifications also articulated in the 2013 final regulations): inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs. If a plan or health insurance coverage provides benefits for a mental health condition or substance use disorder in any of these

---

requirement to provide EHB, which does not apply to grandfathered health plans, the requirements of MHPAEA do not apply to grandfathered health plans offered in the small group market.

[53] A QHP is a health insurance plan that is certified by a health insurance exchange that it meets certain minimum standards established under the Affordable Care Act and described in subpart C of 45 CFR part 156. *See* 45 CFR 155.20.

[54] Section 1302 of the Affordable Care Act requires non-grandfathered health plans in the individual and small group markets to cover essential health benefits (EHB), which include items and services in the following ten benefit categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. *See* 45 CFR 156.115 for description of the benefits a health plan must provide to provide EHB.

[55] Section 1302(b)(1)(E) of the Affordable Care Act; 45 CFR 156.115(a)(3).

[56] 74 FR 19155 (Apr. 28, 2009).

[57] 75 FR 5410 (Feb. 2, 2010).

[58] 78 FR 68240 (Nov. 13, 2013).

classifications of benefits, benefits for that condition or disorder must be provided in every classification in which medical/surgical benefits are provided. The 2013 final regulations specify that the parity requirements apply to financial requirements, such as deductibles, copayments, and coinsurance; quantitative treatment limitations that are expressed numerically, such as day or visit limits; and NQTLs, which are generally non-numerical requirements that limit the scope or duration of benefits, such as prior authorization requirements, step therapy requirements, and standards for provider admission to participate in a network, including methodologies for determining reimbursement rates.

Under MHPAEA, financial requirements and treatment limitations imposed on mental health or substance use disorder benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.[59] The 2013 final regulations defined the "substantially all" numerical standard for a financial requirement or quantitative treatment limitation as two-thirds, using the same approach as the regulations implementing MHPA 1996 with respect to aggregate annual and lifetime limits.[60] The 2013 final regulations also quantified "predominant" to mean the level of the financial requirement or quantitative treatment limitation that applies to more than one-half of medical/surgical benefits in the relevant classification subject to the financial requirement or quantitative treatment limitation. Using these numerical standards, the Departments established a mathematical test by which plans and issuers could determine if a financial requirement or quantitative treatment limitation that applies to medical/surgical benefits in a classification may be applied to mental health and substance use disorder benefits in that

---

[59] Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

[60] With respect to aggregate lifetime and annual limits under MHPA 1996, the regulations in 26 CFR 54.9812-1(b); 29 CFR 2590.712(b), and 45 CFR 146.136(b) set forth rules based on whether a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit that applies to less than one-third or at least two-thirds of all medical/surgical benefits. These provisions do not address the provisions of PHS Act section 2711, as incorporated by ERISA section 715 and Code section 9815, which prohibit imposing lifetime and annual limits on the dollar value of EHBs. As a result, plans and issuers cannot impose lifetime and annual dollar limits on mental health and substance use disorder benefits that are not EHBs, if such a limit applies to less than one-third of all medical/surgical benefits.

classification, and if so, what level of the financial requirement or quantitative treatment limitation is the most restrictive level that could be imposed on mental health or substance use disorder benefits within the classification.

MHPAEA generally prohibits separate financial requirements and treatment limitations that apply only to mental health and substance use disorder benefits.[61] The 2013 final regulations also prohibit plans and issuers from applying separate cumulative financial requirements, such as deductibles or out-of-pocket maximums, or separate cumulative quantitative treatment limitations, such as annual or lifetime day or visit limits, to mental health or substance use disorder benefits in a classification.[62]

In addition, the 2013 final regulations require that a group health plan or health insurance issuer may not impose an NQTL with respect to mental health and substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to mental health and substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation to medical/surgical benefits in the same classification.[63] The 2013 final regulations also implemented the statutory disclosure requirements imposed on group health plans and health insurance issuers that are subject to MHPAEA's requirements.[64]

C. Guidance

As described earlier in this preamble, since the promulgation of the 2013 final regulations, the Departments have provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties to facilitate

[61] Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).
[62] 26 CFR 54.9812-1(c)(3)(v), 29 CFR 2590.712(c)(3)(v), 45 CFR 146.136(c)(3)(v) and 147.160.
[63] 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), 45 CFR 146.136(c)(4)(i) and 147.160.
[64] 26 CFR 54.9812-1(d), 29 CFR 2590.712(d), 45 CFR 146.136(d) and 147.160.

the implementation and enforcement of MHPAEA. Specifically, the Departments have jointly issued 15 sets of FAQs with 96 questions, eight enforcement fact sheets, six compliance assistance tools and templates, seven reports to Congress, six press releases, and seven consumer publications. In general, the Departments' FAQs are designed to provide additional guidance and clarification on how MHPAEA applies in specific contexts and are informed by questions raised by interested parties and scenarios encountered in the context of the Departments' enforcement efforts. For example, FAQs Part 34 addresses how MHPAEA applies to treatment of substance use disorders (such as treating opioid use disorder with medication) and provides examples of impermissible NQTLs (such as more stringent fail-first or step-therapy requirements, including where an individual cannot reasonably satisfy if there are no available providers that can provide services related to the requirement in the participant's geographic area).[65]

Guidance issued by the Departments also reflects stakeholder feedback and, in several instances, guidance documents were proposed before they were issued in final form. For example, the Departments proposed FAQs Part 39 on April 23, 2018. The finalized FAQs Part 39 was issued on September 5, 2019, and incorporate insights from the regulated community regarding compliance issues faced by plans and issuers, as well as issues faced by plan participants and their authorized representatives when seeking information about mental health and substance use disorder benefits. FAQs Part 39 also provides guidance on how the law and regulations apply to treatments for eating disorders, opioid use disorder, and ASD, as well as exclusions for experimental or investigative treatments, and standards for provider admission to a plan's or issuer's network, including the methodology for determining reimbursement rates for mental health and substance use disorder providers.[66]

In addition to FAQs issued after the promulgation of the 2013 final regulations, the Departments have issued, generally every 2 years, an updated compliance program guidance

---

[65] *See* FAQs Part 34, Q4-Q9.
[66] *See* FAQs Part 39, Q1-8.

document (the MHPAEA Self-Compliance Tool), which is intended to help plans and issuers, State regulators, and other interested parties comply with and understand MHPAEA and the additional related requirements under ERISA that apply to group health plans. The Departments most recently issued the MHPAEA Self-Compliance Tool in 2020 (2020 MHPAEA Self-Compliance Tool).[67] The 2020 MHPAEA Self-Compliance Tool includes an illustrative, non-exhaustive list of NQTLs, a process for conducting NQTL comparative analyses, a list of the types of documents and information that a plan or issuer should have available to support its analyses, and illustrations of specific fact patterns to aid in compliance.[68]

The 2020 MHPAEA Self-Compliance Tool includes a stepwise process a plan or issuer can follow to perform an analysis assessing whether its NQTLs satisfy MHPAEA's parity requirements.[69] Under this stepwise process, the plan or issuer should identify all NQTLs that apply to benefits under the plan or coverage. The plan or issuer should also identify all the medical/surgical benefits and mental health and substance use disorder benefits to which each NQTL applies. After identifying all NQTLs and the benefits to which each NQTL applies, the 2020 MHPAEA Self-Compliance Tool suggests the plan or issuer identify the factors considered in the design of each NQTL. The plan or issuer should also identify the sources used to define those factors. Plans and issuers have flexibility in determining the factors and sources of factors to apply to NQTLs, so long as they are comparable and applied no more stringently to mental health and substance use disorder benefits than to medical/surgical benefits in the respective benefits classification. When identifying the sources of the factors considered in designing an

---

[67] Section 13001(a) of the 21st Century Cures Act added section 2726(a)(6) of the PHS Act, which directs the Departments to provide a publicly available compliance program guidance document that is updated every 2 years.
[68] *See* Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf. The Departments issued the proposed 2020 MHPAEA Self-Compliance Tool on June 19, 2020, and requested comments from interested parties. Engagement with interested parties through written comments and listening sessions provided vital feedback for finalizing the 2020 update to the MHPAEA Self-Compliance Tool, and that final version includes revisions in response to that feedback.
[69] *Id*. at section F (at pp. 21-28).

NQTL, the plan or issuer should also identify any threshold of a factor that will implicate the NQTL.

After identifying the plan's NQTLs, their application to mental health and substance use disorder benefits and to medical/surgical benefits, the factors used in designing each NQTL, and the sources of those factors, the plan or issuer should determine whether the processes, strategies, and evidentiary standards used in applying the NQTL are comparable and no more stringently applied to mental health and substance use disorder benefits than to medical/surgical benefits, both as written and in operation, in the relevant benefit classification. For instance, if a plan's or issuer's utilization review is conducted by different entities or individuals for mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer should have measures in place to ensure comparable application of utilization review policies.

The 2020 MHPAEA Self-Compliance Tool stresses that measuring and evaluating results and quantitative outcomes can be helpful to identify potential areas of noncompliance. For example, comparing a plan's or issuer's average reimbursement rates for both mental health and substance use disorder providers and medical/surgical providers against an external benchmark of reimbursement rates, such as Medicare, may help identify whether the underlying methodology used to determine the plan's or issuer's reimbursement rates warrants additional review. The 2020 MHPAEA Self-Compliance Tool notes that substantially disparate results are a red flag that a plan or issuer may be imposing an NQTL on mental health and substance use disorder benefits in a way that fails to satisfy the parity requirements. Other warning signs of potential noncompliance identified in the 2020 MHPAEA Self-Compliance Tool include generally paying at or near Medicare reimbursement rates for mental health or substance use disorder benefits, while paying much more than Medicare reimbursement rates for

medical/surgical benefits, and reimbursing psychiatrists, on average, less than medical/surgical physicians for the same evaluation and management codes.[70]

The 2020 MHPAEA Self-Compliance Tool also provides many compliance tips on how an NQTL should be analyzed. For example, a plan or issuer should have information available to substantiate how factors are used to design or apply any specific NQTL to both medical/surgical benefits and mental health or substance use disorder benefits. The plan or issuer should be clear as to whether and why any factors were given more weight than others and should be able to explain any variation in the application of a guideline or evidentiary standard, including the process and factors relied upon for establishing the variation. To comply with MHPAEA's parity requirements, plans and issuers must adopt measures for mental health and substance use disorder providers that are at least comparable to and no more stringently applied (with regard to limiting the scope and duration of a participant's, beneficiary's, or enrollee's benefits under the plan or coverage) than those applied to medical/surgical providers. This includes taking steps to help address provider shortages, ensure an adequate network of mental health and substance use disorder providers, and ensure reasonable patient wait times to avoid noncompliance with MHPAEA's parity requirements. By providing a basic framework for plans and issuers to do a stepwise analysis and providing additional warning signs and tips, the 2020 MHPAEA Self-Compliance Tool has provided additional guidance for plans and issuers to comply with the requirements of MHPAEA with respect to NQTLs.

D. The Consolidated Appropriations Act, 2021 and Related Guidance

The CAA, 2021 was enacted on December 27, 2020.[71] Section 203 of Title II of Division BB of the CAA, 2021 amended MHPAEA, in part, by adding Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8) to expressly require group health plans and health insurance issuers offering group or individual health insurance coverage that include both

[70] 2020 MHPAEA Self-Compliance Tool, at p. 21, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.
[71] Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020).

medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits to perform and document their comparative analyses of the design and application of NQTLs.[72] Further, plans and issuers are required to make their comparative analyses and other applicable information available to the Departments or applicable State authorities, upon request.[73] The comparative analysis requirement took effect on February 10, 2021, 45 days after the date of enactment of the CAA, 2021.

In order to advance compliance with MHPAEA, the CAA, 2021 states that the Departments shall request that a group health plan or health insurance issuer offering group or individual health insurance coverage submit comparative analyses, with respect to a plan or coverage, that involve potential MHPAEA violations, in response to complaints against a plan or coverage regarding potentially noncompliant NQTLs, and in any other instances that the Departments determine appropriate.[74] These comparative analyses must include:

(1) the specific plan or coverage terms or other relevant terms regarding the NQTLs and a description of all mental health and substance use disorder benefits and medical/surgical benefits to which each such term applies in each benefit classification;

(2) the factors used to determine how the NQTLs will apply to mental health or substance use disorder benefits and medical/surgical benefits;

(3) the evidentiary standards used to develop the identified factors, when applicable, provided that each factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical/surgical benefits;

(4) the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder

---

[72] Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).
[73] *Id*.
[74] Code section 9812(a)(8)(B)(i), ERISA section 712(a)(8)(B)(i), and PHS Act section 2726(a)(8)(B)(i).

benefits, as written and in operation, are comparable to, and are applied no more stringently than those used to apply the NQTLs to medical/surgical benefits in the benefits classification; and

(5) the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with MHPAEA requirements.[75]

The CAA, 2021 further sets forth a process by which the Departments must evaluate the requested NQTL comparative analyses and enforce the comparative analyses requirements. If the relevant Department with jurisdiction over the group health plan (or health insurance coverage) determines that a plan or issuer has not provided sufficient information for the relevant Department to review the comparative analyses, the CAA, 2021 provides that the Departments shall specify the information the plan or issuer must submit to be responsive to the request.[76] In instances in which the Departments have reviewed the requested comparative analyses and determined that the plan or issuer is not in compliance with MHPAEA, the plan or issuer must specify the actions it will take to come into compliance and submit additional comparative analyses that demonstrate compliance not later than 45 days after the initial determination of noncompliance.[77] Following the 45-day corrective action period, if the relevant Department makes a final determination that the plan or issuer is still not in compliance, the plan or issuer must notify all individuals enrolled in the plan or coverage of this determination, not later than 7 days after such final determination.[78]

The CAA, 2021 also requires the Departments, after review of the comparative analyses, to share information on findings of compliance and noncompliance with the State where the plan is located or the State where the issuer is licensed to do business, in accordance with any information sharing agreement entered into with the State.[79] Additionally, as explained in more

---

[75] Code section 9812(a)(8)(A)(i)-(v), ERISA section 712(a)(8)(A)(i)-(v), and PHS Act section 2726(a)(8)(A)(i)-(v).
[76] Code section 9812(a)(8)(B)(ii), ERISA section 712(a)(8)(B)(ii), and PHS Act section 2726(a)(8)(B)(ii).
[77] Code section 9812(a)(8)(B)(iii)(I), ERISA section 712(a)(8)(B)(iii)(I), and PHS Act section 2726(a)(8)(B)(iii)(I).
[78] *Id*.
[79] Code section 9812(a)(8)(C)(iii), ERISA section 712(a)(8)(C)(iii), and PHS Act section 2726(a)(8)(C)(iii).

detail later in this preamble, the CAA, 2021 requires the Departments to submit annually to Congress and make publicly available a report summarizing the comparative analyses requested by the Departments. The report must state, in part, whether each plan or issuer submitted sufficient information to permit review; whether and why the plan or issuer is in compliance with MHPAEA; the specific information each plan or issuer needed to submit to allow for a review of their comparative analysis; and, for each plan or issuer the Departments determined not to be in compliance, specifications of the actions that must be taken to come into compliance.[80]

On April 2, 2021, the Departments issued FAQs Part 45 to provide guidance on the amendments to MHPAEA made by the CAA, 2021 and to promote compliance by plans and issuers. FAQs Part 45 underscores that, for a comparative analysis to be treated as sufficient under the CAA, 2021, it must contain a detailed, written, and reasoned explanation of the specific plan terms and practices at issue and include the bases for the plan's or issuer's conclusion that the NQTL complies with MHPAEA. As FAQs Part 45 explains, at a minimum, a sufficient NQTL comparative analysis must include a robust discussion of certain elements, including a clear description of the specific NQTL; plan terms; policies at issue; and identification of any factors, evidentiary standards, sources, strategies, and processes considered in the design and application of the NQTL and in determining which benefits, including both mental health and substance use disorder benefits and medical/surgical benefits, are subject to the NQTL. To the extent a plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, its analysis should include the precise definitions used and any supporting sources. The analysis also should explain whether the plan or issuer imposes any variation in the application of a guideline or standard between mental health and substance use disorder benefits and medical/surgical benefits, and if so, should describe the processes and factors used for establishing that variation. The plan or issuer should provide a reasoned discussion, including citations or any specific evidence of its findings and

[80] Code section 9812(a)(8)(B)(iv), ERISA section 712(a)(8)(B)(iv), and PHS Act section 2726(a)(8)(B)(iv).

conclusions, as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified within each affected classification and their relative stringency, both as written and in operation.

FAQs Part 45 highlights that a general statement of compliance by plans and issuers, coupled with a conclusory reference to broadly stated processes, strategies, evidentiary standards, or other factors is insufficient to meet the statutory requirements for an NQTL comparative analysis. Accordingly, a comparative analysis that consists of conclusory or generalized statements, without specific supporting evidence and detailed explanations, or the production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis, fails to satisfy the statutory requirements.

In addition, FAQs Part 45 provides guidance as to the types of documents that plans and issuers should be prepared to make available to support the analysis and conclusions reached in their comparative analyses. This includes records documenting NQTL processes and detailing how the plan or issuer applies NQTLs to both medical/surgical and mental health or substance use disorder benefits, documents and other information relevant to the factors identified, and samples of covered and denied mental health or substance use disorder and medical/surgical benefits claims. FAQs Part 45 also highlights several NQTLs that DOL anticipated focusing on in the near term.

FAQs Part 45 also notes that under the CAA, 2021, plans and issuers must make available their respective comparative analyses of NQTLs and other applicable information to the applicable State authority upon request. Additionally, plans and issuers must make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants and beneficiaries in plans subject to ERISA and to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage upon request in connection with an appeal of an

adverse benefit determination. If a provider or other individual is acting as a patient's authorized representative, the provider or other authorized representative may request these documents.

E. Reports to Congress

DOL is required to send Congress a biennial report on MHPAEA implementation,[81] and the Departments are required to send Congress an annual report on NQTL comparative analyses reviews.[82] To satisfy these requirements, on January 25, 2022, the Departments issued the first report to Congress since the enactment of the CAA, 2021 (2022 MHPAEA Report to Congress).[83] The 2022 MHPAEA Report to Congress contains extensive descriptions of the Departments' MHPAEA enforcement efforts, outreach efforts, consumer and compliance assistance efforts, and guidance to interested parties, including information related to the requirement that plans and issuers perform and document comparative analyses with respect to the design and application of NQTLs.

Contemporaneously with these proposed rules, the Departments are issuing the second report to Congress since the enactment of the CAA, 2021, the MHPAEA Comparative Analysis Report to Congress, July 2023 (2023 MHPAEA Report to Congress).[84] The 2023 MHPAEA Report to Congress details efforts by the Departments to implement and enforce the amendments to MHPAEA made by the CAA, 2021. The 2023 MHPAEA Report to Congress focuses on the Departments' enforcement efforts regarding NQTLs during the second year of CAA, 2021 implementation, looks broadly at the 18-month period since plans and issuers were first required to make their comparative analyses and other applicable information available on request,

---

[81] ERISA section 712(f).

[82] Section 203 of the CAA, 2021 (Pub. L. 116-260, 134 Stat. 1182 (Dec. 27, 2020)). In addition, the Departments were required to send Congress an annual report on complaints and investigations concerning compliance with the requirements of MHPAEA from 2017 until 2021. *See* section 13003 of the 21st Century Cures Act (Cures Act), Pub. L. 114-255, 130 Stat. 1033 (Dec. 13, 2016), as amended by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. 115-271, 132 Stat. 3894 (Oct. 24, 2018).

[83] 2022 MHPAEA Report to Congress, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf.

[84] 2023 MHPAEA Report to Congress, July 2023, available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf and https://www.cms.gov/cciio/resources/forms-reports-and-other-resources#mental-health-parity.

discusses common deficiencies in comparative analyses submitted by plans and issuers, and explores examples of results that the Departments have achieved through enforcement.

The 2023 MHPAEA Report to Congress notes that nearly all of the comparative analyses reviewed by the Departments during the relevant time period contained insufficient information upon initial receipt and identifies common deficiencies in the comparative analyses prepared by plans and issuers. Specifically, many initial responders seemed unprepared to submit their comparative analyses upon request and some plans did not complete or start a comparative analysis until after one was requested. Some comparative analyses lacked specific supporting evidence, detailed explanations, or sufficient detail to draw meaningful comparisons. For example, many plans' comparative analyses failed to adequately explain whether or how factors were comparably applied to mental health and substance use disorder benefits and to medical/surgical benefits. Also, many plans and issuers provided supporting documents for which the relevance and probative value was not readily apparent.

Some plans also failed to identify the specific mental health or substance use disorder benefits and medical/surgical benefits or MHPAEA benefit classification to which an NQTL applied. Additionally, some comparative analyses failed to identify or define every relevant factor. In other instances, plans failed to demonstrate the application of identified factors in the design of an NQTL, and most comparative analyses failed to evaluate the relative stringency of how the NQTL was applied to mental health or substance use disorder benefits versus medical/surgical benefits. When data was included in a comparative analysis, the data often lacked meaning because the plan or issuer did not provide a description of its source, how the source was selected, or information about underlying calculations. Many comparative analyses for standards to participate in a network did not adequately address apparent differences in access standards for medical/surgical providers as opposed to mental health and substance use disorder providers, such as different time and distance standards or provider-to-member ratios.

F. MHPAEA Opt Out for Self-Funded Non-Federal Governmental Plans

Prior to the enactment of the Affordable Care Act, PHS Act section 2721(b)(2), as added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), permitted sponsors of self-funded, non-Federal governmental plans to elect to exempt those plans from (that is, "opt out of") any or all of the following requirements of title XXVII of the PHS Act:

1. Limitations on preexisting condition exclusion periods under PHS Act section 2701 (redesignated as section 2704 by the Affordable Care Act).

2. Requirements for special enrollment periods under PHS Act section 2701 (redesignated as section 2704 by the Affordable Care Act).

3. Prohibitions against discriminating against individual participants and beneficiaries based on health status (but not including provisions added by the Genetic Information Nondiscrimination Act of 2008) under PHS Act section 2702 (redesignated as section 2705 by the Affordable Care Act).

4. Standards relating to benefits for newborns and mothers under PHS Act section 2704 (redesignated as section 2725 by the Affordable Care Act).

5. Parity in the application of certain limits to mental health and substance use disorder benefits (including requirements of MHPAEA) under PHS Act section 2705 (redesignated as section 2726 by the Affordable Care Act).

6. Required coverage for reconstructive surgery following mastectomies under PHS Act section 2706 (redesignated as section 2727 by the Affordable Care Act).

7. Coverage of dependent students on a medically necessary leave of absence under PHS Act section 2707 (redesignated as section 2728 by the Affordable Care Act).

The Affordable Care Act redesignated PHS Act section 2721 as section 2722 and amended PHS Act section 2722(a)(2) to allow sponsors of self-funded, non-Federal governmental plans to only opt out of requirements categories 4-7 listed above.

In response to the Affordable Care Act amendments, HHS issued guidance on September 21, 2010, indicating that, for plan years beginning on or after September 23, 2010, plan sponsors of non-collectively bargained plans could elect to be exempt only from requirements categories 4–7 listed above and that requirements categories 1–3 were no longer available for exemption.[85] Group health plans maintained pursuant to a collective bargaining agreement ratified before March 23, 2010, and that had been exempted from any of the first three requirements categories listed above, would not have to come into compliance with those requirements categories until the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement.

On March 21, 2014, HHS published proposed regulations in the **Federal Register** that proposed to revise the provisions of 45 CFR 146.180 to reflect the amendments made by the Affordable Care Act, consistent with the September 21, 2010, guidance.[86] On May 27, 2014, HHS finalized those proposed regulations with modifications related to how opt out elections must be filed.[87]

The CAA, 2023,[88] enacted on December 29, 2022, eliminated the election for self-funded, non-Federal governmental plans to opt out of MHPAEA.[89] Specifically, PHS Act section 2722(a)(2), as amended by the CAA, 2023, provides that no election to opt out of compliance with the requirements of MHPAEA may be made on or after December 29, 2022 (the date of enactment of the CAA, 2023) and that generally no such election with respect to MHPAEA expiring on or after June 27, 2023 (the date that is 180 days after the date of enactment of the

---

[85] Office of Consumer Information and Insurance Oversight, Amendments to the HIPAA opt-out provision (formerly section 2721(b)(2) of the Public Health Service Act) made by the Affordable Care Act (Sept. 21, 2010), available at www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.
[86] 79 FR 15808 (Mar. 21, 2014).
[87] 79 FR 30240 (May 27, 2014).
[88] Pub. L. 117–328, 136 Stat. 4459.
[89] Division FF, Title I, Subtitle C, Chapter 3, sec. 1321, Pub. L. 117-328, 136 Stat. 4459. As a result of the CAA, 2023 amendments to PHS Act section 2722(a)(2), self-funded, non-Federal governmental plan sponsors may opt out of only the following three PHS Act requirement categories: Standards relating to benefits for newborns and mothers (PHS Act section 2725), Required coverage for reconstructive surgery following mastectomies (PHS Act section 2727), and Coverage for dependent students on a medically necessary leave of absence (PHS Act section 2728).

CAA, 2023), may be renewed.[90] In addition, PHS Act section 2722(a)(2), as amended by the CAA, 2023, includes an exception for certain collectively bargained plans. Specifically, a self-funded, non-Federal governmental plan that is subject to multiple collective bargaining agreements of varying lengths and that has a MHPAEA opt-out election in effect on December 29, 2022, that expires on or after June 27, 2023, may extend such election until the date on which the term of the last collective bargaining agreement expires.[91]

HHS issued a Bulletin on June 7, 2023, that informs self-funded, non-Federal governmental plans and other interested parties about the CAA, 2023 amendments to PHS Act section 2722(a)(2), outlines when plans that currently opt out of compliance with MHPAEA are required to come into compliance with these requirements, and specifies the form and manner for submission of opt-out renewal election requests[92] to operationalize the special rule for certain collectively bargained plans.[93]

II. Overview of the Proposed Rules – Departments of the Treasury, Labor, and HHS

The Departments are proposing these rules to further MHPAEA's fundamental goal of ensuring that limitations on mental health and substance use disorder benefits provided by group health plans or health insurance issuers offering group or individual health insurance coverage are no more restrictive than the predominant limitations applicable to substantially all medical/surgical benefits, and to further implement important new statutory requirements to ensure that plans and issuers document their NQTL comparative analyses and other applicable information to demonstrate whether the processes, strategies, evidentiary standards, and other factors used to apply an NQTL to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those used to apply the limitation with respect to medical/surgical benefits in the same benefit classification. The goal of these proposed

---

[90] PHS Act section 2722(a)(2)(F)(i).
[91] PHS Act section 2722(a)(2)(F)(ii).
[92] *See* 45 CFR 146.180(b) and (f).
[93] Center for Consumer Information and Insurance Oversight, Insurance Standards Bulletin Series – INFORMATION, Sunset of MHPAEA opt-out provision for self-funded, non-Federal governmental group health plans (June 7, 2023), available at https://www.cms.gov/files/document/hipaa-opt-out-bulletin.pdf.

rules is to ensure that individuals with mental health conditions and substance use disorders can benefit from the full protections afforded to them under MHPAEA, while offering clear guidance to plans and issuers on how to comply with MHPAEA's requirements.

These proposed rules would be codified in 26 CFR part 54, 29 CFR part 2590, and 45 CFR parts 146 and 147. Specifically, these proposed rules would amend certain provisions of existing MHPAEA regulations at 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136 to incorporate new and revised definitions of key terms, as well as to specify additional steps that plans and issuers must take to meet their obligations under MHPAEA. These proposed rules also would add a new regulation at 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 establishing minimum standards for developing NQTL comparative analyses to assess whether an NQTL, as written and in operation, complies with MHPAEA's requirements. In addition, these proposed rules would set forth the content elements of comparative analyses and the timeframe for plans and issuers to respond to a request from the Departments to submit their comparative analyses. Additionally, HHS proposes an amendment to 45 CFR 147.160 to specify that proposed regulations at 45 CFR 146.137 would apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent that this proposed provision would apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.[94] Consistent with the existing text at 45 CFR 147.160(a), HHS also proposes to extend the same requirements and framework outlined in the proposed amendments to 45 CFR 146.136 in these proposed rules to individual health insurance coverage in the same manner and to the same extent as such proposed amendments, if finalized, would apply to group health insurance coverage. Finally, HHS also proposes amendments to 45 CFR 146.180 to reflect the sunset of the election option

[94] Non-grandfathered health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small group market is required to comply with the requirements under PHS Act section 2726 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of EHB, and as such would also be required to comply with the comparative analysis requirements proposed under 45 CFR 146.137. *See* 45 CFR 156.115(a)(3).

for self-funded, non-Federal governmental plans to opt out of compliance with MHPAEA, consistent with changes made by the CAA, 2023 to PHS Act section 2722(a)(2).[95]

The Departments are soliciting public comment on all aspects of these proposed rules.

A. Amendments to Existing Regulations at 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136

1. Purpose Section - 26 CFR 54.9812-1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1)

In general, the fundamental purpose of MHPAEA, its existing implementing regulations, and these proposed rules is to ensure that participants and beneficiaries in a group health plan or in group health insurance coverage offered by a health insurance issuer that offers mental health or substance use disorder benefits are not subject to greater restrictions, such as more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations, when seeking those benefits than when they seek medical/surgical benefits under the terms of the plan or coverage. This should serve as the guiding principle for group health plans and health insurance issuers offering group health insurance coverage as they work to comply with MHPAEA and its implementing regulations. While MHPAEA generally does not mandate coverage of mental health or substance use disorder benefits, these proposed rules aim to better ensure that plans and issuers that cover such benefits implement MHPAEA in accordance with its express terms and fundamental purpose.

Accordingly, the Departments propose to add a purpose section to the regulations, specifying that a fundamental purpose of MHPAEA and its implementing regulations is to ensure that participants and beneficiaries covered under a plan or health insurance coverage that offers mental health or substance use disorder benefits are not subject to more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to covered

[95] Division FF, Title I, Subtitle C, Chapter 3, sec. 1321, Pub. L. 117-328, 136 Stat. 4459 (Dec. 29. 2022).

mental health and substance use disorder benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage.[96] The purpose section would further state that in complying with the provisions of MHPAEA and its implementing regulations, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health and substance use disorder benefits under the plan or coverage than plans and issuers impose on access to generally comparable medical/surgical benefits. Further, these proposed rules provide that MHPAEA and its implementing regulations should be interpreted in a manner that is consistent with this purpose. The Departments seek comment on the proposed addition of a purpose section to the implementing regulations and the proposed language.

2. Meaning of Terms - 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2)

The Departments propose to amend the 2013 final regulations to revise several existing definitions, add new definitions of key terms, and add language to specify that, except where the context clearly indicates otherwise, the definitions in 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2) would also apply to the new proposed comparative analysis requirements set forth in proposed 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137, which are discussed in more detail later in this preamble.[97]

Under MHPAEA, the term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage.[98] This statutory

---

[96] While the Departments recognize the relevant statutory text for dollar limits does not use the term "predominant" and different rules apply, the purpose of MHPA 1996 was similar and therefore the provisions for dollar limits should generally be read and applied in a similar manner. *See, e.g.*, Government Accountability Office (GAO), Mental Health Parity Act, May 2000, at p. 13, available at https://www.gao.gov/assets/hehs-00-95.pdf ("To help address the discrepancies in coverage between mental and other illnesses, the Congress passed the Mental Health Parity Act of 1996.").

[97] To accommodate the proposed addition of the "purpose" provision in paragraph (a)(1), these proposed rules would also redesignate the definitions from paragraph (a) to paragraph (a)(2) of 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136.

[98] Code section 9812(e)(3), ERISA section 712(e)(3), and PHS Act section 2726(e)(3).

definition further clarifies that the term does not include mental health or substance use disorder benefits.[99] The terms "mental health benefits" and "substance use disorder benefits" are defined by the statute to mean benefits with respect to services for mental health conditions or substance use disorders, respectively, as defined under the terms of the plan and in accordance with applicable Federal and State law.[100] The definitions of all three of these terms included in the 2013 final regulations further provide that any condition defined by the plan or coverage as being or as not being a medical/surgical condition, mental health condition, or substance use disorder, respectively, must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the International Classification of Diseases (ICD), or State guidelines).

The Departments have received questions from interested parties about what it means for a definition of a mental health condition or substance use disorder to be "consistent with" generally recognized independent standards of current medical practice, and whether, for purposes of MHPAEA, a condition is a medical condition, a mental health condition, or a substance use disorder when State insurance law and generally recognized independent standards of current medical practice conflict. In response to these requests for further guidance, the Departments propose to amend the existing regulatory definitions of the terms "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" to address these questions and help delineate more clearly what is a medical/surgical benefit, a mental health benefit, or a substance use disorder benefit for purposes of complying with MHPAEA.

Specifically, the Departments propose to amend the definition of the term "medical/surgical benefits" to mean benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health

---

[99] *Id.*

[100] *See* Code section 9812(e)(4)-(5), ERISA section 712(e)(4)-(5), and PHS Act section 2726(e)(4)-(5).

insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. These proposed rules would also amend this regulatory definition of "medical/surgical benefits" to provide that, notwithstanding the first sentence, any condition or procedure defined by the plan or coverage as being or not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent that generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure as medical/surgical benefits, as long as such definitions are in accordance with applicable Federal and State law.

The Departments propose to remove the reference to State guidelines in the definition of medical/surgical benefits. This proposed amendment is more consistent with the statute, and importantly, would no longer allow plans and issuers to rely on standards that are not applicable to the plan or coverage at issue in applying financial requirements or treatment limitations to mental health and substance use disorder benefits.[101] Generally recognized independent standards of current medical practice more accurately align with how a plan should characterize benefits for purposes of compliance with MHPAEA, and this provision would minimize situations where contradictions with State guidelines create conflicts and improperly limit the protections under MHPAEA.

The Departments propose to make similar changes to the definitions of "mental health benefits" and "substance use disorder benefits" by amending the first sentences of these definitions, removing the reference to State guidelines, and clarifying that, notwithstanding the

[101] For example, some self-insured ERISA plans have argued that they can rely on State insurance law definitions that characterize a particular condition as a medical condition, mental health condition, or substance use disorder based on State guidelines despite the fact that State insurance law is generally not applicable to self-insured ERISA plans and such plans do not otherwise consistently comply with State insurance law.

terms of a plan or coverage, any condition or disorder defined by the plan or coverage as being or not being a mental health condition or a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice. Specifically, under these proposed rules, to be consistent with generally recognized independent standards of current medical practice, the plan's or coverage's definition of "mental health benefits" must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. Similarly, the plan's or coverage's definition of "substance use disorders" must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM.[102] Similar to the proposed revisions to the definition of "medical/surgical benefits," the proposed amended definitions of "mental health benefits" and "substance use disorder benefits" also provide that, to the extent generally recognized independent standards of current medical practice do not address whether a condition or disorder is a mental health condition or substance use disorder, respectively, plans and issuers may define the condition or disorder in accordance with applicable Federal and State law.

The ICD would be defined as the World Health Organization's International Classification of Diseases adopted by HHS through 45 CFR 162.1002 or successor regulations, and the DSM would be defined as the American Psychiatric Association's Diagnostic and

---

[102] Substance use disorders that fall under any of the diagnostic categories listed in the mental and behavioral health disorders chapter of the most current version of the ICD or that are listed in the most current version of the DSM would be excluded from the definition of the term "mental health benefits" because they would be included in the definition of the term "substance use disorder benefits."

Statistical Manual of Mental Disorders. Because the proposed amendments to the definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits," refer to the most current version of the ICD or DSM, respectively, these proposed rules also explain how to determine which version is the most current as of a particular date. This serves to provide plans and issuers with clarity on when they would be required to begin to rely on a new version of the ICD or DSM after it is released, and sufficient time after the adoption of an updated version of the ICD or DSM to ensure that the terms of their plan or coverage are consistent with any changes made from the previous version. The definitions would specify that, for purposes of compliance with these proposed rules, the most current version of the ICD or DSM, respectively, would be that which is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

These proposed rules also would permit plans and issuers to use a more current version of the ICD or DSM than the version in effect 1 year before the first day of the applicable plan year. In addition, the Departments recognize that future versions of the ICD or DSM may include revisions to the categories of conditions or disorders or chapters listed in the proposed amended definitions for "mental health benefits" and "substance use disorder benefits," which could affect the characterization of a benefit under MHPAEA. Therefore, the proposed amended definitions for these two terms also refer to "equivalent categories" and "equivalent chapters" to help plans and issuers understand how they would apply the proposed definitions, if finalized, and how to implement such changes if they are made in the future. The Departments request comments on this aspect of these proposed amended definitions.

To ensure parity between mental health and substance use disorder benefits and medical/surgical benefits, it is critical that plans and issuers define mental health conditions and substance use disorders in a manner consistent with the purposes of MHPAEA. While plans and issuers have some discretion in defining mental health benefits and substance use disorder benefits, this discretion must be exercised in a manner that comports with generally recognized

independent standards of current medical practice. Moreover, the proposed amended definitions for "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" specify that plans and issuers may use applicable State law to inform their definitions, but only to the extent that those laws are consistent with and do not contradict generally recognized independent standards of current medical practice (or to the extent these standards do not address whether a condition or disorder is a medical condition or surgical procedure or a mental health condition or substance use disorder). Under both the 2013 final regulations and these proposed rules, plans and issuers must be prepared to provide supporting documentation to demonstrate that the way the plan or issuer has defined a condition or disorder for purposes of MHPAEA is consistent with generally recognized independent standards of current medical practice. The Departments solicit comments on whether any additional clarification is needed on how State law may interact with the proposed amended definitions for these key terms.

As discussed earlier in this section of the preamble, the Departments are proposing these amendments to the definitions of the terms "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" in part to ensure that the use of State laws does not prevent the application of MHPAEA's protections with respect to conditions or disorders that are recognized as mental health conditions and substance use disorders under generally recognized independent standards of current medical practice. The Departments recognize that States may enact various laws for different purposes. Therefore, the Departments are proposing to make clear that when a plan or issuer relies upon a State law to inform its definitions for purposes of MHPAEA, the plan or issuer must ensure that definitions operate to apply MHPAEA's protections to mental health conditions and substance use disorders, as they are generally defined by the medical community. The Departments also clarify that under the proposed framework, to the extent a State law or generally recognized independent standards of current medical practice define a condition or disorder as a mental health condition or substance use disorder, plans and issuers must treat all benefits for the condition or disorder as mental health benefits or substance

use disorder benefits, respectively, for purposes of analyzing parity and compliance with MHPAEA. The Departments solicit comments on any potential challenges of applying MHPAEA to all benefits for a mental health condition or substance use disorder where items and services can be delivered for both medical conditions or surgical procedures and mental health conditions or substance use disorders, and whether additional clarifications or modifications to the proposed definitions are necessary.

Interested parties also have requested that the Departments confirm whether specific conditions are mental health conditions for purposes of MHPAEA. Under these proposed rules, as under the existing MHPAEA regulations and section 13007 of the Cures Act,[103] the Departments confirm that eating disorders, such as anorexia nervosa, bulimia nervosa, and binge-eating disorder, are mental health conditions under generally recognized independent standards of current medical practice.[104] Therefore, benefits for treatment of eating disorders are mental health benefits for purposes of MHPAEA and may not be defined as medical/surgical benefits under a plan or coverage.[105]

Similarly, in response to questions from interested parties, these proposed rules would make clear that, for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice.[106] Therefore, under the proposed amended definition and framework established in these proposed rules, if a plan or issuer generally provides benefits for ASD, ASD may not be defined by the plan or issuer as a medical/surgical condition. In addition, the plan or issuer may not impose any financial requirements or treatment limitations in a classification on benefits for ASD treatment that are

---

[103] Section 13007 of the Cures Act states that, if a plan or an issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of MHPAEA.
[104] *See, e.g.*, Diagnostic and Statistical Manual of Mental Disorders (5th ed.), section II, Feeding and Eating Disorders; ICD-10, Chapter 05.
[105] The Departments previously clarified that eating disorders are mental health conditions, and therefore treatment of an eating disorder is a mental health benefit, in FAQs Part 38, Q1. *See* DSM (5th ed.), section II, Feeding and Eating Disorders.
[106] *See* DSM (5th ed.), section II, Autism Spectrum Disorder.

more restrictive than the predominant financial requirements or treatment limitations that apply to substantially all medical/surgical benefits in the classification. The plan or issuer also may not impose any financial requirements or treatment limitations, including exclusions for Applied Behavior Analysis (ABA) therapy (one of the primary treatments for ASD), that are separately applicable to ASD benefits in a classification and not to any medical/surgical benefits in the same classification. The Departments propose to incorporate new examples illustrating the application of MHPAEA to eating disorders and ASD, as discussed later in this preamble. The Departments solicit comments on other specific mental health conditions or substance use disorders that may warrant additional clarification for purposes of analyzing parity and compliance with MHPAEA.

In addition to the proposals outlined above to amend certain existing definitions, these proposed rules also would add several new definitions to codify the meaning of terms used in paragraph (c)(4)(i) of the 2013 final regulations, which requires the processes, strategies, evidentiary standards, and other factors used in applying an NQTL to mental health or substance use disorder benefits to be comparable to, and no more stringently applied than those used to apply the NQTL to medical/surgical benefits in the same classification. These terms and the standard were incorporated into MHPAEA's statutory language in the amendments made by the CAA, 2021.[107] The Departments propose to add new definitions for the terms "processes," "strategies," "evidentiary standards," and "factors" to the list of definitions for key terms proposed to be included in 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2) of these proposed rules. These new definitions would provide clarity to plans and issuers, as well as to State regulators and participants and beneficiaries, and help facilitate compliance with the provisions of these proposed rules related to NQTLs and the development of sufficient comparative analyses required under the CAA, 2021 and proposed 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137. Although the Departments have issued guidance with

[107] *See, e.g.*, Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

examples that demonstrate how these terms apply, interested parties have stated that it can be difficult to determine what constitutes relevant processes, strategies, evidentiary standards, and other factors. The Departments solicit comments on these proposed definitions, including any alternate definitions or additional clarifications that should be considered.

The Departments propose to add a definition of the term "evidentiary standards" to mean any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to an NQTL, including specific benchmarks or thresholds. The proposed definition further provides that evidentiary standards may be empirical, statistical, or clinical in nature, and include sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary, and reasonable" rates paid for items and services), and clinical treatment guidelines. The proposed definition provides that evidentiary standards would also include internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers, and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Under these proposed rules, evidentiary standards generally would not be considered factors, but instead would be considered or relied upon in designing or applying a factor. Under the framework established in the 2013 final regulations, the terms within the phrase "processes, strategies, evidentiary standards, and other factors" were treated as having overlapping meanings, and specifically, the term "other factors" was treated as a catch-all. The CAA, 2021 codified in the statute the phrase "processes, strategies, evidentiary standards, and other

factors."[108] However, the CAA, 2021 added to MHPAEA other references to factors and evidentiary standards that indicate the drafters meant to distinguish between factors and evidentiary standards. For example, Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act 2726(a)(8)(A)(iii) refer to the evidentiary standards *that are used for* the factors to determine that an NQTL will apply to benefits, and those provisions go on to distinguish between factors and any other sources or evidence relied upon to design or apply an NQTL. The proposed definition of evidentiary standards is consistent with the use of these terms by Congress in the CAA, 2021 amendments to MHPAEA and the Departments' goal of clarifying the meanings of these terms to help the regulated community comply with MHPAEA's requirements. The Departments request comments on this approach, including whether there are any circumstances under which an evidentiary standard should also be considered a factor under these proposed rules (such as, for example, when the plan or issuer only relies upon a single evidentiary standard to design or apply an NQTL, and no additional processes, strategies, or other factors).

The Departments also propose to clarify that the definition of the term "factors" should be read broadly, so that factors are all information, including processes and strategies (but generally not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design an NQTL or used to determine whether or how the NQTL applies to benefits under the plan or coverage. The proposed definition of the term "factors" also would include information (but generally not evidentiary standards) that the plan or issuer considered but rejected, consistent with previous guidance on MHPAEA in the context of the documents or plan information the Departments consider relevant to a compliance determination.[109] The proposed definition also provides

---

[108] Code section 9812(a)(7)(B)(ii)(II) and (8)(A)(iv), ERISA section 712(a)(7)(B)(ii)(II) and (8)(A)(iv), and PHS Act section 2726(a)(7)(B)(ii)(II) and (8)(A)(iv).

[109] *See* FAQs Part 31, Q9, which states that a plan must provide documents and plan information to a participant or beneficiary, or their authorized representative, including the specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that

examples of factors, which include, but are not limited to, provider discretion in determining diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

Under these proposed rules, factors would include processes and strategies, but the Departments note that there may be factors that do not satisfy the proposed definitions of "processes" or "strategies." By defining the term "factor" broadly, the Departments intend to capture any information used to design or apply an NQTL (other than evidentiary standards generally), regardless of whether a plan or issuer believes that information could also be characterized as a process or a strategy, as those terms are proposed to be defined under these proposed rules.

Additionally, the Departments propose to define "processes" and "strategies" as types of factors, in a manner that makes clear the differences between the two terms as they relate to the design and application of an NQTL. Specifically, the Departments would define "processes" as relating to the application of an NQTL, while "strategies" would relate to the design of an NQTL.

The Departments therefore propose to define "processes" to mean actions, steps, or procedures that a plan or issuer uses to apply an NQTL. "Processes" would include requirements established by the plan or issuer for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative, or a provider or facility. The proposed definition further provides that processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving

---

were relied upon and were rejected) in determining that the NQTL will apply to a particular mental health and substance use disorder benefit or any medical/surgical benefits within the benefit classification at issue.

the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements; and the development and approval of a treatment plan. The proposed definition also provides that processes include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of NQTLs, such as: how a panel of staff members applies the NQTL (including the qualifications of staff involved, number of staff members allocated, and time allocated); consultations with panels of experts in applying the NQTL; and reviewer discretion in adhering to criteria hierarchy when applying an NQTL.

These proposed rules would define "strategies" as practices, methods, or internal metrics that a plan or issuer considers, reviews, or uses to design an NQTL. The proposed definition provides that examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; deviation from generally accepted standards of care; the selection of information (such as from medical or clinical guidelines) deemed reasonably necessary to make a medical necessity determination; reliance on treatment guidelines or guidelines provided by third-party organizations; and rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules. These proposed rules would further specify that strategies also include the creation and composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of NQTLs, including the plan's decisions related to qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the NQTL; and the composition of the panels used to design an NQTL.

To illustrate the interaction of the definitions of these terms, a plan might rely on various combinations of processes, strategies, evidentiary standards, and other factors in designing and applying a prior authorization NQTL for in-network, non-hospital-based, inpatient/residential facilities for non-emergency medical/surgical or mental health or substance use disorder

treatment. For example, the *strategies* used by the plan to design the NQTL could include the development of the clinical rationales the plan used in determining when to approve or deny benefits for the facility, and the composition of the staff of the plan that chose what information would be deemed necessary to determine whether a participant or beneficiary has an immediate, clinically valid need for treatment at the facility. The *processes* the plan used in applying the NQTL could include the specific steps a participant or beneficiary (or their authorized representative, including their provider or the facility) would need to take to obtain prior authorization, such as obtaining a written treatment plan. The processes would also include the procedures used by staff or other representatives of the plan (or the service provider of the plan) in determining whether a particular request for prior authorization would be approved. These processes and strategies would also be considered *factors*, as would the licensing and accreditation requirements for non-hospital-based, inpatient/residential facilities and the severity or chronicity of a patient's condition when they are seeking treatment at such a facility. Finally, the *evidentiary standards* used to design or apply the factors would include, for example, the benchmarks or thresholds the plan uses to inform the number of days of treatment at the facility that would be authorized at one time, as well as published research studies on the efficacy of the treatment in this particular facility setting.

Finally, the Departments propose to amend the definition of "treatment limitation" to clarify that the illustrative list of NQTLs to which the definition refers is non-exhaustive, and to amend the last sentence to state that a complete exclusion of all benefits for a particular condition or disorder is not a treatment limitation for purposes of this definition. By changing the existing reference in the definition from a "permanent" exclusion to a "complete" exclusion, the proposed amended definition of "treatment limitation" would better reflect a plan's or issuer's ability to amend the terms of their plan or coverage and affirm that this part of the definition refers to an exclusion of all benefits for a particular condition or disorder.

While NQTLs are generally defined as treatment limitations that are not expressed numerically, the application of an NQTL in a numerical way does not modify its nonquantitative character simply because the NQTL sometimes involves numerical standards. For example, standards to participate in a network would be NQTLs because such standards are treatment limitations that typically are not expressed numerically. Nevertheless, these standards sometimes rely on or involve numerical standards, such as reimbursement rates. In this case, the numerical expression of a reimbursement rate does not modify the nonquantitative character of the standards related to network composition. Therefore, such standards would still be evaluated in accordance with the rules for NQTLs under the statute and these proposed rules.

The Departments solicit comments on all aspects of these proposed amendments to existing definitions, as well as the new proposed definitions. The Departments also request comment on what additional clarifications or examples might be helpful in understanding these amended and new proposed defined terms.

3. Nonquantitative Treatment Limitations - 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4)

As explained earlier in this preamble, the Departments are proposing changes that are designed to prevent plans and issuers from designing and implementing NQTLs that impose greater limits on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. These proposed rules would add additional requirements for plans and issuers that apply NQTLs with respect to mental health and substance use disorder benefits, to prevent the imposition of a greater burden on participants and beneficiaries accessing those benefits, while preserving the ability of plans and issuers to impose those NQTLs to the extent they are consistent with generally recognized independent professional medical or clinical standards or standards related to fraud, waste, and abuse. Subject to those two narrow exceptions, these proposed rules provide that plans and issuers would not be permitted to impose an NQTL unless (1) the NQTL is no more restrictive as applied to mental health and substance use disorder

benefits than to medical/surgical benefits (also referred to in this preamble as the no more restrictive requirement);[110] (2) the plan or issuer satisfies requirements related to the design and application of the NQTL (also referred to in this preamble as the design and application requirements);[111] and (3) the plan or issuer collects, evaluates, and considers the impact of relevant data on access to mental health and substance use disorder benefits relative to access to medical/surgical benefits; and subsequently takes reasonable action as necessary to address any material differences in access shown in the data to ensure compliance with MHPAEA (also referred to in this preamble as the relevant data evaluation requirements).[112]

The proposed rules do not require or suggest a particular sequence to the analysis for evaluating compliance, and no inferences should be drawn from the order in which each of these independent requirements appear in the proposed regulatory text. For example, a plan or issuer designing or applying an NQTL with respect to mental health or substance use disorder benefits could begin analyzing compliance with MHPAEA by looking at the design and application requirements under these proposed rules before fully evaluating whether the NQTL with respect to mental health or substance use disorder benefits complies with the no more restrictive requirement. Additionally, if a plan or issuer, in the process of complying with the relevant data evaluation requirements, identifies material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, those differences would be considered a strong indicator that the plan or issuer violated the proposed no more restrictive requirement or the design and application requirements.[113] In such instances, if the plan or issuer took the additional steps required under the material differences requirement at 26 CFR 54.9812-

---

[110] Proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i).
[111] Proposed 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii).
[112] Proposed 26 CFR 54.9812-1(c)(4)(iv), 29 CFR 2590.712(c)(4)(iv), and 45 CFR 146.136(c)(4)(iv).
[113] *But see* the special rule for NQTLs related to network composition at proposed 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), and 45 CFR 146.136(c)(4)(iv)(C), which states that, when designing and applying one or more NQTLs related to network composition standards, a plan fails to meet the no more restrictive requirement and the design and application requirements, in operation, if the relevant data show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification.

1(c)(4)(iv)(B), 29 CFR 2590.712(c)(4)(iv)(B), or 45 CFR 146.136(c)(4)(iv)(B) (and the special rule for NQTLs related to network composition at 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), or 45 CFR 146.136(c)(4)(iv)(C) did not apply), then the plan or issuer would meet all three independent requirements.[114] The Departments solicit comments on this proposed approach.

If a plan or issuer fails to meet any of the three requirements with respect to an NQTL in a classification, these proposed rules state that the NQTL would violate MHPAEA and may not be imposed on mental health or substance use disorder benefits in the classification. Where a plan or issuer fails to satisfy the requirements of one part of these proposed rules for NQTLs, the plan or issuer must make changes to the terms of the plan or coverage or the way the NQTL is designed or applied to ensure compliance with MHPAEA.

These proposed rules also would prohibit plans and issuers from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.[115] Additionally, the proposed rules would require plans and issuers to collect and evaluate relevant outcomes data and address any material differences in access between mental health and substance use disorder benefits and medical/surgical benefits as necessary to ensure compliance. This proposed provision also would impose a special rule for NQTLs related to network composition.[116]

Finally, these proposed rules would make clear that a plan or issuer that has received a final determination of noncompliance under the comparative analysis review process established by the CAA, 2021, including a final determination of noncompliance based on failure to provide

---

[114] The plan or issuer would also be required to document any steps taken in accordance with the material differences requirement (and the special rule for NQTLs related to network composition, if applicable) as part of its comparative analyses. Even if the plan or issuer had assessed compliance prior to the steps taken in accordance with the material differences requirement and the special rule for NQTLs related to network composition, the plan or issuer would be required to re-evaluate whether the no more restrictive requirement and the design and application requirements are met with respect to the adjusted NQTL.

[115] Proposed 26 CFR 54.9812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B).

[116] Proposed 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), and 45 CFR 146.136(c)(4)(iv)(C).

a sufficient comparative analysis, also could be in violation of the substantive requirements that apply to NQTLs under MHPAEA, as determined by the Departments. Upon such a determination, the Departments would direct the plan or issuer to not impose the NQTL that is the subject of the comparative analysis, unless and until the plan or issuer can demonstrate compliance or take appropriate action to remedy the violation.[117] The Departments request comments on all aspects of these proposed amendments and additions to the rules regarding NQTLs.

a. Requirement that NQTLs be No More Restrictive for Mental Health and Substance Use Disorder Benefits - *26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i)*

These proposed rules, if finalized, would redesignate, from what is currently 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) to 26 CFR 54.9812-1(c)(4)(ii)(A), 29 CFR 2590.712 (c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A), the general rule for evaluating NQTLs, and add new language to these paragraphs to impose additional requirements for NQTLs. As noted elsewhere in the preamble, these proposed rules would provide that a plan or issuer may not apply any NQTL to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.[118] While the 2013 final regulations largely relied on an analysis of the processes, strategies, evidentiary standards, and other factors used in the application of NQTLs, proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) is consistent with the fundamental purpose of MHPAEA and more closely mirrors the statutory language in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act 2726(a)(3)(A), which states that plans and issuers "…shall ensure that…the treatment limitations applicable

[117] Proposed 26 CFR 54.9812-1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii).
[118] As explained later in this preamble, the Departments are also proposing to add clarifying language to these proposed rules to make clear that any references to the term "classifications" in MHPAEA's implementing regulations also includes permissible sub-classifications, including with respect to NQTLs.

to…mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan ([or coverage]) . . . ."

To that end, the proposed rules provide an explanation of how the terms "restrictive," "substantially all," and "predominant" would apply in the context of the no more restrictive requirement in proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). To comply with these proposed rules, if finalized, plans and issuers would be required to follow similar steps to those that apply when analyzing parity with respect to financial requirements or quantitative treatment limitations under the 2013 final regulations. These steps would involve determining the portion of plan payments for medical/surgical benefits subject to an NQTL in a classification; whether the NQTL applies to substantially all medical/surgical benefits in the classification; the predominant variation of the NQTL that applies to medical/surgical benefits in the classification; and whether the NQTL, as applied to mental health and substance use disorder benefits in the classification, is more restrictive than the predominant variation of the NQTL as applied to substantially all medical/surgical benefits.

First, in determining whether an NQTL applies to substantially all medical/surgical benefits in a classification, plans and issuers would be required to determine the portion of plan payments for medical/surgical benefits expected to be subject to the NQTL based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the NQTL). Similar to the longstanding rules for financial requirements and quantitative treatment limitations, these proposed rules would provide that for NQTLs, any reasonable method may be used to determine the dollar amount expected to be paid under the plan or coverage for medical/surgical benefits. In the Departments' view, for a method to be reasonable with respect to large group market and self-insured group health plans, a plan or issuer would be required to consider group health plan-level claims data to perform the

substantially all and predominant analyses, and must rely on such data if it is credible to perform the required projections.[119] Similarly, for small group market plans, an issuer would be required to consider "plan"-level (as opposed to the "product"-level) claims data to perform the substantially all analysis, using the definitions of "plan" and "product" in 45 CFR 144.103, and would be required to rely on such data if it is credible to perform the required projections.[120] However, if an actuary who is subject to and meets the qualification standards for the issuance of a statement of actuarial opinion regarding health plans in the United States,[121] including having the necessary education and experience to provide the actuarial opinion, determines that a group health plan or issuer does not have sufficient data at the plan level for a reasonable projection of future claims costs for the "substantially all" analyses, the group health plan or issuer should utilize other reasonable claims data to make a projection to conduct actuarially-appropriate analyses. As part of using a "reasonable method" to make these projections, plans and issuers should document the assumptions used in choosing a data set and making projections. Plans and issuers would not be required to perform the parity analysis under proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712 (c)(4)(i), and 45 CFR 146.136(c)(4)(i) each plan year unless there is a change in plan benefit design or utilization that would affect an NQTL within a classification. The Departments solicit comments on whether there are any challenges or other considerations with this approach regarding which level of data plans and issuers should look to in performing this prong of the analysis, and whether there should be a different standard given the different nature of NQTLs.

---

[119] *See* FAQs Part 34, Q3 (interpreting the reasonable method requirement with respect to financial requirements and quantitative treatment limits).

[120] 45 CFR 144.103 generally defines "product" as a discrete package of health insurance coverage benefits offered using a particular product network type within a service area, and "plan" as the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. In this context, the term "plan" is not synonymous with the term "group health plan." This approach would also apply to individual health insurance coverage under HHS regulations that incorporate the group market rules by reference.

[121] The U.S. Qualification Standards apply to members of the six U.S.-based organizations who issue Statements of Actuarial Opinion in the United States. The organizations are the American Academy of Actuaries, American Society of Pension Professionals and Actuaries, American Society of Enrolled Actuaries, Casualty Actuarial Society, Conference of Consulting Actuaries, and Society of Actuaries.

Second, plans and issuers would be required to determine whether the NQTL applies to substantially all medical/surgical benefits in the classification, based on the plan payments for medical/surgical benefits subject to an NQTL as a portion of the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year. An NQTL would be considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in that classification. Whether the NQTL applies to at least two-thirds of all medical/surgical benefits would be determined without regard to whether the NQTL was triggered based on a particular factor or evidentiary standard. For example, if a plan or issuer applies a general exclusion for all benefits in a classification that are for experimental or investigative treatment, and defines experimental or investigative treatment to be treatments with less than a certain number of peer-reviewed studies demonstrating efficacy, the exclusion would be treated as applying to all of the benefits in the classification – not just those that may be subject to the general exclusion for experimental or investigative treatment because they lack the requisite number of peer-reviewed studies (that is, those that actually triggered the NQTL based on the evidentiary standard). These proposed rules further provide that if an NQTL does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that NQTL would not be permitted to be applied to mental health or substance use disorder benefits in that classification.

The Departments request comment on whether any additional clarification is needed for plans and issuers to determine whether an NQTL applies to substantially all medical/surgical benefits in a classification. The Departments acknowledge that there are significant differences between financial requirements or quantitative treatment limitations and NQTLs and therefore also request comments on whether plans and issuers maintain systems capable of making such determinations and the potential administrative burdens that would be associated with such determinations. Specifically, the Departments are interested in feedback on the approach under these proposed rules for determining substantially all medical/surgical benefits in a classification

with respect to certain NQTLs, including those that are used to exclude benefits under the plan or coverage (such as exclusions for experimental or investigational treatment). The Departments also solicit comments on the interaction of this approach with other statutory requirements for plans and issuers prohibiting certain NQTLs on medical/surgical benefits (such as the prohibition on prior authorization for any minimum hospital length of stay after childbirth under the Newborns' and Mothers' Health Protection Act[122]).

If an NQTL applies to substantially all medical/surgical benefits in a classification, the third step would require plans and issuers to determine the predominant variation of the NQTL that is applied to substantially all medical/surgical benefits subject to the NQTL in the classification. The Departments propose that the term "predominant" would, for this purpose, mean the most common or most frequent variation of an NQTL within a benefit classification. For example, if a plan applies inpatient concurrent review commencing 1 day, 3 days, or 7 days after admission, depending on the reason for a stay in a hospital or other inpatient facility, or the procedure performed during such a stay, the plan imposes three different variations of the NQTL within the benefit classification. Under this example, to determine which variation is predominant, the plan would determine the portion of inpatient benefits subject to each of the three different variations of the NQTL based on the dollar amount of all plan payments expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the NQTL). Similarly, if a plan applies an NQTL such as prior authorization in a manner that differs based on the manner of review (auto-adjudication vs. manual review) and the number of levels of review (first-level review vs. first-level review and peer-to-peer review), the plan would regard each unique combination as a separate variation. If the plan or issuer imposes only one variation of an NQTL, that variation is considered the predominant NQTL for purposes of the no more restrictive requirement.

---

[122] Code section 9811, ERISA section 711, and PHS Act sections 2725 and 2751; 26 CFR 54.9811-1, 29 CFR 2590.711, and 45 CFR 146.130 and 148.170.

Variations of an NQTL for purposes of the determination of which is "predominant" are different than levels of a type of financial requirement or quantitative treatment limitation. Because of the nature of NQTLs, the same mathematical principles for combining plan payments to get to more than one-half for a financial requirement or quantitative treatment limitation may not always be transferrable when determining which variation of an NQTL is predominant. Therefore, for purposes of NQTLs, the "predominant" variation would be the most common or frequent variation of the NQTL. The most common or frequent variation would be the variation that applies to the highest portion of all medical/surgical benefits within a classification that are subject to the NQTL based on expected plan payments. This proposed definition mirrors the statutory definition of the term "predominant" in Code section 9812(a)(3)(B)(ii), ERISA section 712(a)(3)(B)(ii), and PHS Act section 2726(a)(3)(B)(ii). However, it is different in some ways from the 2013 final regulations for financial requirements and quantitative treatment limitations, because the distinct nature of NQTLs necessitates looking to the most common or frequent *variation* rather than comparing and combining numerical *levels*. Using the inpatient concurrent review example described earlier in this section of the preamble, if the plan had determined that applying concurrent review 7 days after admission was the predominant variation, the plan would be prohibited from applying a more restrictive variation of that NQTL to mental health or substance use disorder benefits in the classification.

The Departments request comment on this approach and any additional clarifications or specificity that is necessary for plans and issuers to determine the predominant NQTL that applies to substantially all medical/surgical benefits in a classification, including what characteristics of a particular NQTL should be considered when determining the predominant variation when a plan or issuer imposes multiple variations, and how to distinguish between what might be a single NQTL without any variations versus what might be variations of a single NQTL. The Departments also request comment on what should be considered the predominant variation of an NQTL when multiple variations are equally common or frequent. Additionally,

the Departments are interested in alternative approaches to determining the predominant variation of an NQTL that would provide clarity across a wide variety of NQTLs and ways that plans and issuers design and apply NQTLs to various types of benefits.

Fourth, under these proposed rules, an NQTL applied to mental health or substance use disorder benefits cannot be more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in the same classification. An NQTL is restrictive if it imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage. For purposes of determining whether an NQTL is restrictive, "conditions, terms, or requirements" would include, but would not be limited to, those that compel an action by or on behalf of a participant or beneficiary (including by their authorized representative or a provider or facility) to access benefits and those that limit access to the full range of treatment options available for a condition or disorder under the plan or coverage. Thus, if an NQTL applied to mental health or substance use disorder benefits is determined to be more restrictive, as written or in operation, than the predominant NQTL applied to substantially all medical/surgical benefits in the same classification, the NQTL would violate MHPAEA, subject to certain exceptions for independent professional medical or clinical standards and standards related to fraud, waste, and abuse, discussed in more detail later in this preamble.

The Departments recognize that the term "restrictive" is not specifically defined in MHPAEA or the 2013 final regulations in the context of the parity analysis for financial requirements and quantitative treatment limitations. The Departments are of the view that it is generally apparent when one financial requirement or quantitative treatment limitation is more restrictive than another. For example, a $25 copayment is clearly more restrictive than a $15 copayment, and a 5-visit limit is more restrictive than a 10-visit limit. However, due to the nature of NQTLs, which generally do not allow for such straightforward comparison, and the fact that many plans and issuers have designed and applied NQTLs to mental health and substance use disorder benefits in a manner that limits access to those benefits as compared to medical/surgical

benefits, the Departments are proposing a definition of "restrictive" to clarify how this term should be interpreted specifically for NQTLs in a manner that is consistent with MHPAEA's fundamental purpose. The Departments solicit comments on any additional clarifications necessary for plans and issuers to apply the no more restrictive requirement with respect to NQTLs applicable to mental health and substance use disorder benefits. The Departments also solicit comments on whether there are any specific NQTLs for which it would be challenging for plans and issuers to determine whether the NQTL is more restrictive with respect to mental health and substance use disorder benefits than medical/surgical benefits, consistent with the proposed definition of "restrictive."

The following example applies each of the steps in the analysis described earlier in this preamble for the proposed no more restrictive requirement at 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). Under this example, a self-insured group health plan imposes a medical management requirement that all inpatient, in-network medical/surgical and mental health and substance use disorder facilities have 24-hour onsite nursing services available. First, the plan would determine the portion of plan payments for medical/surgical benefits that are subject to the NQTL, based on the dollar amount of all plan payments for medical/surgical benefits in the inpatient, in-network classification expected to be paid under the plan for the plan year. Second, based on this calculation, the plan would determine whether the NQTL applies to at least two-thirds of inpatient, in-network medical/surgical benefits. Because all medical/surgical benefits in the classification are subject to the medical management requirement, the NQTL would apply to substantially all medical/surgical benefits in the classification. Third, the plan would identify the predominant, or most common or frequent, variation of the NQTL based on the portion of plan payments for medical/surgical benefits that are subject to each variation of the NQTL. In this case, because there is only one variation (the requirement that facilities have 24-hour on-site nursing services available), that variation of the NQTL would be predominant under the framework in these proposed rules. Finally, the plan

would evaluate whether the NQTL as applied to mental health and substance use disorder benefits is more restrictive, as written or in operation, than the predominant NQTL applicable to substantially all medical/surgical benefits in the inpatient, in-network classification. Because the requirement that facilities have 24-hour on-site nursing services available does not impose additional conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage for mental health or substance use disorder benefits as compared to medical/surgical benefits by, for example, compelling an additional action by a participant or beneficiary to access mental health and substance use disorder benefits or limiting access to the full range of treatment options available, for mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification, this NQTL would satisfy the no more restrictive requirement under 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) of these proposed rules.

If a plan or issuer analyzes an NQTL and determines that it satisfies the no more restrictive requirement under these proposed rules, it would also still be required under these proposed rules to analyze the NQTL under the design and application requirements and the relevant data evaluation requirements, discussed later in this preamble, to ensure compliance with MHPAEA. As discussed earlier in this preamble, the Departments note that, while the no more restrictive requirement appears first in these proposed rules, nothing in these proposed rules is intended to require that compliance with the no more restrictive requirement be assessed before the other requirements for NQTLs in proposed 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). The Departments propose adding several examples, described later in this preamble, to illustrate how the no more restrictive requirement, the design and application requirements, and the relevant data evaluation requirements in these proposed rules apply to various factual scenarios.

Under these proposed rules, the Departments do not intend to interfere with a plan's or issuer's attempts to ensure that coverage for benefits for the treatment of mental health

conditions and substance use disorders is consistent with generally accepted independent professional medical or clinical standards. Similarly, the Departments do not intend for the no more restrictive requirement to prevent plans and issuers from applying reasonably designed and carefully circumscribed measures adopted for the purpose of detecting or preventing and proving fraud, waste, and abuse. The Departments recognize that the application of independent professional medical or clinical standards and standards related to fraud, waste, and abuse generally improve and help to ensure appropriate care for participants and beneficiaries, rather than restrict access to needed benefits. The Departments also acknowledge that there are instances in which the application of independent professional medical or clinical standards might result in plans and issuers applying NQTLs to mental health or substance use disorder benefits that would otherwise be more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in the same classification when applying the no more restrictive requirement in proposed 26 CFR 54.9812-1(c)(4)(i)(A) through (D), 29 CFR 2590.712(c)(4)(i)(A) through (D), and 45 CFR 146.136(c)(4)(i)(A) through (D). Therefore, the Departments propose that an NQTL applied to mental health or substance use disorder benefits in any classification would not be considered to violate the no more restrictive requirement if the NQTL impartially applies independent professional medical or clinical standards or applies standards related to fraud, waste, and abuse, that meet specific requirements, discussed in more detail later in this preamble.

b. Requirements Related to Design and Application of the NQTL - *26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii)*

As mentioned earlier in this preamble, these proposed rules would redesignate the requirement currently in 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) as paragraph (c)(4)(ii)(A) and would amend the requirement codified in the 2013 final regulations to align with the Departments' consistent interpretation that a plan or issuer may not impose an NQTL with respect to mental health or substance use disorder benefits

in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in *designing and applying* the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in *designing and applying* the limitation with respect to medical/surgical benefits in the classification. To codify this interpretation, and for consistency with statutory language added by the CAA, 2021, the Departments propose to revise the regulatory text to make this requirement explicit.

Under these proposed rules, a key consideration in determining whether, in designing or applying an NQTL to mental health or substance use disorder benefits, the processes, strategies, evidentiary standards, or other factors are applied no more stringently than those used in designing and applying the limitation to medical/surgical benefits in the classification, would be whether any process, strategy, evidentiary standard, or other factor restricts access more so to mental health or substance use disorder benefits than to generally comparable medical/surgical benefits. This approach is consistent with the proposed new purpose section set forth in these proposed rules and discussed earlier in this preamble.

Under these proposed rules, if a plan or issuer imposes an NQTL that impartially applies independent professional medical or clinical standards to medical/surgical benefits and mental health or substance use disorder benefits that would not be considered a violation of the no more restrictive requirement or the relevant data evaluation requirements. However, the plan or issuer would still need to comply with the design and application requirements in proposed 26 CFR 54.49812-1(c)(4)(ii)(A), 29 CFR 2590.712(c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A). That is, the plan or issuer would not be permitted to impose an NQTL with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use

disorder benefits in the classification are comparable to, and are applied no more stringently than those used in designing and applying the NQTL with respect to medical/surgical benefits in the classification. Similarly, if a plan or issuer imposes standards related to fraud, waste, and abuse in a manner described in the proposed rules, the plan or issuer would still be required to comply with the design and application requirements and the relevant data evaluation requirements in proposed 26 CFR 54.49812-1(c)(4)(ii) and (iv), 29 CFR 2590.712(c)(4)(ii) and (iv), and 45 CFR 146.136(c)(4)(ii) and (iv).

The Departments also propose to add a new provision to further ensure that processes, strategies, evidentiary standards, and other factors used in designing and applying an NQTL to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, those used in designing and applying an NQTL to medical/surgical benefits in the same classification. Specifically, for purposes of determining comparability and stringency under the design and application requirements of 26 CFR 54.49812-1(c)(4)(ii)(A), 29 CFR 2590.712(c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A), these proposed rules would prohibit plans and issuers from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. Various factors and evidentiary standards that plans and issuers have previously relied on, or currently rely on, to design or apply NQTLs to mental health or substance use disorder benefits might themselves discriminate against mental health and substance use disorder benefits by treating them in a different and less favorable manner. Consistent with MHPAEA's fundamental purpose, the Departments are of the view that plans and issuers should not be permitted to rely on such factors or evidentiary standards to design and apply an NQTL if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health and substance use disorder benefits as compared to medical/surgical benefits. These proposed rules establish this

requirement as a threshold component of the analysis that a plan or issuer would be required to undertake when analyzing an NQTL's compliance with the design and application requirements under these proposed rules.[123]

For purposes of these proposed rules, independent professional medical or clinical standards described in proposed 26 CFR 54.49812-1(c)(4)(v)(A), 29 CFR 2590.712(c)(4)(v)(A), and 45 CFR 146.136(c)(4)(v)(A) would not be considered to discriminate against mental health or substance use disorder benefits, consistent with the exceptions to other requirements for NQTLs in described elsewhere in this preamble. Similarly, standards related to fraud, waste, and abuse under proposed 26 CFR 54.49812-1(c)(4)(v)(B), 29 CFR 2590.712(c)(4)(v)(B), and 45 CFR 146.136(c)(4)(v)(B) would also not be considered to discriminate against mental health or substance use disorder benefits. The Departments request comments on this approach. The Departments also solicit comments on any additional clarifications necessary for plans and issuers to apply this standard with respect to NQTLs applicable to mental health and substance use disorder benefits, as the term "discriminate" is proposed to be defined in these proposed rules.

Under these proposed rules, information is considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances. Such relevant facts and circumstances include, but are not limited to, the source of the information, the purpose or context of the information, and the content of the information. Therefore, plans and issuers would not be permitted to rely on information that reflects bias, as those factors or evidentiary standards would be discriminatory under these proposed rules. For this purpose, the Departments are of the view that information

[123] The Departments note that the prohibition on discriminatory factors and evidentiary standards in proposed 26 CFR 54.49812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B) is not intended to affect the application of any other Federal or State laws for other purposes, and solicit comments on any potential interactions with other such laws that may warrant additional clarification.

that results in the less favorable treatment of mental health and substance use disorder benefits without legitimate justification or that is otherwise not objective would be considered to be biased and to discriminate against mental health and substance use disorder benefits. Under these proposed rules, the determination of whether information is objective and unbiased would be based on all the relevant facts and circumstances including, but not limited to, the source of the information, the purpose or context of the information, and the content of the information. When determining which information, evidence, sources, or standards should inform the factors or evidentiary standards used to design or apply an NQTL, plans and issuers would not be permitted under these proposed rules to use information, evidence, sources, or standards if they are biased in favor of imposing greater restrictions on access to covered mental health and substance use disorder benefits or not objective, based on all the relevant facts and circumstances.

More specifically, the proposed rules would prohibit plans and issuers from relying on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA's requirements where the use of such data results in less favorable treatment of mental health and substance use disorder benefits. As an example, under these proposed rules, a plan or issuer would not be permitted to calculate reimbursement rates based on historical data on total plan spending for each specialty that is divided between mental health and substance use disorder providers and medical/surgical providers, when the total spending by the plan was based on a time period when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA, if the data results in less favorable treatment of mental health and substance use disorder benefits. Consequently, plans and issuers could not use such data to develop a factor or evidentiary standard for the design or application of an NQTL to mental health or substance use disorder benefits.

Under these proposed rules, to the extent a plan or issuer relies on any factor or evidentiary standard that discriminates against mental health or substance use disorder benefits, or any information, evidence, sources, or standards that inform such factors or evidentiary

standards to design and apply NQTLs, the plan or issuer violates the requirement set forth in proposed 26 CFR 54.9812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B). The Departments request comments on all aspects of these provisions of the proposed rules, including whether additional definitions are necessary to comply with these requirements.

c. Illustrative, Non-Exhaustive List of NQTLs - *26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii)*

These proposed rules, if finalized, would move the illustrative, non-exhaustive list of NQTLs from 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii) to 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712 (c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) and make several minor changes to this provision. First, these proposed rules would amend this provision to make clear that this illustrative list of NQTLs is non-exhaustive and that there are additional NQTLs not listed in this paragraph.[124] As stated in the definition of the term "treatment limitations" in the 2013 final regulations and these proposed rules, an NQTL is any provision that limits the scope or duration of benefits for treatment under a plan or coverage that is not a quantitative treatment limitation. Some interested parties have requested that the Departments issue an exhaustive list of NQTLs to provide clarity as to the exact provisions for which plans and issuers are expected to perform and document comparative analyses pursuant to the CAA, 2021. Others have asked the Departments not to provide such a list, asserting that doing so could encourage plans and issuers to create new NQTLs outside the list or rename NQTLs in an attempt to circumvent MHPAEA's requirements.

Because of the broad scope of the meaning of the term "nonquantitative treatment limitation,"[125] and the fact that plan or coverage terms that otherwise limit the scope or duration

---

[124] The Departments are also proposing to add the term "non-exhaustive" to cross-references to the illustrative, non-exhaustive list of NQTLs, contained in the definition of "treatment limitations" in 26 CFR 54.9812-1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a) and in the clarification of the term "type of financial requirement or treatment limitation" in 26 CFR 54.9812-1(c)(1)(ii), 29 CFR 2590.712(c)(1)(ii), and 45 CFR 146.136(c)(1)(ii).

[125] 26 CFR 54.9812-1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a) state that "[t]reatment limitations include…nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage."

of benefits for treatment in similar ways may use different terminology, the Departments are not proposing to issue an exhaustive list of NQTLs. However, the Departments are proposing to add examples of additional NQTLs to these proposed rules, as discussed later in this preamble. Previous Reports to Congress[126] also include lists of the NQTLs that have been the subject of comparative analyses reviewed by the Departments. Additionally, the 2020 MHPAEA Self-Compliance Tool provides an illustrative, non-exhaustive list of NQTLs.[127] As the Departments encounter additional NQTLs, the Departments expect to highlight them in future resources. The list of NQTLs, therefore, is more accurately framed as a non-exhaustive list of examples that can be updated, as appropriate, as part of the resources the Departments make available to assist the regulated community and interested parties in their efforts to understand and comply with MHPAEA.

These proposed rules would also amend the illustrative, non-exhaustive list of NQTLs to replace "[s]tandards for provider admission to participate in a network, including reimbursement rates" with "standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage." The standards that govern how the network is constructed and defined are critical limitations on the availability of benefits under the plan or coverage. Accordingly, the Departments reaffirm that standards related to network composition are subject to the requirements applicable to NQTLs, including their design and application as set forth in these proposed rules. Standards related to network composition operate to limit the scope or duration of benefits for treatment – a fundamental characteristic of an

---

[126] *See, e.g.*, 2022 MHPAEA Report to Congress, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf and https://www.cms.gov/files/document/2022-mhpaea-report-congress.pdf.

[127] Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.

NQTL. The design, administration, and composition of networks that comply with MHPAEA's requirements are essential to participants and beneficiaries having access to treatment for mental health conditions and substance use disorders in parity with medical/surgical benefits.

Additionally, the Departments recognize that some plans and issuers use other related NQTLs, such as credentialing standards, to help ensure an adequate number of available providers as part of their standards related to network composition. Therefore, the Departments propose to specifically include credentialing standards and procedures for ensuring the network includes an adequate number of each category of mental health and substance use disorder providers and facilities relative to the number of medical/surgical providers and facilities in the illustrative, non-exhaustive list of NQTLs to make clear that plans and issuers setting standards to participate in a network through the application of one or more NQTLs would be required to satisfy the requirements for NQTLs under these proposed rules.

In the 2013 final regulations, the phrase "usual, customary, and reasonable charges," found in the illustrative list of NQTLs is often used to refer to a plan's method for determining out-of-network rates. However, the Departments are aware that plans and issuers may use other methods to determine out-of-network rates, such as using a percentage of Medicare rates.[128] These proposed rules therefore would amend the description of this illustrative NQTL to encompass a broader range of methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates.

Finally, these proposed rules would add a specific reference to prior authorization requirements as an example of a medical management standard limiting or excluding benefits based on medical necessity or medical appropriateness, consistent with Example 1 in 26 CFR

---

[128] *See* NY Times, Insurers Alter Cost Formula, and Patients Pay More, available at https://www.nytimes.com/2012/04/24/nyregion/health-insurers-switch-baseline-for-out-of-network-charges.html; FairHealth, "Types of Out-of-Network Reimbursement," available at https://www.fairhealthprovider.org/download/your-costs/Types%20of%20Out-of-Network%20Reimbursement.pdf

54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) of the 2013 final regulations. In addition to proposing amendments to the NQTLs included in the illustrative, non-exhaustive list codified in this provision, the Departments emphasize that even if an NQTL is not included on this list, a plan or issuer is not excused from compliance with the same standards and framework outlined in these proposed rules. That is, the many other NQTLs not included in the list codified in this provision would also be subject to the same standards and framework outlined in these proposed rules. Examples of additional NQTLs not listed include, but are not limited to, concurrent care review; billing restrictions, such as a requirement for a licensed provider to bill through or under the supervision of another type of licensed provider; retrospective review; treatment plan requirements; refusal to cover treatment until completion of a comprehensive assessment by specific providers; outlier management; and limitations based on expectation of improvement, likelihood of progress, or demonstration of progress. The Departments request comments on the proposed amendments to this provision and additional clarifications that may be necessary with respect to specific NQTLs listed.

d. Required Use of Outcomes Data and Special Rule for NQTLs Related to Network Composition - *26 CFR 54.9812-1(c)(4)(iv), 29 CFR 2590.712(c)(4)(iv), and 45 CFR 146.136(c)(4)(iv)*

As the Departments have highlighted in previous guidance, substantially disparate results are often a red flag that a plan or issuer may be imposing an NQTL in a manner that does not comply with MHPAEA.[129] The Departments are of the view that relevant outcomes data should be collected and evaluated as part of analyzing whether an NQTL with respect to mental health or substance use disorder benefits in a classification, is more restrictive, in operation, than the predominant NQTL that is applied to substantially all medical/surgical benefits in the classification. Additionally, the comparative analysis requirement added to MHPAEA by the CAA, 2021 requires a demonstration of whether the processes, strategies, evidentiary standards, and other factors used to apply an NQTL to mental health or substance use disorder benefits, as

[129]2020 MHPAEA Self-Compliance Tool; *see* FAQs Part 39, Q7.

written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to medical/surgical benefits in a classification.[130]

In evaluating how such processes, strategies, evidentiary standards, and other factors are applied in operation, it is necessary to look at how the plan is administered in operation, which in the Departments' view necessarily requires review and consideration of quantitative outcomes data to get a sense of how the NQTL functions in the context of the plan's or issuer's administration and provision of benefits. For example, the Departments have highlighted in prior guidance that plans and issuers should have samples of covered and denied mental health and substance use disorder and medical/surgical benefit claims available to support the comparative analysis.[131] It is critical that a plan or issuer collect information to assess relevant data that show the outcomes that result from the application of an NQTL, evaluate those outcomes (which, as stated earlier in this preamble, may be a red flag that the plan or issuer is imposing an impermissible NQTL that disparately impacts access to covered mental health or substance use disorder benefits), and take reasonable action as necessary to address any material differences in access.

Of particular concern to the Departments are the NQTLs described in 26 CFR 54.9812-1(c)(4)(iii)(D), 29 CFR 2590.712(c)(4)(iii)(D), and 45 CFR 146.136(c)(4)(iii)(D) of these proposed rules. These NQTLs involve standards related to network composition, which include but are not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage. These standards are critical to ensuring parity in access to mental health and substance use disorder

---

[130] *See* Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).
[131] *See* FAQs Part 45, Q4.

benefits for participants and beneficiaries. The Departments are also aware that there is a growing disparity between in-network reimbursement rates for mental health and substance use disorder providers and medical/surgical providers, which may more negatively impact access under a plan or coverage to mental health and substance use disorder benefits as compared with medical/surgical benefits.[132] Additionally, there is a significant disparity between how often participants and beneficiaries have little or no choice under their plan or coverage but to utilize out-of-network mental health and substance use disorder providers and facilities, as compared to medical/surgical providers and facilities.[133]

Therefore, the Departments propose to add a requirement to provide that, when designing and applying an NQTL, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether such NQTL, in operation, complies with proposed 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii). These proposed rules would permit the Departments to specify the type, form, and manner for this data collection and evaluation in future guidance.

Under these proposed rules, the relevant data that a plan or issuer would be required to collect and evaluate for all NQTLs (in each individual comparative analysis) includes, but is not limited to, the number and percentage of relevant claims denials, as well as any other data relevant to the NQTLs as required by State law or private accreditation standards. The Departments seek comments on whether plans and issuers collect such data as part of their normal business operations, as well as whether there are NQTLs for which the number and percentage of relevant claims denials would not be relevant for evaluating the impact of the

---

[132] Melek, S., Davenport, S., Gray, T. J. (2019). Addiction and mental health vs. physical health: Widening disparities in network use and provider reimbursement (p. 6). Milliman. https://assets.milliman.com/ektron/Addiction_and_mental_health_vs_physical_health_Widening_disparities_in_network_use_and_provider_reimbursement.pdf.

[133] *Id*.

NQTL. The Departments also seek comments on any additional guidance plans and issuers would need to comply with the requirements of proposed 26 CFR 54.9812-1(c)(4)(iv), 29 CFR 2590.712 (c)(4)(iv), and 45 CFR 146.136(c)(4)(iv) for newly imposed NQTLs or for NQTLs imposed by new plans or issuers, for which relevant data may not be immediately available.

Moreover, because of the Departments' specific concerns about standards related to network composition and other related NQTLs, these proposed rules would require that, in addition to the relevant data required for all NQTLs, plans and issuers must collect and evaluate additional relevant data for NQTLs related to network composition. Such data would include, but would not be limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). While this list of data for NQTLs related to network composition is not reflective of the full list of data that plans and issuers often use to assess their networks, these specific data points provide a cross-section of relevant data points that the Departments have looked at in their MHPAEA compliance reviews and investigations, or that States and other interested parties have found useful.[134] The Departments solicit comments on these specific data points, including whether provider reimbursement rates should be compared to Medicare reimbursement rates as an alternative to billed charges or another external benchmark.

Pursuant to these proposed rules, to the extent the relevant data evaluated under these proposed rules reveal material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the differences would be considered a strong indicator that the plan or issuer violates proposed 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR

---

[134] *See, e.g.*, 2020 MHPAEA Self-Compliance Tool, Appendix II available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf; Washington State, Model Data Definitions and Methodology Form (used by Washington State for their Second Market Scan), available at http://www.mhtari.org/model-data-definitions-method.pdf; Maryland, Instructions for Completing Data Supplement 1 Report (Utilization Review) Form, available at https://insurance.maryland.gov/Consumer/Pages/workgroups.aspx.

2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii). While under this provision, material differences alone would not be dispositive (except, as discussed below, for NQTLs related to network composition), and would not automatically result in a finding of noncompliance, a plan or issuer would be required to take reasonable action to address any material differences in access as necessary to ensure compliance, in operation, with 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii) of these proposed rules. Whether any particular action would be considered reasonable in response to any given material differences in access resulting from an evaluation of outcomes data would be determined based on the relevant facts and circumstances, including the NQTL itself, the relevant data, the extent of the material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and the impact of the material differences in access on participants and beneficiaries. The Departments also solicit comments on what additional information is necessary to clarify what would constitute reasonable action in response to relevant data that reveals material differences in access.

In addition to taking reasonable action to address material differences in access, the plan or issuer would also be required to document in their comparative analyses any such action that has been or is being taken by the plan or issuer to mitigate those material differences, under proposed 26 CFR 54.9812-2(c)(5)(v), 29 CFR 2590.712-1(c)(5)(v), and 45 CFR 146.137(c)(5)(v), as discussed later in this preamble. This requirement would allow plans and issuers to explain why material differences in access demonstrated by the outcomes data should not result in a violation of the rules for NQTLs. The Departments solicit comments on all aspects of the material difference standard at proposed 26 CFR 54.9812-1(c)(4)(iv)(B), 29 CFR 2590.712(c)(4)(iv)(B), and 45 CFR 146.136(c)(4)(iv)(B), including how to define a material difference in access. The Departments are particularly interested in comments regarding how "material difference" could be defined in a manner that translates into tangible quantitative research methods that would ensure that data is analyzed using statistical tools and results in

meaningful information for plans and issuers to use in addressing barriers to accessing benefits. Specifically, the Departments seek comment on whether materiality should be defined in terms of the results of statistical testing and request feedback from interested parties on the optimal method for assembling data and statistical analysis.

Network composition is the result of the design and application of a myriad of NQTLs and is informed by various processes, strategies, evidentiary standards, and other factors, many of which interact in complex ways and are often either difficult to evaluate separately, or do not portray an adequate picture of the overall relative impact on access when analyzed separately. For example, plans and issuers may develop or consult several standards to help inform their network composition, such as State licensing standards, quality and performance metrics, patient utilization in particular geographic regions, and overall provider availability. Because plans and issuers generally look to the cumulative effect of such standards, practices, and strategies when designing their networks, it is important that plans and issuers also look to the cumulative effect of such standards, practices, and strategies when evaluating any data and standards related to network composition for compliance with MHPAEA.

The Departments are concerned that some plans or issuers may define their NQTLs related to network composition in a way that silos interrelated processes, strategies, and evidentiary standards that should be evaluated together under a plan's or issuer's standards related to network composition. In the Departments' view, all NQTLs related to network composition, taken together, must be designed and applied in compliance with MHPAEA's parity requirements to ensure that networks do not materially disfavor access to mental health and substance use disorder benefits when compared to medical/surgical benefits. Furthermore, because such NQTLs will inherently impact a participant's or beneficiary's access to mental health and substance use disorder benefits, the Departments are of the view that material differences in access shown by outcomes data related to such NQTLs should be subject to a higher level of scrutiny than for other NQTLs.

Accordingly, these proposed rules include a special rule for NQTLs related to network composition. Under these proposed rules at 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), and 45 CFR 146.136(c)(4)(iv)(C), when designing and applying one or more NQTLs related to network composition standards, a plan or issuer fails to meet the requirements of proposed 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii), in operation, if the relevant data show material differences in access to in-network mental health or substance use disorder benefits as compared to in-network medical/surgical benefits in a classification. The Departments also solicit comments on the likely impacts, costs, and benefits of treating network composition as an NQTL for purposes of the regulation, as opposed to treating it merely as an outcome of other NQTLs. To what extent would such an approach better promote equal access to networks? What are potential unintended consequences or implementation issues? In soliciting these comments, the Departments recognize that there is no one established and universal set of metrics for determining the parity of networks, and that parity across mental health and substance use disorder and medical/surgical networks does not necessarily mean equal number of providers in a classification. As such, the Departments recognize that different plans and issuers may take different approaches to ensuring that their mental health and substance use disorder networks are as robust as their medical/surgical networks. The Departments also recognize that there may be significant challenges for some plans and issuers to ensure that their mental health and substance use disorder networks are not more restrictive in operation than their medical/surgical networks. Accordingly, in addition to the comments solicited in the accompanying Technical Release 2023-01P discussed later in this preamble, the Departments solicit comments in this document on ways to compare or assess the parity of mental health and substance use disorder and medical/surgical networks, while accommodating the different approaches and different challenges that plans and issuers face in building strong mental health and substance use disorder and medical/surgical networks.

The Departments are aware that some plans and issuers rely on minimum time and distance standards set by a private accreditation organization or by other Federal or State programs as the basis for a factor or evidentiary standard for an NQTL related to network composition. Under these proposed rules, plans and issuers would not be permitted to solely rely on this information as an evidentiary standard or to inform a factor used to design and apply an NQTL, unless the plan or issuer complies with the relevant data evaluation requirements and the special rule for NQTLs related to network composition to determine whether the relevant data show material differences in access to in-network mental health or substance use disorder benefits as compared to in-network medical/surgical benefits in a classification. The Departments are of the view that minimum time and distance standards set by a private accreditation organization or by other Federal or State programs may provide a helpful starting point for plans and issuers to develop factors or evidentiary standards but note that these standards are often not designed with purposes of MHPAEA compliance in mind. Therefore, to comply with the relevant data evaluation requirements and the special rule for NQTLs related to network composition under these proposed rules, a plan or issuer may need to go beyond the minimum times and distances outlined in such standards, and also ensure that they do not result in less favorable treatment for mental health and substance use disorder benefits under the plan or coverage, based on all the relevant facts and circumstances. The Departments solicit comments on what additional clarifications are needed on how this proposed provision would apply to the use of private accreditation standards and other Federal or State program standards.

Plans and issuers would be required to take action to address material differences in access or no longer impose the relevant NQTLs. Such actions could include, for example, ensuring that they or their service providers (as applicable) make special efforts to contract with a broad range of mental health and substance use disorder providers who are available, including authorizing greater compensation or other inducements to the extent necessary; expanding telehealth arrangements as appropriate to manage regional shortages; notifying participants and

beneficiaries in clear and prominent language on the website, employee brochures, and the summary plan description of a toll-free number for help finding in-network providers; ensuring that the plan's or issuer's service providers (as applicable) reach out to the treating professionals and facilities to see if they will enroll in the network; and ensuring the network directories are accurate and reliable.

The Departments recognize that shortages of mental health and substance use disorder providers could pose challenges to issuers, plans, and their service providers.[135] If, despite taking appropriate action, the relevant data continues to reveal material differences in access, such as, because of provider shortages that the plan or issuer cannot effectively address through no fault of its own, the Departments would not cite such a plan or issuer for failure to comply with 26 CFR 54.9812-1(c)(4)(iv), 29 CFR 2590.712(c)(4)(iv), and 45 CFR 146.136(c)(4)(iv) with respect to the plan's or issuer's NQTL(s) related to network composition if the plan or issuer otherwise complied with the other applicable MHPAEA requirements. Plans and issuers should be prepared, however, to document the actions they have taken and to demonstrate why any disparities are attributable to provider shortages in the geographic area, rather than their NQTLs related to network composition. The Departments request comments on this provision, including on whether and how to allow plans and issuers to account for external circumstances that impact material differences in access. The Departments specifically request comment on how to ensure that any permitted allowances would be sufficiently narrow so they do not permit plans and issuers to inappropriately rely on external circumstances, including provider shortages, as a reason they cannot comply with this provision, and similarly welcome comments on the types of external circumstances, actions, and responses that should be treated as properly mitigating materially different access shown by outcomes data.

---

[135] *See* White House Issue Brief, Reducing the Economic Burden of Unmet Mental Health Needs, available at https://www.whitehouse.gov/cea/written-materials/2022/05/31/reducing-the-economic-burden-of-unmet-mental-health-needs/ (acknowledging that provider shortages exist and 37% of the population live in areas with mental health practitioner shortages).

These proposed rules would also specify that plans and issuers are not required to comply with the relevant data evaluation requirements for NQTLs that impartially apply generally recognized independent professional medical or clinical standards, consistent with the exceptions to other requirements for NQTLs described elsewhere in this preamble. The Departments solicit comments regarding the degree to which such NQTLs would cause material differences in access revealed by the proposed data that plans and issuers would be required to evaluate with respect to other NQTLs, and how these rules should address multi-faceted causation of material differences in access. Proposed 26 CFR 54.49812-1(c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(D), and 45 CFR 146.136(c)(4)(iv)(D) would not provide a comparable exception for standards related to fraud, waste, and abuse. As a result, for these standards, plans and issuers would be required to comply with the relevant data evaluation requirements under these proposed rules. While standards related to fraud, waste, and abuse are important tools for plans and issuers, the Departments are of the view that those tools are more likely than independent professional medical or clinical standards to result in NQTLs that improperly restrict access to mental health or substance use disorder benefits and the impact of those NQTLs on access to mental health and substance use disorder benefits should be assessed. Therefore, the Departments propose that plans and issuers that apply NQTLs to detect or prevent and prove fraud, waste, and abuse to mental health and substance use disorder benefits in a classification would be required to comply with the relevant data evaluation requirements with respect to those NQTLs. The Departments solicit comments on these proposals related to the relevant data evaluation requirements and the special rule for NQTLs related to network composition, including whether plans and issuers (and their service providers) generally collect this data as part of their normal business operations.

Contemporaneously with these proposed rules, DOL is issuing Technical Release 2023-01P that sets out principles and seeks public comment to inform future guidance with respect to required data submissions for NQTLs related to network composition and a potential

enforcement safe harbor.[136] Specifically, the Technical Release solicits feedback on the type, form, and manner for the data that plans and issuers would be required to include, along with other relevant data as appropriate, as part of their comparative analyses for NQTLs related to network composition (which must be submitted to the Departments upon request). The Technical Release also solicits feedback on how to define certain thresholds for required data and a potential enforcement safe harbor to be specified in future guidance that, if satisfied, would demonstrate to the Departments that a plan or coverage provides comparable access to in-network of providers for mental health and substance use disorder benefits as compared to medical/surgical benefits. In turn, if the safe harbor threshold is met, the plan or issuer would not be subject to Federal enforcement under MHPAEA with respect to NQTLs related to network composition for a specified period of time. The Departments encourage interested parties to review the Technical Release and submit their comments consistent with the instructions contained in it (separate from any comments they submit in response to these proposed rules). The Departments also solicit comments on this approach, including whether the Departments should incorporate additional specific data elements, such as those collected by States, into these proposed rules.

e. Independent Professional Medical or Clinical Standards and Standards to Detect or Prevent and Prove Fraud, Waste, and Abuse - *26 CFR 54.9812-1(c)(4)(v), 29 CFR 2590.712(c)(4)(v), and 45 CFR 146.136(c)(4)(v)*

As explained earlier in this preamble, the Departments do not intend to interfere with a plan's or issuer's attempts to ensure that NQTLs for benefits for treatment of mental health conditions or substance use disorders are consistent with generally accepted independent professional medical or clinical standards of care or are appropriately designed and carefully circumscribed measures used solely for the purpose of detecting or preventing and proving fraud, waste, and abuse. The Departments recognize that the application of generally recognized

[136] The Technical Release was developed in collaboration with HHS and Treasury, and all comments submitted to DOL will be shared with them and posted on the EBSA website.

independent professional medical or clinical standards and appropriately designed and carefully circumscribed fraud, waste, and abuse measures generally improve care and outcomes for participants and beneficiaries, rather than restrict access to benefits.

Therefore, as discussed earlier in this preamble, the Departments propose to provide exceptions to the proposed requirements in 26 CFR 54.9812-1(c)(4)(i), (c)(4)(ii)(B), and (c)(4)(iv), 29 CFR 2590.712(c)(4)(i), (c)(4)(ii)(B), and (c)(4)(iv), and 45 CFR 146.136(c)(4)(i), (c)(4)(ii)(B), and (c)(4)(iv) (the no more restrictive requirements, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements) for NQTLs that impartially apply generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits. Under these proposed rules, the exception would not be available to any plan or issuer with respect to an NQTL that fails to impartially apply such standards, or deviates from those standards in any way, such as by imposing additional or different requirements.

The Departments also propose to provide an exception to the proposed no more restrictive requirements in 26 CFR 54.9812-1(c)(4)(i) and (c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(i) and (c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(i) and (c)(4)(ii)(B) for NQTLs reasonably designed to detect or prevent, and prove fraud, waste, and abuse, based on indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data. Additionally, these proposed rules would require such NQTLs to also be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits. The Departments believe NQTLs reasonably designed to detect or prevent and prove fraud, waste, and abuse can help improve the overall efficiency of the health care delivery system and play an important role in safeguarding the interests of participants and beneficiaries, where narrowly designed to avoid creating more restrictive limitations on access to mental health and substance use disorder benefits. To ensure that NQTLs reasonably designed to detect or

prevent and prove fraud, waste, and abuse are also narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits, such NQTLs are still subject to the relevant data evaluation requirements. Additionally, these proposed rules do not provide any exception from the design and application requirements under 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii), although as discussed earlier in this preamble, NQTLs that apply independent professional medical or clinical standards or standards related to fraud, waste, and abuse in a manner that meets the requirements of this section would not be considered to discriminate against mental health or substance use disorder benefits. The only circumstances in which plans and issuers would not be required to satisfy all three of the requirements of proposed 26 CFR 54.9812-1(c)(4)(i), (ii), and (iv); 29 CFR 2590.712(c)(4)(i), (ii), and (iv); and 45 CFR 146.136(c)(4)(i), (ii), and (iv) to meet their obligations to demonstrate compliance with MHPAEA's parity requirements for NQTLs would be if the NQTL is subject to one of these two exceptions. In instances that an NQTL qualifies for one of these exceptions, the plan or issuer would still be required to comply with the requirements for which the exception or exceptions do not apply.

The Departments stress that these exceptions are not intended to create potential loopholes that would undermine the statutory requirement that NQTLs applied to mental health and substance use disorder benefits be no more restrictive than the predominant NQTLs applicable to substantially all medical/surgical benefits. If these rules are finalized as proposed and the Departments become aware of the creation of new standards for the purpose of imposing NQTLs that are more restrictive with respect to mental health and substance use disorder benefits (or the establishment of new organizations that create such standards), they may provide additional guidance consistent with MHPAEA's fundamental purpose, as necessary.

The Departments solicit comments on these proposed exceptions, including ways to better or more specifically frame them (such as, for example, specifying that generally recognized independent professional medical or clinical standards must be independent, peer-

reviewed, or unaffiliated with plans and issuers), consistent with the Departments' view that these exceptions should be narrowly tailored. The Departments also solicit comments on how the framework outlined in these proposed rules could be improved to better ensure that individuals with mental health conditions and substance use disorders benefit from MHPAEA's consumer protections, while also allowing plans and issuers to apply generally recognized independent professional medical or clinical standards and to adopt appropriate, narrowly tailored measures to detect or prevent and prove fraud, waste, and abuse.

f. Effect of Final Determination of Noncompliance - *26 CFR 54.9812-1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii)*

The Departments propose to add language to these proposed rules specifying that, if a plan or issuer receives a final determination from the relevant Secretary that it is not in compliance with the requirements of proposed 26 CFR 54.9816-2, 29 CFR 2590.712-1, and 45 CFR 146.137 with respect to an NQTL, the NQTL would violate 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) and the relevant Secretary may direct the plan or issuer not to impose the NQTL, unless and until the plan or issuer demonstrates to the relevant Secretary compliance with the requirements of MHPAEA or takes appropriate action to remedy the violation. Whereas the requirement in the introductory paragraph of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) states that a plan or issuer may not impose an NQTL in the first instance unless it meets all of the applicable substantive requirements for NQTLs under these proposed rules, this proposed provision addresses the effect of a final determination of noncompliance with the NQTL comparative analysis documentation requirements under proposed 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137.

The MHPAEA statute requires "such plan or coverage *shall ensure that*" the treatment limitations comply with the substantive requirements of the statute.[137] The statute further requires that the plan or issuer perform and document adequate comparative analyses for NQTLs

[137] Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

to ensure compliance.[138] Accordingly, under these proposed rules plans and issuers would be required to ensure that they are complying with MHPAEA's requirements at all times an NQTL is imposed with respect to mental health or substance use disorder benefits and, as explained later in this preamble, plans and issuers would be required to ensure that they have performed and documented comparative analyses for their NQTLs imposed on mental health or substance use disorder benefits (regardless of the timing of any request for such documentation) to ensure compliance. When a plan or issuer has not substantiated compliance with MHPAEA for an NQTL applied to mental health and substance use disorder benefits, the application of the NQTL also would violate MHPAEA. At the same time, the Departments acknowledge that whether and how to cease the application of an impermissible NQTL depends on the nature of the NQTL, the impact on access to mental health or substance use disorder benefits, and other facts and circumstances that are specific to a particular case.

Therefore, when a plan or issuer receives a final determination from the Departments with respect to an NQTL based on failure to demonstrate compliance with proposed 26 CFR 54.9816-2, 29 CFR 2590.712-1, and 45 CFR 146.137, including because the plan or issuer has not submitted a sufficient comparative analysis to demonstrate compliance, these proposed rules would treat such a failure not only as a violation of the NQTL comparative analysis documentation requirements but also as a violation of the substantive NQTL rules under proposed 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). The Departments recognize that an immediate cessation of the application of an NQTL may not be feasible for all NQTLs; accordingly, a determination by the Departments of whether to require immediate cessation would be based on the evaluation of facts and circumstances involved in the specific violation and nature of the underlying NQTL. Such facts may include, for example, the level of disruption in the provision of benefits under the plan or coverage if the NQTL immediately ceased to apply, the practicality and complexities involved in the cessation of the

[138] Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8).

NQTL, the effect on participants and beneficiaries and the likely time period needed to cease or modify the NQTL. The Departments also note that such determination would take into account feedback from the plan or issuer. These facts and circumstances would also be relevant to the Departments' assessment of the plan's or issuer's overall efforts to come into compliance with MHPAEA. The Departments stress that, as discussed later in this preamble, the review process for the NQTL comparative analyses allows multiple opportunities for plans and issuers to provide additional information to the Departments and correct a deficient or insufficient comparative analysis. The application of proposed 26 CFR 54.9812-1(c)(4)(vii), 29 CFR 2590.712 (c)(4)(vii), and 45 CFR 146.136(c)(4)(vii) would be illustrated by a new proposed Example 7 of 26 CFR 54.9812-1(c)(4)(viii), 29 CFR 2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii), discussed later in this preamble. The Departments solicit comments on this proposed provision, including whether there are specific challenges or considerations the Departments should be cognizant of, as a general matter, in approaching situations that involve ceasing application of a particular NQTL.

g. NQTL Examples - *26 CFR 54.9812-1(c)(4)(viii), 29 CFR 2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii)*

These proposed rules also would amend 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii), redesignated as part of these proposed rules as 26 CFR 54.9812-1(c)(4)(viii), 29 CFR 2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii). These proposed rules would revise some existing examples, remove other existing examples, and add several new examples to further demonstrate the rules of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), as proposed to be amended in these rules.

In some cases, the Departments propose to revise existing examples to show how an NQTL would be analyzed under paragraph (c)(4) in accordance with the proposed amendments. In other cases, the Departments are proposing to replace existing examples with new fact patterns that would more clearly demonstrate how these proposed rules for NQTLs would apply to plans and issuers. In each example in 26 CFR 54.9812-1(c)(4)(viii), 29 CFR

2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii), a group health plan is subject to the requirements of MHPAEA and provides coverage for both medical/surgical benefits and mental health and substance use disorder benefits. Additionally, in examples that conclude that the plan or issuer violates one provision of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), such examples do not necessarily imply compliance with all of the other relevant provisions (as these examples do not analyze compliance with all other provisions). The Departments solicit comments on these new examples and the proposed amendments to existing examples.

Example 1 - More restrictive prior authorization requirement in operation. First, the Departments propose to amend existing Example 1 to illustrate the effect of a disparity in the routine approval of benefits for mental health conditions and substance use disorders compared to benefits for medical/surgical conditions in a classification. This proposed amended example would retain similar facts to the existing example, in which a plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. While the plan approves inpatient, in-network benefits for medical/surgical conditions for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan, the approvals for 7 days are most common under this plan. However, for mental health and substance use disorder benefits, the plan routinely approves only 1 day of inpatient, in-network benefits before a treatment plan must be submitted by the patient's attending provider and approved by the plan. In this example, the difference in the duration of approvals is not the result of independent professional medical or clinical standards or standards related to fraud, waste, and abuse, but rather reflects the application of a heightened standard to the provision of the mental health and substance use disorder benefits in the relevant classification.

The existing conclusion to Example 1 states that the plan violates the no more restrictive requirement in 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) because it is applying a stricter NQTL in operation to mental health and substance use disorder benefits than is applied to medical/surgical benefits. The proposed amended conclusion would provide additional explanation to illustrate how the prior authorization NQTL would be analyzed under these proposed rules (and revise the conclusion to indicate that paragraph (c)(4)(i) of those sections would be redesignated as paragraph (c)(4)(ii)(A), and new requirements would be added at paragraph (c)(4)(i)). The proposed conclusion would explain that the NQTL applies to at least two-thirds of all medical/surgical benefits in the inpatient, in-network classification, because it applies to all inpatient medical/surgical benefits in that classification. The most common or frequent variation of this NQTL, and, therefore, the predominant NQTL that applies to medical/surgical benefits in the classification, is the routine approval of inpatient benefits for 7 days before the patient's attending provider must submit a treatment plan. However, the plan routinely approves inpatient, in-network benefits for mental health and substance use disorder conditions for only 1 day before the patient's attending provider must submit a treatment plan. In doing so, the plan does not impartially apply independent professional medical or clinical standards or apply standards related to fraud, waste, and abuse that qualify for the exceptions in proposed 26 CFR 54.9812-1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E).

In this proposed amended Example 1, in operation, the prior authorization NQTL imposed on mental health and substance use disorder benefits in the inpatient in-network classification is more restrictive than the predominant prior authorization requirement applicable to substantially all medical/surgical benefits in the classification, because the practice of approving 1 day of inpatient, in-network mental health and substance use disorder benefits limits access to the full range of treatment options available for benefits for a condition or disorder under the plan or coverage as compared to the routine 7-day approval that is given for inpatient,

in-network medical/surgical benefits. As the prior authorization requirement violates the no more restrictive requirement, the proposed amended example does not address the other aspects of the NQTL parity analysis under these proposed rules (the design and application requirements or the relevant data evaluation requirements), because the plan would violate MHPAEA, even if it satisfied those requirements.

Example 2 - More restrictive peer-to-peer concurrent review requirements in operation. In new Example 2 in these proposed rules, a plan follows a written process for the concurrent review of all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under the process, a first-level review is conducted in every instance in which concurrent review applies, and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. While the written process only requires review by the second-level reviewer to either deny or approve the request, in operation, second-level reviewers for mental health and substance use disorder benefits conduct a peer-to-peer review with a provider (acting as the authorized representative of a participant or beneficiary) before coverage of the treatment is approved. The peer-to-peer review requirement is not the result of independent professional medical or clinical standards or standards related to fraud, waste, and abuse. The plan does not impose a peer-to-peer review, as written or in operation, as part of the second-level review for medical/surgical benefits.

In this proposed example, the concurrent review requirement violates the no more restrictive requirement at proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). The concurrent review NQTL applies to at least two-thirds of all medical/surgical benefits within the inpatient, in-network classification because the plan follows

the concurrent review process for all medical/surgical benefits. The most common or frequent variation of this NQTL and, therefore, the predominant NQTL that applies to all medical/surgical benefits in the classification, is that peer-to-peer review is not imposed as part of second-level review. The plan does not impartially apply independent professional medical or clinical standards or apply standards related to fraud, waste, and abuse that qualify for the exceptions in 26 CFR 54.9812-1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E) of these proposed rules. While, as written, the plan's concurrent review requirements are the same for medical/surgical benefits and mental health and substance use disorder benefits, in operation, by compelling an additional action (peer-to-peer review as part of second-level review) to access only mental health or substance use disorder benefits, the plan applies the concurrent review NQTL to mental health or substance use disorder benefits in a manner that is more restrictive than the predominant concurrent review requirements applied to substantially all medical/surgical benefits in the inpatient, in-network classification. Because the plan violates the no more restrictive requirement, the example does not analyze compliance with the design and application requirements or the relevant data evaluation requirements in these proposed rules.

Example 3 - More restrictive peer-to-peer review medical necessity standard in operation; deviation from independent professional medical and clinical standards. The Departments propose to add new Example 3 focusing on the imposition of an additional NQTL (completion of peer-to-peer review) on benefits for substance use disorders that is more restrictive than the predominant NQTL applicable to substantially all medical/surgical benefits in the classification. In this example, the plan generally requires that all treatment be medically necessary in the inpatient, out-of-network classification. For both medical/surgical benefits and mental health and substance use disorder benefits, the written medical necessity standards are based on independent professional medical or clinical standards that do not require peer-to-peer review. In operation, the plan covers out-of-network benefits for medical/surgical or mental health inpatient treatment

outside of a hospital if the physician documents medical appropriateness, but for out-of-network substance use disorder inpatient treatment outside of a hospital, the plan requires a physician to also complete peer-to-peer review.

In this example, the plan violates proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). The medical necessity NQTL applies to at least two-thirds of all medical/surgical benefits in the out-of-network, inpatient classification. The most common or frequent variation of the NQTL and, therefore, the predominant NQTL that applies to substantially all medical/surgical benefits, is the requirement that a physician document medical appropriateness without peer-to-peer review. The plan purports to satisfy the exception for independent professional medical or clinical standards in proposed 26 CFR 54.9812-1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E), but deviates from those standards in operation by imposing the additional requirements to complete peer-to-peer review with respect to substance use disorder inpatient treatment outside of a hospital within the classification. As written, the plan provisions apply the NQTL to mental health and substance use disorder benefits in the inpatient, out-of-network classification in the same manner as for medical/surgical benefits. However, in operation, the medical necessity NQTL imposed on out-of-network substance use disorder benefits for treatment outside of a hospital is more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in the classification because it limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits. The NQTL is not the result of independent professional medical or clinical standards or standards related to fraud, waste, and abuse that qualify for the exceptions to the no more restrictive requirement under these proposed rules. Because the plan violates the no more restrictive requirement, the example does not analyze compliance with the design and application requirements or the relevant data evaluation requirements under these proposed rules.

Example 4 – Not comparable and more stringent methods for determining reimbursement rates in operation. New proposed Example 4 would illustrate how plans and issuers must ensure compliance in operation with the design and application requirements under 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii) for a plan's reimbursement rate methodology NQTL, based in part on guidance in FAQs Part 39.[139] For purposes of this example, the facts assume that the plan's methods for determining reimbursement rates for mental health and substance use disorder benefits satisfy the no more restrictive requirement. In this example, a plan's base reimbursement rates for outpatient, in-network providers are determined based on a variety of factors, including the provider's required training, licensure, and expertise. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code vary based on a combination of factors, such as the nature of the service, provider type, number of providers qualified to provide the service in a given geographic area, and market need (demand). As a result, reimbursement rates for mental health, substance use disorder, and medical/surgical benefits furnished by non-physician providers are generally less than for physician providers. In operation, the plan reduces the reimbursement rate for mental health and substance use disorder non-physician providers from that paid to mental health and substance use disorder physicians by the same percentage for every CPT code but does not do the same for non-physician medical/surgical providers.

In this proposed new example, the plan violates the design and application requirements under these proposed rules. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers by the same percentage for every CPT code, but does not apply the same reduction to non-physician providers of medical/surgical services, in operation, the factors used in applying the NQTL to mental health and substance use disorder benefits are not comparable

[139] FAQs Part 39, Q6.

to, and are applied more stringently than, the factors used in applying the limitation with respect to medical/surgical benefits. To continue to apply the current reimbursement rate methodology, the plan would need to ensure that the percentage reduction for mental health and substance use disorder non-physician providers complies with the design and application requirements as compared to the percentage reduction for medical/surgical non-physician providers. Because the plan violates the design and application requirements of these proposed rules, the example does not analyze compliance with the relevant data evaluation requirements (and the facts stipulate compliance with the no more restrictive requirement).

Example 5 – Exception for impartially applied generally recognized independent professional medical or clinical standards. In new proposed Example 5, a group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The medical management requirement impartially applies independent professional medical or clinical standards in a manner that qualifies for the exception in proposed 26 CFR 54.9812-1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E). The plan does not rely on any other factors or evidentiary standards, and the processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims based on the impartial application of the independent professional medical or clinical standards by the NQTL.

The proposed new example would conclude that the plan does not violate 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these proposed rules. The medical management NQTL imposed on mental health and substance use disorder benefits does not violate the no more restrictive requirement or the relevant data evaluation requirements because the plan impartially applies independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits in a manner that qualifies for the exception under proposed 26 CFR 54.9812-1(c)(4)(i)(E) and (c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(i)(E) and (c)(4)(iv)(D), and 45 CFR 146.136(c)(4)(i)(E) and (c)(4)(iv)(D), respectively. Moreover, the independent professional medical or clinical standards are not considered to be a discriminatory factor or evidentiary standard and, as written and in operation, the plan complies with the design and application requirements with respect to the NQTL, regardless of the fact that the application of the NQTL resulted in higher percentages of claim denials for mental health and substance use disorder benefits as compared to medical/surgical benefits.

Example 6 - More restrictive prior authorization requirement; exception for impartially applied generally recognized independent professional medical or clinical standards not met. New proposed Example 6 would incorporate guidance issued in FAQs Part 34,[140] as well as these proposed rules. In this example, the provisions of a plan state that it applies independent professional medical and clinical standards consistent with generally accepted standards of care for setting prior authorization requirements for both medical/surgical and mental health and substance use disorder prescription drugs. The relevant generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes (the American Society of Addiction Medicine national practice guidelines) does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan

[140] *See* FAQs Part 34, Q8.

requires prior authorization for buprenorphine/naloxone combination at each refill (every 30 days) for treatment of opioid use disorder.

In Example 6, the plan violates the no more restrictive requirement under 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) of these proposed rules. The plan does not qualify for the proposed exception for independent professional medical or clinical standards, because although the provisions of the plan state that it applies independent professional medical and clinical standards, the plan deviates from the relevant standards with respect to prescription drugs to treat opioid use disorder. The prior authorization NQTL is applied to at least two-thirds of all medical/surgical benefits in the prescription drugs classification. The most common or frequent variation of this NQTL and, therefore, the predominant NQTL that applies to substantially all medical/surgical benefits in the classification is following generally recognized independent professional medical and clinical standards (consistent with generally accepted standards of care). The prior authorization requirements imposed on substance use disorder benefits are more restrictive than the predominant requirement applicable to substantially all medical/surgical benefits in the classification, because the plan imposes additional requirements on substance use disorder benefits that limit access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the no more restrictive requirement under the proposed rules, the example does not analyze compliance with the design and application requirements or the relevant data evaluation requirements.

The Departments note that, if the NQTL satisfied the no more restrictive requirement, in compliance with proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i), the clarification in FAQs Part 34 would still be relevant to this example. In that guidance, the Departments explained that, if the plan had used a Pharmacy and Therapeutics (P&T) committee to decide how to cover prescription drugs and to evaluate whether to follow or

deviate from nationally recognized treatment guidelines for setting prior authorization requirements, this approach may not have violated MHPAEA. Nonetheless, as explained in the FAQs, use of the P&T committee would need to be evaluated for compliance with MHPAEA's NQTL requirements (for example, by evaluating whether the P&T committee is composed of comparable experts for mental health conditions and substance use disorders, as compared to the experts for medical/surgical conditions, and how these experts evaluated nationally recognized treatment guidelines in setting prior authorization requirements for medications for mental health conditions, substance use disorders, and medical/surgical conditions). Although this language on P&T committees has not been added to the text of this example, this guidance continues to apply.

Example 7 – Impermissible NQTL imposed following a final determination of noncompliance and direction by Secretary. New proposed Example 7 would illustrate the application of the provisions of these proposed rules at 26 CFR 54.9812-1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii). In this example, following an initial request by the Secretary for a plan's comparative analysis of an NQTL pursuant to proposed 26 CFR 54.9812-2(d), 29 CFR 2590.712-1(d), and 45 CFR 146.137(d), the plan submits a comparative analysis for the NQTL. After review of the comparative analysis, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in the relevant classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation with respect to medical/surgical benefits in the classification. Pursuant to proposed 26 CFR 54.9812-2(d)(3), 29 CFR 2590.712-1(d)(3), and 45 CFR 146.137(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination, and the Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of proposed 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). The plan receives a final determination of noncompliance from the

Secretary, which informs the plan that it is not in compliance with proposed 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) and directs the plan not to impose the NQTL by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. As of that date, the plan makes no changes to its plan terms by that date and continues to impose the NQTL.

The proposed example would conclude that the plan violates the requirements of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) by imposing the NQTL after the Secretary directs the plan not to impose the NQTL, pursuant to proposed 26 CFR 54.9812-1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii).

Example 8 – Provider network admission standards not more restrictive and compliant with requirements for design and application of NQTLs. The Departments propose to amend Example 7 of the 2013 final regulations (and redesignate it as Example 8) to better align the example with the amended requirements for NQTLs set forth in these proposed rules. In this example, as part of a plan's standards for provider admission to its network in the outpatient, in-network classification, any provider seeking to contract with the plan must have supervised clinical experience. As a result of that standard, master's level mental health therapists are required to obtain supervised clinical experience beyond their licensure to participate in the network, while master's level medical/surgical providers, psychiatrists and Ph.D.-level psychologists do not require additional experience beyond their licensure (because their licensure already requires supervised clinical experience). The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the NQTL. This includes in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). This data demonstrates that participants and beneficiaries seeking outpatient care are able to access outpatient, in-network mental health and substance use disorder providers at the same frequency

as outpatient, in-network medical/surgical providers, that mental health and substance use disorder providers are active in the network and are accepting new patients to the same extent as medical/surgical providers, and that mental health and substance use disorder providers are within similar time and distances to plan participants and beneficiaries as are medical/surgical providers. This data also does not identify material differences in what the plan or issuer pays psychiatrists or non-physician mental health providers, compared to physicians or non-physician medical/surgical providers, respectively, both for the same reimbursement codes and as compared to Medicare rates. Material differences could suggest that, in operation, NQTLs related to methodologies for determining reimbursement rates are being applied in a non-comparable or more restrictive manner for mental health or substance use disorder services than medical/surgical services, resulting in a material difference in access.

The conclusion to Example 8 states that the plan does not violate 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these proposed rules. The standards for provider admission to the plan's network are applied to at least two-thirds of all medical/surgical benefits in the outpatient, in-network classification, as they apply to all medical/surgical benefits in the classification. Additionally, the most common or frequent variation of the NQTL (the predominant NQTL that applies to substantially all medical/surgical benefits) in the classification is having a certain number of years of supervised clinical experience. The conclusion notes that the standards for provider admission to the plan's network that are imposed with respect to mental health or substance use disorder benefits are no more restrictive, as written and in operation, than the predominant standards for provider admission applicable to substantially all medical/surgical benefits in the classification, because the standards do not limit access to the full range of treatment options available for a mental health condition or substance use disorder under the plan or coverage as compared to medical/surgical benefits. The requirement that providers have a certain number of years of supervised clinical experience that the plan relied on to design and apply the NQTL is not considered to discriminate

against mental health or substance use disorder benefits, even though this results in the requirement that master's level mental health therapists obtain supervised clinical experience beyond their licensure, unlike master's level medical/surgical providers. In addition, as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification. Finally, the plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the NQTL, which does not show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in the classification.

Example 9 – More restrictive requirement for primary caregiver participation applied to ABA therapy. As discussed earlier in this preamble, the Departments are proposing amendments clarifying in these proposed rules that ASD is a mental health condition under generally recognized independent standards of current medical practice. Thus, ASD is a mental health condition, and coverage for treatment for ASD is a mental health benefit as defined in 26 CFR 54.9812-1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a) of the 2013 final regulations and 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2) of these proposed rules. In new proposed Examples 9 and 10, the Departments would illustrate the application of MHPAEA to ASD treatment, consistent with ASD being classified as a mental health condition. In proposed new Example 9, a plan generally applies medical necessity criteria in adjudicating claims for coverage of all outpatient, in-network medical/surgical and mental health and substance use disorder benefits, including ABA therapy for the treatment of ASD. The medical necessity criteria for coverage of ABA therapy requires evidence that the participant's or beneficiary's primary caregivers actively participate in ABA therapy, as documented by consistent attendance in parent, caregiver, or guardian training sessions. In adding this

requirement, the plan deviates from independent professional medical or clinical standards, and there are no similar medical necessity criteria requiring evidence of primary caregiver participation to receive coverage for any medical/surgical benefits.

Proposed Example 9 would violate the no more restrictive requirement of these proposed rules. The conclusion notes that the plan applies medical necessity criteria to at least two-thirds of all outpatient, in-network medical/surgical benefits, as they apply to all medical/surgical benefits in the classification. The most common or frequent variation of this NQTL (the predominant NQTL) that applies to substantially all medical/surgical benefits in the classification does not include the requirement to provide evidence that the participant's or beneficiary's primary caregivers actively participate in the treatment. The plan does not qualify for the exception in 26 CFR 54.9812-1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E) of these proposed rules in applying its restriction on coverage for ABA therapy because the plan deviates from the independent professional medical or clinical standards by imposing a different requirement that does not comport with independent professional medical or clinical standards (consistent with generally accepted standards of care). The proposed new example would conclude that the plan's treatment of ABA therapy and the imposition of the additional requirement to provide evidence that primary caregivers actively participate in treatment violates proposed 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) because the NQTL imposed on mental health and substance use disorder benefits in the example is more restrictive than the predominant medical necessity requirement imposed on substantially all medical/surgical benefits (which does not include the requirement to provide evidence that primary caregivers actively participate in treatment). Because the plan violates the no more restrictive requirement, the example does not analyze compliance with the design and application requirements or the relevant data evaluation requirements of these proposed rules.

Example 10 - More restrictive exclusion for experimental or investigative treatment applied to ABA therapy. Proposed new Example 10 would incorporate guidance issued as part of FAQs Part 39.[141] In this example, a plan, as written, generally excludes coverage for all treatments that are experimental or investigative for medical conditions and surgical procedures, mental health conditions, and substance use disorders in the outpatient, in-network classification. As a result, the plan generally excludes experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD.

In this proposed new example, the coverage exclusion for experimental or investigative treatment applies to at least two-thirds of all medical/surgical benefits, as it applies to all outpatient medical/surgical benefits in the outpatient, in-network classification. The most common or frequent variation of this NQTL and, therefore, the predominant NQTL applicable to substantially all medical/surgical benefits is the exclusion under the plan for coverage of experimental treatment of medical conditions and surgical procedures when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. In operation, the exclusion for experimental or investigative treatment imposed on ABA therapy is more restrictive than the

[141] *See* FAQs Part 39, Q1.

predominant variation of the NQTL for experimental or investigative treatment imposed on substantially all medical/surgical benefits in the classification because the exclusion limits access to the full range of treatment options available for a mental health condition under the plan as compared to medical/surgical benefits. This is the case, despite the fact that the requisite number of professionally recognized treatment guidelines and randomized controlled trials support its use to treat certain children with ASD. Therefore, the plan's application of the experimental exclusion to ABA therapy violates the no more restrictive requirement in 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i), and the example does not analyze compliance with the design and application requirements or the relevant data evaluation requirements under these proposed rules.

Example 11 – Separate EAP exhaustion treatment limitation applicable only to mental health benefits. The Departments also propose to amend Example 6 of the 2013 final regulations and redesignate it as Example 11. In this example, the employer maintains both a major medical plan and an employee assistance plan (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health and substance use disorder benefits under the employer's major medical coverage only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

In this example, limiting eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is an NQTL subject to MHPAEA and violates these proposed rules. Because the limitation does not apply to medical/surgical benefits, it is a separate NQTL applicable only to mental health and substance use disorder benefits, which violates 26 CFR 54.9812-1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi) of these proposed rules. The Departments also note that this EAP would

generally not qualify as excepted benefits as set forth in the final excepted benefits rules (published after the 2013 final regulations).[142] Under those rules, the benefits provided under an EAP are excepted if the EAP does not provide significant benefits in the nature of medical care, the benefits under the EAP are not coordinated with benefits under another group health plan, no employee premiums or contributions are required as a condition of participation in the EAP, and there is no cost sharing under the EAP. In this example, the benefits under the EAP are coordinated with the benefits of another group health plan, since participants in the major medical group health plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the major medical plan.

Example 12 – Separate residential exclusion treatment limitation applicable only to mental health benefits. Proposed new Example 12 would demonstrate that MHPAEA specifically prohibits separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits. In this example, a plan generally covers inpatient, in-network and inpatient, out-of-network treatment in any setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan also has an exclusion for residential treatment, which the plan defines as an inpatient benefit, for mental health and substance use disorder benefits. This exclusion was not generated through any broader NQTL (such as medical necessity or other clinical guideline). The proposed new example would conclude that the plan violates 26 CFR 54.9812-1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi) of these proposed rules. Because the plan does not apply a comparable exclusion to inpatient benefits for medical/surgical conditions, the exclusion of residential treatment is a separate NQTL applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network

[142] 26 CFR 54.9831-1(c)(3)(vi)(B)(*1*), 29 CFR 2590.732(c)(3)(vi)(B)(*1*), and 45 CFR 146.145(b)(3)(vi)(B)(*1*); 79 FR 59130 (Oct. 1, 2014).

classifications that does not apply with respect to any medical/surgical benefits in the same benefit classifications.

Example 13 – Standards for provider admission to a network. Finally, proposed new Example 13 would illustrate how plans and issuers may comply with these proposed rules with regard to parity, including the requirement to collect and evaluate data, with respect to standards related to network composition, including standards for provider and facility admission to participate in a network or for continued network participation, methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of providers and facilities to provide covered services under the plan or coverage. As highlighted above, the proper design, administration, and composition of networks are essential to participants and beneficiaries having access to treatment for mental health conditions and substance use disorders in parity with access to treatment for medical conditions and surgical procedures, and this proposed example illustrates the steps that plans and issuers may take to improve such access.

In this proposed new example, a plan applies NQTLs related to network composition in the outpatient, in-network and inpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The facts of the example stipulate that the plan's NQTLs related to network composition for mental health and substance use disorder benefits satisfy the no more restrictive requirement and the design and application requirements in the outpatient, in-network and inpatient, in-network classifications. It further stipulates that the plan collects and evaluates all relevant data in a manner reasonably designed to assess the impact of the NQTLs related to network composition on access to mental health and substance use disorder benefits as compared with medical and surgical benefits and considers the impact as part of the plan's analysis of whether the NQTLs, in operation, comply with the no more restrictive requirement and the design and application requirements of these proposed rules.

The plan determined that the data did not reveal any material differences in access. That data included metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates; in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions); and survey data from participants on the extent to which they forgo or pay out-of-pocket for treatment because of challenges finding in-network providers. The efforts the plan made when designing and applying its NQTLs related to network composition, which ultimately led to its outcomes data not revealing any material differences in access to benefits for mental health or substance use disorders as compared with medical/surgical benefits, included making sure that the plan's service providers are making special efforts to enroll available providers, including by authorizing greater compensation or other inducements to the extent necessary, and expanding telehealth arrangements as appropriate to manage regional shortages. The plan also notifies participants in clear and prominent language on its website, employee brochures, and the summary plan description of a toll-free number available to help participants find in-network providers. In addition, when plan participants submit bills for out-of-network items and services, the plan directs their service providers to reach out to the treating providers and facilities to see if they will enroll in the network.

The proposed new example would conclude that the plan does not violate 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), or 45 CFR 146.136(c)(4). The plan's NQTLs related to network composition comply with the no more restrictive requirement, the design and application requirements, and the relevant data evaluation requirements and the data does not reveal any material differences in access to mental health and substance use disorder benefits as

compared to medical/surgical benefits, as a result of the actions the plan took (as set forth in the facts) when initially designing its NQTLs related to network composition

Because the plan takes comparable actions to ensure that its mental health and substance use disorder provider network is as accessible as its medical/surgical provider network and exercises careful oversight over its service providers and the comparative robustness of the networks with an eye to ensuring that network composition results in access to in-network benefits for mental health and substance use disorder services,, plan participants and beneficiaries can access covered mental health and substance use disorder services and benefits as readily as medical/surgical benefits. This is reflected in the plan's carefully designed metrics and assessment of network composition. The Departments recognize, however, that there are significant challenges to building networks of mental health and substance use disorder providers that result in parity. If, despite taking such comprehensive action in accordance with the requirements of proposed 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), and 45 CFR 146.136(c)(4)(iv)(C), a plan's or issuer's participants, or beneficiaries still experience materially greater reliance on out-of-network, rather than in-network, mental health or substance use disorder benefits because of provider shortages that the plan or issuer cannot effectively address through no fault of its own, the Departments would not treat the plan or issuer as in violation of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), provided that the plan or issuer is otherwise in compliance with the requirements of these sections.

The Departments solicit comments on these proposed amended and added examples, including with respect to how these proposed examples illustrate the application of the provisions of these proposed rules related to NQTLs. The Departments also solicit comments on any additional examples that might be helpful to interested parties with respect to any specific provision of these proposed rules applicable to NQTLs or any specific NQTLs that apply to mental health and substance use disorder benefits.

4. Prohibition on Financial Requirements and Treatment Limitations Applicable Only to Mental Health or Substance Use Disorder Benefits - 26 CFR 54.9812-1(c)(2)(i) and (c)(4)(vi), 29 CFR 2590.712(c)(2)(i) and (c)(4)(vi), and 45 CFR 146.136(c)(2)(i) and (c)(4)(vi)

The Departments propose to amend the general parity requirement set forth in 26 CFR 54.9812-1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i) by adding a sentence to reiterate that a plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The general parity requirement set forth in paragraph (c)(2)(i) provides that a plan or issuer that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. The general parity requirement also states that the application of paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of the regulations; the application of paragraph (c)(2) to NQTLs is addressed in paragraph (c)(4) of the regulations.

Code section 9812(a)(3)(A)(i), ERISA section 712(a)(3)(A)(i), and PHS Act section 2726(a)(3)(A)(i) specifically prohibit separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits, and Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii) specifically prohibit separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits. While the text of the 2013 final regulations does not explicitly incorporate these statutory prohibitions, financial requirements and quantitative treatment limitations that are imposed only with respect to mental health or substance use

disorders could not meet the substantially all or predominant standards in the parity requirements contained in paragraph (c)(3) of 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136, as adopted in the 2013 final regulations. Moreover, an example in the 2013 final regulations demonstrates and affirms that an NQTL applied only to mental health or substance use disorder benefits would not be permissible.[143] These proposed amendments to the general parity requirement set forth in 26 CFR 54.9812-1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i) would directly incorporate the statutory prohibitions by expressly stating that plans and issuers are not permitted to impose any kind of financial requirement or treatment limitation that applies only to mental health or substance use disorder benefits and not to medical/surgical benefits in the same classification.

Because the general parity requirement set forth in 26 CFR 54.9812-1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i) of the 2013 final regulations also states that the application of paragraph (c)(2) to NQTLs is addressed in paragraph (c)(4) of the regulations, the Departments also propose to add similar language to these proposed rules for NQTLs at 26 CFR 54.9812-1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi), which cross-references the language proposed to be added to paragraph (c)(2)(i). This proposed language would state that a plan or issuer may not apply any NQTL that is applicable only with respect to mental health or substance use disorder benefits and not with respect to any medical/surgical benefits in the same benefit classification. For this purpose, an exclusion of benefits for a mental health condition or substance use disorder in a classification that is merely an expression of another NQTL, such as medical necessity requirements or experimental or investigational exclusions, that is applied with respect to medical/surgical benefits in the same classification would not be considered a separately applicable treatment limitation. For example, a plan's exclusion of coverage for ABA therapy is not an expression of a broader NQTL if it was not

[143] *See* 26 CFR 54.9812-1(c)(4)(iii) Ex. 6, 29 CFR 2590.712(c)(4)(iii) Ex. 6, and 45 CFR 146.136(c)(4)(iii) Ex. 6. The Departments are proposing to renumber this example, and to add a clarification on interaction with the Departments' group market excepted benefit rules, but otherwise propose to leave this example unamended.

generated through a process or strategy, or informed by an evidentiary standard of, a broader NQTL like medical necessity. As a result, such an NQTL would be evaluated under 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) to determine whether such NQTL is permitted.

The Departments solicit comments on this proposal.

5. Other Proposed Amendments

The Departments propose to amend 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) to specify that if a plan or issuer provides any benefits for a mental health condition or substance use disorder in any classification of benefits, benefits for that mental health condition or substance use disorder must be provided in every classification in which medical/surgical benefits are provided. For this purpose, if a plan or issuer provides any benefits for a mental health condition or substance use disorder in any classification of benefits, the plan or issuer would not be considered to provide benefits for the mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided unless the plan or issuer provides meaningful benefits for treatment for that condition or disorder in each classification, as determined in comparison to the benefits provided for medical/surgical conditions in such classification. This requirement would ensure that, when plans and issuers cover benefits for a range of services or treatments for medical/surgical conditions in a classification, plans and issuers cannot provide, for example, only one limited benefit for a mental health condition or substance use disorder in that classification. The Departments request comments on this proposal, including whether and how to define "meaningful benefits" for purposes of this provision as well as other potential alternatives. For example, the Departments request comments on whether it would be more practical to require plans and issuers to provide "substantial coverage" of mental health and substance use disorder benefits or benefits for the "primary or most common or frequent types of treatment for a covered condition or disorder" in each classification in which medical/surgical benefits are

provided, and if so, how to define and make comparisons about what constitutes "substantial coverage" or the "primary or most common or frequent types of treatment" for medical/surgical and mental health or substance use disorder benefits.

The preamble of the 2013 final regulations addressed an issue characterized as "scope of services" or "continuum of care."[144] Scope of services generally refers to the types of treatments and treatment settings that are covered by a group health plan or health insurance coverage. The preamble to the 2013 final regulations explained that plans and issuers must assign mental health and substance use disorder benefits and medical/surgical benefits to the six classifications of benefits in a consistent manner, and explained that this rule also generally applies to benefits for intermediate levels of care provided under the plan or coverage.[145] The 2013 regulations further explained that plan or coverage exclusions affecting the scope of services provided under the plan or coverage, such as restrictions based on geographic location, facility type, and provider specialty, among others, must comply with the NQTL parity standard. The Departments recognize that the proposal to require meaningful benefits for mental health and substance use disorder services in a classification is related to scope of services and request comments on whether additional guidance is needed regarding how this proposed requirement would interact with the approach related to scope of services adopted under the 2013 final regulations.

As mentioned above, the proposed amendments to 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) would also state that, if a plan provides any benefits for a mental health condition or substance use disorder, benefits would be required to be provided for *that condition or disorder* in each classification for which any medical/surgical benefits are provided. This proposed language would make explicit in the regulations the

---

[144] 78 FR 68240, 68246-7 (Nov. 13, 2013).

[145] The preamble to the 2013 final regulations stated, "For example, if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for mental health or substance user disorders as an inpatient benefit. In addition, if a plan or issuer treats home health care as an outpatient benefit, then any covered intensive outpatient mental health or substance use disorder services and partial hospitalization must be considered outpatient benefits as well." 78 FR 68240, 68247 (Nov. 13, 2013).

Departments' interpretation that the requirement to provide coverage in each classification in which medical/surgical benefits are provided applies on a condition or disorder basis, an interpretation that the Departments have held since the interim final rules.[146] The Departments solicit comments on these provisions of these proposed rules on classifications of benefits, including whether additional flexibility is needed to account for benefits that are difficult to place into classifications under the current structure, and whether additional guardrails or protections should be required.

The Departments propose to add two additional examples to 26 CFR 54.9812-1(c)(2)(ii)(C), 29 CFR 2590.712(c)(2)(ii)(C), and 45 CFR 146.136(c)(2)(ii)(C) to illustrate the application of these proposed amendments to the rules. Proposed Example 5 would involve a plan that generally covers treatment for ASD, a mental health condition, and covers outpatient, out-of-network developmental evaluations for ASD but excludes all other benefits for outpatient treatment for ASD, including ABA therapy, when provided on an out-of-network basis. Based on independent standards of current medical practice, ABA therapy is one of the primary treatments for ASD in children. In this proposed example, the plan generally covers the full range of outpatient treatments and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. This proposed example provides that the plan would violate the proposed rules in 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) because it fails to provide meaningful benefits for treatment of ASD in the outpatient, out-of-network classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification.

Under proposed Example 6, a plan generally covers diagnosis and treatment for eating disorders, a mental health condition, but specifically excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification. Nutrition counseling is one of the primary treatments for eating disorders. The plan generally provides

[146] 75 FR 5410, 5413 (Feb. 2, 2010).

benefits for the primary treatments for medical conditions and surgical procedures in the outpatient, in-network classification. In this proposed example, the exclusion of coverage for nutrition counseling for eating disorders results in the plan failing to provide meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification. Therefore, the plan violates the proposed rules in 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii). The Departments note that, if the plan covers medical/surgical benefits for nutritional counseling, this plan would also violate the proposed rules in 26 CFR 54.9812-1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136 (c)(4)(vi) prohibiting separate NQTLs applicable only to mental health or substance use disorder benefits.

The 2013 final regulations set forth the only classifications of benefits that may be used in applying the parity rules for financial requirements and treatment limitations, and listed specific instances when a plan or issuer may divide benefits into sub-classifications beyond the six classifications permitted in paragraph (c)(2)(ii)(A) of the 2013 final regulations. Specifically, a plan (or health insurance coverage) may apply different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Additionally, if a plan or issuer provides benefits through multiple tiers of in-network providers (such as an in-network tier of other preferred providers with more generous cost-sharing than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical

benefits or mental health or substance use disorder benefits.[147] A plan or issuer is also permitted to divide its benefits furnished on an outpatient basis into two sub-classifications: (1) office visits (such as physician visits), and (2) all other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).[148] These proposed rules at 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A) would clarify that plans and issuers may use the permissible sub-classifications under the 2013 final regulations when applying all of the rules for financial requirements and treatment limitations, including NQTLs.

After any of these permissible sub-classifications are established, a plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification. These proposed rules would clarify at 26 CFR 54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii) that plans and issuers are not permitted to divide benefits into any sub-classifications other than those specifically permitted under this paragraph. While this proposed amendment would not make any substantive changes to the existing rule, the Departments are proposing to make these regulatory amendments to further reiterate that plans and issuers are not permitted to sub-divide the classifications other than as described in paragraph (c)(3)(iii).

The Departments have received questions and requests for guidance on how to comply with MHPAEA's requirements with respect to telehealth benefits. Specifically, some of these questions have asked where telehealth fits into the existing classifications and sub-classifications of benefits, and whether changes to the Departments' framework and existing regulations implementing MHPAEA are necessary to account for telehealth benefits. The Departments are

---

[147] 26 CFR 54.9812-1(c)(3)(iii)(B), 29 CFR 2590.712(c)(3)(iii)(B), and 45 CFR 146.136(c)(3)(iii)(B).
[148] 26 CFR 54.9812-1(c)(3)(iii)(C), 29 CFR 2590.712(c)(3)(iii)(C), and 45 CFR 146.136(c)(3)(iii)(C).

not proposing to make any changes to the classifications and sub-classifications other than the proposed amendments described in the prior paragraph. The Departments expect plans and issuers to treat telehealth benefits the same way they treat those benefits when provided in person in determining the classification or sub-classification in which a particular benefit belongs and in ensuring compliance with the requirements of MHPAEA, as required under the 2013 final rules. The Departments request comment on issues related to telehealth later in this preamble.

Treasury and DOL also propose to amend 26 CFR 54.9812-1(d)(3) and 29 CFR 2590.712(d)(3) by adding cross-references to proposed 26 CFR 54.9812-2 and 29 CFR 2590.712-1. This amendment would clarify the comparative analyses and any other applicable information required under the CAA, 2021 are considered to be instruments under which a plan is established or operated, and therefore, ERISA plans generally must furnish those documents to plan participants and beneficiaries upon request within 30 days, as required under section 104 of ERISA and 29 CFR 2520.104b-1. Additionally, the Departments propose to amend 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) to clarify that the comparative analyses and any other applicable information required under the CAA, 2021 and these proposed rules qualify as documents, records, and other information relevant to the claimant's claim for benefits to which plans and issuers must provide reasonable access, upon request and free of charge. This clarification is consistent with new proposed 26 CFR 54.9812-2(e)(2), 29 CFR 2590.712-1(e)(2), and 45 CFR 146.137(e)(2), discussed later in this preamble, which generally would require plans and issuers to make available the comparative analyses required to be performed and documented under the CAA, 2021 when requested by participants and beneficiaries in ERISA plans, including by a provider or other person acting as a participant's or beneficiary's authorized representative. These comparative analyses are instruments under which the plan is established and operated, and participants and beneficiaries should be able to request this information in order to ensure they are informed about their health plans or group health insurance coverage. Additionally, these comparative analyses would be

relevant to a claimant's claim for benefits and should therefore be available to participants or beneficiaries, and providers or other individuals acting as a participant's or beneficiary's authorized representative.

Finally, the Departments propose to amend 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) to include a reference to 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), and 45 CFR 146.137(g) and to reflect current HHS regulations at 45 CFR 156.115(a)(3). Existing regulations at 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) state that nothing in paragraphs (f) and (g) of the 2013 final regulations related to MHPAEA's small employer exemption and increased cost exemption, respectively, changes the requirement under HHS regulations at 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, must comply with the provisions of 45 CFR 146.136 to satisfy the requirement to provide essential health benefits (EHBs). HHS has updated 45 CFR 156.115(a)(3) to state that provision of essential health benefits means that a health plan provides benefits that "[w]ith respect to the mental health and substance use disorder services, including behavioral health treatment services, required under § 156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations."[149] Therefore, to be consistent with the language contained in 45 CFR 156.115(a)(3), and to ensure that the cross-reference between the Departments' MHPAEA implementing regulations and HHS' EHB implementing regulations includes the requirement to comply with the provisions on comparative analyses, the Departments propose to amend 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) to state that nothing in paragraph (f)

[149] Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond, 86 FR 53412 (September 27, 2021), available at https://www.federalregister.gov/documents/2021/09/27/2021-20509/patient-protection-and-affordable-care-act-updating-payment-parameters-section-1332-waiver.

or (g) of those sections, or in proposed 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), or 45 CFR 146.136-1(g), would change the requirements of 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the PHS Act and its implementing regulations to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

The Departments solicit comments on these proposals. Additionally, the Departments request comments on whether there are any other steps the Departments can take to promote compliance with these proposed rules or other provisions of MHPAEA, and what other guidance or technical support from the Departments would be helpful to ensuring compliance with MHPAEA.

B. New Regulations at 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137

As explained earlier in this preamble, the CAA, 2021 amended MHPAEA, in part, to expressly require plans and issuers that offer both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits to perform and document their comparative analyses of the design and application of NQTLs, and make their comparative analyses available to the Departments or applicable State authorities upon request.[150] On April 2, 2021, the Departments issued FAQs Part 45 to provide guidance on the amendments to MHPAEA made by the CAA, 2021, including the NQTL comparative analyses requirements. Since the issuance of this guidance, interested parties have requested additional guidance and clarifications on the NQTL comparative analysis requirements. In addition to the proposed amendments to existing provisions of the MHPAEA

[150] Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

regulations outlined earlier in this preamble, these proposed rules would, using the definitions indicated in 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2), codify in regulations the requirement that a plan or issuer that imposes any NQTL on mental health or substance use disorder benefits must perform and document comparative analyses of the design and application of all NQTLs, consistent with Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A). The new proposed rules also set forth the content requirements for NQTL comparative analyses, including the proposed requirement that plans and issuers include and evaluate relevant data as part of their comparative analyses to ensure compliance with MHPAEA.

The Departments are proposing these content requirements in response to requests from interested parties for more details on how plans and issuers should perform and document comparative analyses and based on lessons learned by the Departments from conducting NQTL comparative analysis reviews since the effective date of the comparative analysis requirement. The proposed additional content requirements are designed to ensure that the comparative analyses focus on the statutory standards and promote parity. The proposal includes specific information and data that plans and issuers would be required to incorporate in each comparative analysis with respect to an NQTL, and the factors and evidentiary standards used to design or apply the NQTL; how plans and issuers would be required to demonstrate in their analysis that, under the terms of their plan or coverage, as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than those used with respect to medical/surgical benefits; and what findings and conclusions would be required to be addressed. These proposed rules would also set forth details with respect to when and how plans and issuers would be required to make those comparative analyses available upon request to the Departments or the applicable State authority, and propose when and how plans and issuers would be required to make comparative analyses available upon request to a

participant, beneficiary, or their authorized representative, including the timeframes and procedures for plans and issuers to provide additional information to the requesting Department or an applicable State authority, provide a corrective action plan,[151] and notify participants and beneficiaries of a final determination of noncompliance. For purposes of this proposed provision, the term "applicable State authority" has the same meaning as under PHS Act section 2791(d)(I) and 45 CFR 144.103, which is, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements title of title XXVII of the PHS Act for the State involved with respect to the issuer.

The Departments request comments on all aspects of these proposed rules contained in 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137, including what additional clarifications would help plans and issuers perform and document sufficient comparative analyses and submit those analyses to the Secretary or applicable State authority upon request. In addition, the Departments are interested in feedback related to the challenges plans and issuers face obtaining the necessary information to perform and document a sufficient comparative analysis. The requirement to perform and document comparative analyses under Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8) is generally applicable to group health plans and issuers offering group or individual health insurance coverage. The Departments are aware that plans and issuers contract with managed behavioral health organizations (MBHOs), third-party administrators (TPAs), or other service providers to provide or administer mental health or substance use disorder benefits.[152] The preamble to the 2013 final regulations notes that the fact that an employer or issuer contracts with one or more entities to provide or administer mental health or substance use disorder benefits or other benefits does not

---

[151] The contents of a corrective action plan will vary from one case to another, but such corrective action plans will generally be required to contain certain basic elements including: 1) identification of the noncompliant NQTL at issue, 2) proposed approaches to address this noncompliance, including strategies to provide relief to beneficiaries and participants who were adversely affected, 3) a timeline for implementation, 4) potential constraints or sources of delay that could adversely affect timely implementation, 5) points of contact for corrective action plan implementation, and 6) any other components deemed necessary by the Departments. When a plan or issuer submits a corrective action plan to the Departments, the plan shall be reviewed for completeness and sufficiency.

[152] 78 FR 68239, 68250 (Nov. 13, 2013).

relieve the employer, issuer, or both of their obligations under MHPAEA.[153] Plans and issuers should have clear protocols and processes in place to ensure that the MBHOs and other TPAs for both medical/surgical and mental health and substance use disorder benefits provide sufficient information regarding plan structure and benefits to each other and the plans and issuers that they serve to ensure that the mental health and substance use disorder benefits are coordinated with the medical/surgical benefits for purposes of compliance with MHPAEA.[154]

The Departments understand that, in practice, plan sponsors often rely on the issuer of fully-insured plans, TPAs of self-insured plans, and other service providers to administer their benefits, including designing and implementing the limitations and coverage terms that are subject to MHPAEA requirements and providing them with comparative analyses (or detailed information to inform the development of comparative analyses) for the NQTLs that the issuers, TPAs, and service providers themselves design and apply to mental health and substance use disorder benefits and medical/surgical benefits under the terms of the plan or coverage. While the States and HHS have enforcement authority over issuers providing health insurance coverage with respect to fully-insured plans,[155] the Departments have limited direct enforcement authority over other service providers (including, for example, an MBHO or the TPA or TPAs of a self-insured health plan).[156] However, under ERISA, such service providers may be fiduciaries with respect to private employment-based group health plans. To the extent such service providers are fiduciaries for private employment-based plans, they are subject to the provisions governing fiduciary conduct and liability, including the provisions for co-fiduciary liability under ERISA section 405. The Departments are committed to using all available authority to ensure

---

[153] *Ibid*.
[154] 2020 MHPAEA Self-Compliance Tool, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.
[155] As noted earlier in this preamble, HHS enforces applicable provisions of Title XXVII of the PHS Act, including the provisions added by MHPAEA, with respect to health insurance issuers offering group and individual health insurance coverage in States that elect not to enforce or fail to substantially enforce MHPAEA or another PHS Act provision.
[156] The 2022 MHPAEA Report to Congress notes that EBSA has used the process outlined in section 203 of the CAA, 2021 as a method to engage with service providers (such as TPAs and MBHOs) to obtain wider-scope corrections affecting many plans at once, including pursuing cases against issuers in their capacity as administrative services-only providers (ASOs) to self-insured plans covered by ERISA.

compliance by plans and issuers with MHPAEA for all entities that play a role in administering and designing benefits. The Departments solicit comments on how best to ensure all the entities involved in the design and administration of a group health plan's benefits provide the necessary information to plans and issuers to support their efforts to comply with MHPAEA.

1. Content of Comparative Analyses - 26 CFR 54.9812-2(c), 29 CFR 2590.712-1(c), and 45 CFR 146.137(c)

The Departments propose requirements at 26 CFR 54.9812-2(c), 29 CFR 2590.712-1(c), and 45 CFR 146.137(c) governing the content of the comparative analyses required by Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). The proposed content requirements for comparative analyses as set forth in these proposed regulations are based on the stepwise process found in the 2020 MHPAEA Self-Compliance Tool, described earlier in this preamble, and by the express requirements of the governing statutory provisions.

Consistent with Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8) these proposed rules would require that a comparative analysis include, at a minimum, with respect to each NQTL imposed under a plan or coverage option on mental health or substance use disorder benefits, six specific elements:

(1) a description of the NQTL;

(2) the identification and definition of the factors used to design or apply the NQTL;

(3) a description of how factors are used in the design or application of the NQTL;

(4) a demonstration of comparability and stringency, as written;

(5) a demonstration of comparability and stringency in operation; and

(6) findings and conclusions.

Additionally, these proposed rules would require each plan or issuer to prepare and make available to the Departments or applicable State authority, upon request, a written list of all NQTLs imposed under the plan or coverage and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each

NQTL. This requirement is consistent with FAQs Part 45, which in addition to highlighting four NQTLs that would be enforcement priorities in the near term,[157] stated that plans and issuers should be prepared to make available a list of all other NQTLs for which they have prepared a comparative analysis and a general description of any documentation considered or relied upon to prepare each analysis.[158] The Departments propose to include a requirement to make such a list available to the Departments in connection with a request for a comparative analysis and to clarify that this requirement applies with respect to comparative analyses prepared for all NQTLs, not just those for which the Departments or an applicable State authority have requested a comparative analysis or other information at any particular time. For plans subject to ERISA, these proposed rules would also require that the plan or issuer provide this list and general description to the named fiduciaries required to review the findings or conclusions of each comparative analysis, as discussed later in this preamble.

For each comparative analysis, the description of the NQTL required under proposed 26 CFR 54.9812-2(c)(1), 29 CFR 2590.712-1(c)(1), and 45 CFR 146.137(c)(1) would be required to identify the NQTL that is the subject of the comparative analysis, including the specific terms of the plan or coverage or other relevant terms regarding the NQTL, the policies or guidelines (internal or external) in which the NQTL appears or is described, and the applicable sections of any other relevant documents, such as provider contracts that describe the NQTL, consistent with Code section 9812(a)(8)(A)(i), ERISA section 712(a)(8)(A)(i), and PHS Act section 2726(a)(8)(A)(i). This would include the documents that contain the specific language of the NQTL that the plan or issuer imposes.

---

[157] *See* FAQs Part 45, Q8 (listing prior authorization requirements for in-network and out-of-network inpatient services; concurrent review for in-network and out-of-network inpatient and outpatient services; standards for provider admission to participate in a network, including reimbursement rates; and out-of-network reimbursement rates (plan methods for determining usual, customary, and reasonable charges). Additionally, in the 2023 MHPAEA Report to Congress, EBSA added two areas of priority for the applicable Reporting Period based on CAA, 2021 implementation experience during the first reporting period: impermissible exclusions of key treatments for mental health conditions and substance use disorders and adequacy standards for mental health and substance use disorder provider networks.

[158] FAQs Part 45, Q8.

The plan or issuer also would be required to identify all mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL applies, including a list of which benefits are considered to be mental health and substance use disorder benefits and which benefits are considered to be medical/surgical benefits (consistent with the proposed definitions of those terms). Additionally, each plan or issuer would be required to include in its comparative analysis a description of which benefits are included in each classification of benefits set forth in 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A). Finally, the plan or issuer would be required to identify the predominant NQTL applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant NQTL as compared to other variations, as well as how the plan identified the variations of the NQTL. This requirement is consistent with the statutory language that requires a description of the medical/surgical benefits subject to the NQTL and would operate in support of the proposed no more restrictive requirement at 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i), discussed earlier in this preamble.

The second proposed content element of the comparative analysis, under proposed 26 CFR 54.9812-2(c)(2), 29 CFR 2590.712-1(c)(2), and 45 CFR 146.137(c)(2), would be that a plan or issuer would be required to identify and define all of the factors considered or relied upon to design or apply the NQTL. The plan or issuer would be required to identify all of the factors considered, as well as the evidentiary standards considered or relied upon to design or apply each factor and the evidence or sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the NQTL.

The plan or issuer would then be required to define each factor. The definition of each factor would be required to include a detailed description of the factor, and a description of each evidentiary standard (and the source of each evidentiary standard) identified. The Departments

stress that when identifying the evidence or sources from which an evidentiary standard is derived, the plan or issuer should be prepared to provide the copies of the actual evidence or source used, as well as the date and relevant citation for the correct version of the document used.

The third proposed content element of the comparative analysis, under 26 CFR 54.9812-2(c)(3), 29 CFR 2590.712-1(c)(3), and 45 CFR 146.137(c)(3) of these proposed rules, would be a description of how each factor is used in the design or application of the NQTL to mental health and substance use disorder benefits and medical/surgical benefits in a classification. This section of the comparative analysis would be required to include a detailed explanation of how each factor identified and defined in the comparative analysis is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the NQTL. The description would also include an explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the NQTL. In instances in which the application of the factor depends on specific decisions made in the administration of benefits, the comparative analysis would be required to provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. For example, for a prior authorization NQTL that uses quality measures as a factor, the plan or issuer would be required to describe the nature of the decisions reviewers make to apply the factor (and the timing of those decisions) and describe the reviewers' professional designations and qualifications (including, for example, whether they are psychiatrists or psychologists) when using the factor to apply the NQTL to mental health benefits.

These proposed rules would further provide that, to the extent that more than one factor is identified and defined with respect to an NQTL, the comparative analysis would be required to

explain how such factors relate to each other; the order in which all the factors are applied, including when they are applied; whether and how any factors are given more weight than others; and the reasons for the ordering or weighting of the factors. The analysis would also be required to address any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the NQTL to mental health and substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations. For purposes of these proposed rules, the terms "deviations" or "variations" in this context refer to any differences in how a factor is applied with respect to an NQTL. For example, if the NQTL that is the subject of a comparative analysis is the calculation of reimbursement rates for out-of-network providers, and the factors used to determine how the NQTL applies to mental health and substance use disorder providers are the geographic location of the providers and licensing and accreditation of providers, the comparative analysis would be required to explain in detail how each factor is used to determine the out-of-network reimbursement rates for both mental health and substance use disorder providers and medical/surgical providers, describe how the two factors relate to each other, and address how the plan or issuer establishes any deviations or variations from these factors.

Under the fourth and fifth proposed content elements of a comparative analysis, these proposed rules would require plans and issuers to demonstrate that, in any classification, under the terms of the plan (or health insurance coverage), *both as written* (under the fourth content element) *and in operation* (under the fifth content element), any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, those used in designing and applying the NQTL with respect to medical/surgical benefits. These content elements are consistent with the statutory requirement that comparative

analyses demonstrate "that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical/surgical benefits in the benefits classification,"[159] as well as the provisions of the 2013 final regulations and these proposed rules that would require plans and issuers to analyze parity with respect to NQTLs as written and in operation (recognizing that a plan or issuer may have written processes or plan or coverage terms that are compliant as written, but might not be compliant in practice).[160]

For example, a plan or issuer might use a factor that allows discretion in applying an NQTL that is not captured in detail in written plan or coverage terms or procedures (such as whether an individual may be safely and effectively transitioned to a lower level of care), which might not be comparable in practice when processing claims for mental health and substance use disorder benefits as compared to when processing claims for medical/surgical benefits. Additionally, a plan or issuer might have written processes that are comparable for an NQTL applicable to mental health and substance use disorder benefits and medical/surgical benefits, but that are applied in a more stringent manner to mental health and substance use disorder benefits than to medical/surgical benefits in operation. Thus, it is essential that the Departments are able to determine that, as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, those used in designing and applying the NQTL to medical/surgical benefits.

To demonstrate comparability and stringency as written under the fourth content element in proposed 26 CFR 54.9812-2(c)(4), 29 CFR 2590.712-1(c)(4), and 45 CFR 146.137(c)(4), plans and issuers would be required to include in their comparative analysis, with respect to the

---

[159] Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).
[160] 26 CFR 54.9812(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i).

NQTL and the factors used in applying the NQTL, documentation of each factor identified and defined in the comparative analysis that was applied to determine whether the NQTL applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification. This would include, as relevant, quantitative data, calculations, or other analyses showing whether, in each classification in which the NQTL applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard, and the evaluation of relevant data as required under 26 CFR 54.9812-1(c)(4)(iv)(A), 29 CFR 2590.712(c)(4)(iv)(A), and 45 CFR 146.136(c)(4)(iv)(A) of these proposed rules, to determine that the NQTL would or would not apply. In addition, such documentation would include records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application. Such records could include meeting minutes, or calculations related to quantitative factors, such as costs.

Plans and issuers would also be required to include in their comparative analysis, in each classification in which the NQTL applies, a comparison of how the NQTL, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the NQTL or that address the application of the NQTL. Additionally, the plan or issuer would be required to include in its comparative analysis documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the NQTL. To the extent there is any deviation(s) or variation(s) in the application of a factor, the plan or issuer would be required to include in their comparative analysis an explanation of the reason(s) for any deviation(s) or variation(s) in the application of a factor used to apply the NQTL, or the application of the NQTL, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or

issuer establishes such deviation(s) or variation(s), including in the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived; in the design of the factors or evidentiary standards; or in the application or design of the NQTL. As noted earlier in this preamble, the terms "deviations" or "variations" refer to any differences in how a factor is applied.

In the fifth proposed content element of a comparative analysis, to demonstrate comparability and stringency in operation, proposed 26 CFR 54.9812-2(c)(5), 29 CFR 2590.712-1(c)(5), and 45 CFR 146.137(c)(5) would require a plan or issuer to include in its comparative analysis, with respect to the NQTL and the factors used in designing and applying the NQTL, a comprehensive explanation of how the plan or issuer ensures that, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. This comprehensive explanation would be required to include an explanation of any methodology and underlying data used to demonstrate the application of the NQTL in operation, and the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL is applicable.

Requiring data to be provided to demonstrate compliance with MHPAEA is not a new concept. To facilitate the compliance review of NQTLs, many States have adopted reporting requirements capturing specific data that reflect how the application of certain NQTLs affect outcomes.[161] Examples of data required to be included in reporting by States includes rates of utilization review (including approvals and denials), rates of appeal for adverse benefit determinations (upheld and overturned), the numbers or rates of prior or concurrent authorization

[161] *See* State Parity Implementation Survey, available at https://www.paritytrack.org/reports/#state-disparities.

requests and denials, percentages of claims for mental health and substance use disorder benefits and medical/surgical benefits that are in-network, and provider reimbursement rates.[162] Additionally, a number of States have established quantitative standards for assessing network adequacy, based on maximum travel time or distance, provider-to-enrollee ratios, and maximum appointment wait times.[163] HHS established similar quantitative standards for assessing network adequacy for QHPs offered through the Federally-facilitated Exchanges starting with benefit year 2023.[164] The proposed requirement that plans and issuers include such data, and their evaluation of such data, as part of a comparative analysis would support the Departments' efforts to ensure compliance with MHPAEA, with a focus on access to mental health and substance use disorder care, by helping to identify instances of operational noncompliance with the requirements of MHPAEA and its implementing regulations.

Therefore, as part of a comparative analysis, under these proposed rules, plans and issuers would be required to include the relevant data required under proposed 26 CFR 54.9812-1(c)(4)(iv)(A), 29 CFR 2590.712(c)(4)(iv)(A), and 45 146.136(c)(4)(iv)(A) and evaluate the outcomes that resulted from the application of the NQTL to mental health or substance disorder benefits and medical/surgical benefits, including an evaluation of such relevant data in their comparative analysis, in order to demonstrate whether, in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than those used in applying the limitation with respect to medical/surgical benefits in the classification. The collection and evaluation of this data would assist plans, issuers, participants, beneficiaries, and the Departments (or applicable State authority) in identifying an NQTL that might not comply with MHPAEA.

---

[162] *See, e.g.*, N.Y. Ins. Law 343(b); D.C. Code Sec. 31-3175.03; and Tex. Ins. Code Sec. 1355.254 (coverage for mental health conditions and substance use disorders).
[163] For examples of these State-imposed quantitative standards for assessing network adequacy, see https://www.ncsl.org/health/health-insurance-network-adequacy-requirements.
[164] 87 FR 27208 (May 6, 2022); 2023 Final Letter to Issuers in the Federally-facilitated Exchanges, available at https://www.cms.gov/sites/default/files/2022-04/Final-2023-Letter-to-Issuers_0.pdf.

As part of this evaluation, the comparative analysis would be required to include a detailed explanation of material differences in outcomes that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to mental health or substance use disorder benefits and medical/surgical benefits, as well as the basis for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the NQTL. The requirement that plans and issuers include the relevant data, and their evaluation and analysis of such data, in their comparative analysis is consistent with the CAA, 2021's amendments to MHPAEA, which require plans and issuers to demonstrate that, in operation, the processes, strategies, evidentiary standards, and other factors used in applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, those used to apply the NQTL to medical/surgical benefits.[165] Similarly, to be compliant with this proposed requirement, plans and issuers must adequately demonstrate that any material differences in outcomes are not due to the processes, strategies, evidentiary standards, and other factors being applied more stringently to mental health or substance use disorder benefits, and that they are designed and applied comparably.

The Departments note that their authority to require data is not limited to the data required by 26 CFR 54.9812-2(c)(5), 29 CFR 2590.712-1(c)(5), and 45 CFR 146.137(c)(5). The proposed requirement to evaluate a comparative analysis for operational compliance with MHPAEA's requirements would permit the Departments to require the plan or issuer to provide, as part of that process, additional data to analyze assertions made in the comparative analysis. For example, the Departments may make such a request in instances in which the Departments conclude that a plan or issuer has not submitted to the Departments sufficient information to assess compliance with MHPAEA as part of its comparative analysis, as described later in this preamble. Plans and issuers performing and documenting the required comparative analysis of an NQTL must also provide any and all relevant information used to design or apply the NQTL, as

[165] Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).

explained earlier in this preamble. Finally, the Departments may also require additional information under their authority to investigate plans and issuers.[166]

The comparative analysis would be required to include a discussion of any measures that have been or are being implemented by the plan or issuer to mitigate any materially disparate outcomes with respect to mental health or substance use disorder benefits and medical/surgical benefits, including the actions the plan or issuer is taking under these proposed rules to address the material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions required by 26 CFR 54.9812-1(c)(4)(iv)(B)(*1*), 29 CFR 2590.712(c)(4)(iv)(B)(*1*), and 45 CFR 146.136(c)(4)(iv)(B)(*1*). As discussed earlier in this preamble and in previous guidance related to MHPAEA, evaluating quantitative outcomes helps to identify areas of potential noncompliance. Therefore, these proposed rules would require that as part of a sufficient comparative analysis, a plan or issuer must carefully assess any outcomes that resulted from the application of an NQTL, explain material differences in those outcomes, and disclose any measures to mitigate those disparate outcomes.

The sixth proposed content element of a comparative analysis under proposed 26 CFR 54.9812-2(c)(6), 29 CFR 2590.712-1(c)(6), and 45 CFR 146.137(c)(6) (and consistent with Code section 9812(a)(8)(A)(v), ERISA section 712(a)(8)(A)(v), and PHS Act section 2726(a)(8)(A)(v)), would require that a comparative analysis address findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. The comparative analysis would be required to include any findings or conclusions indicating that the plan or coverage is not (or might not be) in compliance with the provisions of these proposed rules for NQTLs, including any actions the plan or issuer has taken or intends to take to address any potential areas of concern or

[166] *See, e.g.*, ERISA section 504.

noncompliance. The comparative analysis would be required to include a reasoned and detailed discussion of those findings and conclusions, as well as citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions.

Additionally, these proposed rules would require that the comparative analysis include the date of the analysis and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis. If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, the comparative analysis would be required to include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of each NQTL applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

Finally, for plans subject to ERISA, the comparative analysis would be required to include a certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the comparative analysis to be in compliance with the content requirements of these proposed rules. This requirement, along with the requirement that the plan provide named fiduciaries with a written list of all NQTLs and a general description of any existing documentation relied on by the plan or issuer in preparing the comparative analysis for each NQTL, would help ensure that plan fiduciaries meet their obligations under ERISA to review the comparative analyses and properly monitor their plans for compliance with MHPAEA.

The Departments emphasize that the proposed requirement to include this information on the factors, evidentiary standards, and sources used to design or apply the NQTL is crucial to understanding whether the NQTL complies with MHPAEA's requirements. Plans and issuers must disclose information as required by MHPAEA to participants and beneficiaries, as well as the Departments, regardless of whether such information is "proprietary" and/or has

"commercial value."[167] Similarly, if finalized, plans and issuers must include all information required in the comparative analyses.

The Departments solicit comments on all aspects of the proposed content elements for NQTL comparative analyses, including whether there are additional considerations, such as the Kennedy Forum's Six-Step Parity Compliance Guide,[168] or comparable State processes, that the Departments should incorporate into these proposed rules. The Departments also solicit comments on whether any of these proposed requirements related to the content of comparative analyses are superfluous, unhelpful, or unreasonably burdensome.

2. Requirement to Provide Comparative Analyses and Notices to the Departments and Other Individuals and Entities - 26 CFR 54.9812-2(d) and (e), 29 CFR 2590.712-1(d) and (e), and 45 CFR 146.137(d) and (e)

As specified in Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8) and FAQs Part 45, effective February 10, 2021, plans and issuers must be prepared to make their comparative analyses available to the Departments or applicable State authorities upon request. These proposed rules set forth proposed requirements related to submission of comparative analyses to the Departments or applicable State authorities once a request has been received by a plan or issuer. However, as discussed later in this section of the preamble, the requirement to perform and document comparative analyses of the design and application of NQTLs is not dependent upon a request by the Secretary or an applicable State authority, and plans and issuers should not wait for a request from the Secretary or applicable State authority to perform and document their comparative analyses.

These proposed rules would require that plans and issuers make a comparative analysis required under 26 CFR 54.9812-2(b), 29 CFR 2590.712-1(b), and 42 CFR 147.137(b) available and submit it upon request by the relevant Secretary. Once a comparative analysis is requested,

---

[167] *See* FAQs Part XXIX, Q12.

[168] The "Six-Step" Parity Compliance Guide for Non-Quantitative Treatment Limitation (NQTL) Requirements, available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/rules-and-regulations/public-comments/faq-38/00018.pdf.

these proposed rules would require plans and issuers to provide a comparative analysis within 10 business days of receipt of a request from the relevant Secretary (or an additional period of time specified by the relevant Secretary). This proposed deadline is consistent with the Departments' current enforcement practices for requesting comparative analyses from plans and issuers and would allow each Secretary to permit extensions of this deadline as warranted on a case-by-case basis.

After a plan or issuer responds to an initial request for a comparative analysis, if the relevant Department (with jurisdiction over the group health plan (or health insurance coverage offered by an issuer in connection with such a plan)) concludes a plan or issuer has not submitted sufficient information for it to review the requested comparative analyses, Code section 9812(a)(8)(B)(ii), ERISA section 712(a)(8)(B)(ii), and PHS Act section 2726(a)(8)(B)(ii) provide that the Departments shall specify to the plan or issuer the additional information the plan or issuer must submit to be responsive to the request. Under these proposed rules, the plan or issuer would be required to furnish this additional information to the relevant Secretary within 10 business days after the relevant Secretary specifies the additional information to be submitted (or an additional period of time specified by the relevant Secretary). As noted earlier in this preamble, a request for additional information by the relevant Department or an applicable State authority may include a request for data to analyze the assertions made in the comparative analyses, consistent with existing authority. This additional information or data may relate to the relevant data specified by the Departments to be included in a comparative analysis (discussed earlier in this preamble) or other data.

In instances that the relevant Department has reviewed a plan's or issuer's comparative analyses (and any additional information submitted upon request), and made an initial determination that the plan or issuer is not in compliance with the requirements related to NQTLs, Code section 9812(a)(8)(B)(iii)(I)(aa), ERISA section 712(a)(8)(B)(iii)(I)(aa), and PHS Act section 2726(a)(8)(B)(iii)(I)(aa) require the plan or issuer to respond to the Departments and

specify the actions the plan or issuer will take to bring the plan or coverage into compliance (a corrective action plan) and provide additional comparative analyses that demonstrate compliance not later than 45 calendar days after the initial determination of noncompliance. Consistent with these statutory provisions, these proposed rules would also require the plan or issuer to respond to the relevant Department and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the relevant Department additional comparative analyses meeting the requirements of these proposed rules that demonstrate compliance with MHPAEA not later than 45 calendar days after the relevant Department's initial determination that the plan or issuer is not in compliance.

If the relevant Department makes a final determination that the plan or issuer is not in compliance following the 45-calendar-day corrective action period, these proposed rules would provide at 26 CFR 54.9812-2(d)(4), 29 CFR 2590.712-1(d)(4), and 45 CFR 146.137(d)(4) that, within 7 calendar days of the receipt of the final determination of noncompliance, the plan or issuer must provide a standalone notice that is not combined with any other notices or disclosures, as required under applicable Federal or State law, to all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of these proposed rules, consistent with Code section 9812(a)(8)(B)(iii)(I)(bb), ERISA section 712(a)(8)(B)(iii)(I)(bb), and PHS Act section 2726(a)(8)(B)(iii)(I)(bb). The plan or issuer would also be required to provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same time frame. The Departments solicit comments on the proposed timing of this notice, including whether requiring the notice to be provided within 7 calendar days of receipt of a final determination of noncompliance would provide sufficient time for plans and issuers to provide notice, or whether allowing the notice to be provided within 7 business days would be more practicable given holidays and weekends that could serve to effectively shorten the 7-calendar-day timeframe.

The notice to participants and beneficiaries (which would include a participant's or beneficiary's authorized representative) informing them that the relevant Department has determined that their plan or coverage violates MHPAEA gives them critically important information for the pursuit and protection of their own benefit claims and rights and provides a powerful incentive for the plan or issuer to take necessary corrective actions to come into compliance following an initial determination of noncompliance.

These proposed rules set forth requirements for the content of this notice and the manner in which it would be required to be provided. These proposed rules would require that the notice be written in plain language and in a manner calculated to be understood by the average plan participant or beneficiary. This concept is consistent with the Departments' transparency in coverage regulations,[169] and the DOL's style and format requirements for summary plan descriptions under ERISA.[170] The notice would be required to include the following statement prominently displayed on the first page, in no less than 14-point font:

"Attention! The [Department of Labor/Department of Health and Human Services/Department of the Treasury] has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act."

The notice would also be required to contain a summary of any changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed. Additionally, the notice would be required to include a summary of the Secretary's final determination that the plan or issuer is not in compliance with MHPAEA, including any provisions or practices identified to be in violation of

[169] 26 CFR 54.9815-2715A1(a)(2)(xx), 29 CFR 2590.715-2715A1(a)(2)(xix), 45 CFR 147.210(a)(2)(xx).
[170] 29 CFR 2520.102-2(a).

MHPAEA, any additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain a copy of the final determination of noncompliance from the plan or issuer. This notice would also be required to include any other actions the plan or issuer is taking to come into compliance with MHPAEA, information on when the plan or issuer will take (or has taken) such actions, and a clear and accurate statement explaining whether the Secretary has indicated that those actions, if completed, will result in compliance. Finally, these proposed rules would require the notice include contact information for questions and complaints, with a statement explaining how participants and beneficiaries can obtain more information about the notice, including a phone number and an email or web portal address for the plan or issuer, and contact information for the relevant Department.

Under these proposed rules, a plan or issuer would be required to make the notice available in paper form. The plan or issuer may also make the notice available electronically (such as by email or an internet posting) if the format is readily accessible, the notice is provided in paper form free of charge upon request, and, in a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email that the documents are available on the internet, provides the internet address, and notifies the participant or beneficiary that the documents are available in paper form upon request. This approach is similar to standards for when a plan or issuer is permitted to provide a copy of their plan's or coverage's summary of benefits and coverage with respect to participants and beneficiaries who are eligible but not enrolled for coverage.[171] For ERISA plans, the plan or issuer would also be required to ensure that the notice is provided to any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within 7 calendar days of receipt of the final determination of noncompliance, so that the service provider or fiduciary can appropriately take the violation into account in deciding

[171] *See* 26 CFR 54.9815-2715(a)(4)(ii)(B), 29 CFR 2590.715-2715(a)(4)(ii)(B), 45 CFR 147.200(a)(4)(ii)(B).

claims in compliance with the requirements of 29 CFR 2590.712(c)(4) and in accordance with section 404(a)(1)(D) of ERISA.

In addition to making the comparative analyses available upon request to the relevant Secretary, 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e) of these proposed rules would require that plans and issuers make available the comparative analyses required by 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 when requested by any applicable State authority. While these proposed rules would codify the statutory requirement to make comparative analyses available to the applicable State authority upon request, these proposed rules do not otherwise apply the timeframes and processes regarding the Secretarial request process to requests made by applicable State authorities. The Departments seek comment on whether, in cases in which an applicable State authority makes a request for an NQTL comparative analysis, the proposed requirements in paragraph (d) related to submission of comparative analyses to the Secretary, including the proposed notice requirement in paragraph (d)(4), should apply to plans and issuers with respect to a request made by the applicable State authority. In cases of an adverse benefit determination, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage would be required to make these comparative analyses available to participants or beneficiaries, and providers or other individuals acting as their authorized representative, upon request and in accordance with the requirements under section 2719 of the PHS Act and its implementing regulations.[172] Finally, the Departments solicit comment on other measures to increase transparency and better inform the general public regarding final agency determinations of noncompliance of plans or issuers with MHPAEA.

Additionally, under these proposed rules, plans subject to ERISA would be required to make these comparative analyses available to participants and beneficiaries upon request, consistent with the interpretation discussed earlier in this preamble that comparative analyses and

[172] 26 CFR 54.9815-2719, 29 CFR 2590.715-2719, and 45 CFR 147.136.

any other applicable information required under the CAA, 2021 and these proposed rules are instruments under which a plan is established or operated. If a provider or other person is acting as a participant's or, beneficiary's, authorized representative, plans subject to ERISA would be required to make this analysis available to the provider or other authorized representative.

The Departments have received questions about when plans and issuers are required to perform and document comparative analyses, and how often they must be updated. The Departments are aware of reports that some plans (or their TPAs or other service providers) and issuers have not documented their comparative analyses and instead wait until the Departments, or an applicable State authority, request comparative analyses, or indicate that the plan or issuer is otherwise under investigation. The Departments are also aware of reports that self-insured plans have been unsuccessful in receiving comparative analyses (or the information required to perform and document comparative analyses) from their TPAs or other service providers in response to a request. The Departments emphasize that the requirement to perform and document comparative analyses of the design and application of NQTLs has been effective under the CAA, 2021 for more than two years (since February 10, 2021) and is an independent statutory obligation that is not dependent upon a request by the Secretary or an applicable State authority. It is an affirmative statutory obligation that applies irrespective of any such request.

The requirements under Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8) and these proposed rules to perform and document comparative analyses of the design and application of NQTLs are essential components of a plan's or issuer's legal obligation to ensure compliance with MHPAEA, and failure to satisfy those requirements puts participants and beneficiaries at risk of their mental health and substance use disorder benefits not being in parity with medical/surgical benefits. Therefore, plans and issuers should work with their service providers to ensure that they have performed and documented comparative analyses for their NQTLs as required by MHPAEA, as amended by the CAA, 2021, regardless of the timing of any request by the Departments, applicable State authorities, or participants and

beneficiaries. Plans and issuers and their service providers must also ensure that the comparative analyses reflect the current terms of the plan or coverage, which may require them to update their comparative analyses, or perform and document new comparative analyses when there is a change in plan benefit design, administration or utilization that is not reflected in the current version of the comparative analyses.

Finally, nothing in these proposed rules, should be construed to prevent the relevant Secretary from acting within the scope of existing authorities to address violations of MHPAEA.

C. Applicability - 26 CFR 54.9812-1(i), 29 CFR 2590.712(i), and 45 CFR 146.136(i) and 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), and 45 CFR 146.137(g)

While the Departments are of the view that the provisions included in these proposed rules, if finalized, are critical to helping to ensure access to vital mental health and substance use disorder benefits, the Departments also recognize that new requirements may take time for plans and issuers to implement. In order to strike an appropriate balance, the Departments propose to amend 26 CFR 54.9812-1(i)(1), 29 CFR 2590.712(i)(1), and 45 CFR 146.136(i)(1) to specify that except as provided in paragraph (i)(2) of the 2013 final regulations, these proposed rules, if finalized, would apply on the first day of the first plan year beginning on or after January 1, 2025.[173] Until the applicability date, plans and issuers would be required to continue to comply with 26 CFR 54.9812-1, revised as of April, 1, 2023, 29 CFR 2590.712, revised as of July 1, 2022, and 45 CFR 146.136, revised as of October 1, 2021, as applicable.

For similar reasons, the Departments also propose that the requirements in 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 of these proposed rules would become effective for plan years beginning on or after January 1, 2025. However, the Departments remind plans and issuers[174] that the statutory provisions added to MHPAEA by the CAA, 2021 are self-

[173] *But see* 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4), which explains how these requirements interact with the requirement to provide EHBs under 45 CFR 147.150 and 156.115.

[174] Consistent with the statute, under these proposed rules, the comparative analysis requirements under proposed 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 would not apply to a plan or issuer that qualifies for the small employer exemption under 26 CFR 54.9812-1(f), 29 CFR 2590.712(f), and 45 CFR 146.136(f) or the increased cost exemption under 26 CFR 54.9812-1(g), 29 CFR 2590.712(g), and 45 CFR 146.136(g).

implementing and took effect on February 10, 2021. Therefore, the proposed delayed applicability date for these proposed rules does not alter a plan's or issuer's obligations under the statute. As such, plans and issuers must continue performing and documenting comparative analyses of the design and application of NQTLs in accordance with the statutory requirements and make them available to the Departments or applicable State authorities before the applicability date of these proposed rules, if finalized. The Departments request comments on the proposed applicability date.

D. Severability - 26 CFR 54.9812-1(j), 29 CFR 2590.712(j), and 45 CFR 146.136(j) and 26 CFR 54.9812-2(h), 29 CFR 2590.712-1(h), and 45 CFR 146.137(h)

The Departments propose to include severability clauses in these proposed rules to capture the Departments' intent that, to the extent a reviewing court holds that any provision of these proposed rules, if finalized, is unlawful by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision would be construed so as to continue to be given the maximum effect permitted by law. The Departments are of the view that this rulemaking, if finalized as proposed or as a substantially similar version, would provide comprehensive protections that implement MHPAEA's requirements. Overall, the aim of these proposed rules is to ensure that individuals with mental health conditions and substance use disorders benefit from the full protections afforded to them under MHPAEA, and that separate elements of this proposal would individually contribute to furthering that aim. The proposed requirements under 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii), for instance, while part of a comprehensive regulatory scheme, are separate aspects of the parity analysis. Similarly, the rule requires plans and issuers to collect and evaluate outcomes data in a manner reasonably designed to assess the impact of the NQTL and consider the impact as part of the plan's or issuer's analysis of whether the limitation, in operation, complies with the requirements under 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii). However, the requirements of

paragraphs (c)(4)(i) and (ii) are meant to stand independently of the requirement to use outcomes data in such a manner and can continue to apply independently if other provisions of this rule are invalidated. Finally, while the Departments are of the view that the unique considerations of the NQTLs related to network composition merit the special rule at 26 CFR 54.9812-1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), and 45 CFR 146.136(c)(4)(iv)(C), the Departments believe that the other requirements of this proposed rule could continue to apply to NQTLs related to network composition, should this special rule be invalidated or stayed pending further action. Consequently, following a potential legal challenge, a court's decision to invalidate one standard does not affect any provision that relates to a separate standard. As indicated, these applications of severability to the provisions in these proposed rules is only an example and is not exhaustive of other potential applications. If a court were to hold that any provisions were invalid or unenforceable, these provisions in the proposed rules state that any affected provisions would be severable from the rest of these proposed rules, if finalized, and would not affect any other provisions or their application to persons not similarly situated or to dissimilar circumstances.

III. Overview of the Proposed Rules – Department of HHS

A. Sunset of MHPAEA Opt Out for Self-Funded Non-Federal Governmental Plans

As noted earlier in this preamble, sponsors of self-funded, non-Federal governmental plans are permitted to opt out of certain requirements categories of title XXVII of the PHS Act.[175] Prior to the enactment of the CAA, 2023, such plans could elect to opt out of compliance with the requirements under MHPAEA, among three other requirements categories of title XXVII of the PHS Act.

The CAA, 2023, enacted on December 29, 2022, included a provision that sunsets the election option with respect to MHPAEA.[176] Specifically, section 1321 of title I of Division FF of the CAA, 2023 amended PHS Act section 2722(a)(2) by adding language specifying that no

[175] PHS Act section 2722(a)(2); 45 CFR 146.180.
[176] Division FF, Title I, Subtitle C, Chapter 3, sec. 1321, Pub. L. 117-328, 136 Stat. 4459 (Dec. 29, 2022).

MHPAEA opt-out election may be made on or after the date of the enactment of the CAA, 2023, and that generally, no MHPAEA opt-out election expiring on or after the date that is 180 days after the date of such enactment may be renewed. The CAA, 2023 included an exception for certain collectively bargained plans with an opt-out election in effect for MHPAEA that allows for a longer transition to come into compliance with MHPAEA. Specifically, the CAA, 2023 added language to PHS Act section 2722(a)(2) indicating that a plan that is subject to multiple collective bargaining agreements of varying lengths that has a MHPAEA opt-out election in effect as of the date of enactment of the CAA, 2023, that expires on or after the date that is 180 days after the enactment of the CAA, 2023, may extend such election until the date on which the term of the last such agreement expires.

As a result of the CAA, 2023 amendments to PHS Act section 2722(a)(2), self-funded, non-Federal governmental plan sponsors may elect to opt out of only the following three PHS Act requirements categories: standards relating to benefits for newborns and mothers (PHS Act section 2725), required coverage for reconstructive surgery following mastectomies (PHS Act section 2727), and coverage for dependent students on a medically necessary leave of absence (PHS Act section 2728).

In this rulemaking, HHS proposes to amend 45 CFR 146.180 to align with the CAA, 2023 amendments to PHS Act section 2722(a)(2). Specifically, HHS proposes to redesignate paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8) and add a new paragraph (a)(3) specifying that a sponsor of a self-funded, non-Federal governmental plan may not elect to exempt its plan(s) from any of the MHPAEA requirements on or after December 29, 2022 (the date of enactment of the CAA, 2023) through the process specified in 45 CFR 146.180. HHS also proposes to add new paragraph (f)(4)(iii) that would specify that in the case of a self-funded, non-Federal governmental plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to any of the MHPAEA requirements in effect as of December 29, 2022, through the process specified in 45 CFR 146.180, that expires

on or after June 27, 2023 (the date that is 180 days after the date of enactment of the CAA, 2023), the plan may extend such election until the date on which the term of the last such agreement expires. HHS also proposes to make conforming edits to paragraphs (a)(2), (a)(5)(i) and (ii), and (a)(6)(ii), as proposed to be redesignated, and paragraph (f)(1). The proposed amendments to 45 CFR 146.180 would apply on the effective date of the final rule. HHS seeks comments on these proposed amendments to implement the sunset of the MHPAEA opt-out election and whether additional guidance or clarifications are necessary.

B. Applicability of MHPAEA to Individual Health Insurance Coverage

The HHS regulation implementing MHPAEA for individual health insurance coverage is codified at 45 CFR 147.160. The regulation currently provides that the group market regulation implementing MHPAEA at 45 CFR 146.136 applies to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market, for policy years beginning on or after the applicability date set forth in 45 CFR 146.136(i). Therefore, through cross-reference, the proposed amendments to 45 CFR 146.136, if finalized, would apply in the same manner to health insurance issuers offering individual health insurance coverage. Further, HHS proposes to include a cross reference in 45 CFR 147.160 to the comparative analysis requirements proposed in 45 CFR 146.137 of these proposed rules. The cross reference would similarly make clear that the comparative analysis requirements apply to health insurance issuers offering individual health insurance coverage in the same manner that those provisions apply to group health plans and health insurance issuers offering coverage in connection with such plans.

These provisions would apply to health insurance issuers offering individual health insurance coverage for policy years beginning on or after January 1, 2026. In the individual market, non-grandfathered individual health insurance coverage must be offered on a calendar year basis. Premium rates must be submitted to the applicable regulator and finalized prior to

January 1 of each calendar year and rates cannot be modified during the year. The proposed applicability date is intended to provide time for issuers offering individual health insurance coverage to account for the effects of these rules following publication of the final rules and prior to when rates and benefits must be finalized and approved for the following calendar year.

Finally, for greater clarity and precision and to align with the statutory terminology, HHS proposes to modify the regulation text to refer to "individual health insurance coverage offered by a health insurance issuer" as opposed to "health insurance coverage offered in the individual market."

IV. Request for Information on Ways to Improve Mental Health and Substance Use Disorder Benefits Through Other Consumer Protection Laws

The Departments are committed to using their full statutory authority to address the nation's mental health and substance use disorder crises. In supporting the Administration's response to these epidemics, the Departments are considering ways to improve the coverage of mental health and substance use disorder benefits through other consumer protection laws, including the Affordable Care Act. The Departments request comments from all interested parties with respect to the following specific areas:

1. Group health plan sponsors depend on administrative service providers, health insurance issuers, and other TPAs to design and manage their plans in a manner that complies with MHPAEA among other Federal consumer protections. However, plan sponsors are generally responsible for ensuring compliance and could, in certain circumstances, be liable for penalties for any violations.[177] Are there ways that TPAs could be further incentivized to facilitate compliance with MHPAEA on behalf of the plans that they design and administer?
2. Section 108 of Title I of Division BB of the CAA, 2021 requires the Departments to issue a rule implementing the provider nondiscrimination provisions in PHS Act section

[177] *See* Code section 4980D.

2706(a). In 2014, the Departments published a request for information on provider nondiscrimination, followed by FAQs on these requirements.[178] Following the enactment of the CAA, 2021, the Departments held a listening session on January 19, 2022 regarding implementation of the provider nondiscrimination provision, in order to foster an exchange of information and views and afford interested individuals and organizations an opportunity to share their perspective on what should be included in forthcoming proposed rules. As the Departments continue to work on proposed rules implementing the provider nondiscrimination provisions, are there ways that the Departments can enhance access to mental health and substance use disorder benefits through their implementation of PHS Act section 2706(a)?

3. Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A-5(a) and (b), as added by section 116 of title I of Division BB of the CAA, 2021, establish standards related to provider directories. The Departments intend to undertake notice and comment rulemaking to implement the provider directory requirements. Are there ways that the Departments can improve the coverage of and enhance access to mental health and substance use disorder benefits through their implementation of these provider directory requirements, particularly in underserved or rural areas where there may be limited access to the internet?
4. Telehealth has become a vital means of providing health care, including mental health and substance use disorder care, especially in rural areas and in light of the COVID-19 PHE. For the duration of any plan year beginning before the end of the COVID-19 PHE, the Departments issued guidance providing relief from the group market reforms under part 7 of ERISA, title XXVII of the PHS Act, and chapter 100 of the Code for a group

[178] 79 FR 14051 (March 12, 2014); FAQs about Affordable Care Act Implementation (Part XXVII) (May 26, 2015), Q4-5, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvii.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part-XXVII-MOOP-2706-FINAL.pdf.

health plan (and health insurance coverage offered in connection with a group health plan) sponsored by a large employer that solely provides benefits for telehealth or other remote care services offered only to employees (or their dependents) who are not eligible for coverage under any other group health plan offered by that employer.[179] However, these arrangements were required to continue to comply with certain Federal group market reforms, including the requirements under MHPAEA.[180] How and to what extent has this guidance affected mental health and substance use disorder care and access? Would any further safeguards be needed? How can the Departments use telehealth or other remote care services to enhance access to mental health and substance use disorder treatment under the Departments' existing authority for both routine and crisis care for behavioral health conditions, including through parity requirements with respect to financial requirements and treatment limitations?

5. Under the internal claims and appeals and external review rules implementing the Affordable Care Act, which are generally applicable to all non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage, claim denials related to medical judgment (including for mental health and substance use disorder benefits) are eligible for external review.[181] The internal claims and appeals rules also provide that claimants (or their authorized representatives) are entitled to, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits.[182] This includes

---

[179] *See* FAQs Part 43, Q14.
[180] *Id*.
[181] *See* 26 CFR 54.9815-2719, 29 CFR 2590.715-2719, and 45 CFR 147.136. Grandfathered plans and issuers must also extend external review to adverse benefit determinations to items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers with respect to patient visits to certain types of participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under the No Surprises Act, including for denials related to compliance with such requirements. Such items and services may include mental health and substance use disorder services. *See* 26 CFR 54.9815-2719(a)(1)(ii), 29 CFR 2590.715-2719(a)(1)(ii), and 45 CFR 147.136(a)(1)(ii).
[182] 26 CFR 54.9815-2719(b)(2)(ii)(C), 29 CFR 2590.715-2719(b)(2)(i) and (b)(2)(ii)(C), 45 CFR 147.136(b)(2)(i) and (b)(2)(ii)(C), and 29 CFR 2560.503-1(h)(2)(iii).

documents with information about the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.[183] How can the Departments leverage ERISA's and the Affordable Care Act's existing claims procedure requirements to help facilitate access to mental health and substance use disorder benefits? For example, if a plan or issuer denies a mental health or substance use disorder benefit based on the plan's or issuer's determination that a lower level of care would be more appropriate, should the plan or issuer be required to identify the relevant lower level of care? Should plans and issuers be required to provide an explanation of how a particular NQTL was applied to particular benefits, beyond what is currently required by the claims procedure rules or other related provisions?

6. Currently, the minimum value rules under HHS and Treasury regulations at 45 CFR 156.145 and 26 CFR 1.36B-6, respectively, specify that an employer-sponsored plan provides minimum value only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan include substantial coverage of inpatient hospital services and physician services. Should HHS and Treasury consider amending the minimum value rule so that it would apply separately and independently to medical/surgical benefits, and to mental health and substance use disorder benefits? Should HHS and Treasury consider amending the minimum value rule to require substantial coverage of mental health and substance use disorder benefits? If so, how should "substantial coverage" be defined in that context?
7. As HHS oversaw the transition to 988 as the new easy-to-remember 3-digit code to access life-saving services through the Suicide & Crisis Lifeline, (https://www.samhsa.gov/find-help/988), there has been increased attention to current gaps in access to and provision of a full continuum of behavioral health crisis services.

[183] 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3).

Final rules under MHPAEA do not specifically address mobile crisis services. Similarly, in the establishment of EHBs as part of required benefits for non-grandfathered individual and small group coverage under the Affordable Care Act, there is no specific reference to behavioral health crisis services as part of the EHB categories. The Departments are interested in determining if there are questions as to how these services fit within the existing categories for either MHPAEA, or the EHB categories. Are there aspects of community-based behavioral health crisis services that the Departments should address in the context of MHPAEA? Should the Departments ensure that community-based behavioral health crisis services are classified in the same way as particular medical/surgical services, and what are those particular services? Should crisis call/text/chat center services, mobile crisis and stabilization services be specifically included as EHBs? Are there ways the Departments can increase access to crisis services with current authorities, including in rural or underserved areas in which there are several challenges to accessing care? How can parity be strengthened across the behavioral health crisis services landscape, including in areas with shortages for behavioral health providers? How can the Departments collaborate with State and local agencies to improve access to existing and future behavioral health crisis services?

V. Regulatory Impact Analysis

A. Summary – *Departments of Health and Human Services and Labor*

The Departments have examined the effects of these proposed rules as required by Executive Order 12866,[184] Executive Order 13563,[185] the Paperwork Reduction Act of 1995,[186] the Regulatory Flexibility Act,[187] section 202 of the Unfunded Mandates Reform Act of 1995,[188] and Executive Order 13132.[189]

---

[184] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).
[185] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).
[186] 44 U.S.C. 3506(c)(2)(A) (1995).
[187] 5 U.S.C. 601 *et seq*. (1980).
[188] 2 U.S.C. 1501 *et seq*. (1995).
[189] Federalism, 64 FR 153 (Aug. 4, 1999).

1.1. Executive Orders 12866 and 13563 – Departments of Health and Human Services and Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, "significant" regulatory actions are subject to review by the Office of Management and Budget (OMB). As amended by Executive Order 14094[190] entitled "Modernizing Regulatory Review" section 3(f) of the Executive order defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may:

(1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Territorial, or Tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

[190] Executive Order 14094, 88 FR 21879 (Apr. 6, 2023).

It has been determined that these proposed rules are significant within the meaning of section 3(f)(1) of the Executive order. Therefore, the Departments have provided an assessment of the potential costs, benefits, transfers, and alternatives associated with these proposed rules, and OMB has reviewed these proposed rules.

1.2. Introduction and Need for Regulations

As explained in section I.A of this preamble, mental health is crucial to a person's overall wellbeing, and access to quality mental health and substance use disorder treatment is as essential for health as access to medical/surgical treatment. Moreover, failure to treat mental health issues can be costly. For example, depression is associated with increased risk of cardiovascular disease, diabetes, stroke, Alzheimer's disease, and osteoporosis, and an untreated substance use disorder may result in hospital emergency room care for a drug overdose.[191] Individuals with mental health conditions or substance use disorders have faced stigma, discrimination, and other barriers inside and outside of the health care system, which can operate as impediments to seeking and obtaining treatment. In 2021, approximately 40 percent of adults 18 and older with a perceived unmet need for mental health services reported that they did not receive services because they could not afford the cost, almost 11 percent thought it may cause their community to have a negative opinion about them, almost 8 percent thought it might impact their job, and almost 12 percent were concerned about confidentiality.[192] Despite deterrents to seeking treatment, the need for these services has only increased, as a reported 41 percent of U.S. adults experienced high levels of psychological distress during the COVID-19 pandemic.[193]

In 2013, the Departments issued final regulations to implement MHPAEA.[194] The 2013 final regulations expanded upon MHPA 1996, which required parity in aggregate lifetime and

---

[191] Government Accountability Office. "Behavioral Health: Research on Health Care Costs of Untreated Conditions is Limited," GAO-19-274, February 2019.
[192] Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2021. Table 6.45B.
[193] Pasquini, Giancarlo, and Scott Keeter. Pews Research Center. "At Least Four-in-Ten US Adults Have Faced High Levels of Psychological Distress During COVID-19 Pandemic." (2022).
[194] 78 FR 68240 (Nov. 13, 2013).

annual dollar limits between mental health benefits and medical/surgical benefits. MHPAEA additionally applies the parity requirements to substance use disorder benefits and provides that the financial requirements (such as deductibles, copays, and coinsurance) and treatment limitations (such as day or visit limits) imposed on mental health or substance use disorder benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification. MHPAEA also prohibits separate treatment limitations that apply only to mental health and substance use disorder benefits.

Since 2013, the Departments have provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties and conducted regular outreach initiatives to facilitate the implementation and enforcement of MHPAEA. The Departments also issued reports to Congress highlighting this work. In addition, Congress has enacted several laws that build on MHPAEA, including the Cures Act, the SUPPORT for Patient and Communities Act (SUPPORT Act),[195] and most recently, the CAA, 2021 and 2023.

Prior to the CAA, 2021, while group health plans and health insurance issuers were prohibited from imposing NQTLs on mental health and substance use disorder benefits that did not comply with MHPAEA and its implementing regulations, there was no statutory requirement that plans or issuers demonstrate their compliance. Under the CAA, 2021, group health plans and health insurance issuers are now required to perform and document comparative analyses of the NQTLs they impose on mental health and substance use disorder benefits and to provide those analyses to the Departments or to an applicable State authority, as applicable, upon request. The CAA, 2021 compels the Departments to request not fewer than 20 such analyses per year. In

[195] Pub. L. 115-271, 132 Stat. 3894 (Oct. 24, 2018). The SUPPORT Act requires that Children's Health Insurance Program (CHIP) plans must cover mental health and substance use disorder services. Financial requirements and treatment limitations applicable to such services shall not differ from those applicable to other medical services under CHIP.

addition, the CAA, 2021 imposes steps that the Departments, after reviewing a comparative analysis, must take following an initial determination that the plan's or issuer's NQTL comparative analysis does not comply with MHPAEA. The Departments are also required to report to Congress annually on the results of their review of the requested NQTL comparative analyses.

As documented in the 2022 MHPAEA Report to Congress,[196] the Departments found that none of the NQTL comparative analyses they reviewed contained sufficient information and documentation from plans and issuers upon initial receipt. Moreover, despite plans' longstanding obligations under MHPAEA, it was apparent that many plans and issuers had not carefully designed and implemented their NQTLs to be compliant with MHPAEA prior to the enactment of CAA, 2021. Consequently, many of the comparative analyses appeared to be focused on finding after-the-fact rationales for decisions and designs involving NQTLs rather than reflecting proper attention to MHPAEA compliance in the first place. Similarly, many of the plans and issuers appeared to generate their analyses for the first time in response to the Departments' requests, rather than in advance, as required by law and as a critical part of the design and application of a MHPAEA-compliant NQTL. The 2023 MHPAEA Report to Congress notes that nearly all the comparative analyses reviewed by the Departments during the relevant time period contained insufficient information upon initial receipt and identifies common deficiencies in the comparative analyses prepared by plans and issuers.[197]

The Departments have made an unprecedented commitment to expand their efforts to ensure parity in access to mental health and substance use disorder treatment, guarantee that individuals with mental health conditions and substance use disorders benefit from the full

---

[196] Available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf.
[197] 2023 MHPAEA Report to Congress, available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

protections required by law, and intend to provide additional guidance to interested parties to facilitate compliance with MHPAEA by issuing these proposed rules.

The proposed amendments to the existing MHPAEA regulations would clarify existing definitions and add new definitions of key terms, clarify the way the parity requirements apply to NQTLs, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. The proposed amendments would also clarify that the way a plan or issuer defines mental health conditions and substance use disorders for purposes of MHPAEA must be consistent with generally recognized independent standards of current medical practice and would add more specificity as to what conditions or disorders plans and issuers must treat as mental health conditions and substance use disorders.

These proposed rules would also add new regulations that would set forth more specific content requirements for comparative analyses required by the CAA, 2021, and outline the process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request. These proposed rules would also require plans and issuers to collect and evaluate relevant data, including but not limited to claims denials, as well as any other data relevant to NQTLs as required by State law or private accreditation standards. Additionally, for NQTLs related to network composition, these proposed rules would require additional data, including, but not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). Under these proposed rules, plans and issuers must collect and evaluate these data while conducting their comparative analyses, regardless of whether the Departments have requested the analyses. As indicated in section I.A.3.d of this preamble, the type, form, and manner for these data requirements may be further defined in guidance, to allow the Departments to provide more detail and adjust the data requirements as

needed to account for enforcement experience and industry trends. Additionally, in these proposed rules, HHS proposes regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for self-funded, non-Federal governmental plans to opt out of requirements under MHPAEA.

The Departments have been particularly concerned with barriers to access for individuals seeking mental health or substance use disorder treatments. A 2022 Harris Poll sponsored by the National Council for Mental Wellbeing found that 21 percent of adults with unmet mental health care needs in the past year and 28 percent of those with unmet substance use care needs in the past year reported their inability to get an appointment immediately prevented them from getting needed care.[198] While up to 70 percent of all primary care visits include a behavioral health component,[199] research suggests that primary care providers face significant barriers to delivering these services, including insufficient resources, inadequate related knowledge, and a lack of time.[200] In seeking out specialists, individuals tend to face less adequate mental health provider networks than medical/surgical provider networks through their plan or coverage. According to a 2021 study, which compared the experiences of patients using out-of-network mental health and out-of-network medical/surgical providers, patients who were receiving mental health treatment only from a mental health practitioner rated their plan's mental health provider network as inadequate more frequently than their plan's medical/surgical provider network.[201] The study noted that specialty mental health practitioners are more likely to opt out of participation in mental health provider networks due to a growing workforce shortage of mental

---

[198] National Council for Mental Wellbeing. "2022 Access to Care Survey Results," May 11, 2022. https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf
[199] Health Affairs. "Combating a Crisis by Integrating Mental Health Services and Primary Care," Health Affairs Forefront, July 8, 2022, available at https://www.healthaffairs.org/do/10.1377/forefront.20220706.603540.
[200] Loeb, Danielle F., Elizabeth A. Bayliss, Ingrid A. Binswanger, Carey Candrian, and Frank V. Degruy. "Primary Care Physician Perceptions on Caring for Complex Patients with Medical and Mental Illness." *Journal of General Internal Medicine* 27 (2012): 945-952. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3403152/; Poghosyan L, Norful AA, Ghaffari A, George M, Chhabra S, Olfson M. "Mental Health Delivery in Primary Care: The Perspectives of Primary Care Providers." Archives of Psychiatric Nursing 2019 Oct; 33(5):63-67. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077950/.
[201] Busch, Susan H., and Kelly Kyanko. "Assessment of Perceptions of Mental Health vs Medical Health Plan Networks Among US Adults with Private Insurance." *JAMA Network Open* 4, no. 10 (2021).

health providers, a high demand for mental health services, and low reimbursements for mental health services compared with other specialties, which has consequentially resulted in higher out-of-network utilization rates for mental health care services. In response to these concerns, the Technical Release that is being issued concurrently with these proposed rules would set out principles and seek public comment to inform guidance with respect to required data submissions for NQTLs related to network composition and a potential time-limited enforcement safe harbor.

The Departments have already seen some promising results in response to their reviews of plans' and issuers' comparative analyses under the requirements of the CAA, 2021, including the removal of some exclusions related to treatment for opioid use disorder with methadone (which must be provided through an opioid treatment program) and ABA therapy, as well as the removal of unnecessary gatekeepers for treatment, such as requiring referrals for appointments and pre-authorization for outpatient services, improving direct access for mental health and substance use disorder benefits. The Departments expect that these proposed rules would expand upon these successes as they would provide plans and issuers with a better understanding of the requirements of MHPAEA with respect to NQTLs and improve how they measure, compare, and demonstrate parity, while clarifying appropriate ways for plans and issuers to modify their policies and procedures to meet parity requirements. The Departments believe these proposed rules and any additional guidance would help plans and issuers comply with these proposed requirements, resulting in improved access to and coverage of mental health and substance use disorders, as intended by MHPAEA.

1.3. Baseline

The baseline for this analysis includes the MHPAEA statute, as amended, implementing regulations, and subsequent guidance. Benefits, costs, and transfers are measured as changes from the baseline under these proposed rules. For example, the CAA, 2021 requires that plans and issuers perform and document NQTL comparative analyses. Starting 45 days after the

enactment of the CAA, 2021, plans and issuers are required to make their comparative analyses available to the Departments or an applicable State authority upon request. Plans and issuers are required to make comparative analyses and other applicable information required by the CAA, 2021 available to participants and beneficiaries in plans subject to ERISA upon request and to make this information available to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage upon request in connection with an adverse benefit determination.[202] This regulatory impact analysis (RIA) therefore does not include benefits or costs for performing and making available the comparative analyses, as these are already required by the provisions of the CAA, 2021 and are in the baseline, but does take into account the expected impacts of these proposed rules on the preparation of plans' and issuers' comparative analyses and how these proposed rules would impact parity and, in turn, access for participants and beneficiaries needing mental health and substance use disorder treatments.

Similarly, existing guidance that has already generated benefits and costs is not accounted for here. Rather, only those changes resulting from these proposed rules are captured in this analysis.

1.4. Summary of Impacts

These proposed rules propose to define certain terms associated with MHPAEA's requirements for NQTLs and provide that a group health plan (or health insurance issuer offering coverage in connection with a group health plan) may not apply any NQTL to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. These proposed rules would require that plans and issuers determine the portion of plan payments for medical/surgical benefits subject to an NQTL based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to

[202] FAQs Part 45, Q6.

be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the NQTL). Plans and issuers would next be required to determine whether the NQTL applies to substantially all medical/surgical benefits in the classification based on the portion of plan payments for medical/surgical benefits subject to the NQTL to determine whether the NQTL applies to at least two-thirds of all medical/surgical benefits in that classification. Plans and issuers would then need to determine which variation of a given NQTL is predominant (that is, the most common or frequent variation). Once this is determined, plans and issuers may not apply any NQTL to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL applicable to substantially all medical/surgical benefits in the same classification. An NQTL is restrictive if it imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage.

These proposed rules also set data requirements and clarify proper documentation of NQTL comparative analyses, which plans and issuers have struggled with, as detailed in the Departments' 2022 Report to Congress[203] and the 2023 Report to Congress,[204] released contemporaneously with these proposed rules. Accordingly, the Departments are of the view that these proposed rules would increase plan and issuer compliance with the requirements for imposing NQTLs under MHPAEA, which would in turn expand access to mental health and substance use disorder benefits and help ensure that limitations on mental health and substance use disorder benefits are no more restrictive than the predominant limitations applicable to substantially all medical/surgical benefits in the same classification. In doing so, access to in-network medically necessary treatments would increase for a significant segment of individuals

[203] 2022 MHPAEA Report to Congress, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf.
[204] 2023 MHPAEA Report to Congress, available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

whose health coverage would be affected by these proposed rules,[205] which would ultimately result in better mental health outcomes and lower out-of-pocket costs related to mental health and substance use disorder benefits for participants, beneficiaries, and enrollees.

Plans and issuers would incur costs to comply with the requirements in these proposed rules. However, the Departments have determined that the benefits of these proposed rules justify the costs. In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with these regulatory actions. The Departments are unable to quantify all benefits, costs, and transfers of these proposed rules, but have sought, where possible, to describe these non-quantified impacts.

The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these proposed rules.

Table 1: Accounting Statement
Benefits:
• Better understanding of and compliance with MHPAEA by plans and issuers. • Better health outcomes for those with mental health conditions or substance use disorders, and a reduction in the negative impacts on families, friends, and coworkers of those with untreated or poorly managed mental health conditions or substance use disorders based on their improved access to treatment. • Better frameworks for determining whether plans and issuers are making decisions and taking actions with respect to mental health and substance use disorder benefits in parity with their decisions and actions regarding medical/surgical benefits.
Costs:
• Costs to plans and issuers to implement changes associated with the revision of plan provisions. • Increased costs to plans and issuers from expanded coverage and utilization of mental health and substance use disorder services. • Costs to plans and issuers from collecting and analyzing data and documenting NQTL comparative analyses consistent with the requirements of these proposed rules of approximately $291.0 million in the first year and approximately $117.6 million in subsequent years or between 0.04 percent and 0.01 percent of health insurance premiums. • Costs to plans and issuers for preparing and mailing the comparative analyses to participants, beneficiaries, and enrollees of approximately $12.1 million annually. • One-time regulatory review costs to plans and issuers of approximately $64.3 million.

[205] Wen, Hefei, Janet R. Cummings, Jason M. Hockenberry, Laura M. Gaydos, and Benjamin G. Druss. "State Parity Laws and Access to Treatment for Substance Use Disorder in the United States: Implications for Federal Parity Legislation." JAMA Psychiatry 70, no. 12 (2013): 1355-1362.

- Potential increase in cost-sharing requirements and/or treatment limitations for medical/surgical care for participants, beneficiaries, and enrollees, if plans and issuers try to achieve parity by imposing new restrictions on medical/surgical coverage, rather than by reducing restrictions on access to mental health or substance use disorder benefits.
- Potential costs to self-funded, non-Federal governmental plans that currently opt out of MHPAEA to come into compliance with requirements under MHPAEA.
- Cost savings to self-funded, non-Federal governmental plans of approximately $11,351 in total from no longer having to send opt-out notices regarding a plan's MHPAEA opt-out election.
- Cost savings for the Federal Government of approximately $2,469 from fewer opt-out notices being submitted by self-funded, non-Federal governmental plans.

Costs	Estimate	Year dollar	Discount Rate	Period Covered
Annualized Monetized ($million/Year)	$161.29	2023	7 percent	2023-2032
	$156.71	2023	3 percent	2023-2032

Transfers:

- Potential transfers from plans and issuers to participants, beneficiaries, and enrollees resulting in lower out-of-pocket spending on mental health and substance use disorder services.
- Potential transfers from participants, beneficiaries, and enrollees to plans and issuers caused by higher premiums associated with lower cost-sharing requirements, increased utilization of mental health and substance use disorder services, provider network improvements, and increased provider reimbursement rates.
- Potential transfers from primary care providers to mental health providers for the treatment of mental health and substance use disorders as a result of decisions by participants, beneficiaries, and enrollees to obtain treatment from a specialist instead of a primary care provider.

1.5. Affected Entities

1.5.1. Plans

Employers with 50 or more employees are required to comply with MHPAEA. Employers with less than 50 employees are required to comply with MHPAEA as part of the EHB requirements of the Affordable Care Act. In this analysis, plan size is used as a proxy for employer size to determine if a plan is affected. The Departments estimate that 1,488,000 fully-insured, non-grandfathered plans with less than 50 participants and approximately 409,800 ERISA-covered group health plans with 50 or more participants, of which approximately

250,000 are self-insured group health plans, would be affected by these proposed rules.[206] In addition, the Departments estimate that these proposed rules would affect approximately 90,100 non-Federal governmental health plans,[207] of which approximately 14,400 are plans with 50 or more participants.[208] The Departments seek comment on these estimates.

HHS estimates that 230 self-funded, non-Federal governmental plans would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election.[209] HHS is aware of at least four plans with collective bargaining agreements whose sponsors' MHPAEA opt-out elections could be in effect beyond 2024. However, other plans might be similarly situated. HHS does not have precise information about the number of participants and beneficiaries of the plans that have elected to opt out of requirements under MHPAEA, as those plans are not required to report this information to HHS. However, HHS

---

[206] Employers with less than 50 employees are required to comply with MHPAEA as part of the EHB requirements of the ACA. The Departments estimate that there are 2,134,934 ERISA-covered group health plans with less than 50 participants based on data from the 2021 Medical Expenditure Panel Survey - Insurance Component and the 2019 County Business Patterns from the Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2021 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2019 County Business Patterns from the Census Bureau. The 2020 Kaiser Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (Kaiser Employer Health Benefits Survey (*Source*: KFF. 2020 Kaiser Employer Health Benefits Survey. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf)). Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,134,934 small ERISA-covered group health plans x 83% x (100% minus 16%) = 1,488,476. MHPAEA only applies to ERISA plans in the group market with 50 or more participants that offer mental health or substance use disorder benefits. The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. Based on the 2021 MEPS-IC and the 2019 County Business Patterns from the Census Bureau, the Departments estimate 61 percent of ERISA-covered group health plans with 50 or more participants are self-insured. Thus, the Departments calculate the number of self-insured group health plans in the following manner: 409,822 ERISA-covered group health plans with 50 or more participants x 61% = 249,991.

[207] Based on the 2017 Census of Governments, there are 90,126 State and local entities. The Departments assume there is one plan per entity on average. Therefore, the Departments estimate that there are 90,126 non-Federal governmental health plans.

[208] MHPAEA applies to non-Federal governmental employers with 50 or more employees that offer mental health or substance use disorder benefits. The Departments have not identified what share of non-Federal governmental plans with 50 or more participants offer mental health or substance use disorder benefits and so have assumed that all of these plans offer them. Using data from the 2021 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2019 County Business Patterns from the Census Bureau, the Departments estimates that 16 percent of ERISA-covered group health plans have 50 or more participants. The Departments use the percent of ERISA-covered group plans with 50 or more participants as a proxy for the percent of non-Federal governmental plans with 50 or more participants. Therefore, the Departments estimate that there are 14,420 public, non-Federal employer group health plans with 50 or more participants that offer mental health or substance use disorder benefits. (90,126 non-Federal governmental health plans x 16 percent of plans with 50 or more employees = 14,420).

[209] Based on the HIPAA opt-out elections for self-funded, non-Federal governmental plans, as of January 6, 2023. Available at https://www.cms.gov/files/document/hipaaoptouts03182021.pdf.

estimates that there are approximately 253 participants, on average, in each self-funded, non-Federal governmental plan.[210] HHS also estimates that there is one beneficiary for each plan participant on average. Therefore, approximately 116,500 participants and beneficiaries would be affected by this proposed provision.[211] HHS seeks comments on the estimated number of self-funded, non-Federal governmental plans and the estimated number of plan participants and beneficiaries that would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election.

1.5.2. Participants, Beneficiaries, and Enrollees Receiving Mental Health and Substance Use Disorder Treatment

There are approximately 55,403,000 participants and 47,990,000 beneficiaries in ERISA-covered group health plans with 50 or more participants,[212] approximately 17,841,000 participants and 15,198,000 beneficiaries in non-Federal governmental plans with 50 or more participants,[213] an estimated 11,187,000 participants and 10,914,000 beneficiaries in ERISA

---

[210] According to data from the Medical Expenditure Panel Survey – Insurance Component (2021) (available at: https://meps.ahrq.gov/mepsweb/https://meps.ahrq.gov/mepsweb/), there are 18,828,246 State and local government employees, and 69.1 percent of these employees (13,010,318) are enrolled in health coverage through their jobs. Of these employees, 64.4 percent (8,378,645 employees) are participants in self-funded plans. Based on data from the 2017 Census of Governments (available at: https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html), there are 90,126 State and local government entities, and according to the Medical Expenditure Panel Survey (2021), 36.7 percent, or 33,076, of State and local government entities self-fund at least one plan. Therefore, the average number of participants per self-funded, non-Federal governmental plan is (8,378,645/33,076) $=$ 253.3. Since HHS also estimates that there is 1 beneficiary for each plan participant on average, the average number of participants and beneficiaries per self-funded non-Federal governmental plan is (253.3 $\times$ 2) $=$ 506.6.

[211] 230 self-funded, non-Federal governmental plans that have elected to opt out of the requirements under MHPAEA $\times$ approximately 506.6 participants and beneficiaries for each self-funded, non-Federal governmental plan on average $=$ 116,500.

[212] Employers with 50 or more employees are required to comply with MHPAEA. Employers with less than 50 employees are required to comply with MHPAEA as part of the EHB requirements of the Affordable Care Act. The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. The Departments estimate that there are 55,402,568 participants in ERISA-covered group health plans with 50 or more participants. Estimates are based off Department tabulations of the March 2021 Current Population Survey (CPS) Auxiliary Data. https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data.

[213] MHPAEA only applies to non-Federal governmental health plans with 50 or more participants that offer mental health or substance use disorder benefits. The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. The Departments estimate that there are 17,840,590 participants in non-Federal governmental health plans with 50 or more participants. Estimates are based on Department tabulations of the March 2021 CPS Auxiliary Data. https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data.

covered, non-grandfathered, fully insured health plans with less than 50 participants,[214] and approximately 11,000,000 individual health insurance coverage policyholders (with approximately 15,000,000 total enrollees).[215]

The receipt of behavioral health services has been increasing since the enactment of MHPAEA. Between 2007 and 2017, private insurance claim lines for behavioral health diagnoses increased by 320 percent.[216] Claims data show that between 2013 and 2019, the percentage of the employment-based coverage population under the age of 65 diagnosed with major depressive disorder increased from 4.1 percent to 5.3 percent, and the percentage of the population diagnosed with anxiety increased from 4.8 percent to 8.1 percent.[217] In 2020, 41 million Americans enrolled in employment-based coverage, including 6 million children, received mental health support, which constituted nearly 25 percent of employment-based health plan participants and beneficiaries.[218] A 2021 survey by the Substance Abuse and Mental Health Services Administration (SAMHSA) indicated that among adults aged 18 or older, 22.8 percent (or 57.8 million people) had any mental illness and 5.5 percent (or 14.1 million people) had serious mental illness in the past year.[219]

---

[214] The Departments estimate that there are 26,311,273 participants and beneficiaries in fully insured, private-sector health plans with less than 50 participants based off Department tabulations of the March 2021 CPS Auxiliary Data. https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data. Assuming, based on Kaiser Family Foundation (KFF) assumptions that 84 percent of participant and beneficiaries are in non-grandfathered plans (*Source*: KFF. 2020 KFF Employer Health Benefits Survey. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf), this would translate into an estimated 22,101,470 participants and beneficiaries in fully-insured, private-sector, non-grandfathered plans with less than 50 participants.

[215] Based on medical loss ratio reports submitted by issuers for the 2021 reporting year, the number of policyholders in individual health insurance coverage offered in the individual market is approximately 11 million. and the number of enrollees was approximately 15,000,000. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.

[216] Gelburd, Robin. "The Mental Health Parity Act: 10 Years Later." *American Journal of Managed Care* (Nov. 22, 2018). https://www.ajmc.com/view/the-mental-health-parity-act-10-years-later.

[217] Fronstin, Paul and Christopher Roebuck. "How Do High-Deductible Health Plans Affect Use of Health Care Services and Spending Among Enrollees with Mental Health Disorders?" EBRI Issue. No. 555, Figure 3. (March 10, 2022) Available at https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_555_mentalhealth-10mar22.pdf?sfvrsn=aec3b2f_2.

[218] America's Health Insurance Plans. "How Employer-Provided Coverage Improves Access to Mental Health Support," May 2022. https://www.ahip.org/documents/202205-CaW_MentalHealth-v03.pdf.

[219] SAMHSA. "Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health." pp. 39-40. https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFFRRev010323.pdf

The COVID-19 PHE has exacerbated the need for mental health and substance use disorder treatment. During the pandemic, many adults consistently reported anxiety and depressive disorders symptoms, with 4 in 10 adults reporting symptoms in February 2021. Two years later, even as the pandemic receded from its peak, approximately 3 in 10 adults were still reporting symptoms of anxiety and depression.[220] A 2021 study also found that a COVID-19 diagnosis increased the incidence of a psychiatric diagnosis within the following 14 to 90 days. Specifically, the study found that approximately 20 percent of adults who received a COVID-19 diagnosis, including adults with and without a past psychiatric diagnosis, were later diagnosed with a mental health disorder.[221]

The pandemic may have long-term effects on mental health and substance use disorders. A 2022 study examined the chronic effects of the pandemic on the mental health of veterans and found that COVID-19 survivors were associated with a higher risk of developing mental health disorders, including anxiety, stress, depression, substance use, and neurocognitive decline, compared to individuals who did not have COVID-19.[222] Another 2022 study examined the mental health outcomes of COVID-19 survivors during the twelve months following their infection and found that COVID-19 survivors reported a high prevalence of depression, anxiety, and PTSD at both the six- and twelve-months follow-up, indicating that the pandemic has long-term adverse mental health impacts on COVID-19 survivors.[223] Finally, a 2023 study found that

---

[220] Panchal, Nirmita, Heather Saunders, Robin Rudowitz, and Cynthia Cox. "The Implications of COVID-19 for Mental Health and Substance Use," KFF Issue Brief March 20, 2023. https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/.

[221] Taquet, Maxime, Sierra Luciano, John R. Geddes, and Paul J. Harrison. "Bidirectional Associations Between COVID-19 and Psychiatric Disorder: Retrospective Cohort Studies Of 62,354 COVID-19 Cases in the USA." *The Lancet Psychiatry* 8, no. 2 (2021): 130-140.

[222] Xie, Yan, Evan Xu, and Ziyad Al-Aly. "Risks of Mental Health Outcomes in People with Covid-19: Cohort Study." *The BMJ* 376 (2022), available at https://www.bmj.com/content/376/bmj-2021-068993.

[223] Mazza, Mario Gennaro, Mariagrazia Palladini, Rebecca De Lorenzo, Beatrice Bravi, Sara Poletti, Roberto Furlan, Fabio Ciceri et al. "One-Year Mental Health Outcomes in a Cohort of COVID-19 Survivors." *Journal of Psychiatric Research* 145 (2022): 118-124.

the pandemic resulted in a long-term increase in the number of psychiatric inpatient admissions, suggesting that there is a post-pandemic need to prioritize psychiatric care.[224]

1.5.3. Issuers and TPAs

The Departments estimate that these proposed rules would affect 476 health insurance issuers that provide benefits in the group and individual health insurance markets, with 1,500 issuer/State combinations.[225] There are an estimated 205 TPAs that provide services to health plans.[226] Finally, the Departments estimate that these proposed rules would affect at least 40 managed behavioral healthcare organizations providing mental health and substance use disorder benefits to group health plans.[227]

Issuers and TPAs provide key support for plan compliance with laws and regulations, including MHPAEA. The Departments' understanding, based on discussions with the regulated community and numerous direct investigations of plans, specifically the review of comparative analyses, is that issuers of fully insured health plans provide a menu of coverage designs from which interested parties select their coverage. The issuers, as the designers of the products and, commonly, the claims administrators, make decisions about what NQTLs to use and how to implement them. Issuers, along with TPAs, are also typically the owners of claims and other data related to plan administration.

Even for plans that self-insure, it is common practice to have issuers and TPAs provide expertise in plan design, administer the claims and networks, and drive compliance (or non-compliance) with MHPAEA. Self-insured plans rarely build independent provider networks and

---

[224] Warwicker, Sean, Denise Sant, Adrian Richard, Jake Cutajar, Annalise Bellizzi, Gertrude Micallef, Daniel Refalo, Liberato Camilleri, and Anton Grech. "A Retrospective Longitudinal Analysis of Mental Health Admissions: Measuring the Fallout of the Pandemic." *International Journal of Environmental Research and Public Health* 20, no. 2 (2023): 1194.

[225] The Departments' estimate of the number of health insurance insurers and the number of issuer/State combinations is based on medical loss ratio reports submitted by issuers for the 2021 reporting year. (*Source*: Centers for Medicare & Medicaid Services. "Medical Loss Ratio Data and System Resources" (2021). https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.)

[226] Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.

[227] The Departments' estimate of the number of insurers is based on industry trade association membership, including the National Behavioral Consortium (https://www.nbcgroup.org/member-directory/) and the Association for Behavioral Health and Wellness (https://abhw.org/about/). Please note that these estimates could undercount small State-regulated insurers.

instead rely on those built by issuers and TPAs. According to the 2019 KFF Employer Benefits Survey, only 8 percent of large, self-insured plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, in order to provide health care and services separate from the provider networks included in the plan network.[228] The Departments analyzed 2020 Form 5500 Schedule C (Service Provider Information) filings of self-insured health plans and determined that 89 percent of those plans indicated that they contracted with a TPA.[229] This statistic provides the Departments with an estimate for the percent of self-insured plans that could perform the work for themselves.

Issuers and TPAs are therefore the ones mostly likely, and the ones the Departments have overwhelmingly observed, performing the work to evaluate NQTLs and provide the comparative analysis and required data. These proposed rules are expected to continue this trend of issuers and TPAs performing the required work for plans. While plans could be charged for these services, this arrangement provides for economies of scale in compliance as issuers evaluate NQTLs, produce or assist in producing the comparative analyses for their products and, in combination with TPAs, provide support for other requirements. Because TPAs and insurance companies providing administrative services only (ASO) overwhelmingly design the plans, administer the networks, manage claims, provide plan services, maintain and hold the data relevant to the comparative analyses, and drive MHPAEA compliance, they are in the best position to conduct comparative analyses, and to provide the analyses in an efficient and cost-effective manner. The Departments expect, as reflected in their own direct observations of the comparative analyses process, that TPAs and issuers would perform most of the work associated with the analyses because they can do so at the lowest cost and greatest scale. Particularly for self-insured plans, however, there may be some additional work required by individual plans to

---

[228] KFF. "KFF Employer Health Benefits Survey, 2019." (September 25, 2019) Table 14.15. *See* https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/.

[229] Because many plans are exempt from filing a Form 5500, the Department only identified 37,934 self-insured health plan filings for 2020. Of these, only 5,537 plans (or roughly 15 percent) attached a Schedule C. Of those plans, 4,920 (or roughly 89 percent) indicated they paid compensation, either directly or indirectly, of at least $5,000 for either claims processing, contract administration, or both.

complete the comparative analysis prepared by the issuer to address unique plan issues. The Departments seek comments on these observations.

1.6. Benefits

The Departments expect that these proposed rules, if finalized, would improve the quality of the comparative analyses conducted by plans and issuers, as required by the CAA, 2021, help plans and issuers better understand and fulfill their obligations under MHPAEA, and promote greater transparency regarding discrepancies between mental health and substance use disorder benefits and medical/surgical benefits. By specifying more details on how to perform and document their NQTL comparative analyses, these proposed rules would increase plan and issuer compliance with the requirements for imposing NQTLs under MHPAEA, and by doing so, increase access to mental health and substance use disorder services. Thus, these proposed rules would generate the following economic and societal benefits for participants, beneficiaries, and enrollees:

- better understanding of and compliance with MHPAEA by plans and issuers,
- greater access to mental health and substance use disorder services,
- better health outcomes among those with mental health conditions or substance use disorders,
- reduced adverse impacts on the families, friends, and coworkers of people who suffer from untreated or poorly managed mental health conditions or substance use disorders, and
- better frameworks for the Departments, plans, and issuers to determine whether plans' and issuers' decisions and actions with respect to mental health and substance use disorder treatments are in parity with their decisions and actions regarding medical/surgical treatments.

This analysis provides a mainly qualitative discussion of the benefits associated with the proposed amendments to the existing MHPAEA regulations, as the Departments do not have the

data necessary to quantify the likely benefits associated with ensuring that NQTLs for mental health and substance use disorder benefits are in parity with medical/surgical benefits. Similarly, this analysis provides a qualitative discussion of the benefits of these proposed rules and discusses how the proposed additional guidance would result in better compliance with the rules related to NQTLs and access to mental health and substance use disorder benefits. The Departments invite comments and data related to how it might quantify these benefits as part of these proposed rules.

1.6.1. Better Understanding of and Compliance with MHPAEA by Plans and Issuers

By placing renewed focus on the elimination of more restrictive barriers to access mental health and substance use disorder benefits, standardizing the definitions associated with parity calculations for mental health and substance use disorder benefits and medical/surgical benefits, providing examples of the application of MHPAEA to NQTLs, and setting forth the content, and data documentation requirements of the NQTL comparative analyses, these proposed rules would clarify and strengthen the obligations of plans and issuers, and promote compliance with MHPAEA. In the course of implementing these proposed rules, parties would adjust their policies and procedures in order to come into compliance and better serve participants, beneficiaries, and enrollees. These proposed rules also help the Departments identify when they need to intervene.

The Departments have already seen, in response to reviews of comparative analyses and requests for additional information, revisions to policies that remove treatment limitations. These proposed rules would help parties better understand what they need to do to comply with MHPAEA, reduce uncertainty about compliance status, and help plans and issuers better identify areas they need to improve.

By improving compliance with MHPAEA, these proposed rules would have the greatest direct impact on individuals who currently forego treatments for a mental health condition or substance use disorder because their health plan imposes barriers to coverage of these services.

The Departments cannot estimate how large this impact would be, though a 2021 survey by SAMHSA indicated that 19 percent of U.S. adults with mental illness that did not receive treatment in the past year at least partially attributed foregoing these services to their health insurance offering insufficient coverage for mental health services.[230]

These proposed rules would also directly benefit individuals who are currently enrolled in a plan with inadequate or narrow networks with regard to mental health and substance use disorder providers compared to the networks for medical/surgical benefits, which prevent participants, beneficiaries, and enrollees from being able to make appointments with in-network providers and timely accessing needed care. A 2017 study of Affordable Care Act Marketplace provider networks found that mental health networks were significantly narrower on average than primary care networks, providing less than half the share of providers practicing within a State-level market.[231] A 2022 survey of private and non-Federal public employers found that while 82 percent of employers believed that there is a sufficient number of primary care providers in the plan networks, only 44 percent of employers believed there is a sufficient number of behavioral health providers in the plan networks.[232] Moreover, a 2022 study of Medicaid patients in Oregon found that mental health services remained inaccessible for many patients due to phantom networks, which are rosters of network providers that list, as in-network providers, mental health and substance use disorder professionals and facilities who are not, in fact, available to participants, beneficiaries, and enrollees for network treatment.[233] Phantom

---

[230] SAMHSA. "Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health." Table 6.50B. The question does not distinguish between sources of insurance, available at https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHNNR122322/2021NSDUHNNR122322.htm.

[231] Zhu, Jane M., Yuehan Zhang, and Daniel Polsky. "Networks in ACA Marketplaces are Narrower for Mental Health Care than for Primary Care." *Health Affairs* 36, no. 9 (September 2017): 1624-1631.

[232] Kaiser Family Foundation. "KFF Employer Benefits Survey, 2022." (October 17, 2022) https://www.kff.org/report-section/ehbs-2022-summary-of-findings.

[233] Zhu, Jane M., Christina J. Charlesworth, Daniel Polsky, and K. John McConnell. "Phantom Networks: Discrepancies Between Reported and Realized Mental Health Care Access in Oregon Medicaid." *Health Affairs* 41, no. 7 (2022): 1013-1022.

networks are also reportedly an issue for participants and beneficiaries of group health plans.[234] A national survey of privately insured individuals that received mental health care treatment found that more than half of those patients that used a provider directory encountered inaccuracies which made them more likely to be treated by an out-of-network provider, and four times as likely to receive a surprise, out-of-network bill.[235] In light of this concern, these proposed rules particularly highlight parity in network composition as an area that requires clarification in the NQTL space.

1.6.2. Greater Access to Mental Health and Substance Use Disorder Treatments

By improving plan and issuer understanding of and compliance with the requirements under MHPAEA, clarifying when and how comparative analyses of NQTLs should be conducted, and ensuring that the NQTLs are no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits, these proposed rules would improve compliance and, in turn, expand access to and utilization of mental health and substance use disorder services.[236] Utilization-related evidence is reviewed in section 1.7, below. The implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election would reduce financial and non-financial barriers to accessing mental health and substance use disorder treatment for participants and beneficiaries of plans sponsored by self-funded, non-Federal governmental entities that currently elect to opt out of requirements under MHPAEA. This would result in increased access to care and lead, as discussed in more detail in the next section, to better health outcomes for plan participants and beneficiaries with a need for mental health care or substance use disorder services.

1.6.3. Better Health Outcomes Among Those with Mental Health Conditions and Substance Use Disorders

---

[234] *See* Ellison, Katherine, "73 Doctors and None Available: How Ghost Networks Hamper Mental Health Care." The Washington Post (Feb. 19, 2022), *available at* https://www.washingtonpost.com/health/2022/02/19/mental-health-ghost-network/.

[235] Busch, Susan H. and Kelly A. Kyanko. "Incorrect Provider Directories Associated with Out-of-Network Mental Health Care and Outpatient Surprise Bills." *Health Affairs*, Vol. 39 No. 6 (June 2020): 975-083.

[236] Wen, Hefei, Janet R. Cummings, Jason M. Hockenberry, Laura M. Gaydos, and Benjamin G. Druss. "State Parity Laws and Access to Treatment for Substance Use Disorder in the United States: Implications for Federal Parity Legislation." *JAMA Psychiatry* 70, no. 12 (2013): 1355-1362.

By expanding access to mental health and substance use disorder services, these proposed rules may also result in better mental health and substance use disorder outcomes. A 2013 study found that State parity laws were associated with a five percent decrease in suicides.[237] A 2022 study found that severe maternal morbidity (SMM) among childbearing individuals with commercial insurance decreased by 53 percent between 2008 and 2019. The authors suggested implementation of MHPAEA may have had a role in the decreasing rates of SMM.[238] An improvement in mental health and substance use disorder outcomes can also improve overall physical health outcomes. A 2017 study found that better past mental health was associated with more physical activity and social interactions, which resulted in an improvement in the present physical health.[239]

1.6.4. Reduced Adverse Impacts on the Families, Friends, and Coworkers of People Who Suffer from Untreated or Poorly Managed Mental Health Conditions and Substance Use Disorders

These proposed rules would help employees and their families meet their mental health care needs, and thus, may improve the productivity and resulting earnings of workers dealing with mental health and substance use disorder issues. Among adults with any mental health condition in 2021, only 47.2 percent received treatment.[240] Moreover, while 15.6 percent of National Survey on Drug Use and Health respondents 12 and older were classified as needing substance use disorder treatment in 2021, only 6.3 percent received treatment that year.[241] One survey found that more than 85 percent of individuals that did not receive needed mental health

---

[237] Lang, Matthew. "The Impact of Mental Health Insurance Laws on State Suicide Rates." *Health Economics* 22, no. 1 (2013).
[238] Admon, Lindsay, Vanessa Dalton, Giselle Kolenic, Anca Tilea, Stephanie V. Hall, and Kara Zivin. "MHPAEA/ACA Policy Implementation and Severe Maternal Morbidity Among Commercially Insured Individuals, 2008–2019 [A192]." *Obstetrics & Gynecology* 139 (2022): 56S.
[239] Ohrnberger, Julius, Eleonora Fichera, and Matt Sutton. "The Relationship between Physical and Mental Health: A Mediation Analysis." *Social Science & Medicine* 195 (2017): 42-49.
[240] SAMHSA. "Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health." Figure 65.
[241] SAMHSA. "Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health." Figure 54 and 57.

or substance use care reported negative impacts, including personal relationship issues, job issues and performing poorly or dropping out of school.[242]

The economic impact of untreated mental health and substance use disorders can be significant. A 2021 study found that the high prevalence of major depressive disorder among U.S. adults has increased workplace costs from $114.6 billion in 2010 to $198.6 billion in 2018.[243] A 2022 study found that, in low and middle-income countries, mental health interventions significantly improved work-related outcomes. Relative to a control group, participants receiving a mental health intervention experienced a 26 percent decrease in their inability to work and participant absence rates declined by 16 percent. The authors noted that these economic effects are "somewhat larger" for populations with severe mental health disorders, compared to populations with mild mental health disorders.[244] Finally, a 2015 study examined the impact of State parity laws on individuals with moderate levels of mental distress and found that State parity laws were associated with an increase in overall employment, weekly wages, and the number of hours worked per week, and attributed these changes to the increased productivity of these workers.[245]

These proposed rules would also have significant indirect impacts on families and social networks of individuals with untreated or poorly managed mental health conditions and substance use disorders, as well as society at large. By increasing access to services, these proposed rules would lead to more people receiving treatment, reducing the burden on family members and other support systems. This includes untreated maternal mental health conditions (MMHCs) which can lead to a reduced ability to work, increased risk of suicide, increased use of

---

[242] National Council for Mental Wellbeing. "2022 Access to Care Survey Results," May 11, 2022. https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf.
[243] Greenberg, Paul E., Andree-Anne Fournier, Tammy Sisitsky, Mark Simes, Richard Berman, Sarah H. Koenigsberg, and Ronald C. Kessler. "The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018)." Pharmacoeconomics 39, no. 6 (2021): 653-665.
[244] Lund, Crick, Kate Orkin, Marc Witte, Thandi Davies, John Walker, Johannes Haushofer, Sarah Murray, Judy Bass, Laura Murray, and Vikram Patel. "Treating Mental Health Conditions Improves Labor Market and Other Economic Outcomes in Low and Middle-Income Countries." *University of Oxford, Working Paper* (2022).
[245] Andersen, Martin. "Heterogeneity and the Effect of Mental Health Parity Mandates on the Labor Market." Journal of Health Economics 43 (2015).

public services such as Medicaid, and worse maternal and child health. A 2022 study of the cost of MMHC to Texas women and their children projected costs for the 2019 birth cohort from the time of conception through five years postpartum to total $2.2 billion.[246] Untreated MMHCs include untreated perinatal mood and anxiety disorders (PMADs), which have been found to account for approximately $48 million in societal costs in Vermont for the average annual birth cohort from conception through five years postpartum, including $12.5 million in productivity loss and $9.4 million in non-obstetric health expenditures.[247] The cost in missed productivity due to workers' fair or poor mental health was estimated as $47.6 billion annually in 2022.[248] A 2022 study found that households with a family member diagnosed with a mental health disorder had lower health status scores compared to households without a mental illness diagnosis, suggesting evidence of family spillover effects on mental illness.[249] Finally, a 2020 study estimated that the societal costs of untreated opioid use disorder was approximately $1.02 trillion, which includes $35 billion in health care costs and $92 billion in lost productivity.[250]

1.7. Costs

These proposed rules aim to promote access to mental health and substance use disorder services under MHPAEA, while seeking to limit costs on plans and issuers. The costs incurred in these activities are discussed below.

A 2019 study which examined the impact of MHPAEA on the utilization of mental health and substance use disorder services in the private, large group employer-sponsored insurance

---

[246] Margiotta, Caroline, Jessica Gao, So O'Neil, Divya Vohra and Kara Zivin. "The Economic Impact of Untreated Maternal Mental Health Conditions in Texas." *BMC Pregnancy Childbirth* 22, 700 (2022). https://doi.org/10.1186/s12884-022-05001-6.

[247] Platt, Isabel, Emma Pendl-Robinson, Eric Dehus, So O'Neil, Divya Vohra, Kara Zivin, Michael Kenny and Laura Pentenrieder. "Estimating the Costs of Untreated Perinatal Mood and Anxiety Disorders in Vermont." *Mathematica*. May 2023. https://www.mathematica.org/publications/societal-costs-of-perinatal-mood-and-anxiety-disorders-in-vermont.

[248] Witters, Dan and Sangeeta Agrawal. "The Economic Cost of Poor Employee Mental Health" Gallup Workplace (December 13, 2022). https://www.gallup.com/workplace/404174/economic-cost-poor-employee-mental-health.aspx?version=print.

[249] Lee, Donghoon, Yeonil Kim, and Beth Devine. "Spillover Effects of Mental Health Disorders on Family Members' Health-related Quality of Life: Evidence from a US Sample." *Medical Decision Making* 42, no. 1 (2022): 80-93.

[250] Florence, Curtis, Feijun Luo, and Ketra Rice. "The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the United States, 2017." *Drug and Alcohol Dependence* 218 (2021): 108350.

market from 2005 to 2015 found that MHPAEA is positively associated with the utilization of outpatient mental health and substance use disorder benefits.[251] A 2020 study of MHPAEA, using 2007 and 2011-12 data from the National Survey of Children's Health, found that among children and adolescents with family income between 150 and 400 percent of the Federal poverty level in States without prior parity laws, the enactment of MHPAEA resulted in a 2.8 percentage point increase in mental health care utilization.[252] In addition, a 2019 study examined the effectiveness of the national primary care-mental health integration (PC-MHI) initiative of the Veterans Health Administration, which aimed to improve access to mental health services by embedding specialists, care managers, or both in primary care clinics to collaboratively care for veterans with psychiatric illness. It found that each percentage-point increase in the proportion of clinic patients seen by the PC-MHI providers was associated with an 11 percent increase in the average total mental health visits per year.[253] Finally, another 2019 study, which examined the effectiveness of hybrid psychiatric care, a combination of in-person and telepsychiatry services, found that hybrid care increased the total number of outpatient encounters and increased the timeliness of care in mental health patients, compared to patients with in-person visits only.[254]

1.7.1. Proposed Amendments to the Existing MHPAEA Regulations (26 CFR 54.9812-1, 29 CFR 2590.712, 45 CFR 146.136)

These proposed rules focus plans and issuers on the impact of NQTLs and associated practices on access to mental health and substance use disorder benefits. The regulations further stress the importance of avoiding NQTLs and practices that impose greater limits on access for participants, beneficiaries, and enrollees for mental health or substance use disorder benefits.

---

[251] Mulvaney-Day, Norah, Brent J. Gibbons, Shums Alikhan, and Mustafa Karakus. "Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health services in the United States, 2005–2016." *American Journal of Public Health* 109, no. S3 (2019): S190-S196.

[252] Li, Xiaoxue, and Jie Ma. "Does Mental Health Parity Encourage Mental Health Utilization Among Children and Adolescents? Evidence From The 2008 Mental Health Parity and Addiction Equity Act (MHPAEA)." *The Journal of Behavioral Health Services & Research* 47, no. 1 (2020): 38-53.

[253] Leung, Lucinda B., Lisa V. Rubenstein, Jean Yoon, Edward P. Post, Erin Jaske, Kenneth B. Wells, and Ranak B. Trivedi. "Veterans Health Administration Investments in Primary Care and Mental Health Integration Improved Care Access." *Health Affairs* 38, no. 8 (2019): 1281-1288.

[254] Hughes, M. Courtney, Jack M. Gorman, Yingqian Ren, Sana Khalid, and Carol Clayton. "Increasing Access to Rural Mental Health Care Using Hybrid Care that Includes Telepsychiatry." *Journal of Rural Mental Health* 43, no. 1 (2019): 30.

For example, as discussed in section II.A.2 of the preamble, the definition of "substance use disorders" must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) or that are listed in the most current version of the DSM as a Substance-Related and Addictive Disorder (or equivalent category). Plans and issuers would also be required to use reasonable methods and analysis to determine if a limitation complies with the requirements of these proposed rules. The Departments believe that the proposed amendments could cause plans and issuers to revise their policies and remove treatment limitations in response to the Departments' clarifications and examples. For instance, a 2016 study examined how private health plans responded to the 2010 interim final regulations and found that the majority of plans had eliminated annual limits related to behavioral health treatments. The percentage of health insurance products with special annual limits on mental health treatments decreased from 28 percent in 2009 to 4 percent in 2010, and a similar decrease was observed for health insurance products with special annual limits on substance use disorder treatments (from 26 percent in 2009 to 3 percent in 2010).[255] Therefore, plans and issuers could incur costs to implement changes associated with coverage revision of plan provisions, which might result in increased costs from expanded utilization of mental health and substance use disorder services. The Departments face uncertainty in quantifying these costs as they cannot estimate the potential increase in utilization and which services might see the largest increase in utilization.

1.7.2. New Regulations (26 CFR 54.9812-2, 29 CFR 2590.712-1, 45 CFR 146.137; 45 CFR 146.180)

[255] Horgan, Constance M., Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, and Timothy B. Creedon. "Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services." *Psychiatric Services* 67, no. 2 (2016): 162-168.

These proposed rules would amend the content and data, and documentation requirements for comparative analyses required by the CAA, 2021 and outline the timeframes and processes for plans and issuers to provide their comparative analyses to the Departments upon request. These proposed rules would require plans and issuers to collect and evaluate relevant data with each comparative analysis requested by the Departments for all NQTLs, including but not limited to the number and percentage of relevant claims denials and any other data required by State law or private accreditation standards, and for NQTLs related to network composition, data including, but not limited to, in-network and out-of-network utilization rates (including time and distance data, data on providers, network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges).

Plans and issuers would incur costs associated with collecting, processing, and analyzing data under the new proposed data requirements, including data on claims denials, data relevant to NQTLs as required by State law or private accreditation standards, in-network and out-of-network utilization rates, network adequacy metrics, provider reimbursement rates and other relevant data. As discussed in section 1.5.3 of this RIA, issuers and TPAs provide key support for plan compliance with MHPAEA and would incur most of the burden given their large involvement in the plan design and NQTL analyses. The Departments request comments on whether plans, issuers, and TPAs already collect and examine this data.

To meet the proposed new content requirements for the comparative analyses, the Departments, based on internal discussion, expect that on average, plans would need to analyze 4 NQTLs and issuers would need to analyze 8 NQTLs. Plans and issuers preparing their own comparative analyses would incur an incremental burden of 10 hours per NQTL in the first year, with 2 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 8 hours for a business operations specialist to prepare the comparative analyses. In the first year, this would result in a cost burden of

approximately $291.0 million.[256] The amount of time spent by plans preparing their own comparative analyses could vary depending on the level of cooperation by the TPA. Once the comparative analyses are performed and documented, plans would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits. In subsequent years, the Departments estimate plans would incur an incremental burden of 4 hours annually per NQTL to update the analyses, with 1 hour for a general or operations manager and 3 hours for a business operations specialist. In subsequent years, this would result in a cost burden of approximately $117.6 million.[257] The Departments seek comments on these assumptions.

Additionally, plans and issuers must make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants and beneficiaries in plans subject to ERISA and to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage upon request in connection with an appeal of an adverse benefit determination. The Departments estimate that on average each plan or issuer would receive one request annually and that plans and issuers would annually incur a burden of 5 minutes for a clerical worker to prepare

---

[256] A labor rate of $132.38 is used for a general or operations manager and a labor rate of $109.96 is used for a business operations specialist. (*Source*: Estimates for total compensation are based on mean hourly wages by occupation from the 2021 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation are from the December 2021 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2020 Service Annual Survey. To obtain overhead cost on an occupational basis, the estimate allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2023 dollars.) The labor rate is applied in the calculation as: [(27,499 ERISA self-insured group health plans x 4 NQTLs x 2 hours x $132.38 for a general or operations manager) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 8 hours x $109.96 for a business operations specialist) + (1,500 issuers x 8 NQTLs x 2 hours x $132.38 for a general or operations manager) + (1,500 issuers x 8 NQTLs x 8 hours x $109.96 for a general or operations manager) + (33,076 self-funded, non-Federal governmental health plans x 4 NQTLs x 2 hours x $132.38 for a general or operations manager) + (33,076 self-funded, non-Federal governmental health plans x 4 NQTLs x 2 hours x $109.96 for a business operations specialist)] = $291,031,092.

[257] A labor rate of $132.38 is used for a general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: [(27,499 ERISA self-insured group health plans x 4 NQTLs x 1 hour x $132.38 for a general or operations manager) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 3 hours x $109.96 for a business operations specialist) + (1,500 x 8 NQTLs x 1 hour x $132.38 for a general or operations manager) + (1,500 issuers x 8 NQTLs x 3 hours x $109.96 for a general or operations manager) + (33,076 self-funded, non-Federal governmental health plans x 4 NQTLs x 1 hours x $132.38 for a general or operations manager) + (33,076 self-funded, non-Federal governmental health plans x 4 NQTLs x 3 hours x $109.96 for a business operations specialist)] = $117,552,718.

and send the comparative analyses to each requesting participant or beneficiary. This would result in an annual cost burden of approximately $10.5 million.[258] The Departments also assume that 58.2 percent of requests would be delivered electronically, resulting in a de minimis cost.[259] The remaining 41.8 percent of requests would be mailed, at a cost of $1.14 each, which is postage for a 3-ounce letter. The annual cost burden to mail the comparative analyses to the participants and beneficiaries requesting them would therefore be approximately $1.6 million.[260]

In the first year, group health plans and issuers would need time to familiarize themselves with these proposed rules and amendments. The Departments assume that on average it would require six and a half hours for an attorney to review these proposed rules and amendments. This would result in a one-time cost burden of $64.3 million.[261]

According to the 2021 National Health Expenditure Data, the total contribution of private employers to health insurance premiums is $554.1 billion. The total contribution of State and

---

[258] The Departments estimate that there are 476 issuers with 1,500 issuer/State combinations offering individual and group health coverage nationwide. A labor rate of $63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (1,898,298 ERISA group health plans + 90,126 non-Federal governmental health plans + 1,500 issuers/State combinations providing coverage in the group and individual market) x 5 minutes x $63.45 = $10,521,787.

[259] According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals aged 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals aged 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who have access to electronic disclosure at work with the 24.7 percent who have access to electronic disclosure outside of work produces a total of 58.2 percent who will receive to electronic disclosure overall.

[260] The Departments assume one request per entity and that each mailed response will cost $1.89 in materials and postage, on average. The mailing and postage cost assume $.05 per printed page, an average document length of 15 pages and $1.14 in postage for a 3-ounce parcel. Therefore, the cost is estimated as (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants + 1,500 issuers/State Combinations + 90,126 non-Federal governmental health plans) x 41.8% x ($1.14 + (15 pages x $0.05)) = $1,572,080.

[261] A labor rate of $159.34 is used for an attorney (this figure reflects the median hourly wage of lawyers according to the DOL Bureau of Labor Statistics Occupational Employment and Wage Statistics for May 2022, doubled to account for overhead costs and benefits). The reading time is calculated based on an average 250 words per minute reading rate. The labor rate is applied in the calculation as: (27,499 self-funded, ERISA group health plans + 33,076 self-funded, non-Federal governmental health plans + 1,500 issuers/State combinations providing coverage in the group and individual market) x 6.5 hours x $159.34 = $64,291,778.

local employers to health insurance premiums is $179.7 billion.[262] The total health expenditure on the individual market is $80.9 billion.[263] In the first year, the cost to comply with these proposed rules is estimated to be approximately $367.4 million,[264] which represents 0.05 percent of total premiums in these markets. In subsequent years, the cost to comply with these proposed rules is estimated to be approximately $129.6 million,[265] which represents 0.02 percent of total premiums in these markets. The Departments request comments regarding the costs associated with these proposed rules and amendments. To be most useful, comments should distinguish between the cost to comply with existing parity requirements and the cost to comply with the requirements of these proposed rules.

HHS assumes that most of the self-funded, non-Federal governmental plans that would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election currently offer mental health and substance use disorder benefits, but that many of these plans might not be complying with MHPAEA. These plans would incur costs to come into compliance. In particular, some plans might have to remove limits on or offer more generous mental health and substance use disorder benefits, which would likely increase utilization of mental health and substance use disorder services, increasing the number of claims submitted, and the overall costs incurred by these plans. Plans that have opted out of requirements under MHPAEA would also need to conduct NQTL comparative analyses if they are not already doing so. HHS is unable to estimate the potential costs to these plans because the extent to which these plans are currently out of compliance is unknown, and costs associated with coming into

---

[262] Centers for Medicare and Medicaid Services. "National Health Expenditure Data." NHE Tables - Table 24. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/nationalhealthaccountshistorical.

[263] Centers for Medicare and Medicaid Services. "National Health Expenditure Data." NHE Tables - Table 21. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/nationalhealthaccountshistorical.

[264] The cost is estimated as follows: $291.0 million for preparing the comparative analyses + $64.3 million for reviewing the proposed rules and amendments + $10.5 million to prepare the comparative analyses upon request to participants and beneficiaries + $1.6 million to distribute the comparative analyses to participants and beneficiaries = $367.4 million.

[265] The cost is estimated as follows: $117.6 million for preparing the comparative analyses + $10.5 million for preparing the comparative analyses upon request to participants and beneficiaries + $1.6 million to distribute the comparative analyses to participants and beneficiaries = $129.6 million.

compliance would vary from plan to plan. HHS seeks comments on the potential costs to these plans to come into compliance with MHPAEA.

HHS estimates that the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election would generate a total cost savings of approximately $11,351 for plans (as discussed in section 2.2 of this RIA), as these plans would no longer be required to submit an opt-out notice to the Federal Government or prepare and disseminate an opt-out notice to plan participants regarding the plan's opt-out election, as long as the plans do not elect to permissibly opt-out of other requirements. This proposed provision would also generate cost savings of approximately $2,469 for the Federal Government, as discussed in section 2.2 of this RIA, as HHS would no longer have to process the opt-out notices submitted by several of these plans.

1.8. Transfers

Improving parity in coverage of mental health and substance use disorder benefits has the potential to increase premiums, change the spending patterns of plans and issuers, and change the utilization patterns of participants, beneficiaries, and enrollees. The Departments recognize these as transfers among participants, beneficiaries, and enrollees, plans and issuers, and mental health and substance use disorder providers and facilities. Specifically, the Departments expect these proposed rules would result in: (1) transfers from plans and issuers to participants, beneficiaries, and enrollees caused by lower out-of-pocket spending; (2) transfers from participants, beneficiaries, and enrollees to plans and issuers caused by higher premiums; and (3) transfers between primary care providers and mental health providers for the treatment of mental health and substance use disorders resulting from the anticipated shift of participants, beneficiaries, and enrollees choosing to obtain treatment from a specialist instead of a primary care provider. The Departments request comment or data on how large these transfers might be.

1.8.1. Transfers From Plans and Issuers to Participants, Beneficiaries, and Enrollees Caused by Lower Out-of-Pocket Spending

These proposed rules could result in a transfer from plans and issuers to participants, beneficiaries, and enrollees through lower out-of-pocket spending for mental health and substance use disorder services. For example, a 2013 study examined the impact of the 2001 parity directive in the Federal Employees Health Benefits (FEHB) Program and found that the annual out-of-pocket spending for FEHB enrollees diagnosed with bipolar disorder, major depression, or adjustment disorder decreased by between $78 and $86.[266] Furthermore, a 2018 study compared commercially-insured children ages 3 to 18 years in 2008 who were continuously enrolled in plans newly subject to parity under MHPAEA to children continuously enrolled in plans never subject to MHPAEA. The 2018 study found that children with mental health conditions who were enrolled in plans subject to parity had, on average, $140 lower annual out-of-pocket mental health spending than expected compared to the comparison group. The study further found that children in or above the 85th percentile in total mental health spending who were enrolled in plans subject to MHPAEA had, on average, $234 lower annual out-of-pocket mental health spending than those in the comparison group.[267] Finally, a 2019 study examined the impact of MHPAEA on mental health services spending in a commercially-insured population diagnosed with mental health disorders and found that MHPAEA resulted in a decrease in the mean out-of-pocket spending per mental health outpatient visit.[268]

1.8.2. Transfers From Participants, Beneficiaries, and Enrollees to Plans and Issuers Caused by Higher Premiums

These proposed rules might also result in a transfer from participants, beneficiaries, and enrollees to plans and issuers in the form of higher premiums. By limiting the ability of plans and issuers to avoid costs of certain mental health and substance use disorder treatments, while

---

[266] Busch, Alisa B., Frank Yoon, Colleen L. Barry, Vanessa Azzone, Sharon-Lise T. Normand, Howard H. Goldman, and Haiden A. Huskamp. "The Effects of Parity on Mental Health and Substance Use Disorder Spending and Utilization: Does Diagnosis Matter?" The American Journal of Psychiatry 170, no. 2 (2013): 180.
[267] Kennedy-Hendricks, Alene, Andrew J. Epstein, Elizabeth A. Stuart, Rebecca L. Haffajee, Emma E. McGinty, Alisa B. Busch, Haiden A. Huskamp, and Colleen L. Barry. "Federal Parity and Spending for Mental Illness." *Pediatrics* 142, no. 2 (2018).
[268] Haffajee, Rebecca L., Michelle M. Mello, Fang Zhang, Alisa B. Busch, Alan M. Zaslavsky, and J. Frank Wharam. "Association Of Federal Mental Health Parity Legislation with Health Care Use and Spending Among High Utilizers of Services." *Medical Care* 57, no. 4 (2019): 245.

increasing access to and utilization of these services, plans and issuers might increase premiums and change cost-sharing requirements (for example, by raising deductibles) to offset these costs. Similarly, by incorporating the statutory requirement that NQTLs be no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits, plans and issuers might reduce the number of NQTLs employed and increase premiums in order to offset the costs of participants utilizing more mental health and substance disorder benefits.

Many studies attempt to isolate the changes in health costs associated with implementing parity. For example, in 2007 the Congressional Budget Office estimated that MHPAEA would increase premiums for group health insurance by 0.4 percent on average.[269] Another study by the Society of Actuaries on mental health parity found in 2005 that, "overall health care costs increased minimally and in some cases were even reduced."[270] The Departments anticipate that these proposed rules would have a minimal impact on premiums, but there may be instances in which plans and issuers may impose higher premiums. The Departments request comments or data on this transfer.

1.8.3. Transfers Between Primary Care Providers and Mental Health Providers

Finally, these proposed rules may result in a transfer from primary care providers to mental health and substance use disorder providers. More specifically, patients may be more likely to visit a mental health or substance use disorder specialist compared to a primary care provider, as these proposed rules clarify the manner in which plans and issuers must provide parity in coverage for mental health and substance use disorder benefits and medical/surgical benefits. A 2012 study that examined the impact of Oregon's 2007 parity law on the choice of provider found that the law was associated with a slight increase in the likelihood of patients seeking care with masters-level specialists, and relatively little change for generalist physicians,

---

[269] Congressional Budget Office. Congressional Budget Office Cost Estimate: S558. March 20, 2007. https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/78xx/doc7894/s558.pdf.
[270] Melek, Steve. "The Cost of Mental Health Parity." Health Section News. Issue 49. (2005) As presented to the Society of Actuaries. https://www.soa.org/globalassets/assets/library/newsletters/health-section-news/2005/march/hsn-2005-iss49-melek-b.pdf.

psychiatrists, and psychologists. The findings suggest that these proposed rules may lead to a slight shift in the use of nonphysician specialists, including masters-level specialists, and away from generalist physicians.[271]

1.8.4. Transfers Associated with the Implementation of the CAA, 2023 Provision That Sunsets the MHPAEA Opt-Out Election for Self-Funded, Non-Federal Governmental Plans

HHS anticipates that the proposed amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for self-funded, non-Federal governmental plans would have similar effects as the other provisions examined in this subsection of the RIA. These proposed amendments might lead to improved coverage of and lower cost-sharing requirements for mental health and substance use disorder benefits for participants and beneficiaries of self-funded, non-Federal governmental plans. This would lead to lower out-of-pocket costs for plan participants and beneficiaries who receive mental health or substance use disorder services. This would be viewed as a transfer from self-funded, non-Federal governmental plans to participants and beneficiaries.

On the other hand, as noted in section 1.7 of this RIA, if the proposed amendments cause plans to remove limits on or offer more generous mental health and substance use disorder benefits, utilization of mental health and substance use disorder services might increase, which may result in the number of claims submitted and the overall costs incurred by plans to also increase. This, in turn, might lead to higher premiums and/or deductibles for plan participants, which may seem to be a transfer from plan participants to self-funded, non-Federal governmental plans, but is instead an indication of who bears the societal cost presented in section 1.7.

1.9. Uncertainty

It is unclear what percentage of participants, beneficiaries, and enrollees experience more restrictive NQTLs and more stringent practices related to the design and implementation of

[271] McConnell, K. John, Samuel HN Gast, and Bentson H. McFarland. "The Effect of Comprehensive Behavioral Health Parity on Choice of Provider." *Medical Care* 50, no. 6 (2012): 527.

mental health and substance use disorder benefits, as compared to medical/surgical benefits. Similarly, it is unclear what percentage of plans and issuers impose greater limitations on mental health and substance use disorder benefits than on medical/surgical benefits. This frequency may differ among small and large plans and issuers. Examining some plans' comparative analyses shows that they are not in full compliance with MHPAEA's requirements for NQTL's although the extent across all plans is not known. As documented in the 2022 MHPAEA Report to Congress, DOL completed a compliance review of 48 NQTLs (36 unique NQTLs), corresponding to 30 plans and issuers as of October 31, 2021. All of these reviews resulted in an initial determination of noncompliance with MHPAEA.[272]

While the Departments expect that these proposed rules would result in plans and issuers expanding coverage of mental health and substance use benefits, it is possible that instead of relaxing the use of NQTLs on mental health and substance use disorder benefits, some plans and issuers may impose additional NQTLs on medical/surgical benefits. As a result, some types of medical/surgical benefits may become less accessible for some participants, beneficiaries, and enrollees, which could lead to an increase in out-of-pocket costs.

There is also a possibility that some plans and issuers would stop offering mental health and substance use disorder benefits. In 2010, 2 percent of employers reported discontinuing their coverage of mental health and substance use disorder treatments.[273] Nevertheless, as discussed in section 1.6 of this RIA, the Departments anticipate that these proposed rules would expand the level of coverage for mental health and substance use disorder benefits, which would result in reduced out-of-pocket spending for plan participants, beneficiaries, and enrollees. The Departments face uncertainty in estimating the magnitude of savings and welcome any

---

[272] 2022 MHPAEA Report to Congress, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf.

[273] Government Accountability Office. "Mental Health and Substance Use: Employers' Insurance Coverage Maintained or Enhanced Since Parity Act, but Effect of Coverage on Enrollees Varied," GAO-12-63, November 2011.

comments and data that can help estimate the amount of decrease in out-of-pocket spending. The Departments also invite comments and data related to other issues identified in this section.

Further, there may be some possible societal spillover effects which may occur as a result of these proposed rules. For example, increasing access to mental health and substance use disorder services may improve public safety in the long-term. A 2017 study on whether State parity laws for substance use disorder treatments was associated with reduced fatal traffic accidents found that passage of State parity laws was associated with reduced annual total traffic fatality rates by 4.1 to 5.4 percent.[274] In addition, a 2021 study which examined the impact of State parity laws on crime between 1994 and 2010 found that the passage of State parity laws was associated with a reduction of violent crimes by 5 to 7 percent and that the resulting lower crime rates were associated with an annual savings of $3 billion.[275] These studies may suggest that the benefits of these proposed rules may go beyond the listed benefits discussed in this RIA.

HHS is unable to precisely forecast how many participants and beneficiaries would be affected by the proposed amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for self-funded, non-Federal governmental plans, as plan sponsors that have elected to opt out of requirements under MHPAEA were not required to report that information to HHS as part of their HIPAA opt-out filings.

It is possible that some self-funded, non-Federal governmental plans would stop offering mental health and substance use disorder benefits in response to the proposed amendments. However, HHS is unable to estimate the potential number of self-funded, non-Federal governmental plans that might do so. It is also possible that some self-funded, non-Federal governmental plans might increase the financial requirements and treatment limitations that apply to medical/surgical benefits in response to this proposed provision, to ensure that these

---

[274] Popovici, Ioana, Johanna Catherine Maclean, and Michael T. French (2017). "The Effects of Health Insurance Parity Laws for Substance Use Disorder Treatment on Traffic Fatalities: Evidence of Unintended Benefits." National Bureau of Economic Research. https://www.nber.org/system/files/working_papers/w23388/revisions/w23388.rev0.pdf?sy=388

[275] Sharma, Keshob. "Do Mental Health Parity Laws Reduce Crime?" (2021).

financial requirements and treatment limitations are comparable to those for mental health and substance use disorder benefits. HHS anticipates that this is a less likely outcome of these proposed amendments.

HHS seeks comments on the potential number of self-funded, non-Federal governmental plans that might stop offering mental health and substance use disorder benefits, as well as the potential number of self-funded, non-Federal governmental plans that might increase financial requirements and treatment limitations for medical/surgical benefits in response to the proposed amendments. HHS also seeks comments on the potential number of participants and beneficiaries that might be affected by these potential plan changes.

1.10. Alternatives

In addition to the regulatory approach outlined in these proposed rules, the Departments considered alternatives when developing policy regarding the implementation of MHPAEA. The Departments considered not expressly incorporating the statutory requirement that NQTLs be no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits. However, as described in section I.E of this preamble, it is clear that plans and issuers too often fail to consider the impact of their NQTLs on access to mental health and substance use disorder benefits, consistent with MHPAEA's fundamental purpose. While the Departments have seen some promising results in response to their reviews of plans' and issuers' comparative analyses under the CAA, 2021's requirements, they have also seen a great deal of confusion about the application of the current regulation to NQTLs and about the parity obligation generally. Based on the Departments' experience with plans' and issuers' attempts to comply with the existing regulations and guidance and the CAA, 2021, they have concluded that the existing MHPAEA regulations failed to sufficiently focus attention on the obligation to ensure that NQTLs, and associated processes, strategies, factors, and evidentiary standards, avoid placing disparate burdens on participants', beneficiaries', and enrollees' access to covered mental health and substance use disorder treatment. Accordingly, the Departments believe that

the proposed amendments would be beneficial to participants, beneficiaries, and enrollees, as plans and issuers revise their policies and remove or amend NQTLs that are inconsistent with MHPAEA.

The Departments also considered not requiring plans and issuers to use specific data elements in preparing their comparative analyses or to provide the data to the Departments upon request. However, during their review of comparative analyses as part of their reporting requirements to Congress, the Departments found that many plans and issuers did not initially provide sufficient information to demonstrate compliance of an NQTL either by design, application, or both. It is often difficult, to assess compliance in operation without such data. By requiring the consideration, use, and production of this data, the regulation should result in improved review of plans' and issuers' policies and processes, and improved parity outcomes for participants, beneficiaries, and enrollees.

1.11. Conclusion

The Departments expect that these proposed rules, if finalized, would provide plans and issuers with a better understanding of the requirements of MHPAEA and improve how they measure, analyze, document, and demonstrate parity with regard to NQTLs. The Departments are of the view that these proposed rules and corresponding associated Technical Release, if finalized, would help plans and issuers produce NQTL comparative analyses that meet the requirements of the CAA, 2021, resulting in improved access to and coverage of mental health and substance use disorder treatments, which should ultimately result in better mental health outcomes.

2. Paperwork Reduction Act

2.1. Paperwork Reduction Act- Departments of Labor and the Treasury

As part of their continuing effort to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and continuing collections of information in

accordance with the Paperwork Reduction Act of 1995 (PRA).[276] This helps to ensure that the public understands the Departments' collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents.

Currently, the Departments are soliciting comments concerning the proposed information collection request (ICR) included in the MHPAEA Notices. To obtain a copy of the ICR, contact the PRA addressee shown below or go to https://www.RegInfo.gov.

The Departments have submitted a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example, permitting electronically delivered responses).

Commenters may send their views on the Department's PRA analysis in the same way they send comments in response to these proposed rules (for example, through the www.regulations.gov website), including as part of a comment responding to the broader NPRM.

PRA Addressee: Address requests for copies of the ICR to James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration,

[276] 44 U.S.C. 3506(c)(2)(A) (1995).

200 Constitution Avenue NW, Room N-5718, Washington, DC 20210; ebsa.opr@dol.gov. (https://www.reginfo.gov/public/do/PRAMain).

Readers should note that the PRA requires a non-incremental analysis of information collections, and hence the overall summary of the paperwork burden estimates in this section includes the entire on-going burden imposed by information collections required by MHPAEA, the CAA, and subsequent guidance. The incremental hour and cost burdens of these proposed rules are discussed in detail below. For a full discussion of all burden related to this information collection please see the supporting statement which is part of the ICR available at https://www.reginfo.gov/public/do/PRAMain.

2.1.1. Amendment to Existing MHPAEA Regulations (29 CFR 2590.712; 26 CFR 54.9812-1)

The proposed amendments to the existing MHPAEA regulations would add new definitions, amend existing definitions, specify new requirements related to NQTLs, amend existing examples of NQTLs, and add new examples of NQTLs, providing clarity to interested parties. The proposed amendments would also specify that mental health and substance use disorder definitions must be consistent with generally recognized independent standards of current medical practice and would add more specificity as to what conditions or disorders plans and issuers would be required to treat as mental health and substance use conditions or disorders.

2.1.2. New Regulation (29 CFR 2590.712-1; 26 CFR 54.9812-2)

These proposed rules set more specific content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or applicable State authority upon request. These proposed rules would also require plans and issuers to collect and evaluate relevant data as part of each comparative analysis, including but not limited to claims denials, data relevant to NQTLs as required by State law or private accreditation standards, utilization rates, network adequacy metrics, and provider reimbursement rates, in fulfillment of the existing

requirement that they evaluate and document their evaluation as part of the analysis of the application of NQTLs related to network composition and provider reimbursement.

For the purpose of this analysis, it is assumed that health insurance issuers would fulfill the data request for fully insured group health plans. This burden is accounted for under HHS' OMB Control number 0938-1393 and is discussed later in this document. It is also assumed that TPAs and other service providers would fulfill the requirements for the vast majority of self-insured group health plans.

2.1.3. Burden Estimates for Both Existing Requirements and Proposed Requirements

The Departments estimate that there are approximately 250,000 ERISA self-insured group health plans with 50 or more participants that are affected by these proposed rules.[277] The Departments believe that the number of self-insured group health plans that actually perform the analysis themselves and incur the full estimated compliance costs may be much smaller. The Departments analyzed 2020 Form 5500 Schedule C (Service Provider Information) filings of self-insured health plans and determined that 89 percent of those plans indicated that they contracted with a TPA.[278] Self-insured group health plans could fulfill the requirements with the help of TPAs and other service providers.

To the extent self-insured plans use plan designs provided by TPAs or service providers responsible for nearly identical fully insured plans, those TPAs or service providers could utilize the analysis already performed for those fully insured plans, while helping these self-insured plans comply with the requirements. The Departments assume that most self-insured health plans

---

[277] MHPAEA only applies to ERISA plans in the group market with 50 or more participants that offer mental health or substance use disorder (MH/SUD) benefits. The Departments have not identified what share of plans with 50 or more participants offer MH/SUD benefits and has therefore assumed that all of these plans offer them. Based on the 2021 Medical Expenditure Survey, 61 percent of ERISA-covered group health plans with 50 or more participants are self-insuring. Thus, the Department calculates the number of ERISA self-insured group health plans with 50 or more participants based on the following manner: 409,822 ERISA group health plans with 50 or more participants x 61% = 249,991.

[278] Because many plans are exempt from filing a Form 5500, the Department only identified 37,934 self-insured health plan filings for 2020. Of these, only 5,537 plans (or roughly 15 percent) attached a Schedule C. Of those plans, 4,920 (or roughly 89 percent) indicated they paid compensation, either directly or indirectly, of at least $5,000 for either claims processing, contract administration, or both.

would utilize service providers to perform the analysis and that only 11 percent[279] (27,499) of the affected self-insured group health plans, primarily the largest, would need to conduct the analyses themselves for their plan specific design.[280] The Departments request comments on the percent of self-insured group health plans that would rely on analyses that TPAs and other service providers have already performed for their other plans, thus reducing estimated burden on plans.

The Departments expect that even these numbers may overestimate the number of self-insured plans that would perform the analysis themselves, without assistance from TPAs or service providers. For example, in DOL's review of comparative analyses, which has focused on self-funded plans, the reliance on insurance companies, TPAs, and other service providers for much or all of the work has been nearly universal. As noted above, this is not surprising because of the outsized role insurance companies, TPAs and other service providers tend to play in designing the plans, administering the networks, managing claims, providing plan services, maintaining and holding the data relevant to the comparative analyses, and driving MHPAEA compliance or noncompliance.

Non-grandfathered, fully insured ERISA plans with less than 50 participants that are subject to MHPAEA under the Essential Health Benefits (EHB) requirements of the Affordable Care Act are likely to have their issuers prepare their comparative analyses. Issuers can take advantage of economies of scale by preparing the required documents for those plans purchasing coverage. HHS has jurisdiction over issuers and therefore is accounting for this portion of the burden in their analysis, in addition to the burden related to non-Federal governmental plans. Accordingly, this analysis considers only the burden associated with ERISA self-insured group health plans, which are under the jurisdiction of the DOL and Treasury.

---

[279] Based on the 2020 Form 5500, 89 percent of self-insured plans filed a Schedule C and indicated using either a Claims Processor, Contract Administrator, or both.

[280] The Departments assume only large plans, defined as a plan with 50 or more participants would self-administer. 249,991 self-funded ERISA plans with 50 or more participants x 11 percent of plans that self-administer = 27,499.

These proposed rules require that group health plans offering group health insurance coverage must make a comparative analysis available upon request by DOL. The CAA, 2021 requires DOL to collect no fewer than 20 comparative analyses per year, but it also provides that DOL shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the DOL determines appropriate. Based on its prior experience and current funding, DOL expects to request 100 comparative analyses each year.[281] To provide DOL with their comparative analyses and associated documentation, DOL estimates, based on internal discussion, it would take a total of five hours for plans, with one hour for a general or operations manager and four hours for a business operations specialist. This would result in a total hour burden of 500 hours with an equivalent cost burden of $57,222 in each year.[282]

These proposed rules require that a plan or issuer document the action that has been or is being taken by the plan or issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as required in the demonstration of comparability and stringency in operation requirement in § 2590.712-1(c)(5)(iv) of these proposed rules. To meet the format, content, data, and documentation requirements for the comparative analysis, DOL expects that plans preparing their own comparative analyses would on average annually perform four NQTL analyses across benefit classifications, based on DOL's experience in reviewing comparative analyses, and assumes that

---

[281] It should be emphasized, however, that DOL currently relies on supplemental appropriations passed as part of CAA, 2021, to fund these enforcement efforts. The supplemental appropriations are currently scheduled to expire at the end of FY 2024 with the consequence that DOL would lose funds for between a quarter and a third of its enforcement program and EBSA would have to commensurately reduce its staff size by approximately 120 full-time employees (FTEs). As a result, its MHPAEA enforcement efforts would necessarily decline, and the estimates of associated expenses would correspondingly decline.

[282] The burden is calculated as follows: (100 ERISA self-insured group health plans x 1 hour for a general or operations manager) + (100 ERISA self-insured group health plans x 4 hours for a business operations specialist) = 500 hours. A labor rate of $132.38 is used for a general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (100 ERISA self-insured group health plans x 1 hour for a general or operations manager x $132.38) + (100 ERISA self-insured group health plans x 4 hours for a business operations specialist x $109.96) = $57,222

each NQTL analysis would require 20 hours in the first year, with 4 hours for a general or operations manager and 16 hours for a business operations specialist.[283] In the first year, this results in a total hour burden of 2,199,921 hours with an equivalent cost burden of $251,767,736.[284] Once the comparative analyses are performed or documented, plans would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits. In subsequent years, DOL estimates it would take a total of 10 hours annually per NQTL to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist. In subsequent years, this results in a total hour burden of 1,099,960 hours with an equivalent cost burden of $125,883,822.[285]

These proposed rules would also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants and beneficiaries in plans subject to ERISA and to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual

---

[283] The estimated hour burden is consistent with the hour burden estimated in the previous PRA supporting statement for 1210-0138. In the PRA supporting statement, the Departments estimated that it would take a total of 20 hours for plans to update each comparative analysis as required by the CAA, 2021 (https://omb.report/icr/202108-1210-015/doc/114767500). This estimate differs by accounting for plans needing to evaluate multiple NQTLs.

[284] The burden is calculated as follows: (27,499 ERISA self-insured group health plans x 4 NQTLs x 4 hours for a general or operations manager) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 16 hours for a business operations specialist) = 2,199,921 hours. A labor rate of $132.38 is used for a general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (27,499 ERISA self-insured group health plans x 4 NQTLs x 4 hours for a general or operations manager x $132.38) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 16 hours for a business operations specialist x $109.96) = $251,767,736. DOL estimates of labor costs by occupation reflect estimates of total compensation and overhead costs. Estimates for total compensation are based on mean hourly wages by occupation from the 2021 Occupational Employment Statistics and estimates of wages and salaries as a percentage of total compensation by occupation from the December 2021 National Compensation Survey's Employee Cost for Employee Compensation. Estimates for overhead costs for services are imputed from the 2020 Service Annual Survey. To obtain overhead cost on an occupational basis, the estimate allocates total industry overhead cost to unique occupations using a matrix of detailed occupational employment for each NAICS industry. All values are in 2023 dollars.

[285] The burden is calculated as follows: (27,499 ERISA self-insured group health plans x 4 NQTLs x 2 hours for a general or operations manager) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 8 hours for a business operations specialist) = 1,099,960 hours. A labor rate of $132.38 is used for a general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (27,499 ERISA self-insured group health plans x 4 NQTLs x 2 hours for a general or operations manager x $132.38) + (27,499 ERISA self-insured group health plans x 4 NQTLs x 8 hours for a business operations specialist x $109.96) = $125,883,822.

health insurance coverage upon request in connection with an appeal of an adverse benefit determination. The Departments estimate that each plan would l receive one request per covered health plan annually and that plans would annually incur a burden of five minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. This results in an hour burden of 158,192 hours with an equivalent cost of $10,037,282.[286] DOL also assumes that 58.2 percent of requests would be delivered electronically, resulting in a de minimis cost.[287] The remaining 41.8 percent of requests would be mailed, the cost of postage for a 3-ounce letter is $1.14. The annual cost burden to mail the comparative analyses to the participants and beneficiaries is $1,499,693.[288]

2.1.4. Recordkeeping Requirement

The Departments posit that plans and issuers already maintain records as part of their regular business practices. Further, ERISA section 107 includes a general six-year retention requirement. For these reasons the Departments estimate a minimal additional burden. The Departments estimate that, on average, any additional recordkeeping requirements would take

---

[286] The hour burden is estimated as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes = 158,192 hours. A labor rate of $63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes x $63.45 = $10,037,282.

[287] According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

[288] The Departments assume one request per entity and that each mailed response will cost $1.89 in materials and postage, on average. The mailing and postage cost assume $.05 per printed page, an average document length of 15 pages and $1.14 in postage for a 3-ounce parcel. Therefore, the cost burden is calculated as follows: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 41.8% x ($1.14 + (15 pages x $0.05)) = $1,499,693.

clerical personnel five minutes annually. This results in an hour burden of 158,192 hours with an equivalent cost of $10,037,282.[289]

2.1.5. Overall Summary

In summary, the total burden, including that associated with prior requirements and by these proposed rules, has a three-year average hour burden of 1,883,110 hours with an equivalent cost of 205,897,135 and a cost burden of $2,182,094.

A summary of paperwork burden estimates follows:

Type of Review: Revision

Agency: Employee Benefits Security Administration, U.S. Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: MHPAEA Notices

OMB Control Number: 1210-0138

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 2,646,306

Estimated Number of Annual Responses: 2,646,306

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 1,883,110 (941,555 for DOL, 941,555 for Treasury)

Estimated Total Annual Burden Cost: $2,182,094 ($1,091,047 for DOL, $1,091,047 for Treasury)

2.2. Paperwork Reduction Act - Department of HHS

As part of its continuing effort to reduce paperwork and respondent burden, HHS conducts a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and continuing collections of information in accordance with the

[289] The hour burden is estimated as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes = 158,192 hours. A labor rate of $63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (1,488,476 fully-insured, non-grandfathered plans with less than 50 participants + 409,822 ERISA-covered group health plans with 50 or more participants) x 5 minutes x $63.45 = $10,037,282.

Paperwork Reduction Act of 1995 (PRA).[290] This helps to ensure that the public understands HHS's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and HHS can properly assess the impact of collection requirements on respondents.

Currently, HHS is soliciting comments concerning the proposed (revised) information collection request (ICR) included in the Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA and the proposed (revised) ICR included in the Compliance with Individual and Group Market Reforms under title XXVII of the Public Health Service Act. To obtain a copy of either ICR, contact the PRA addressee shown below or go to https://www.RegInfo.gov.

HHS has submitted a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. HHS and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronically delivered responses).

Commenters may send their views on HHS PRA analysis in the same way they send comments in response to the NPRM as a whole (e.g., through the www.regulations.gov website), including as part of a comment responding to the broader NPRM.

---

[290] 44 U.S.C. 3506(c)(2)(A) (1995).

To obtain copies of the supporting statement and any related forms for the proposed collections, please visit CMS's website at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.

2.2.1. Amendments to Existing MHPAEA Regulations (45 CFR 146.136)

The proposed amendments to the existing MHPAEA regulations would add new definitions, amend existing definitions, clarify the rules for NQTLs, amend existing examples of NQTLs, and add new examples of NQTLs, providing clarity to the regulated community. The proposed amendments would also clarify that mental health and substance use disorder definitions must be consistent with generally recognized standards of care and would add more specificity as to what conditions or disorders plans and issuers would be required to treat as mental health conditions and substance use disorders.

2.2.2. New Regulations (45 CFR 146.137)

These proposed rules set forth content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request. These proposed rules would also require plans and issuers to collect and evaluate relevant data as part of each comparative analysis, including but not limited to claims denials, data relevant to NQTLs as required by State law or private accreditation standards, utilization rates, network adequacy metrics, and provider reimbursement rates, in fulfillment of the existing requirement that they evaluate and document their evaluation as part of the analysis of the application of NQTLs related to network composition and provider reimbursement. As discussed above, HHS enforces applicable provisions of Title XXVII of the PHS Act, including the provisions added by MHPAEA, with respect to health insurance issuers offering group and individual health insurance coverage in States that elect not to enforce or fail to substantially enforce MHPAEA or another PHS Act provision and therefore HHS is accounting for this

portion of the burden in their analysis, in addition to accounting for the burden on sponsors of non-Federal governmental plans.

2.2.3. Burden Estimates for Both Existing Requirements and Proposed Requirements

Issuers offering individual or group health insurance coverage usually have multiple products offered in multiple States. HHS estimates a total of 476 issuers offering individual and group health coverage nationwide, with 1,500 issuer/State combinations offering coverage in multiple States.

These proposed rules require that health insurance issuers offering group health insurance coverage make their comparative analyses available upon request by HHS. The CAA, 2021 requires HHS to collect not fewer than 20 comparative analyses per year, but it also provides that HHS shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which HHS determines appropriate. Thus, HHS expects to request at least 20 comparative analyses each year. HHS estimates that to provide the comparative analyses and associated documentation, it would take a total of 5 hours for each plan or issuer, with 1 hour for a general or operations manager and 4 hours for a business operations specialist. This would result in a total hour burden of 100 hours with an equivalent cost burden of $11,444 in each year.[291] HHS seeks comment on the average number of NQTLs for plans offered by non-Federal governmental plans and issuers.

These proposed rules would require that issuers document the action that has been or is being taken by the issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as required by 45 CFR 146.137(c)(5)(iv). To meet the proposed new content and data, and documentation requirements

[291] The burden is calculated as follows: (20 plans and issuers x 1 hour for a general or operations manager) + (20 plans and issuers x 4 hours for a business operations specialist) = 100 hours. A labor rate of $132.38 is used for a general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rate is applied in the calculation as: (20 plans and issuers x 1 hour for a general or operations manager x $132.38) + (20 plans and issuers x 4 hours for a business operations specialist x $109.96) = $11,444.

for the comparative analyses, HHS expects that each issuer will on average annually perform 8 NQTL comparative analyses, based on the Departments' experience in reviewing comparative analyses, and assumes that each NQTL comparative analysis would require 20 hours in the first year, with 4 hours for a general or operations manager and 16 hours for a business operations specialist. In the first year, this would result in a total hour burden of 240,000 hours with an equivalent cost burden of $27,466,560.[292] Once the comparative analyses are performed or documented, issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits. In subsequent years, HHS estimates it would take a total of 10 hours annually to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist. In subsequent years, this would result in a total hour burden of 120,000 hours with an equivalent cost burden of $13,733,280.[293]

Sponsors of self-funded, non-Federal governmental plans are responsible for performing and documenting their NQTL comparative analyses. HHS estimates that there are 33,076 self-funded, non-Federal governmental health plans.[294] To meet the proposed new, content, data, and documentation requirements for NQTL comparative analyses, HHS expects that each plan sponsor would on average annually perform 4 NQTL analyses and assumes that each NQTL comparative analysis would require a total of 20 hours in the first year, with 4 hours for a general or operations manager and 16 hours for a business operations specialist. In the first year, this

---

[292] The burden is estimated as follows: (1,500 issuers × 8 NQTLs x 4 hours for a general or operations manager) + (1,500 issuers × 8 NQTLs x 16 hours for a business operations specialist) = 240,000 hours. A labor rate of $132.38 is used for general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rates are applied in the calculation as: (1,500 issuers × 8 NQTLs x 4 hours for a general or operations manager × $132.38) + (1,500 issuers × 8 NQTLs x 16 hours for a business operations specialist × $109.96) = $27,466,560.

[293] The burden is estimated as follows: (1,500 issuers × 8 NQTLs x 2 hours for a general or operations manager) + (1,500 issuers × 8 NQTLs x 8 hours for a business operations specialist) = 120,000 hours. A labor rate of $132.38 is used for general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rates are applied in the calculation as: (1,500 issuers × 8 NQTLs x 2 hours for a general or operations manager × $132.38) + (1,500 issuers × 8 NQTLs x 2 hours for a business operations specialist × $109.96) = $13,733,280.

[294] Based on the 2017 Census of Governments, there are 90,126 non-Federal governmental health plans. Based on the 2021 Medical Expenditure Panel Survey, the Department estimates that 36.7 percent of non-Federal governmental health plans are self-funded. Thus, 90,126 plans x 36.7 percent = 33,076 self-funded, non-Federal governmental health plans.

would result in a total hour burden of 2,646,080 hours with an equivalent cost burden of $302,827,980.[295] Once the comparative analyses are performed or documented, plan sponsors would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits. In subsequent years, HHS estimates it would take a total of 10 hours annually to update the analyses, 2 hours for a general or operations manager and 8 hours for a business operations specialist. In subsequent years, this would result in a total hour burden of 1,323,040 hours with an equivalent cost burden of approximately $151,413,990.[296]

These proposed rules would also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants and beneficiaries in plans subject to ERISA and to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage upon request in connection with an appeal of an adverse benefit. HHS estimates that each non-Federal governmental plan and each issuer would receive one request annually and that plans and issuers would annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant, beneficiary, or enrollee. This would result in a total burden of approximately 7,636 hours annually with an equivalent cost of approximately $484,504.[297] HHS also assumes that 58.2 percent of requests

---

[295] The burden is estimated as follows: (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 4 hours for a general or operations manager) + (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 16 hours for a business operations specialist) = 2,646,080 hours. A labor rate of $132.38 is used for general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rates are applied in the calculation as: (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 4 hours for a general or operations manager × $132.38) + (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 16 hours for a business operations specialist × $109.96) = $302,827,980.

[296] The burden is estimated as follows: (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 2 hours for a general or operations manager) + (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 8 hours for a business operations specialist) = 1,323,040 hours. A labor rate of $132.38 is used for general or operations manager and a labor rate of $109.96 is used for a business operations specialist. The labor rates are applied in the calculation as: (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 2 hours for a general or operations manager × $132.38) + (33,076 self-funded non-Federal governmental plans × 4 NQTLs x 8 hours for a business operations specialist × $109.96) = $151,413,990.

[297] The hour burden is calculated as (90,126 non-Federal governmental plans + 1,500 issuer/State combinations) x 5 minutes = 7,636 hours. A labor rate of $63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (90,126 non-Federal governmental plans + 1,500 issuer/State combinations) x 5 minutes x $63.45 = $484,504.

would be delivered electronically, resulting in a de minimis cost.[298] The remaining 41.8 percent of requests would be mailed, and the cost of postage for a 3-ounce letter is $1.14. The annual cost burden to mail the comparative analyses to the participants and beneficiaries would therefore be approximately $72,386.[299]

2.2.4. Recordkeeping Requirement

HHS posits that plans and issuers already maintain records as part of their regular business practices. HHS therefore estimates a minimal additional burden associated with these proposed rules. HHS estimates that each non-Federal governmental plan and issuer would annually incur a burden of 5 minutes, on average, for clerical personnel to meet the additional recordkeeping requirements, resulting in a total burden of approximately 7,636 hours annually with an equivalent cost of approximately $484,504.[300]

HHS will revise the information collection approved under OMB Control Number 0938-1393 to account for this burden.[301]

2.2.5. ICRs Regarding the Self-Funded, Non-Federal Governmental Plan Opt-Out Provisions (45 CFR 146.180)

---

[298] According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy or the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

[299] The Departments assume one request per entity and that each mailed response will cost $1.89 in materials and postage, on average. The mailing and postage cost assume $.05 per printed page, an average document length of 15 pages and $1.14 in postage for a 3-ounce parcel. Therefore, the cost burden is calculated as follows: (1,500 issuers + 90,126 non-Federal governmental health plans) x 41.8% x ($1.14 + (15 pages x $0.05)) = $72,386.

[300] The hour burden is calculated as (90,126 non-Federal governmental plans + 1,500 issuer/State combinations) x 5 minutes = 7,636 hours. A labor rate of $63.45 is used for a clerical worker. The labor rate is applied in the calculation as: (90,126 non-Federal governmental plans + 1,500 issuer/State combinations) x 5 minutes x $63.45 = $484,504.

[301] CMS-10773, "Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA."

2.2.5.1. Notice to Federal Government of Self-Funded, Non-Federal Governmental Plan Opt-Out: Plan Burden Reduction - Preparation and Processing of Opt-Out Election Notice

The proposed amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for sponsors of self-funded, non-Federal governmental plans would eliminate the need for sponsors to submit a notice to the Federal Government regarding their plan's opt-out election (or, for sponsors of multiple plans, their plans' opt-out elections), as long as the sponsors do not elect to permissibly opt out of other requirements.[302] Based on the HIPAA opt-out filings, HHS estimates that the sponsors of 185 plans would no longer be required to submit a notice to the Federal Government regarding their plan's opt-out election (or, for sponsors of multiple plans, notices regarding their plans' opt-out elections). Previously, HHS estimated that for each self-funded, non-Federal governmental plan whose sponsor has elected to opt out of the requirements, a compensation and benefits manager would need 15 minutes annually to fill out and electronically submit the model notification form to HHS, with an equivalent cost of approximately $34.[303] Therefore, these proposed amendments would result in a total annual burden reduction (related to the need to submit a notice to the Federal Government) for sponsors of 185 plans of 46 hours (at a wage rate of $137.64 per hour), with an equivalent annual cost savings of approximately $6,331.[304]

These proposed amendments would also generate cost savings for the Federal Government, as HHS would no longer have to process the opt-out notices submitted by plan sponsors. The processing of the opt-out notices is performed by an HHS employee. The average

---

[302] Based on the HIPAA opt-out filings, sponsors of 46 self-funded, non-Federal governmental plans permissibly opt out of other requirements (standards relating to benefits for mothers and newborns, required coverage for reconstructive surgery following mastectomies, and/or coverage of dependent students on medically necessary leave of absence).

[303] This includes the time required by the individual signing the certification to conduct a thorough review of the election contents.

[304] The total annual burden reduction is calculated as: 185 plans x 15 minutes = 46 hours. A labor rate of $137.64 is used for a compensation and benefits manager. The labor rate is applied in the calculation as: 185 plans x 15 minutes x $137.64 = $6,331.

salary of the employee who completes this task, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, is $53.67 per hour for a GS-13, step 1 employee.[305] HHS estimates that on average it takes an HHS employee 15 minutes to process an opt-out notice submitted by a plan sponsor, with an equivalent cost of approximately $13. Because sponsors of 185 plans in total would no longer be required to submit a notice to the Federal Government on behalf of their plan(s), this proposed provision would therefore result in a total annual burden reduction for the Federal Government of 46 hours, with equivalent annual cost savings of approximately $2,469.[306]

2.2.5.2. Notice to Plan Participants of Self-Funded, Non-Federal Governmental Plan Opt-Out: Plan Burden Reduction - Preparation and Processing of Opt-Out Election Notice

The proposed amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for sponsors of self-funded non-Federal governmental plans would also eliminate the need for those sponsors to prepare and disseminate an opt-out notice to plan participants regarding their plan sponsors' opt-out election, as long as the sponsors do not elect to permissibly opt out of other requirements. Previously, HHS estimated that for each self-funded, non-Federal governmental plan whose sponsor has elected to opt out of the requirements, an administrative assistant would need 15 minutes to develop and update the HHS standardized disclosure statement annually, with an equivalent cost of approximately $10. Therefore, this proposed provision would result in a total annual burden reduction (related to the need to prepare and disseminate opt-out notices to plan participants) for sponsors of 185 plans of 46 hours (at a wage rate of $41.74), with an equivalent annual cost savings of approximately $1,920.[307] Further, self-funded, non-Federal governmental plan sponsors would no longer be

---

[305] *See* Office of Personnel Management 2023 General Schedule (GS) Locality Pay Tables, available at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf.

[306] The total annual burden reduction for the Federal government is calculated as: 185 plans x 15 minutes = 46 hours. A labor rate of $53.67 is used for an HHS employee. The labor rate is applied in the calculation as: 185 plans x 15 minutes x $53.67 = $2,469.

[307] The total annual burden reduction is calculated as: 185 plans x 15 minutes = 46 hours. A labor rate of $41.74 is used for an administrative assistant. The labor rate is applied in the calculation as: 185 plans x 15 minutes x $41.74 = $1,920.

required to print and mail the opt-out notice to plan participants and would therefore no longer incur costs associated with this requirement. As noted earlier in this section 1.5.1, HHS estimates that there are approximately 253 participants in each self-funded, non-Federal governmental plan, and therefore approximately 46,863 notices[308] would no longer have to be printed and mailed. Because plan sponsors would no longer need to print the 1-page notice (at an estimated cost of $0.05 per page), plan sponsors would experience a total cost savings of approximately $2,343.[309]

The burden related to HIPAA opt-outs is currently approved under OMB Control Number 0938-0702.[310] HHS will update the information collection to account for this burden reduction.

2.2.6. Overall Summary

In summary, the total new burden imposed by these proposed rules regarding NQTL comparative analyses and compliance, has a three-year average hour burden of approximately 1,939,425 hours with an equivalent cost of approximately $221,176,812 and a total cost burden of approximately $72,386. The proposed amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for sponsors of self-funded, non-Federal governmental plans would result in an annual burden reduction of approximately 92 hours with an equivalent annual cost savings of approximately $8,251.

A summary of the change in paperwork burden estimates follows:

Type of Review: Revision

Agency: Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services.

---

[308] 185 plans × slightly more than 253 participants per plan on average ≈ 46,863 notices in total.
[309] The total cost savings is calculated as: 46,863 notices x $0.05 = $2,343.
[310] CMS-10430, "Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act."

Title: Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA

OMB Control Number: 0938-1393

Affected Public: Businesses or other for-profits, Not-for-profit institutions, State, Local, or Tribal Governments

Estimated Number of Respondents: 91,626

Estimated Number of Annual Responses: 91,626

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 1,939,425

Estimated Total Annual Burden Cost: $72,386

Title: Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act

OMB Control Number: 0938-0702

Affected Public: State, Local, or Tribal Governments

Estimated Number of Respondents: (185)

Estimated Number of Annual Responses: (185)

Frequency of Response: Annual

Estimated Total Annual Burden Hours: (92)

Estimated Total Annual Burden Cost: ($2,343)

Note: Numbers in parentheses denote a burden reduction.

3. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[311] imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act[312] and are likely to have a significant economic impact on a

[311] 5 U.S.C. 601 *et seq*. (1980).
[312] 5 U.S.C. 551 *et seq*. (1946).

substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis of the proposed rule.

The Departments have limited data to determine if these proposed amendments would have a significant impact on a substantial number of small entities. The Departments have prepared this initial regulatory flexibility analysis and request data or other information it would need to make a determination. The Departments request data or information on the number of plans and issuers that are not conducting adequate comparative analyses and how the proposed additional guidance would result in better compliance and access to those benefits.

3.1. Need for and Objectives of the Rule

As documented in the 2022 MHPAEA Report to Congress and the 2023 MHPAEA Report to Congress,[313] the Departments found that none of the NQTL comparative analyses they reviewed upon initial receipt contained sufficient information and documentation.

The proposed amendments to the existing MHPAEA regulations would clarify existing definitions, add new definitions of key terms, require plans and issuers to determine which NQTLs apply to substantially all medical/surgical benefit classifications and what variation of a given NQTL is the predominant (that is, most common or frequent) variation, ensure that the application of the parity requirements to NQTLs is no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. The proposed amendments would also clarify that mental health and substance use disorder definitions must be consistent with generally recognized independent standards of current medical practice and would add more

[313] 2022 MHPAEA Report to Congress, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf; 2023 MHPAEA Report to Congress, available at www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

specificity as to what plans and issuers must treat as mental health conditions or substance use disorders.

These proposed rules would amend existing guidance, set more specific content requirements for comparative analyses required by the CAA, 2021, clarify when a comparative analysis needs to be performed and for which NQTLs, and outline the process for plans and issuers to provide their comparative analyses to the Departments upon request. These proposed rules would also require plans and issuers to collect and evaluate relevant data with each comparative analysis requested by the Departments, including but not limited to claims denials, data relevant to NQTLs as required by State law or private accreditation standards, utilization rates, network adequacy metrics, and provider reimbursement rates, in fulfillment of the existing requirement that they evaluate and document their evaluation as part of the analysis of the application of NQTLs related to network composition and provider reimbursement. The data would be further defined in future guidance, which will allow the Departments to adjust the data requirements as needed to account for enforcement experience and industry trends. The Departments also anticipate that future guidance would also set forth an enforcement safe harbor for NQTLs related to network composition for plans and issuers that meet certain standards with the data they submit.

The Departments expect that these proposed rules would result in plans and issuers having a better understanding of the MHPAEA requirements with respect to NQTLs. These proposed rules would also improve the manner in which parity is measured, compared, and demonstrated by plans and issuers. The Departments believe these proposed rules and future guidance would improve the compliance of plans and issuers with these requirements, resulting in greater access to and utilization of treatment for mental health and substance use disorders, as intended by MHPAEA.

3.2. Affected Small Entities

For purposes of analysis under the RFA, DOL considers employee benefit plans with fewer than 100 participants to be small entities. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3) of ERISA, the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), DOL has previously issued (see 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10) simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, that cover fewer than 100 participants and satisfy certain requirements. While some large employers have small plans, small plans are maintained generally by small employers. Thus, the Departments believe that assessing the impact of these proposed rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business based on size standards promulgated by the Small Business Administration (SBA) pursuant to the Small Business Act.

As discussed in subsection 1.5.1 of the RIA, these proposed rules would affect all small ERISA-covered group health plans, including fully-insured group health plans and self-insured group health plans, as well as small health insurance issuers and non-Federal governmental plans. The Departments estimate that these proposed rules would affect approximately 114,200 fully insured plans with 50 to 100 participants,[314] and approximately 1,488,000 fully insured, non-grandfathered plans with less than 50 participants.[315]

---

[314] The Departments estimate that there are 152,254 ERISA-covered group health plans with 50 to 100 participants based on the 2021 Medical Expenditure Survey - Insurance Component (MEPS-IC) and the 2019 County Business Patterns from the Census Bureau. The Departments also estimate that 75 percent of ERISA-covered group health plans with 50 to 100 participants are fully insured based on assumptions referencing this same data. Thus, the Departments have calculated the number of fully insured plans with 50 to 100 participants in the following manner: 152,254 ERISA-covered group health plans with 50 to 100 participants x 75% = 114,191.

[315] Employers with less than 50 employees are required to comply with MHPAEA as part of the Essential Health Benefits requirements. The Departments estimate that there are 2,134,934 ERISA-covered group health plans with less than 50 participants based on data from the 2021 MEPS-IC and the 2019 County Business Patterns from the

The Departments also estimate that approximately 38,000 self-insured group health plans with 50 to 100 participants would be affected by these proposed rules.[316] The Departments estimate that approximately 27,000 self-insured group health plans would not utilize a service provider, and would incur the cost directly,[317] and the other self-insured health plans would utilize service providers to perform the analysis. The largest would need to conduct the analyses themselves for their plan-specific design. Finally, the Departments estimate that approximately 14,400 non-Federal governmental health plans would be affected by these proposed rules, of which the majority of plans are assumed to be large.[318]

As discussed in subsection 1.5.3 of the RIA, these proposed rules would also affect health insurance issuers. The Departments estimate that these proposed rules would affect 476 health insurance issuers providing mental health and substance use disorder benefits in the group and

---

Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2021 MEPS-IC. The 2020 Kaiser Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan, therefore, the Departments assume the percent of firms offering at least one non-grandfathered health plan is 84% (100% minus 16%). (*Source*: KFF. 2020 Kaiser Employer Health Benefits Survey.) https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,134,934 small ERISA-covered group health plans x 83% x 84% = 1,488,475.

[316] MHPAEA only applies to ERISA plans in the group market with 50 or more participants that offer mental health or substance use disorder benefits. The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so have assumed that all of these plans offer them. The Departments seeks comments on this assumption. Based on the 2021 MEPS-IC, 25 percent of ERISA-covered group health plans with 50 to 100 participants are self-insured. Thus, the Departments calculate the number of self-insured group health plans with 50 to 100 participants based on the following manner: 152,254 ERISA-covered group health plans with less than 100 participants x 25% of ERISA-covered group health plans with 50 to 100 participants are self-insured = 38,064.

[317] Based on the 2020 Form 5500, 89 percent of self-insured plans filed a Schedule C and indicated using either a Claims Processor, Contract Administrator, or both.

[318] Based on the 2017 Census of Government, there are 90,126 State and local entities. The Departments assume that there is one plan per entity, on average. Therefore, the Departments estimate that there are 90,126 non-Federal governmental health plans. MHPAEA applies to non-Federal governmental employers with 50 or more employees that offer mental health or substance use disorder benefits. The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has have assumed that all of these plans offer them. The Departments seek comments on this assumption. Based on the 2021 Medical Expenditure Survey Insurance Component (MEPS-IC) and the 2019 County Business Patterns from the Census Bureau, 16 percent of ERISA-covered group health plans have 50 or more participants. The Departments use the percent of ERISA-covered group plans with more than 50 participants as a proxy for the percent of non-Federal governmental plans with more than 50 participants. Therefore, the Departments estimate there are 14,420 public, non-Federal employer group health plans with 50 or more participants that offer mental health or substance use disorder benefits (90,126 non-Federal governmental health plans x 16 percent of plans with 50 or more employees).

individual health insurance markets, with 1,500 issuer/State combinations offering coverage in multiple States.[319]

Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $47 million or less are considered small entities for this NAICS code.[320] The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from medical loss ratio (MLR) annual report submissions for the 2021 MLR reporting year, approximately 87 out of 483 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[321] However, it should be noted that over 77 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies, are likely to have non-health lines of business that would result in their revenues exceeding $47 million. To produce a conservative estimate, for the purposes of this analysis, the Departments assume 8.6 percent,[322] or 129 issuer/State combinations are considered small entities.[323]

The proposed amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election would affect sponsors of self-funded, non-Federal governmental plans, some of which might be small entities. As noted in section 1.10 of this RIA, the extent to which these plans are out of compliance is unknown, and the costs for them to come into compliance are expected to vary from plan to plan. HHS seeks comments on the number of small

---

[319] The Departments' estimate of the number of health insurance insurers and the number of issuer/State combinations is based on medical loss ratio reports submitted by issuers for the 2021 reporting year. (*Source*: Centers for Medicare & Medicaid Services. "Medical Loss Ratio Data and System Resources" (2021). https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.)

[320] Available at: https://www.sba.gov/document/support--table-size-standards, as of March 2023.

[321] Available at: https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.

[322] Based on data from the NAICS Association for NAICS code 524114, the Departments estimate the percent of businesses within the industry of Direct Health and Medical Insurer Carriers with less than $47 million in annual sales. (*See* NAICS Association. "Market Analysis Profile: NAICS Code Annual Sales." *https://www.naics.com/business-lists/counts-by-naics-code/.*)

[323] 1,500 issuers/State combination x 8.6 percent = 129 small issuers.

entities that would be impacted by the implementation of the sunset provision and the potential effects on small entities.

3.3. Impact of the Rule

3.3.1. Amendments to Existing MHPAEA Regulation (26 CFR 54.9812-1, 29 CFR 2590.712, 45 CFR 146.136)

The proposed amendments to the existing MHPAEA regulations would clarify existing definitions, add new definitions, require plans and issuers to determine which NQTLs apply to substantially all medical/surgical benefit classifications and what level or variation of a given NQTL is the most common or frequent, ensure that the application of NQTLs is generally no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. The proposed amendments would also clarify that mental health benefits and substance use disorder benefits must be defined to be consistent with generally recognized independent standards of current medical practice and would add more specificity as to what plans and issuers must treat as mental health conditions or substance use disorders. The Departments believe that the proposed amendments might cause small plans and issuers to revise their policies and remove treatment limitations. Therefore, small plans and issuers could incur costs to revise plan provisions which may result in increased costs from expanded utilization of mental health and substance use disorder services. The Departments face uncertainty in quantifying these costs as they cannot estimate the increase in utilization and which particular services may see the largest increase in utilization.

3.3.2. New Regulations (26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 and 146.180)

These proposed rules would amend existing guidance, set more specific content requirements for comparative analyses required by the CAA, 2021, clarify when the comparative analysis needs to be performed and for which NQTLs, and outline the timeframes and process

for plans and issuers to provide their comparative analyses to the Departments upon request. Participants, beneficiaries, and enrollees may also request the comparative analyses at any time. These proposed rules would also require plans and issuers to collect and evaluate relevant data as part of each comparative analysis, including but not limited to claims denials, data relevant to NQTLs as required by State law or private accreditation standards, utilization rates, network adequacy metrics, and provider reimbursement rates, in fulfillment of the existing requirement that they evaluate and document their evaluation as part of the analysis of the application of NQTLs related to network composition and provider reimbursement. The Departments believe that plans and issuers would incur costs in collecting, preparing, and analyzing the data. The Departments request comments on whether plans and issuers already collect and examine this data. Additionally, in these proposed rules, HHS proposes regulatory amendments to implement the provision in the CAA, 2023 that sunsets the election option for self-funded, non-Federal governmental plans to opt out of requirements under MHPAEA.

In the first year, the Departments estimate that self-insured group health plans and health insurance issuers would incur an incremental per-entity cost of approximately $5,600 and $5,800, respectively associated with these proposed rules and amendments. In the subsequent years, the Departments estimate that self-insured group health plans and health insurance issuers would both incur an incremental per-entity cost of approximately $1,900 associated with these proposed rules and amendments. The Departments note that these per-entity costs are the average costs, and these costs are expected to vary by plan or issuer depending on the number of NQTL analyses performed.

3.4. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

4. Special Analyses – Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to

the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

5. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any 1 year by State, local, and Tribal governments, in the aggregate, or by the private sector.[324] In 2023, that threshold is approximately $177 million. For purposes of the Unfunded Mandates Reform Act, as well as Executive Order 12875,[325] this proposal includes Federal mandates that the Departments expect would result in such expenditures by State, local, or Tribal governments, or the private sector. UMRA requires that regulations including such Federal mandates provide a qualitative and quantitative assessment of the anticipated costs and benefits of the regulations. For the purposes of these proposed rules, the RIA shall meet this obligation.

6. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among the various levels of government.[326] Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of

[324] 2 U.S.C. 1501 *et seq*. (1995).
[325] Enhancing the Intergovernmental Partnership, 58 FR 58093 (Oct. 28, 1993).
[326] Federalism, 64 FR 153 (Aug. 4, 1999).

their consultation and the nature of the concerns of State and local officials in the preamble to these proposed rules.

In the Departments' view, these proposed rules could have federalism implications because they would have direct effects on the States, on the relationship between the Federal Government and the States, and on the distribution of power and responsibilities among various levels of government. These proposed rules could also have federalism implications because the Departments propose to remove the reference to State guidelines in the definition of medical/surgical benefits, mental health benefits, and substance use disorder benefits, and amend the definition to provide that any condition or procedure defined by the plan or coverage as being or not being a medical condition or surgical procedure, mental health condition, or substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice, such as the ICD or DSM. Finally, these proposed rules could have federalism implications because the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election would require State and local government sponsors of self-funded plans that currently opt out of requirements under MHPAEA to come into compliance.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the MHPAEA requirements are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of MHPAEA. The conference report accompanying HIPAA indicates that this is intended to be

the “narrowest” preemption of State laws. (See House Conf. Rep. No. 104-736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.)

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the MHPAEA requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to “prevent the application of” MHPAEA and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

Throughout the process of developing these proposed rules, to the extent feasible within the specific preemption provisions of HIPAA as it applies to MHPAEA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

The Departments welcome input from affected States regarding this assessment.

List of Subjects

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

Douglas W. O'Donnell,
Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Lisa M. Gomez,
Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 54 as follows:

PART 54 – PENSION EXCISE TAXES

1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

2. Amend § 54.9812-1 by:

a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);

b. In newly redesignated paragraph (a)(2):

i. Revising the introductory text;

ii. Adding the definitions of "DSM," "Evidentiary standards," "Factors," and "ICD" in alphabetical order;

iii. Revising the definitions of "Medical/surgical benefits" and "Mental health benefits";

iv. Adding the definitions of "Processes" and "Strategies" in alphabetical order; and

v. Revising the definitions of "Substance use disorder benefits" and "Treatment limitations";

c. Revising paragraphs (c)(1)(ii), (c)(2)(i), and (c)(2)(ii)(A) introductory text;

d. In paragraph (c)(2)(ii)(C), designating *Examples 1* through *4* as paragraphs (c)(2)(ii)(C)(*1*) through (*4*) and revising newly designated paragraphs (c)(2)(ii)(C)(*1*) through (*4*);

e. Adding paragraphs (c)(2)(ii)(C)(*5*) and (*6*);

f. Revising paragraphs (c)(3)(i)(A), (C), and (D);

g. In paragraph (c)(3)(iii), adding introductory text;

h. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and

i. Adding paragraph (j).

The revisions and additions read as follows:

§ 54.9812-1 Parity in mental health and substance use disorder benefits.

(a) Purpose and meaning of terms—(1) Purpose. This section and § 54.9812-2 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under Code section 9812. A fundamental purpose of Code section 9812, this section, and § 54.9812-2 is to ensure that participants and beneficiaries in a group health plan that offers mental health or substance use disorder benefits are not subject to more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan, as further provided in this section and § 54.9812-2. Accordingly, in complying with the provisions of Code section 9812, this section, and § 54.9812-2, plans must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health and substance use disorder benefits under the plan than they impose on access to generally comparable medical/surgical benefits. The provisions of Code section 9812, this section, and § 54.9812-2 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) Meaning of terms. For purposes of this section and § 54.9812-2, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM is the version that is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

Evidentiary standards are any evidence, sources, or standards that a group health plan considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary and reasonable" rates paid for items and services), and clinical treatment guidelines; internal plan data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through 45 CFR 162.1002. For the purpose of this definition, the most current version of the ICD is the version that is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental

health condition, plans may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Processes include but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements; and the development and approval of a treatment plan. Processes also include the specific procedures used by staff or other representatives of a plan (or the service provider of a plan) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include but are not limited to: the development of the clinical rationale used in approving or denying benefits; deviation from generally accepted standards of care; the selection of information deemed reasonably necessary to make a medical necessity determination; reliance on treatment guidelines or guidelines provided by third-party organizations; and rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules. Strategies also include the creation and composition of the staff or other representatives of a plan (or the service provider of a plan) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's decisions related to the qualifications

of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. (See paragraph (c)(4)(iii) of this section for an illustrative, non-exhaustive list of

nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(iii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) General rule. A group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this

section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) In general. If a plan provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), benefits for that mental health condition or substance use disorder must be provided in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii), a plan providing any benefits for a mental health condition or substance use disorder in any classification of benefits does not provide benefits for the mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided unless the plan provides meaningful benefits for treatment for that condition or disorder in each such classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification. In determining the classification in which a particular benefit belongs, a plan must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) * * *

(*1*) Example 1—(*i*) Facts. A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement.

For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*1*) (Example 1), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(*2*) Example 2—(*i*) Facts. A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*2*) (Example 2), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(*3*) Example 3—(*i*) Facts. Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (Example 2), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*3*) (Example 3), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(*4*) Example 4—(*i*) Facts. Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (Example 2), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*4*) (Example 4), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(*5*) Example 5—(*i*) Facts. A plan generally covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental evaluations for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavioral analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*5*) (Example 5), the plan violates the rules of this paragraph (c)(2)(ii). Because the plan only covers one type of benefit for ASD in the outpatient, out-of-network classification and excludes all other benefits for ASD in the classification, but generally covers the full range of medical/surgical benefits in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(*6*) Example 6—(*i*) Facts. A plan generally covers diagnosis and treatment for eating disorders, a mental health condition, but specifically excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification. Nutrition counseling is one of the primary treatments for eating disorders. The plan generally provides benefits for the primary treatments for medical/surgical conditions in the outpatient, in-network classification.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*6*) (Example 6), the plan violates the rules of this paragraph (c)(2)(ii). The exclusion of coverage for nutrition counseling for eating disorders results in the plan failing to provide meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification.

(3) * * *

(i) * * *

(A) Substantially all. For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) Portion based on plan payments. For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for

the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) Special rules. Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) Multi-tiered prescription drug benefits. If a plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) Multiple network tiers. If a plan provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may

divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) Examples. The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) Example 1—(*1*) Facts. (*i*) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Table 1 to Paragraph (c)(3)(iv)(A)(*1*)(*i*)

Coinsurance rate	0 %	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

(*ii*) The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(A) (Example 1), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-

network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) Example 2—(*1*) Facts. (*i*) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Table 2 to Paragraph (c)(3)(iv)(B)(*1*)(*i*)

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

(*ii*) The plan projects plan costs of $800x to be subject to copayments ($200x + $200x +$300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(B) (Example 2), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels – the $50 copayment, the $20 copayment, and the $15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

(C) Example 3—(*1*) Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(C) (Example 3), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) Example 4—(*1*) Facts. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as "generic", "preferred brand name", "non-preferred brand name", or "specialty" complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(*1*)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(*2*) Conclusion. In this paragraph (c)(3)(iv)(D) (Example 4), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) Example 5—(*1*) Facts. A plan has two-tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(E) (Example 5), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) Example 6—(*1*) Facts. With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(F) (Example 6), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) Example 7—(*1*) Facts. Same facts as in paragraph (c)(3)(iv)(F)(*1*) of this section (Example 6), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(G) (Example 7), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) Nonquantitative treatment limitations. Subject to paragraph (c)(4)(v) of this section, a group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in a classification unless the plan's imposition of the limitation meets the requirements of paragraphs (c)(4)(i), (ii), and (iv) of this section. If a group health plan fails to meet any of these requirements with respect to a nonquantitative treatment limitation, the limitation violates Code section 9812(a)(3)(A)(ii) and may not be imposed by the plan.

(i) Requirement that nonquantitative treatment limitations be no more restrictive for mental health benefits and substance use disorder benefits. A group health plan may not apply any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the same classification.

(A) Restrictive. For purposes of this paragraph (c)(4)(i), a nonquantitative treatment limitation is restrictive to the extent it imposes conditions, terms, or requirements that limit

access to benefits under the terms of the plan. Conditions, terms, or requirements include, but are not limited to, those that compel an action by or on behalf of a participant or beneficiary to access benefits or limit access to the full range of treatment options available for a condition or disorder under the plan.

(B) Substantially all. For purposes of this paragraph (c)(4)(i), a nonquantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in that classification, consistent with paragraph (c)(4)(i)(D) of this section. Whether the nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits is determined without regard to whether the nonquantitative treatment limitation was triggered based on a particular factor or evidentiary standard. If a nonquantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that limitation cannot be applied to mental health or substance use disorder benefits in that classification.

(C) Predominant. For purposes of this paragraph (c)(4)(i), the term predominant means the most common or most frequent variation of the nonquantitative treatment limitation within a classification, determined in accordance with the method outlined in paragraph (c)(4)(i)(D) of this section, to the extent the plan imposes multiple variations of a nonquantitative treatment limitation within the classification. For example, multiple variations of inpatient concurrent review include review commencing 1 day, 3 days, or 7 days after admission, depending on the reason for the stay.

(D) Portion based on plan payments. For purposes of paragraphs (c)(4)(i)(B) and (C) of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a nonquantitative treatment limitation is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or the portion of the plan year after a change in benefits that affects the

applicability of the nonquantitative treatment limitation). Any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits.

(E) Exceptions for independent professional medical or clinical standards and standards to detect or prevent and prove fraud, waste, and abuse. Notwithstanding paragraphs (c)(4)(i)(A) through (D) of this section, a plan that applies a nonquantitative treatment limitation that impartially applies independent professional medical or clinical standards or applies standards to detect or prevent and prove fraud, waste, and abuse, as described in paragraph (c)(4)(v)(A) or (B) of this section, to mental health or substance use disorder benefits in any classification will not be considered to violate this paragraph (c)(4)(i) with respect to such nonquantitative treatment limitation.

(ii) Additional requirements related to design and application of the nonquantitative treatment limitation—(A) In general. Consistent with paragraph (a)(1) of this section, a plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) Prohibition on discriminatory factors and evidentiary standards. For purposes of determining comparability and stringency under paragraph (c)(4)(ii)(A) of this section, a plan may not rely upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(ii)(B):

(*1*) Impartially applied generally recognized independent professional medical or clinical standards described in paragraph (c)(4)(v)(A) of this section are not considered to discriminate against mental health or substance use disorder benefits.

(*2*) Standards reasonably designed to detect or prevent and prove fraud, waste, and abuse described in paragraph (c)(4)(v)(B) of this section are not considered to discriminate against mental health or substance use disorder benefits.

(*3*) Information is considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances including, but not limited to, the source of the information, the purpose or context of the information, and the content of the information.

(iii) Illustrative, non-exhaustive list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan;

(E) Plan methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan.

(iv) Required use of outcomes data—(A) In general. When designing and applying a nonquantitative treatment limitation, a plan must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's analysis of whether the limitation, in operation, complies with paragraphs (c)(4)(i) and (ii) of this section. The Secretary, jointly with the Secretary of the Department of Labor and the Secretary of Health and Human Services, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iv)(A).

(*1*) For purposes of this paragraph (c)(4)(iv)(A), relevant data includes, but is not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(*2*) In addition to the relevant data set forth in paragraph (c)(4)(iv)(A)(*1*) of this section, relevant data for nonquantitative treatment limitations related to network composition standards includes, but is not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges).

(B) Material differences. Subject to paragraph (c)(4)(iv)(C) of this section, to the extent the relevant data evaluated pursuant to paragraph (c)(4)(iv)(A) of this section show material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the differences will be considered a strong indicator that the plan violates paragraph (c)(4)(i) or (ii) of this section. In such instances, the plan:

(*1*) Must take reasonable action to address the material differences in access as necessary to ensure compliance, in operation, with paragraphs (c)(4)(i) and (ii) of this section; and

(*2*) Must document the action that has been or is being taken by the plan to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as required by § 54.9812-2(c)(5)(iv).

(C) Special rule for nonquantitative treatment limitations related to network composition. Notwithstanding paragraph (c)(4)(iv)(B) of this section, when designing and applying one or more nonquantitative treatment limitation(s) related to network composition standards, a plan fails to meet the requirements of paragraphs (c)(4)(i) and (ii) of this section, in operation, if the relevant data show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification.

(D) Exception for independent professional medical or clinical standards. A plan designing and applying a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that impartially applies independent professional medical or clinical standards, as described in paragraph (c)(4)(v)(A) of this section, is not required to comply with the requirements of this paragraph (c)(4)(iv) with respect to that classification.

(v) Independent professional medical or clinical standards and standards to detect or prevent and prove fraud, waste, and abuse. (A) To qualify for the exceptions in paragraphs (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(iv)(D) of this section for independent professional medical or clinical standards, a nonquantitative treatment limitation must impartially apply generally

recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits, and may not deviate from those standards in any way, such as by imposing additional or different requirements.

(B) To qualify for the exceptions in paragraphs (c)(4)(i)(E) and (c)(4)(ii)(B) of this section to detect or prevent and prove fraud, waste, and abuse, a nonquantitative treatment limitation must be reasonably designed to detect or prevent and prove fraud, waste, and abuse, based on indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data, and also be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits.

(vi) Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits. Consistent with paragraph (c)(2)(i) of this section, a group health plan may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(vii) Effect of final determination of noncompliance under § 54.9812-2. If a group health plan receives a final determination from the Secretary that the plan is not in compliance with the requirements of § 54.9812-2 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan not to impose the nonquantitative treatment limitation, unless and until the plan demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(viii) Examples. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. Additionally, in examples that conclude that the plan violates one provision of this

paragraph (c)(4), such examples do not necessarily imply compliance with other provisions of this paragraph (c)(4), as these examples do not analyze compliance with all other provisions of this paragraph (c)(4).

(A) Example 1 (More restrictive prior authorization requirement in operation)—(*1*) Facts. A plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. While inpatient, in-network benefits for medical/surgical conditions are approved for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan, the approvals for 7 days are most common under this plan. For inpatient, in-network mental health and substance use disorder benefits, routine approval is most commonly given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The difference in the duration of approvals is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse, but rather reflects the application of a heightened standard to the provision of the mental health and substance use disorder benefits in the relevant classification.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(A) (Example 1), the plan violates the rules of paragraph (c)(4)(i) of this section. Under the terms of the plan, prior authorization applies to at least two-thirds of all medical/surgical benefits in the relevant classification (inpatient, in-network), since it applies to all benefits in the relevant classification. Further, the most common or frequent variation of the nonquantitative treatment limitation applied to medical/surgical benefits in the relevant classification (the predominant nonquantitative treatment limitation) is the routine approval of inpatient, in-network benefits for 7 days before the patient's attending provider must submit a treatment plan. However, the plan routinely approves inpatient, in-network benefits for mental health and substance use disorder conditions for only 1 day before the patient's attending provider must submit a treatment plan (and, in doing so, does not impartially apply independent professional medical or clinical standards or apply standards to detect or prevent and prove fraud, waste, and abuse that qualify for the exceptions in paragraph (c)(4)(i)(E) of this section). In operation, therefore, the prior authorization requirement imposed on inpatient, in-network mental health and substance use disorder benefits is more restrictive than the predominant prior authorization requirement applicable to substantially all medical/surgical benefits in the inpatient, in-network classification because the practice of approving only 1 day of inpatient benefits limits access to the full range of treatment options available for a condition or disorder under the plan as compared to the routine 7-day approval that is given for inpatient, in-network medical/surgical benefits. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(B) Example 2 (More restrictive peer-to-peer concurrent review requirements in operation)—(*1*) Facts. A plan follows a written process for the concurrent review of all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under the process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. While the written process only requires review by the second-level reviewer to either deny or

approve the request, in operation, second-level reviewers for mental health and substance use disorder benefits conduct a peer-to-peer review with a provider (acting as the authorized representative of a participant or beneficiary) before coverage of the treatment is approved. The peer-to-peer review requirement is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse. The plan does not impose a peer-to-peer review, as written or in operation, as part of the second-level review for medical/surgical benefits.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(B) (Example 2), the plan violates the rules of paragraph (c)(4)(i) of this section. The concurrent review nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits within the inpatient, in-network classification because the plan follows the concurrent review process for all medical/surgical benefits. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is that peer-to-peer review is not imposed as part of second-level review. The plan does not impartially apply independent professional medical or clinical standards or apply standards to detect or prevent and prove fraud, waste, and abuse that qualify for the exceptions in paragraph (c)(4)(i)(E) of this section. As written, the plan's concurrent review requirements are the same for medical/surgical benefits and mental health and substance use disorder benefits. However, in operation, by compelling an additional action (peer-to-peer review as part of second-level review) to access only mental health or substance use disorder benefits, the plan applies the limitation to mental health and substance use disorder benefits in a manner that is more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the inpatient, in-network classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(C) Example 3 (More restrictive peer-to-peer review medical necessity standard in operation; deviation from independent professional medical and clinical standards)—(*1*) Facts. A plan generally requires that all treatment be medically necessary in the inpatient, out-of-network classification. For both medical/surgical benefits and mental health and substance use disorder benefits, the written medical necessity standards are based on independent professional medical or clinical standards that do not require peer-to-peer review. In operation, the plan covers out-of-network benefits for medical/surgical or mental health inpatient treatment outside of a hospital if the physician documents medical appropriateness, but for out-of-network benefits for substance use disorder inpatient treatment outside of a hospital, the plan requires a physician to also complete peer-to-peer review.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(C) (Example 3), the plan violates the rules of paragraph (c)(4)(i) of this section. The medical necessity nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in the inpatient, out-of-network classification. The most common or frequent variation of the nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is the requirement that a physician document medical appropriateness without peer-to-peer review. The plan purports to impartially apply independent professional medical or clinical standards that would otherwise qualify for the exception in paragraph (c)(4)(i)(E) of this section, but deviates from those standards by imposing the additional requirement to complete peer-to-peer review for inpatient, out-of-network benefits for substance use disorder outside of a hospital. Therefore, the exception in paragraph (c)(4)(i)(E) of this section does not apply. As written, the plan provisions apply the nonquantitative treatment limitation to mental health and substance use disorder benefits in the inpatient, out-of-network classification in the same manner as for medical/surgical benefits. However, in operation, the

nonquantitative treatment limitation imposed with respect to out-of-network substance use disorder benefits for treatment outside of a hospital is more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification because it limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(D) Example 4 (Not comparable and more stringent methods for determining reimbursement rates in operation)—(*1*) Facts. A plan's base reimbursement rates for outpatient, in-network providers are determined based on a variety of factors, including the providers' required training, licensure, and expertise. For purposes of this example, the plan's nonquantitative treatment limitations for determining reimbursement rates for mental health and substance use disorder benefits are not more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification under paragraph (c)(4)(i) of this section. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code vary based on a combination of factors, such as the nature of the service, provider type, number of providers qualified to provide the service in a given geographic area, and market need (demand). As a result, reimbursement rates for mental health, substance use disorder, and medical/surgical benefits furnished by non-physician providers are generally less than for physician providers. In operation, the plan reduces the reimbursement rate for mental health and substance use disorder non-physician providers from that paid to mental health and substance use disorder physicians by the same percentage for every CPT code but does not apply the same reductions for non-physician medical/surgical providers.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(D) (Example 4), the plan violates the rules of paragraph (c)(4)(ii) of this section. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate to physician providers by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services, in operation, the factors used in applying the nonquantitative treatment limitation to mental health and substance use disorder benefits are not comparable to, and are applied more stringently than, the factors used in applying the limitation with respect to medical/surgical benefits. Because the facts assume that the plan's methods for determining reimbursement rates comply with paragraph (c)(4)(i) of this section and the plan violates the rules of paragraph (c)(4)(ii) of this section, this example does not analyze compliance with paragraph (c)(4)(iv) of this section.

(E) Example 5 (Exception for impartially applied generally recognized independent professional medical or clinical standards)—(*1*) Facts. A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The medical management requirement impartially applies independent professional medical or clinical standards in a manner that qualifies for the exception in paragraph (c)(4)(i)(E) of this section. The plan does not rely on any other factors or evidentiary standards and the processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health

and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims based on the impartial application of the independent professional medical or clinical standards by the nonquantitative treatment limitation.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(E) (Example 5), the plan does not violate the rules of this paragraph (c)(4). The medical management nonquantitative treatment limitation imposed on mental health and substance use disorder benefits does not violate paragraph (c)(4)(i) or (iv) of this section because it impartially applies independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits in a manner that qualifies for the exceptions in paragraphs (c)(4)(i)(E) and (c)(4)(iv)(D) of this section, respectively. Moreover, the nonquantitative treatment limitation does not violate paragraph (c)(4)(ii) of this section because the independent professional medical or clinical standards are not considered to be a discriminatory factor or evidentiary standard under paragraph (c)(4)(ii)(B) of this section. Additionally, as written and in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, out-of-network classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying the limitation with respect to medical/surgical benefits in the classification, regardless of the fact that the application of the nonquantitative treatment limitation resulted in higher percentages of claim denials for mental health and substance use disorder benefits as compared to medical/surgical benefits.

(F) Example 6 (More restrictive prior authorization requirement; exception for impartially applied generally recognized independent professional medical or clinical standards not met)—(*1*) Facts. The provisions of a plan state that it applies independent professional medical and clinical standards (consistent with generally accepted standards of care) for setting prior authorization requirements for both medical/surgical and mental health and substance use disorder prescription drugs. The relevant generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination at each refill (every 30 days) for treatment of opioid use disorder.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(F) (Example 6), the plan violates the rules of paragraph (c)(4)(i) of this section. The plan does not qualify for the exception in paragraph (c)(4)(i)(E) of this section, because, although the provisions of the plan state that it applies independent professional medical and clinical standards, the plan deviates from the relevant standards with respect to prescription drugs to treat opioid use disorder. The prior authorization nonquantitative treatment limitation is applied to at least two-thirds of all medical/surgical benefits in the prescription drugs classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is following generally recognized independent professional medical and clinical standards (consistent with generally accepted standards of care). The prior authorization requirements imposed on substance use disorder benefits are more restrictive than the predominant nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in the classification, because the plan imposes additional requirements on substance use disorder benefits that limit access to the full range of treatment options available for a condition or disorder under the plan as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of

paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(G) Example 7 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)—(*1*) Facts. Following an initial request by the Secretary for a plan's comparative analysis of a nonquantitative treatment limitation pursuant to § 54.9812-2(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the relevant classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Pursuant to § 54.9812-2(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination, and the Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). The plan receives a final determination of noncompliance from the Secretary, which informs the plan that it is not in compliance with this paragraph (c)(4) and directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the nonquantitative treatment limitation.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(G) (Example 7), the plan violates the requirements of this paragraph (c)(4) by imposing the nonquantitative treatment limitation after the Secretary directs the plan not to impose it, pursuant to paragraph (c)(4)(vii) of this section.

(H) Example 8 (Provider network admission standards not more restrictive and compliant with requirements for design and application of NQTLs)—(*1*) Facts. As part of a plan's standards for provider admission to its network, in the outpatient, in-network classification, any provider seeking to contract with the plan must have a certain number of years of supervised clinical experience. As a result of that standard, master's level mental health therapists are required to obtain supervised clinical experience beyond their licensure, while master's level medical/surgical providers, psychiatrists, and Ph.D.-level psychologists do not require additional experience beyond their licensure because their licensure already requires supervised clinical experience. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation. This includes in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). This data demonstrates that participants and beneficiaries seeking outpatient care are able to access outpatient, in-network mental health and substance use disorder providers at the same frequency as outpatient, in-network medical/surgical providers, that mental health and substance use disorder providers are active in the network and are accepting new patients to the same extent as medical/surgical providers, and that mental health and substance use disorder providers are within similar time and distances to plan participants and beneficiaries as are medical/surgical providers. This data also does not identify material differences in what the plan pays psychiatrists or non-physician mental health providers, compared to physicians or non-physician medical/surgical providers, respectively, both for the same reimbursement codes and as compared to Medicare rates.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(H) (Example 8), the plan does not violate this paragraph (c)(4). The standards for this nonquantitative treatment limitation, namely provider admission to the plan's network, are applied to at least two-thirds of all medical/surgical benefits in the outpatient, in-network classification, as it applies to all medical/surgical benefits in the classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) that applies to substantially all medical/surgical benefits in the classification is having a certain number of years of supervised clinical experience. The standards for provider admission to the plan's network that are imposed with respect to mental health or substance use disorder benefits are no more restrictive, as written or in operation, than the predominant variation of the nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in the classification, because the standards do not limit access to the full range of treatment options available for a condition or disorder under the plan as compared to medical/surgical benefits in the same classification. The requirement that providers have a certain number of years of supervised clinical experience that the plan relied upon to design and apply the nonquantitative treatment limitation is not considered to discriminate against mental health or substance use disorder benefits, even though this results in the requirement that master's level mental health therapists obtain supervised clinical experience beyond their licensure, unlike master's level medical/surgical providers. In addition, as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification, because the plan applies the same standard to all providers in the classification. Finally, the plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits, which does not show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in the classification.

(I) Example 9 (More restrictive requirement for primary caregiver participation applied to ABA therapy)—(*1*) Facts. A plan generally applies medical necessity criteria in adjudicating claims for coverage of all outpatient, in-network medical/surgical and mental health and substance use disorder benefits, including ABA therapy for the treatment of ASD, which is a mental health condition. The plan's medical necessity criteria for coverage of ABA therapy requires evidence that the participant's or beneficiary's primary caregivers actively participate in ABA therapy, as documented by consistent attendance in parent, caregiver, or guardian training sessions. In adding this requirement, the plan deviates from independent professional medical or clinical standards, and there are no similar medical necessity criteria requiring evidence of primary caregiver participation in order to receive coverage of any medical/surgical benefits.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(I) (Example 9), the plan violates paragraph (c)(4)(i) of this section. The plan applies medical necessity criteria to at least two-thirds of all outpatient, in-network medical/surgical benefits, as they apply to all medical/surgical benefits in the classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) that applies to substantially all medical/surgical benefits in the classification does not include the requirement to provide evidence that the participant's or beneficiary's primary caregivers actively participate in the treatment. The plan does not qualify for the exception in paragraph (c)(4)(i)(E) of this section in applying its restriction on coverage for ABA therapy because the plan deviates from the independent professional medical or clinical standards by imposing a different requirement. As a result, the nonquantitative treatment limitation imposed on mental health and substance use disorder benefits is more restrictive than the predominant medical necessity requirement imposed

on substantially all medical/surgical benefits in the classification (which does not include the requirement to provide evidence that primary caregivers actively participate in treatment). Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(J) Example 10 (More restrictive exclusion for experimental or investigative treatment applied to ABA therapy)—(*1*) Facts. A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(J) (Example 10), the plan violates the rules of paragraph (c)(4)(i) of this section. The coverage exclusion for experimental or investigative treatment applies to at least two-thirds of all medical/surgical benefits, as it applies to all medical/surgical benefits in the outpatient, in-network classification. The most common or frequent variation of this nonquantitative treatment limitation in the classification (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is the exclusion under the plan for coverage of experimental treatment of medical/surgical conditions when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. In operation, the exclusion for experimental or investigative treatment imposed on ABA therapy is more restrictive than the predominant variation of the nonquantitative treatment limitation for experimental or investigative treatment imposed on substantially all medical/surgical benefits in the classification because the exclusion limits access to the full range of treatment options available for a condition or disorder under the plan as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(K) Example 11 (Separate EAP exhaustion treatment limitation applicable only to mental health benefits)—(*1*) Facts. An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(K) (Example 11), limiting eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements

of this paragraph (c). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(vi) of this section. Additionally, this EAP would not qualify as excepted benefits under §54.9831-1(c)(3)(vi)(B)(*1*) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) Example 12 (Separate residential exclusion treatment limitation applicable only to mental health benefits)—(*1*) Facts. A plan generally covers inpatient, in-network and inpatient out-of-network treatment in any setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan also has an exclusion for residential treatment, which the plan defines as an inpatient benefit, for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(*2*) Conclusion. In this paragraph (c)(4)(viii)(L) (Example 12), the plan violates the rules of paragraph (c)(4)(vi) of this section. Because the plan does not apply a comparable exclusion to inpatient benefits for medical/surgical conditions, the exclusion of residential treatment is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications that does not apply with respect to any medical/surgical benefits in the same benefit classification.

(M) Example 13 (Standards for provider admission to a network)—(*1*) Facts. A plan applies nonquantitative treatment limitations related to network composition in the outpatient in-network and inpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. For purposes of this example, these facts assume that these nonquantitative treatment limitations related to network composition for mental health and substance use disorder benefits are not more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classifications under paragraph (c)(4)(i) of this section. The facts also assume that, as written and in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network access to mental health or substance use disorder benefits in the outpatient in-network and inpatient in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(ii) of this section. The plan collects and evaluates all relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitations related to network composition on access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's analysis of whether the standards, in operation, comply with paragraphs (c)(4)(i) and (ii) of this section. The plan determined that the data did not reveal any material differences in access. That data included metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates; in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions); and survey data from participants on the extent to which they forgo or pay out-of-pocket for treatment because of challenges finding in-network providers. The efforts the plan made when designing and applying its nonquantitative treatment limitations related to network composition,

which ultimately led to its outcomes data not revealing any material differences in access to benefits for mental health or substance use disorders as compared with medical/surgical benefits, included making sure that the plan's service providers are making special efforts to enroll available providers, including by authorizing greater compensation or other inducements to the extent necessary, and expanding telehealth arrangements as appropriate to manage regional shortages. The plan also notifies participants in clear and prominent language on its website, employee brochures, and the summary plan description of a toll-free number available to help participants find in-network providers. In addition, when plan participants submit bills for out-of-network items and services, the plan directs their service providers to reach out to the treating providers and facilities to see if they will enroll in the network.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(M) (Example 13), the plan does not violate this paragraph (c)(4). As stated in the Facts section, the plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraphs (c)(4)(i) and (ii) of this section. The plan collects and evaluates relevant data, as required under paragraph (c)(4)(iv)(A) of this section, and the data does not reveal any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as a result of the actions the plan took (as set forth in the facts) when initially designing its nonquantitative treatment limitations related to network composition. Because the plan takes comparable actions to ensure that their mental health and substance use disorder provider network is as accessible as their medical/surgical provider network and exercises careful oversight over both their service providers and the comparative robustness of the networks with an eye to ensuring that network composition results in access to in-network benefits for mental health and substance use disorder services that is as generous as for medical/surgical services, plan participants and beneficiaries can access covered mental health and substance use disorder services and benefits as readily as medical/surgical benefits. This is reflected in the plan's carefully designed metrics and assessment of network composition.

* * * * *

(d) * * *

(3) Provisions of other law. Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and 29 CFR 2520.104b-1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits; the processes, strategies, evidentiary standards, and other

factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan; and the comparative analyses and other applicable information required by § 54.9812-2. In addition, 29 CFR 2560.503-1 and § 54.9815-2719T set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 54.9812-2.

(e) * * *

(4) Coordination with EHB requirements. Nothing in paragraph (f) or (g) of this section or § 54.9812-2(g) changes the requirements of 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) In general. Except as provided in paragraph (i)(2) of this section, this section applies to group health plans on the first day of the first plan year beginning on or after January 1, 2025. Until the applicability date in the preceding sentence, plans are required to continue to comply with 26 CFR 54.9812-1, revised as of April 1, 2023.

* * * * *

(j) Severability. If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

3. Add § 54.9812-2 to read as follows:

§ 54.9812-2 Nonquantitative treatment limitation comparative analysis requirements.

(a) Meaning of terms. Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 54.9812-1(a)(2).

(b) In general. In the case of a group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) Comparative analysis content requirements. With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group

health plan, the comparative analysis performed by the plan must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan and a general description of any information considered or relied upon by the plan in preparing the comparative analysis for each nonquantitative treatment limitation.

(1) Description of the nonquantitative treatment limitation. The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits;

(iii) A description of which benefits are included in each classification set forth in § 54.9812-1(c)(2)(ii)(A); and

(iv) Identification of the predominant nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan determined which variation is the predominant nonquantitative treatment limitation as compared to other variations, as well as how the plan identified the variations of the nonquantitative treatment limitation.

(2) Identification and definition of the factors used to design or apply the nonquantitative treatment limitation. The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of all of the factors considered, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor; and

(B) A description of each evidentiary standard (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section.

(3) Description of how factors are used in the design and application of the nonquantitative treatment limitation. The comparative analysis must include a description of how each factor identified and defined pursuant to paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and

how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan establishes such deviation(s) or variation(s).

(4) Demonstration of comparability and stringency as written. The comparative analysis must evaluate whether, in any classification, under the terms of the plan as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard, and the evaluation of relevant data as required under § 54.9812-1(c)(4)(iv)(A), to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reason(s) for any deviation(s) or variation(s) in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as

compared to medical/surgical benefits, and how the plan establishes such deviation(s) or variation(s), including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) Demonstration of comparability and stringency in operation. The comparative analysis must evaluate whether, in any classification, under the terms of the plan in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan ensures that, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation; and

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(ii) Identification of the relevant data collected and evaluated as required under § 54.9812-1(c)(4)(iv)(A);

(iii) An evaluation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including the relevant data as required under § 54.9812-1(c)(4)(iv)(A);

(iv) A detailed explanation of material differences in outcomes evaluated pursuant to paragraph (c)(5)(iii) of this section that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits and the bases for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(v) A discussion of any measures that have been or are being implemented by the plan to mitigate any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan is taking under § 54.9812-1(c)(4)(iv)(B)(*1*) to address material differences to ensure compliance with § 54.9812-1(c)(4)(i) and (ii).

(6) Findings and conclusions. The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan is not (or might not be) in compliance with the requirements of § 54.9812-1(c)(4), including any actions the plan has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iv) The date of the analysis and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan to be an expert, an assessment of each expert's qualifications and the extent to which the plan ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of each nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) Requirements related to submission of comparative analyses to the Secretary upon request—(1) Initial request by the Secretary for comparative analysis. A group health plan must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) Additional information required after a comparative analysis is deemed to be insufficient. In instances in which the Secretary determines that the plan has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to review the comparative analysis required in paragraph (b) of this section, the Secretary will specify to the plan the additional information the plan must submit to the Secretary to be responsive to the request under paragraph (d)(1) of this section. Any such information must be provided to the Secretary by the plan within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) Initial determination of noncompliance, required action, and corrective action plan. In instances in which the Secretary reviewed the comparative analysis submitted under paragraph

(d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan is not in compliance with the requirements of § 54.9812-1(c)(4) or this section, the plan must respond to the Secretary and specify the actions the plan will take to bring the plan into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (b) of this section that demonstrate compliance with § 54.9812-1(c)(4) and this section, not later than 45 calendar days after the Secretary's initial determination that the plan is not in compliance.

(4) Requirement to notify participants and beneficiaries of final determination of noncompliance—(i) In general. If the Secretary makes a final determination of noncompliance, the plan must notify all participants and beneficiaries enrolled in the plan that the plan has been determined to not be in compliance with the requirements of § 54.9812-1(c)(4) or this section with respect to such plan. Such notice must be provided within 7 calendar days of receipt of the final determination of noncompliance, and the plan must provide a copy of the notice to the Secretary, and any service provider involved in the claims process.

(ii) Content of notice. The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: "Attention! Department of the Treasury has determined that [insert the name of group health plan] is not in compliance with the Mental Health Parity and Addiction Equity Act.";

(B) A summary of changes the plan has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed;

(C) A summary of the Secretary's final determination that the plan is not in compliance with § 54.9812-1(c)(4) or this section, including any provisions or practices identified as being in violation of MHPAEA, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan a copy of the final determination of noncompliance;

(D) Any additional actions the plan is taking to come into compliance with § 54.9812-1(c)(4) or this section, when the plan will take such actions, and a clear and accurate statement explaining whether the Secretary has indicated that those actions, if completed, will result in compliance; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(*1*) The plan's phone number and an email or web portal address; and

(*2*) The Employee Benefits Security Administration's phone number and email or web portal address.

(iii) Manner of notice. The plan must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an Internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) Requests for a copy of a comparative analysis. In addition to making a comparative analysis available upon request to the Secretary, a plan must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) Rule of construction. Nothing in this section or § 54.9812-1 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 54.9812-1 or this section.

(g) Applicability. The provisions of this section apply to group health plans described in § 54.9812-1(e), to the extent the plan is not exempt under § 54.9812-1(f) or (g), for plan years beginning on or after January 1, 2025.

(h) Severability. If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

4. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a-n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L.104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Division M, Pub. L. 113-235, 128 Stat. 2130; Pub. L. 116-260 134 Stat. 1182; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

5. Amend § 2590.712 by:

a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);

b. In newly redesignated paragraph (a)(2):

i. Revising the introductory text;

ii. Adding the definitions of "DSM," "Evidentiary standards," "Factors," and "ICD" in alphabetical order;

iii. Revising the definitions of "Medical/surgical benefits" and "Mental health benefits";

iv. Adding the definitions of "Processes" and "Strategies" in alphabetical order; and

v. Revising the definitions of "Substance use disorder benefits" and "Treatment limitations";

c. Revising paragraphs (c)(1)(ii), (c)(2)(i), and (c)(2)(ii)(A) introductory text;

d. In paragraph (c)(2)(ii)(C), designating *Examples 1* through *4* as paragraphs (c)(2)(ii)(C)(*1*) through (*4*) and revising newly designated paragraphs (c)(2)(ii)(C)(*1*) through (*4*);

e. Adding paragraphs (c)(2)(ii)(C)(*5*) and (*6*);

f. Revising paragraphs (c)(3)(i)(A), (C), and (D);

g. In paragraph (c)(3)(iii), adding introductory text;

h. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and

i. Adding paragraph (j).

The revisions and additions read as follows:

§ 2590.712 Parity in mental health and substance use disorder benefits

(a) Purpose and meaning of terms—(1) Purpose. This section and § 2590.712-1 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under ERISA section 712. A fundamental purpose of ERISA section 712, this section, and § 2590.712-1 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage, as further provided in this section and § 2590.712-1. Accordingly, in complying with the provisions of ERISA section 712, this section, and § 2590.712-1, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to

mental health and substance use disorder benefits under the plan or coverage than they impose on access to generally comparable medical/surgical benefits. The provisions of ERISA section 712, this section, and § 2590.712-1 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) Meaning of terms. For purposes of this section and § 2590.712-1, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM is the version that is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary and reasonable" rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to

determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through 45 CFR 162.1002. For the purpose of this definition, the most current version of the ICD is the version that is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal

and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Processes include but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements; and the development and approval of a treatment plan. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment

limitation, and reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include but are not limited to: the development of the clinical rationale used in approving or denying benefits; deviation from generally accepted standards of care; the selection of information deemed reasonably necessary to make a medical necessity determination; reliance on treatment guidelines or guidelines provided by third-party organizations; and rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules. Strategies also include the creation and composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the

diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(iii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(iii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) General rule. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) In general. If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), benefits for that mental health condition or substance use disorder must be provided in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii), a plan (or health insurance coverage) providing any benefits for a mental health condition or substance use disorder in any classification of benefits does not provide benefits for the mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided unless the plan (or health insurance coverage) provides meaningful benefits for treatment for that condition or disorder in each such classification, as determined in comparison to the benefits provided for medical/surgical

conditions in the classification. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) * * *

(*1*) Example 1—(*i*) Facts. A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*1*) (Example 1), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(*2*) Example 2—(*i*) Facts. A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*2*) (Example 2), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(*3*) Example 3—(*i*) Facts. Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (Example 2), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*3*) (Example 3), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(*4*) Example 4—(*i*) Facts. Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (Example 2), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*4*) (Example 4), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(*5*) Example 5—(*i*) Facts. A plan generally covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental evaluations for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavioral analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*5*) (Example 5), the plan violates the rules of this paragraph (c)(2)(ii). Because the plan only covers one type of benefit for ASD in the outpatient, out-of-network classification and excludes all other benefits for ASD in the classification, but generally covers the full range of medical/surgical benefits in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(*6*) Example 6—(*i*) Facts. A plan generally covers diagnosis and treatment for eating disorders, a mental health condition, but specifically excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification. Nutrition counseling is one of the primary treatments for eating disorders. The plan generally provides benefits for the primary treatments for medical/surgical conditions in the outpatient, in-network classification.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*6*) (Example 6), the plan violates the rules of this paragraph (c)(2)(ii). The exclusion of coverage for nutrition counseling for eating disorders results in the plan failing to provide meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification.

(3) * * *

(i) * * *

(A) Substantially all. For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A),

benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) Portion based on plan payments. For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) Special rules. Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) Multi-tiered prescription drug benefits. If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) Multiple network tiers. If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) Examples. The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) Example 1—(*1*) Facts. (*i*) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Table 1 to Paragraph (c)(3)(iv)(A)(*1*)(*i*)

Coinsurance rate	0 %	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

(*ii*) The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(A) (Example 1), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) Example 2—(*1*) Facts. (*i*) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Table 2 to Paragraph (c)(3)(iv)(B)(*1*)(*i*)

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

(*ii*) The plan projects plan costs of $800x to be subject to copayments ($200x + $200x +$300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(B) (Example 2), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels – the $50 copayment, the $20 copayment, and the $15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

(C) Example 3—(*1*) Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(C) (Example 3), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) Example 4—(*1*) Facts. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as "generic", "preferred brand name", "non-preferred brand name", or "specialty" complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(*1*)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which	Specialty drugs

			may have Tier 1 or Tier 2 alternatives)	
Percent paid by plan	90%	80%	60%	50%

(*2*) Conclusion. In this paragraph (c)(3)(iv)(D) (Example 4), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) Example 5—(*1*) Facts. A plan has two-tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(E) (Example 5), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) Example 6—(*1*) Facts. With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services).The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(F) (Example 6), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) Example 7—(*1*) Facts. Same facts as in paragraph (c)(3)(iv)(F)(*1*) of this section (Example 6), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(G) (Example 7), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) Nonquantitative treatment limitations. Subject to paragraph (c)(4)(v) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in a classification unless the plan's or coverage's imposition of the limitation meets the requirements of paragraphs (c)(4)(i), (ii), and (iv) of this section. If a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) fails to meet any of these requirements with respect to a nonquantitative treatment limitation, the limitation violates section 712(a)(3)(A)(ii) of ERISA and may not be imposed by the plan (or health insurance coverage).

(i) Requirement that nonquantitative treatment limitations be no more restrictive for mental health benefits and substance use disorder benefits. A group health plan (or health insurance issuer offering coverage in connection with a group health plan) may not apply any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the same classification.

(A) Restrictive. For purposes of this paragraph (c)(4)(i), a nonquantitative treatment limitation is restrictive to the extent it imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage. Conditions, terms, or requirements include, but are not limited to, those that compel an action by or on behalf of a participant or beneficiary to access benefits or limit access to the full range of treatment options available for a condition or disorder under the plan or coverage.

(B) Substantially all. For purposes of this paragraph (c)(4)(i), a nonquantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in that classification, consistent

with paragraph (c)(4)(i)(D) of this section. Whether the nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits is determined without regard to whether the nonquantitative treatment limitation was triggered based on a particular factor or evidentiary standard. If a nonquantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that limitation cannot be applied to mental health or substance use disorder benefits in that classification.

(C) Predominant. For purposes of this paragraph (c)(4)(i), the term predominant means the most common or most frequent variation of the nonquantitative treatment limitation within a classification, determined in accordance with the method outlined in paragraph (c)(4)(i)(D) of this section, to the extent the plan or issuer imposes multiple variations of a nonquantitative treatment limitation within the classification. For example, multiple variations of inpatient concurrent review include review commencing 1 day, 3 days, or 7 days after admission, depending on the reason for the stay.

(D) Portion based on plan payments. For purposes of paragraphs (c)(4)(i)(B) and (C) of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a nonquantitative treatment limitation is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the nonquantitative treatment limitation). Any reasonable method may be used to determine the dollar amount expected to be paid under a plan or coverage for medical/surgical benefits.

(E) Exceptions for independent professional medical or clinical standards and standards to detect or prevent and prove fraud, waste, and abuse. Notwithstanding paragraphs (c)(4)(i)(A) through (D) of this section, a plan or issuer that applies a nonquantitative treatment limitation that impartially applies independent professional medical or clinical standards or applies standards to detect or prevent and prove fraud, waste, and abuse, as described in paragraph

(c)(4)(v)(A) or (B) of this section, to mental health or substance use disorder benefits in any classification will not be considered to violate this paragraph (c)(4)(i) with respect to such nonquantitative treatment limitation.

(ii) Additional requirements related to design and application of the nonquantitative treatment limitation—(A) In general. Consistent with paragraph (a)(1) of this section, a plan or issuer may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) Prohibition on discriminatory factors and evidentiary standards. For purposes of determining comparability and stringency under paragraph (c)(4)(ii)(A) of this section, a plan or issuer may not rely upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(ii)(B):

(*1*) Impartially applied generally recognized independent professional medical or clinical standards described in paragraph (c)(4)(v)(A) of this section are not considered to discriminate against mental health or substance use disorder benefits.

(*2*) Standards reasonably designed to detect or prevent and prove fraud, waste, and abuse described in paragraph (c)(4)(v)(B) of this section are not considered to discriminate against mental health or substance use disorder benefits.

(*3*) Information is considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances including, but not limited to, the source of the information, the purpose or context of the information, and the content of the information.

(iii) Illustrative, non-exhaustive list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iv) Required use of outcomes data—(A) In general. When designing and applying a nonquantitative treatment limitation, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether the limitation, in operation, complies with paragraphs (c)(4)(i) and (ii) of this section. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iv)(A).

(*1*) For purposes of this paragraph (c)(4)(iv)(A), relevant data includes, but is not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(*2*) In addition to the relevant data set forth in paragraph (c)(4)(iv)(A)(*1*) of this section, relevant data for nonquantitative treatment limitations related to network composition standards includes, but is not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges).

(B) Material differences. Subject to paragraph (c)(4)(iv)(C) of this section, to the extent the relevant data evaluated pursuant to paragraph (c)(4)(iv)(A) of this section show material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the differences will be considered a strong indicator that the plan or issuer violates paragraph (c)(4)(i) or (ii) of this section. In such instances, the plan or issuer:

(*1*) Must take reasonable action to address the material differences in access as necessary to ensure compliance, in operation, with paragraphs (c)(4)(i) and (ii) of this section; and

(*2*) Must document the action that has been or is being taken by the plan or issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as required by § 2590.712-1(c)(5)(iv).

(C) Special rule for nonquantitative treatment limitations related to network composition. Notwithstanding paragraph (c)(4)(iv)(B) of this section, when designing and applying one or more nonquantitative treatment limitation(s) related to network composition standards, a plan or issuer fails to meet the requirements of paragraphs (c)(4)(i) and (ii) of this section, in operation, if the relevant data show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification.

(D) Exception for independent professional medical or clinical standards. A plan or issuer designing and applying a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that impartially applies independent professional medical or clinical standards, as described in paragraph (c)(4)(v)(A) of this section, is not required to comply with the requirements of this paragraph (c)(4)(iv) with respect to that classification.

(v) Independent professional medical or clinical standards and standards to detect or prevent and prove fraud, waste, and abuse. (A) To qualify for the exceptions in paragraphs (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(iv)(D) of this section for independent professional medical or clinical standards, a nonquantitative treatment limitation must impartially apply generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits, and may not deviate from those standards in any way, such as by imposing additional or different requirements.

(B) To qualify for the exceptions in paragraphs (c)(4)(i)(E) and (c)(4)(ii)(B) of this section to detect or prevent and prove fraud, waste, and abuse, a nonquantitative treatment limitation must be reasonably designed to detect or prevent and prove fraud, waste, and abuse, based on indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data, and also be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits.

(vi) Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits. Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(vii) Effect of final determination of noncompliance under § 2590.712-1. If a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) receives a final determination from the Secretary that the plan or issuer is not in compliance with the requirements of § 2590.712-1 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan or issuer not to impose the nonquantitative treatment limitation, unless and until the plan or issuer demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(viii) Examples. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. Additionally, in examples that conclude that the plan or issuer violates one provision of this paragraph (c)(4), such examples do not necessarily imply compliance with other provisions

of this paragraph (c)(4), as these examples do not analyze compliance with all other provisions of this paragraph (c)(4).

(A) Example 1 (More restrictive prior authorization requirement in operation)—(*1*) Facts. A plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. While inpatient, in-network benefits for medical/surgical conditions are approved for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan, the approvals for 7 days are most common under this plan. For inpatient, in-network mental health and substance use disorder benefits, routine approval is most commonly given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The difference in the duration of approvals is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse, but rather reflects the application of a heightened standard to the provision of the mental health and substance use disorder benefits in the relevant classification.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(A) (Example 1), the plan violates the rules of paragraph (c)(4)(i) of this section. Under the terms of the plan, prior authorization applies to at least two-thirds of all medical/surgical benefits in the relevant classification (inpatient, in-network), since it applies to all benefits in the relevant classification. Further, the most common or frequent variation of the nonquantitative treatment limitation applied to medical/surgical benefits in the relevant classification (the predominant nonquantitative treatment limitation) is the routine approval of inpatient, in-network benefits for 7 days before the patient's attending provider must submit a treatment plan. However, the plan routinely approves inpatient, in-network benefits for mental health and substance use disorder conditions for only 1 day before the patient's attending provider must submit a treatment plan (and, in doing so, does not impartially apply independent professional medical or clinical standards or apply standards to detect or prevent and prove fraud, waste, and abuse that qualify for the exceptions in paragraph (c)(4)(i)(E) of this section). In operation, therefore, the prior authorization requirement imposed on inpatient, in-network mental health and substance use disorder benefits is more restrictive than the predominant prior authorization requirement applicable to substantially all medical/surgical benefits in the inpatient, in-network classification because the practice of approving only 1 day of inpatient benefits limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to the routine 7-day approval that is given for inpatient, in-network medical/surgical benefits. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(B) Example 2 (More restrictive peer-to-peer concurrent review requirements in operation)—(*1*) Facts. A plan follows a written process for the concurrent review of all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under the process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. While the written process only requires review by the second-level reviewer to either deny or

approve the request, in operation, second-level reviewers for mental health and substance use disorder benefits conduct a peer-to-peer review with a provider (acting as the authorized representative of a participant or beneficiary) before coverage of the treatment is approved. The peer-to-peer review requirement is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse. The plan does not impose a peer-to-peer review, as written or in operation, as part of the second-level review for medical/surgical benefits.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(B) (Example 2), the plan violates the rules of paragraph (c)(4)(i) of this section. The concurrent review nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits within the inpatient, in-network classification because the plan follows the concurrent review process for all medical/surgical benefits. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is that peer-to-peer review is not imposed as part of second-level review. The plan does not impartially apply independent professional medical or clinical standards or apply standards to detect or prevent and prove fraud, waste, and abuse that qualify for the exceptions in paragraph (c)(4)(i)(E) of this section. As written, the plan's concurrent review requirements are the same for medical/surgical benefits and mental health and substance use disorder benefits. However, in operation, by compelling an additional action (peer-to-peer review as part of second-level review) to access only mental health or substance use disorder benefits, the plan applies the limitation to mental health and substance use disorder benefits in a manner that is more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the inpatient, in-network classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(C) Example 3 (More restrictive peer-to-peer review medical necessity standard in operation; deviation from independent professional medical and clinical standards)—(*1*) Facts. A plan generally requires that all treatment be medically necessary in the inpatient, out-of-network classification. For both medical/surgical benefits and mental health and substance use disorder benefits, the written medical necessity standards are based on independent professional medical or clinical standards that do not require peer-to-peer review. In operation, the plan covers out-of-network benefits for medical/surgical or mental health inpatient treatment outside of a hospital if the physician documents medical appropriateness, but for out-of-network benefits for substance use disorder inpatient treatment outside of a hospital, the plan requires a physician to also complete peer-to-peer review.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(C) (Example 3), the plan violates the rules of paragraph (c)(4)(i) of this section. The medical necessity nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in the inpatient, out-of-network classification. The most common or frequent variation of the nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is the requirement that a physician document medical appropriateness without peer-to-peer review. The plan purports to impartially apply independent professional medical or clinical standards that would otherwise qualify for the exception in paragraph (c)(4)(i)(E) of this section, but deviates from those standards by imposing the additional requirement to complete peer-to-peer review for inpatient, out-of-network benefits for substance use disorder outside of a hospital. Therefore, the exception in paragraph (c)(4)(i)(E) of this section does not apply. As written, the plan provisions apply the nonquantitative treatment limitation to mental health and substance use disorder benefits in the inpatient, out-of-network

classification in the same manner as for medical/surgical benefits. However, in operation, the nonquantitative treatment limitation imposed with respect to out-of-network substance use disorder benefits for treatment outside of a hospital is more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification because it limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(D) Example 4 (Not comparable and more stringent methods for determining reimbursement rates in operation)—(*1*) Facts. A plan's base reimbursement rates for outpatient, in-network providers are determined based on a variety of factors, including the providers' required training, licensure, and expertise. For purposes of this example, the plan's nonquantitative treatment limitations for determining reimbursement rates for mental health and substance use disorder benefits are not more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification under paragraph (c)(4)(i) of this section. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code vary based on a combination of factors, such as the nature of the service, provider type, number of providers qualified to provide the service in a given geographic area, and market need (demand). As a result, reimbursement rates for mental health, substance use disorder, and medical/surgical benefits furnished by non-physician providers are generally less than for physician providers. In operation, the plan reduces the reimbursement rate for mental health and substance use disorder non-physician providers from that paid to mental health and substance use disorder physicians by the same percentage for every CPT code but does not apply the same reductions for non-physician medical/surgical providers.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(D) (Example 4), the plan violates the rules of paragraph (c)(4)(ii) of this section. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate to physician providers by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services, in operation, the factors used in applying the nonquantitative treatment limitation to mental health and substance use disorder benefits are not comparable to, and are applied more stringently than, the factors used in applying the limitation with respect to medical/surgical benefits. Because the facts assume that the plan's methods for determining reimbursement rates comply with paragraph (c)(4)(i) of this section and the plan violates the rules of paragraph (c)(4)(ii) of this section, this example does not analyze compliance with paragraph (c)(4)(iv) of this section.

(E) Example 5 (Exception for impartially applied generally recognized independent professional medical or clinical standards)—(*1*) Facts. A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The medical management requirement impartially applies independent professional medical or clinical standards in a manner that qualifies for the exception in paragraph (c)(4)(i)(E) of this section. The plan does not rely on any other factors or evidentiary standards and the processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to

medical/surgical benefits. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims based on the impartial application of the independent professional medical or clinical standards by the nonquantitative treatment limitation.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(E) (Example 5), the plan does not violate the rules of this paragraph (c)(4). The medical management nonquantitative treatment limitation imposed on mental health and substance use disorder benefits does not violate paragraph (c)(4)(i) or (iv) of this section because it impartially applies independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits in a manner that qualifies for the exceptions in paragraphs (c)(4)(i)(E) and (c)(4)(iv)(D) of this section, respectively. Moreover, the nonquantitative treatment limitation does not violate paragraph (c)(4)(ii) of this section because the independent professional medical or clinical standards are not considered to be a discriminatory factor or evidentiary standard under paragraph (c)(4)(ii)(B) of this section. Additionally, as written and in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, out-of-network classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying the limitation with respect to medical/surgical benefits in the classification, regardless of the fact that the application of the nonquantitative treatment limitation resulted in higher percentages of claim denials for mental health and substance use disorder benefits as compared to medical/surgical benefits.

(F) Example 6 (More restrictive prior authorization requirement; exception for impartially applied generally recognized independent professional medical or clinical standards not met)—(*1*) Facts. The provisions of a plan state that it applies independent professional medical and clinical standards (consistent with generally accepted standards of care) for setting prior authorization requirements for both medical/surgical and mental health and substance use disorder prescription drugs. The relevant generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination at each refill (every 30 days) for treatment of opioid use disorder.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(F) (Example 6), the plan violates the rules of paragraph (c)(4)(i) of this section. The plan does not qualify for the exception in paragraph (c)(4)(i)(E) of this section, because, although the provisions of the plan state that it applies independent professional medical and clinical standards, the plan deviates from the relevant standards with respect to prescription drugs to treat opioid use disorder. The prior authorization nonquantitative treatment limitation is applied to at least two-thirds of all medical/surgical benefits in the prescription drugs classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is following generally recognized independent professional medical and clinical standards (consistent with generally accepted standards of care). The prior authorization requirements imposed on substance use disorder benefits are more restrictive than the predominant nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in the classification, because the plan imposes additional requirements on substance use disorder benefits that limit access to the full range of

treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(G) Example 7 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)—(*1*) Facts. Following an initial request by the Secretary for a plan's comparative analysis of a nonquantitative treatment limitation pursuant to § 2590.712-1(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the relevant classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Pursuant to § 2590.712-1(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination, and the Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). The plan receives a final determination of noncompliance from the Secretary, which informs the plan that it is not in compliance with this paragraph (c)(4) and directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the nonquantitative treatment limitation.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(G) (Example 7), the plan violates the requirements of this paragraph (c)(4) by imposing the nonquantitative treatment limitation after the Secretary directs the plan not to impose it, pursuant to paragraph (c)(4)(vii) of this section.

(H) Example 8 (Provider network admission standards not more restrictive and compliant with requirements for design and application of NQTLs)—(*1*) Facts. As part of a plan's standards for provider admission to its network, in the outpatient, in-network classification, any provider seeking to contract with the plan must have a certain number of years of supervised clinical experience. As a result of that standard, master's level mental health therapists are required to obtain supervised clinical experience beyond their licensure, while master's level medical/surgical providers, psychiatrists, and Ph.D.-level psychologists do not require additional experience beyond their licensure because their licensure already requires supervised clinical experience. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation. This includes in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). This data demonstrates that participants and beneficiaries seeking outpatient care are able to access outpatient, in-network mental health and substance use disorder providers at the same frequency as outpatient, in-network medical/surgical providers, that mental health and substance use disorder providers are active in the network and are accepting new patients to the same extent as medical/surgical providers, and that mental health and substance use disorder providers are within similar time and distances to plan participants and beneficiaries as are medical/surgical providers. This data also does not identify material differences in what the plan or issuer pays psychiatrists or non-physician mental health providers, compared to physicians or non-physician medical/surgical providers, respectively, both for the same reimbursement codes and as compared to Medicare rates.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(H) (Example 8), the plan does not violate this paragraph (c)(4). The standards for this nonquantitative treatment limitation, namely provider admission to the plan's network, are applied to at least two-thirds of all medical/surgical benefits in the outpatient, in-network classification, as it applies to all medical/surgical benefits in the classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) that applies to substantially all medical/surgical benefits in the classification is having a certain number of years of supervised clinical experience. The standards for provider admission to the plan's network that are imposed with respect to mental health or substance use disorder benefits are no more restrictive, as written or in operation, than the predominant variation of the nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in the classification, because the standards do not limit access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. The requirement that providers have a certain number of years of supervised clinical experience that the plan relied upon to design and apply the nonquantitative treatment limitation is not considered to discriminate against mental health or substance use disorder benefits, even though this results in the requirement that master's level mental health therapists obtain supervised clinical experience beyond their licensure, unlike master's level medical/surgical providers. In addition, as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification, because the plan applies the same standard to all providers in the classification. Finally, the plan or issuer collects and evaluates relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits, which does not show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in the classification.

(I) Example 9 (More restrictive requirement for primary caregiver participation applied to ABA therapy)—(*1*) Facts. A plan generally applies medical necessity criteria in adjudicating claims for coverage of all outpatient, in-network medical/surgical and mental health and substance use disorder benefits, including ABA therapy for the treatment of ASD, which is a mental health condition. The plan's medical necessity criteria for coverage of ABA therapy requires evidence that the participant's or beneficiary's primary caregivers actively participate in ABA therapy, as documented by consistent attendance in parent, caregiver, or guardian training sessions. In adding this requirement, the plan deviates from independent professional medical or clinical standards, and there are no similar medical necessity criteria requiring evidence of primary caregiver participation in order to receive coverage of any medical/surgical benefits.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(I) (Example 9), the plan violates paragraph (c)(4)(i) of this section. The plan applies medical necessity criteria to at least two-thirds of all outpatient, in-network medical/surgical benefits, as they apply to all medical/surgical benefits in the classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) that applies to substantially all medical/surgical benefits in the classification does not include the requirement to provide evidence that the participant's or beneficiary's primary caregivers actively participate in the treatment. The plan does not qualify for the exception in paragraph (c)(4)(i)(E) of this section in applying its restriction on coverage for ABA therapy because the plan deviates from the independent professional medical or clinical standards by imposing a different requirement. As a

result, the nonquantitative treatment limitation imposed on mental health and substance use disorder benefits is more restrictive than the predominant medical necessity requirement imposed on substantially all medical/surgical benefits in the classification (which does not include the requirement to provide evidence that primary caregivers actively participate in treatment). Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(J) Example 10 (More restrictive exclusion for experimental or investigative treatment applied to ABA therapy)—(*1*) Facts. A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(J) (Example 10), the plan violates the rules of paragraph (c)(4)(i) of this section. The coverage exclusion for experimental or investigative treatment applies to at least two-thirds of all medical/surgical benefits, as it applies to all medical/surgical benefits in the outpatient, in-network classification. The most common or frequent variation of this nonquantitative treatment limitation in the classification (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is the exclusion under the plan for coverage of experimental treatment of medical/surgical conditions when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. In operation, the exclusion for experimental or investigative treatment imposed on ABA therapy is more restrictive than the predominant variation of the nonquantitative treatment limitation for experimental or investigative treatment imposed on substantially all medical/surgical benefits in the classification because the exclusion limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(K) Example 11 (Separate EAP exhaustion treatment limitation applicable only to mental health benefits)—(*1*) Facts. An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(K) (Example 11), limiting eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(vi) of this section. Additionally, this EAP would not qualify as excepted benefits under § 2590.732(c)(3)(vi)(B)(*1*) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) Example 12 (Separate residential exclusion treatment limitation applicable only to mental health benefits)—(*1*) Facts. A plan generally covers inpatient, in-network and inpatient out-of-network treatment in any setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan also has an exclusion for residential treatment, which the plan defines as an inpatient benefit, for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(*2*) Conclusion. In this paragraph (c)(4)(viii)(L) (Example 12), the plan violates the rules of paragraph (c)(4)(vi) of this section. Because the plan does not apply a comparable exclusion to inpatient benefits for medical/surgical conditions, the exclusion of residential treatment is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications that does not apply with respect to any medical/surgical benefits in the same benefit classification.

(M) Example 13 (Standards for provider admission to a network)—(*1*) Facts. A plan applies nonquantitative treatment limitations related to network composition in the outpatient in-network and inpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. For purposes of this example, these facts assume that these nonquantitative treatment limitations related to network composition for mental health and substance use disorder benefits are not more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classifications under paragraph (c)(4)(i) of this section. The facts also assume that, as written and in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network access to mental health or substance use disorder benefits in the outpatient in-network and inpatient in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(ii) of this section. The plan collects and evaluates all relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitations related to network composition on access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's or issuer's analysis of whether the standards, in operation, comply with paragraphs (c)(4)(i) and (ii) of this section. The plan determined that the data did not reveal any material differences in access. That data included metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates; in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions); and

survey data from participants on the extent to which they forgo or pay out-of-pocket for treatment because of challenges finding in-network providers. The efforts the plan made when designing and applying its nonquantitative treatment limitations related to network composition, which ultimately led to its outcomes data not revealing any material differences in access to benefits for mental health or substance use disorders as compared with medical/surgical benefits, included making sure that the plan's service providers are making special efforts to enroll available providers, including by authorizing greater compensation or other inducements to the extent necessary, and expanding telehealth arrangements as appropriate to manage regional shortages. The plan also notifies participants in clear and prominent language on its website, employee brochures, and the summary plan description of a toll-free number available to help participants find in-network providers. In addition, when plan participants submit bills for out-of-network items and services, the plan directs their service providers to reach out to the treating providers and facilities to see if they will enroll in the network.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(M) (Example 13), the plan does not violate this paragraph (c)(4). As stated in the Facts section, the plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraphs (c)(4)(i) and (ii) of this section. The plan collects and evaluates relevant data, as required under paragraph (c)(4)(iv)(A) of this section, and the data does not reveal any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as a result of the actions the plan took (as set forth in the facts) when initially designing its nonquantitative treatment limitations related to network composition. Because the plan takes comparable actions to ensure that their mental health and substance use disorder provider network is as accessible as their medical/surgical provider network and exercises careful oversight over both their service providers and the comparative robustness of the networks with an eye to ensuring that network composition results in access to in-network benefits for mental health and substance use disorder services that is as generous as for medical/surgical services, plan participants and beneficiaries can access covered mental health and substance use disorder services and benefits as readily as medical/surgical benefits. This is reflected in the plan's carefully designed metrics and assessment of network composition.

* * * * *

(d) * * *

(3) Provisions of other law. Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and § 2520.104b-1 of this chapter provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental

health and substance use disorder benefits; the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan; and the comparative analyses and other applicable information required by § 2590.712-1. In addition, § 2560.503-1 of this chapter and § 2590.715-2719 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 2590.712-1.

(e) * * *

(4) Coordination with EHB requirements. Nothing in paragraph (f) or (g) of this section or § 2590.712-1(g) changes the requirements of 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) In general. Except as provided in paragraph (i)(2) of this section, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025. Until the applicability date in the preceding sentence, plans and issuers are required to continue to comply with 29 CFR 2590.712, revised as of July 1, 2022.

* * * * *

(j) Severability. If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

6. Add § 2590.712-1 to read as follows:

§ 2590.712-1 Nonquantitative treatment limitation comparative analysis requirements.

(a) Meaning of terms. Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 2590.712(a)(2).

(b) In general. In the case of a group health plan (or health insurance issuer offering group health insurance coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c)

of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) Comparative analysis content requirements. With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each nonquantitative treatment limitation. This list and general description must be provided to the named fiduciaries of the plan who are required to review the findings or conclusions of each comparative analysis, as required under paragraph (c)(6)(vi) of this section.

(1) Description of the nonquantitative treatment limitation. The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits;

(iii) A description of which benefits are included in each classification set forth in § 2590.712(c)(2)(ii)(A); and

(iv) Identification of the predominant nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant nonquantitative treatment limitation as compared to other variations, as well as how the plan identified the variations of the nonquantitative treatment limitation.

(2) Identification and definition of the factors used to design or apply the nonquantitative treatment limitation. The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of all of the factors considered, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor; and

(B) A description of each evidentiary standard (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section.

(3) Description of how factors are used in the design and application of the nonquantitative treatment limitation. The comparative analysis must include a description of how each factor identified and defined pursuant to paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviation(s) or variation(s).

(4) <u>Demonstration of comparability and stringency as written</u>. The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in

designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard, and the evaluation of relevant data as required under § 2590.712(c)(4)(iv)(A), to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each

classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reason(s) for any deviation(s) or variation(s) in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviation(s) or variation(s), including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) Demonstration of comparability and stringency in operation. The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer ensures that, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation; and

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(ii) Identification of the relevant data collected and evaluated as required under § 2590.712(c)(4)(iv)(A);

(iii) An evaluation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including the relevant data as required under § 2590.712(c)(4)(iv)(A);

(iv) A detailed explanation of material differences in outcomes evaluated pursuant to paragraph (c)(5)(iii) of this section that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits and the bases for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(v) A discussion of any measures that have been or are being implemented by the plan or issuer to mitigate any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer is taking under § 2590.712(c)(4)(iv)(B)(*1*) to address material differences to ensure compliance with § 2590.712(c)(4)(i) and (ii).

(6) Findings and conclusions. The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is not (or might not be) in compliance with the requirements of § 2590.712(c)(4), including any actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iv) The date of the analysis and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis;

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of each nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits; and

(vi) A certification by one or more named fiduciaries who have reviewed the comparative analysis stating whether they found the comparative analysis to be in compliance with the content requirements of paragraph (c) of this section.

(d) <u>Requirements related to submission of comparative analyses to the Secretary upon request</u>—(1) <u>Initial request by the Secretary for comparative analysis</u>. A group health plan or health insurance issuer offering group health insurance coverage must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) Additional information required after a comparative analysis is deemed to be insufficient. In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to review the comparative analysis required in paragraph (b) of this section, the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1) of this section. Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) Initial determination of noncompliance, required action, and corrective action plan. In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 2590.712(c)(4) or this section, the plan or issuer must respond to the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (b) of this section that demonstrate compliance with § 2590.712(c)(4) and this section, not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) Requirement to notify participants and beneficiaries of final determination of noncompliance—(i) In general. If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 2590.712(c)(4) or this section with respect to such plan or coverage. Such notice must be provided within 7 calendar days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, and any service provider

involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same time frame.

(ii) Content of notice. The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: "Attention! The Department of Labor has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.";

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed;

(C) A summary of the Secretary's final determination that the plan or issuer is not in compliance with § 2590.712(c)(4) or this section, including any provisions or practices identified as being in violation of MHPAEA, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 2590.712(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has indicated that those actions, if completed, will result in compliance; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(*1*) The plan's or issuer's phone number and an email or web portal address; and

(*2*) The Employee Benefits Security Administration's phone number and email or web portal address.

(iii) Manner of notice. The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an Internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) Requests for a copy of a comparative analysis. In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority;

(2) A participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits; and

(3) Participants and beneficiaries, who may request the comparative analysis at any time under ERISA section 104.

(f) Rule of construction. Nothing in this section or § 2590.712 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 2590.712 or this section.

(g) Applicability. The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 2590.712(e), to the

extent the plan or issuer is not exempt under § 2590.712(f) or (g), for plan years beginning on or after January 1, 2025.

(h) Severability. If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 146 and 147 as set forth below:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

7. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

8. Amend § 146.136 is amended by:

a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);

b. In newly redesignated paragraph (a)(2):

i. Revising the introductory text;

ii. Adding the definitions of "DSM," "Evidentiary standards," "Factors," and "ICD" in alphabetical order;

iii. Revising the definitions of "Medical/surgical benefits" and "Mental health benefits";

iv. Adding the definitions of "Processes" and "Strategies" in alphabetical order; and

v. Revising the definitions of "Substance use disorder benefits" and "Treatment limitations";

c. Revising paragraphs (c)(1)(ii), (c)(2)(i), and (c)(2)(ii)(A) introductory text;

d. In paragraph (c)(2)(ii)(C), designating *Examples 1* through *4* as paragraphs (c)(2)(ii)(C)(*1*) through (*4*) and revising newly designated paragraphs (c)(2)(ii)(C)(*1*) through (*4*);

e. Adding paragraphs (c)(2)(ii)(C)(*5*) and (*6*);

f. Revising paragraphs (c)(3)(i)(A), (C), and (D);

g. In paragraph (c)(3)(iii), adding introductory text;

h. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and

i. Adding paragraph (j).

The revisions and additions read as follows:

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) Purpose and meaning of terms – (1) Purpose. This section and § 146.137 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under PHS Act section 2726. A fundamental purpose of PHS Act section 2726, this section, and § 146.137 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage, as further provided in this section and § 146.137. Accordingly, in complying with the provisions of PHS Act section 2726, this section, and § 146.137, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health and substance use disorder benefits under the plan or coverage than they impose on access to generally comparable medical/surgical benefits. The provisions of PHS section 2726, this section, and § 146.137 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) Meaning of terms. For purposes of this section and § 146.137, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM is the version that is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary and reasonable" rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through § 162.1002 of this subtitle. For the purpose of this definition, the most current version of the ICD is the version that is applicable no earlier than on the date that is 1 year before the first day of the applicable plan year.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance

use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Processes include but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements; and the development and approval of a treatment plan. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include but are not limited to: the development of the clinical rationale used in approving or denying benefits; deviation from

generally accepted standards of care; the selection of information deemed reasonably necessary to make a medical necessity determination; reliance on treatment guidelines or guidelines provided by third-party organizations; and rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules. Strategies also include the creation and composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not

address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(iii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) Type of financial requirement or treatment limitation. When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(iii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) General rule. A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied

to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) In general. If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), benefits for that mental health condition or substance use disorder must be provided in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii), a plan (or health insurance coverage) providing any benefits for a mental health condition or substance use disorder in any classification of benefits does not provide benefits for the mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided unless the plan (or health insurance coverage) provides meaningful benefits for treatment for that condition or disorder in each such classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or

treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) * * *

(*1*) Example 1—(*i*) Facts. A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*1*) (Example 1), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(*2*) Example 2—(*i*) Facts. A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*2*) (Example 2), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(*3*) Example 3—(*i*) Facts. Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (Example 2), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*3*) (Example 3), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(*4*) Example 4—(*i*) Facts. Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (Example 2), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*4*) (Example 4), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(*5*) Example 5—(*i*) Facts. A plan generally covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental evaluations for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavioral analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*5*) (Example 5), the plan violates the rules of this paragraph (c)(2)(ii). Because the plan only covers one type of benefit for ASD in the outpatient, out-of-network classification and excludes all other benefits for ASD in the classification, but generally covers the full range of medical/surgical benefits in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(*6*) Example 6—(*i*) Facts. A plan generally covers diagnosis and treatment for eating disorders, a mental health condition, but specifically excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification. Nutrition counseling is one of the primary treatments for eating disorders. The plan generally provides benefits for the primary treatments for medical/surgical conditions in the outpatient, in-network classification.

(*ii*) Conclusion. In this paragraph (c)(2)(ii)(C)(*6*) (Example 6), the plan violates the rules of this paragraph (c)(2)(ii). The exclusion of coverage for nutrition counseling for eating disorders results in the plan failing to provide meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for medical/surgical conditions in the classification.

(3) * * *

(i) * * *

(A) Substantially all. For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment

limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) Portion based on plan payments. For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) Clarifications for certain threshold requirements. For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) Special rules. Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) Multi-tiered prescription drug benefits. If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits

based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) Multiple network tiers. If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) Examples. The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) Example 1—(*1*) Facts. (*i*) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Table 1 to Paragraph (c)(3)(iv)(A)(*1*)(*i*)

Coinsurance rate	0 %	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

(*ii*) The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(A) (Example 1), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) Example 2—(*1*) Facts. (*i*) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Table 2 to Paragraph (c)(3)(iv)(B)(*1*)(*i*)

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

(*ii*) The plan projects plan costs of $800x to be subject to copayments ($200x + $200x +$300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(B) (Example 2), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a

copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels – the $50 copayment, the $20 copayment, and the $15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

(C) Example 3—(*1*) Facts. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(C) (Example 3), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) Example 4—(*1*) Facts. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as "generic", "preferred brand name", "non-preferred brand name", or "specialty" complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(*1*)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(*2*) Conclusion. In this paragraph (c)(3)(iv)(D) (Example 4), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial

requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) Example 5—(*1*) Facts. A plan has two-tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(E) (Example 5), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) Example 6—(*1*) Facts. With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(F) (Example 6), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) Example 7—(*1*) Facts. Same facts as in paragraph (c)(3)(iv)(F)(*1*) of this section (Example 6), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(*2*) Conclusion. In this paragraph (c)(3)(iv)(G) (Example 7), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) Nonquantitative treatment limitations. Subject to paragraph (c)(4)(v) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in a classification unless the plan's or coverage's imposition of the limitation meets the requirements of paragraphs (c)(4)(i), (ii), and (iv) of this section. If a

group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) fails to meet any of these requirements with respect to a nonquantitative treatment limitation, the limitation violates section 2726(a)(3)(A)(ii) of the PHS Act and may not be imposed by the plan (or health insurance coverage).

(i) Requirement that nonquantitative treatment limitations be no more restrictive for mental health benefits and substance use disorder benefits. A group health plan (or health insurance issuer offering coverage in connection with a group health plan) may not apply any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the same classification.

(A) Restrictive. For purposes of this paragraph (c)(4)(i), a nonquantitative treatment limitation is restrictive to the extent it imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage. Conditions, terms, or requirements include, but are not limited to, those that compel an action by or on behalf of a participant or beneficiary to access benefits or limit access to the full range of treatment options available for a condition or disorder under the plan or coverage.

(B) Substantially all. For purposes of this paragraph (c)(4)(i), a nonquantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in that classification, consistent with paragraph (c)(4)(i)(D) of this section. Whether the nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits is determined without regard to whether the nonquantitative treatment limitation was triggered based on a particular factor or evidentiary standard. If a nonquantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that limitation cannot be applied to mental health or substance use disorder benefits in that classification.

(C) Predominant. For purposes of this paragraph (c)(4)(i), the term predominant means the most common or most frequent variation of the nonquantitative treatment limitation within a classification, determined in accordance with the method outlined in paragraph (c)(4)(i)(D) of this section, to the extent the plan or issuer imposes multiple variations of a nonquantitative treatment limitation within the classification. For example, multiple variations of inpatient concurrent review include review commencing 1 day, 3 days, or 7 days after admission, depending on the reason for the stay.

(D) Portion based on plan payments. For purposes of paragraphs (c)(4)(i)(B) and (C) of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a nonquantitative treatment limitation is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the nonquantitative treatment limitation). Any reasonable method may be used to determine the dollar amount expected to be paid under a plan or coverage for medical/surgical benefits.

(E) Exceptions for independent professional medical or clinical standards and standards to detect or prevent and prove fraud, waste, and abuse. Notwithstanding paragraphs (c)(4)(i)(A) through (D) of this section, a plan or issuer that applies a nonquantitative treatment limitation that impartially applies independent professional medical or clinical standards or applies standards to detect or prevent and prove fraud, waste, and abuse, as described in paragraph (c)(4)(v)(A) or (B) of this section, to mental health or substance use disorder benefits in any classification will not be considered to violate this paragraph (c)(4)(i) with respect to such nonquantitative treatment limitation.

(ii) Additional requirements related to design and application of the nonquantitative treatment limitation—(A) In general. Consistent with paragraph (a)(1) of this section, a plan or issuer may not impose a nonquantitative treatment limitation with respect to mental health or

substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) Prohibition on discriminatory factors and evidentiary standards. For purposes of determining comparability and stringency under paragraph (c)(4)(ii)(A) of this section, a plan or issuer may not rely upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(ii)(B):

(*1*) Impartially applied generally recognized independent professional medical or clinical standards described in paragraph (c)(4)(v)(A) of this section are not considered to discriminate against mental health or substance use disorder benefits.

(*2*) Standards reasonably designed to detect or prevent and prove fraud, waste, and abuse described in paragraph (c)(4)(v)(B) of this section are not considered to discriminate against mental health or substance use disorder benefits.

(*3*) Information is considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances including, but not limited to, the source of the information, the purpose or context of the information, and the content of the information.

(iii) Illustrative, non-exhaustive list of nonquantitative treatment limitations. Nonquantitative treatment limitations include –

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iv) Required use of outcomes data—(A) In general. When designing and applying a nonquantitative treatment limitation, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether the limitation, in operation, complies with paragraphs (c)(4)(i) and (ii) of this section. The Secretary, jointly with

the Secretary of the Treasury and the Secretary of Labor, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iv)(A).

(*1*) For purposes of this paragraph (c)(4)(iv)(A), relevant data includes, but is not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(*2*) In addition to the relevant data set forth in paragraph (c)(4)(iv)(A)(*1*) of this section, relevant data for nonquantitative treatment limitations related to network composition standards includes, but is not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges).

(B) Material differences. Subject to paragraph (c)(4)(iv)(C) of this section, to the extent the relevant data evaluated pursuant to paragraph (c)(4)(iv)(A) of this section show material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the differences will be considered a strong indicator that the plan or issuer violates paragraph (c)(4)(i) or (ii) of this section. In such instances, the plan or issuer:

(*1*) Must take reasonable action to address the material differences in access as necessary to ensure compliance, in operation, with paragraphs (c)(4)(i) and (ii) of this section; and

(*2*) Must document the action that has been or is being taken by the plan or issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as required by § 146.137(c)(5)(iv).

(C) Special rule for nonquantitative treatment limitations related to network composition. Notwithstanding paragraph (c)(4)(iv)(B) of this section, when designing and applying one or more nonquantitative treatment limitation(s) related to network composition standards, a plan or issuer fails to meet the requirements of paragraphs (c)(4)(i) and (ii) of this section, in operation, if the relevant data show material differences in access to in-network mental health and

substance use disorder benefits as compared to in-network medical/surgical benefits in a classification.

(D) Exception for independent professional medical or clinical standards. A plan or issuer designing and applying a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that impartially applies independent professional medical or clinical standards, as described in paragraph (c)(4)(v)(A) of this section, is not required to comply with the requirements of this paragraph (c)(4)(iv) with respect to that classification.

(v) Independent professional medical or clinical standards and standards to detect or prevent and prove fraud, waste, and abuse. (A) To qualify for the exceptions in paragraphs (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(iv)(D) of this section for independent professional medical or clinical standards, a nonquantitative treatment limitation must impartially apply generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits, and may not deviate from those standards in any way, such as by imposing additional or different requirements.

(B) To qualify for the exceptions in paragraphs (c)(4)(i)(E) and (c)(4)(ii)(B) of this section to detect or prevent and prove fraud, waste, and abuse, a nonquantitative treatment limitation must be reasonably designed to detect or prevent and prove fraud, waste, and abuse, based on indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data, and also be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits.

(vi) Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits. Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with

respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(vii) Effect of final determination of noncompliance under § 146.137. If a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) receives a final determination from the Secretary that the plan or issuer is not in compliance with the requirements of § 146.137 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan or issuer not to impose the nonquantitative treatment limitation, unless and until the plan or issuer demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(viii) Examples. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. Additionally, in examples that conclude that the plan or issuer violates one provision of this paragraph (c)(4), such examples do not necessarily imply compliance with other provisions of this paragraph (c)(4), as these examples do not analyze compliance with all other provisions of this paragraph (c)(4).

(A) Example 1 (More restrictive prior authorization requirement in operation)—(*1*) Facts. A plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. While inpatient, in-network benefits for medical/surgical conditions are approved for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan, the approvals for 7 days are most common under this plan. For inpatient, in-network mental health and substance use disorder benefits, routine approval is most commonly given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The difference in the duration of approvals is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse, but rather reflects the application of a heightened standard to the provision of the mental health and substance use disorder benefits in the relevant classification.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(A) (Example 1), the plan violates the rules of paragraph (c)(4)(i) of this section. Under the terms of the plan, prior authorization applies to at least two-thirds of all medical/surgical benefits in the relevant classification (inpatient, in-network), since it applies to all benefits in the relevant classification. Further, the most common

or frequent variation of the nonquantitative treatment limitation applied to medical/surgical benefits in the relevant classification (the predominant nonquantitative treatment limitation) is the routine approval of inpatient, in-network benefits for 7 days before the patient's attending provider must submit a treatment plan. However, the plan routinely approves inpatient, in-network benefits for mental health and substance use disorder conditions for only 1 day before the patient's attending provider must submit a treatment plan (and, in doing so, does not impartially apply independent professional medical or clinical standards or apply standards to detect or prevent and prove fraud, waste, and abuse that qualify for the exceptions in paragraph (c)(4)(i)(E) of this section). In operation, therefore, the prior authorization requirement imposed on inpatient, in-network mental health and substance use disorder benefits is more restrictive than the predominant prior authorization requirement applicable to substantially all medical/surgical benefits in the inpatient, in-network classification because the practice of approving only 1 day of inpatient benefits limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to the routine 7-day approval that is given for inpatient, in-network medical/surgical benefits. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(B) Example 2 (More restrictive peer-to-peer concurrent review requirements in operation)—(*1*) Facts. A plan follows a written process for the concurrent review of all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under the process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. While the written process only requires review by the second-level reviewer to either deny or approve the request, in operation, second-level reviewers for mental health and substance use disorder benefits conduct a peer-to-peer review with a provider (acting as the authorized representative of a participant or beneficiary) before coverage of the treatment is approved. The peer-to-peer review requirement is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse. The plan does not impose a peer-to-peer review, as written or in operation, as part of the second-level review for medical/surgical benefits.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(B) (Example 2), the plan violates the rules of paragraph (c)(4)(i) of this section. The concurrent review nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits within the inpatient, in-network classification because the plan follows the concurrent review process for all medical/surgical benefits. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is that peer-to-peer review is not imposed as part of second-level review. The plan does not impartially apply independent professional medical or clinical standards or apply standards to detect or prevent and prove fraud, waste, and abuse that qualify for the exceptions in paragraph (c)(4)(i)(E) of this section. As written, the plan's concurrent review requirements are the same for medical/surgical benefits and mental health and substance use disorder benefits. However, in operation, by compelling an additional action (peer-to-peer review as part of second-level review) to access only mental health or substance use disorder benefits, the plan applies the limitation to mental health and substance use disorder benefits in a manner that is more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the inpatient, in-network classification. Because the plan violates

the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(C) Example 3 (More restrictive peer-to-peer review medical necessity standard in operation; deviation from independent professional medical and clinical standards)—(*1*) Facts. A plan generally requires that all treatment be medically necessary in the inpatient, out-of-network classification. For both medical/surgical benefits and mental health and substance use disorder benefits, the written medical necessity standards are based on independent professional medical or clinical standards that do not require peer-to-peer review. In operation, the plan covers out-of-network benefits for medical/surgical or mental health inpatient treatment outside of a hospital if the physician documents medical appropriateness, but for out-of-network benefits for substance use disorder inpatient treatment outside of a hospital, the plan requires a physician to also complete peer-to-peer review.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(C) (Example 3), the plan violates the rules of paragraph (c)(4)(i) of this section. The medical necessity nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in the inpatient, out-of-network classification. The most common or frequent variation of the nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is the requirement that a physician document medical appropriateness without peer-to-peer review. The plan purports to impartially apply independent professional medical or clinical standards that would otherwise qualify for the exception in paragraph (c)(4)(i)(E) of this section, but deviates from those standards by imposing the additional requirement to complete peer-to-peer review for inpatient, out-of-network benefits for substance use disorder outside of a hospital. Therefore, the exception in paragraph (c)(4)(i)(E) of this section does not apply. As written, the plan provisions apply the nonquantitative treatment limitation to mental health and substance use disorder benefits in the inpatient, out-of-network classification in the same manner as for medical/surgical benefits. However, in operation, the nonquantitative treatment limitation imposed with respect to out-of-network substance use disorder benefits for treatment outside of a hospital is more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification because it limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(D) Example 4 (Not comparable and more stringent methods for determining reimbursement rates in operation)—(*1*) Facts. A plan's base reimbursement rates for outpatient, in-network providers are determined based on a variety of factors, including the providers' required training, licensure, and expertise. For purposes of this example, the plan's nonquantitative treatment limitations for determining reimbursement rates for mental health and substance use disorder benefits are not more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification under paragraph (c)(4)(i) of this section. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code vary based on a combination of factors, such as the nature of the service, provider type, number of providers qualified to provide the service in a given geographic area, and market need (demand). As a result, reimbursement rates for mental health, substance use disorder, and medical/surgical benefits furnished by non-physician providers are generally less than for physician providers. In operation, the plan reduces the reimbursement rate for mental health and substance use disorder non-physician providers from that paid to mental health and substance use disorder physicians by

the same percentage for every CPT code but does not apply the same reductions for non-physician medical/surgical providers.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(D) (Example 4), the plan violates the rules of paragraph (c)(4)(ii) of this section. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate to physician providers by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services, in operation, the factors used in applying the nonquantitative treatment limitation to mental health and substance use disorder benefits are not comparable to, and are applied more stringently than, the factors used in applying the limitation with respect to medical/surgical benefits. Because the facts assume that the plan's methods for determining reimbursement rates comply with paragraph (c)(4)(i) of this section and the plan violates the rules of paragraph (c)(4)(ii) of this section, this example does not analyze compliance with paragraph (c)(4)(iv) of this section.

(E) Example 5 (Exception for impartially applied generally recognized independent professional medical or clinical standards)—(*1*) Facts. A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The medical management requirement impartially applies independent professional medical or clinical standards in a manner that qualifies for the exception in paragraph (c)(4)(i)(E) of this section. The plan does not rely on any other factors or evidentiary standards and the processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims based on the impartial application of the independent professional medical or clinical standards by the nonquantitative treatment limitation.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(E) (Example 5), the plan does not violate the rules of this paragraph (c)(4). The medical management nonquantitative treatment limitation imposed on mental health and substance use disorder benefits does not violate paragraph (c)(4)(i) or (iv) of this section because it impartially applies independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits in a manner that qualifies for the exceptions in paragraphs (c)(4)(i)(E) and (c)(4)(iv)(D) of this section, respectively. Moreover, the nonquantitative treatment limitation does not violate paragraph (c)(4)(ii) of this section because the independent professional medical or clinical standards are not considered to be a discriminatory factor or evidentiary standard under paragraph (c)(4)(ii)(B) of this section. Additionally, as written and in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, out-of-network classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying the limitation with respect to medical/surgical benefits in the classification, regardless of the fact that the application of the nonquantitative treatment limitation resulted in higher percentages of claim denials for mental health and substance use disorder benefits as compared to medical/surgical benefits.

(F) Example 6 (More restrictive prior authorization requirement; exception for impartially applied generally recognized independent professional medical or clinical standards not met)—(*1*) Facts. The provisions of a plan state that it applies independent professional medical and clinical standards (consistent with generally accepted standards of care) for setting prior authorization requirements for both medical/surgical and mental health and substance use disorder prescription drugs. The relevant generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination at each refill (every 30 days) for treatment of opioid use disorder.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(F) (Example 6), the plan violates the rules of paragraph (c)(4)(i) of this section. The plan does not qualify for the exception in paragraph (c)(4)(i)(E) of this section, because, although the provisions of the plan state that it applies independent professional medical and clinical standards, the plan deviates from the relevant standards with respect to prescription drugs to treat opioid use disorder. The prior authorization nonquantitative treatment limitation is applied to at least two-thirds of all medical/surgical benefits in the prescription drugs classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is following generally recognized independent professional medical and clinical standards (consistent with generally accepted standards of care). The prior authorization requirements imposed on substance use disorder benefits are more restrictive than the predominant nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in the classification, because the plan imposes additional requirements on substance use disorder benefits that limit access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(G) Example 7 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)—(*1*) Facts. Following an initial request by the Secretary for a plan's comparative analysis of a nonquantitative treatment limitation pursuant to § 146.137(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the relevant classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Pursuant to § 146.137(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination, and the Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). The plan receives a final determination of noncompliance from the Secretary, which informs the plan that it is not in compliance with this paragraph (c)(4) and directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the nonquantitative treatment limitation.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(G) (Example 7), the plan violates the requirements of this paragraph (c)(4) by imposing the nonquantitative treatment limitation after the Secretary directs the plan not to impose it, pursuant to paragraph (c)(4)(vii) of this section.

(H) Example 8 (Provider network admission standards not more restrictive and compliant with requirements for design and application of NQTLs)—(*1*) Facts. As part of a plan's standards for provider admission to its network, in the outpatient, in-network classification, any provider seeking to contract with the plan must have a certain number of years of supervised clinical experience. As a result of that standard, master's level mental health therapists are required to obtain supervised clinical experience beyond their licensure, while master's level medical/surgical providers, psychiatrists, and Ph.D.-level psychologists do not require additional experience beyond their licensure because their licensure already requires supervised clinical experience. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation. This includes in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). This data demonstrates that participants and beneficiaries seeking outpatient care are able to access outpatient, in-network mental health and substance use disorder providers at the same frequency as outpatient, in-network medical/surgical providers, that mental health and substance use disorder providers are active in the network and are accepting new patients to the same extent as medical/surgical providers, and that mental health and substance use disorder providers are within similar time and distances to plan participants and beneficiaries as are medical/surgical providers. This data also does not identify material differences in what the plan or issuer pays psychiatrists or non-physician mental health providers, compared to physicians or non-physician medical/surgical providers, respectively, both for the same reimbursement codes and as compared to Medicare rates.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(H) (Example 8), the plan does not violate this paragraph (c)(4). The standards for this nonquantitative treatment limitation, namely provider admission to the plan's network, are applied to at least two-thirds of all medical/surgical benefits in the outpatient, in-network classification, as it applies to all medical/surgical benefits in the classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) that applies to substantially all medical/surgical benefits in the classification is having a certain number of years of supervised clinical experience. The standards for provider admission to the plan's network that are imposed with respect to mental health or substance use disorder benefits are no more restrictive, as written or in operation, than the predominant variation of the nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in the classification, because the standards do not limit access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. The requirement that providers have a certain number of years of supervised clinical experience that the plan relied upon to design and apply the nonquantitative treatment limitation is not considered to discriminate against mental health or substance use disorder benefits, even though this results in the requirement that master's level mental health therapists obtain supervised clinical experience beyond their licensure, unlike master's level medical/surgical providers. In addition, as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification, because the plan applies the same standard to all providers in the classification.

Finally, the plan or issuer collects and evaluates relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits, which does not show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in the classification.

(I) Example 9 (More restrictive requirement for primary caregiver participation applied to ABA therapy)—(*1*) Facts. A plan generally applies medical necessity criteria in adjudicating claims for coverage of all outpatient, in-network medical/surgical and mental health and substance use disorder benefits, including ABA therapy for the treatment of ASD, which is a mental health condition. The plan's medical necessity criteria for coverage of ABA therapy requires evidence that the participant's or beneficiary's primary caregivers actively participate in ABA therapy, as documented by consistent attendance in parent, caregiver, or guardian training sessions. In adding this requirement, the plan deviates from independent professional medical or clinical standards, and there are no similar medical necessity criteria requiring evidence of primary caregiver participation in order to receive coverage of any medical/surgical benefits.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(I) (Example 9), the plan violates paragraph (c)(4)(i) of this section. The plan applies medical necessity criteria to at least two-thirds of all outpatient, in-network medical/surgical benefits, as they apply to all medical/surgical benefits in the classification. The most common or frequent variation of this nonquantitative treatment limitation (the predominant nonquantitative treatment limitation) that applies to substantially all medical/surgical benefits in the classification does not include the requirement to provide evidence that the participant's or beneficiary's primary caregivers actively participate in the treatment. The plan does not qualify for the exception in paragraph (c)(4)(i)(E) of this section in applying its restriction on coverage for ABA therapy because the plan deviates from the independent professional medical or clinical standards by imposing a different requirement. As a result, the nonquantitative treatment limitation imposed on mental health and substance use disorder benefits is more restrictive than the predominant medical necessity requirement imposed on substantially all medical/surgical benefits in the classification (which does not include the requirement to provide evidence that primary caregivers actively participate in treatment). Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(J) Example 10 (More restrictive exclusion for experimental or investigative treatment applied to ABA therapy)—(*1*) Facts. A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(J) (Example 10), the plan violates the rules of paragraph (c)(4)(i) of this section. The coverage exclusion for experimental or investigative treatment applies to at least two-thirds of all medical/surgical benefits, as it applies to all

medical/surgical benefits in the outpatient, in-network classification. The most common or frequent variation of this nonquantitative treatment limitation in the classification (the predominant nonquantitative treatment limitation) applicable to substantially all medical/surgical benefits is the exclusion under the plan for coverage of experimental treatment of medical/surgical conditions when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. In operation, the exclusion for experimental or investigative treatment imposed on ABA therapy is more restrictive than the predominant variation of the nonquantitative treatment limitation for experimental or investigative treatment imposed on substantially all medical/surgical benefits in the classification because the exclusion limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits in the same classification. Because the plan violates the rules of paragraph (c)(4)(i) of this section, this example does not analyze compliance with paragraph (c)(4)(ii) or (iv) of this section.

(K) Example 11 (Separate EAP exhaustion treatment limitation applicable only to mental health benefits)—(*1*) Facts. An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(K) (Example 11), limiting eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(vi) of this section. Additionally, this EAP would not qualify as excepted benefits under §146.145(b)(3)(vi)(B)(*1*) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) Example 12 (Separate residential exclusion treatment limitation applicable only to mental health benefits)—(*1*) Facts. A plan generally covers inpatient, in-network and inpatient out-of-network treatment in any setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan also has an exclusion for residential treatment, which the plan defines as an inpatient benefit, for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(*2*) Conclusion. In this paragraph (c)(4)(viii)(L) (Example 12), the plan violates the rules of paragraph (c)(4)(vi) of this section. Because the plan does not apply a comparable exclusion to inpatient benefits for medical/surgical conditions, the exclusion of residential treatment is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications that does not apply with respect to any medical/surgical benefits in the same benefit classification.

(M) Example 13 (Standards for provider admission to a network)—(*1*) Facts. A plan applies nonquantitative treatment limitations related to network composition in the outpatient in-network and inpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. For purposes of this example, these facts assume that these nonquantitative treatment limitations related to network composition for mental health and substance use disorder benefits are not more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classifications under paragraph (c)(4)(i) of this section. The facts also assume that, as written and in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network access to mental health or substance use disorder benefits in the outpatient in-network and inpatient in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(ii) of this section. The plan collects and evaluates all relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitations related to network composition on access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's or issuer's analysis of whether the standards, in operation, comply with paragraphs (c)(4)(i) and (ii) of this section. The plan determined that the data did not reveal any material differences in access. That data included metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates; in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions); and survey data from participants on the extent to which they forgo or pay out-of-pocket for treatment because of challenges finding in-network providers. The efforts the plan made when designing and applying its nonquantitative treatment limitations related to network composition, which ultimately led to its outcomes data not revealing any material differences in access to benefits for mental health or substance use disorders as compared with medical/surgical benefits, included making sure that the plan's service providers are making special efforts to enroll available providers, including by authorizing greater compensation or other inducements to the extent necessary, and expanding telehealth arrangements as appropriate to manage regional shortages. The plan also notifies participants in clear and prominent language on its website, employee brochures, and the summary plan description of a toll-free number available to help participants find in-network providers. In addition, when plan participants submit bills for out-of-network items and services, the plan directs their service providers to reach out to the treating providers and facilities to see if they will enroll in the network.

(*2*) Conclusion. In this paragraph (c)(4)(viii)(M) (Example 13), the plan does not violate this paragraph (c)(4). As stated in the Facts section, the plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraphs (c)(4)(i) and (ii) of this section. The plan collects and evaluates relevant data, as required under paragraph (c)(4)(iv)(A) of this section, and the data does not reveal any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as a result of the actions the plan took (as set forth in the facts) when initially designing its nonquantitative treatment limitations related to network composition. Because the plan takes comparable actions to ensure that their mental health and substance use disorder provider network is as accessible as their medical/surgical provider network and exercises careful oversight over both their service providers and the comparative robustness of the networks with

an eye to ensuring that network composition results in access to in-network benefits for mental health and substance use disorder services that is as generous as for medical/surgical services, plan participants and beneficiaries can access covered mental health and substance use disorder services and benefits as readily as medical/surgical benefits. This is reflected in the plan's carefully designed metrics and assessment of network composition.

* * * * *

(d) * * *

(3) Provisions of other law. Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, § 147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 146.137.

(e) * * *

(4) Coordination with EHB requirements. Nothing in paragraph (f) or (g) of this section or § 146.137(g) changes the requirements of §§ 147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits

required under §§ 156.110(a)(5) and 156.115(a) of this subchapter, must comply with the requirements under section 2726 of the PHS Act and its implementing regulations in this subchapter to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) In general. Except as provided in paragraph (i)(2) of this section, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025. Until the applicability date in the preceding sentence, plans and issuers are required to continue to comply with 45 CFR 146.136, revised as of October 1, 2021.

* * * * *

(j) Severability. If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

9. Add § 146.137 to read as follows:

§ 146.137 Nonquantitative treatment limitation comparative analysis requirements.

(a) Meaning of terms. Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 146.136(a)(2).

(b) In general. In the case of a group health plan (or health insurance issuer offering group health insurance coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes

any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) Comparative analysis content requirements. With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each nonquantitative treatment limitation.

(1) Description of the nonquantitative treatment limitation. The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a

list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits;

(iii) A description of which benefits are included in each classification set forth in § 146.136(c)(2)(ii)(A); and

(iv) Identification of the predominant nonquantitative treatment limitation applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant nonquantitative treatment limitation as compared to other variations, as well as how the plan identified the variations of the nonquantitative treatment limitation.

(2) Identification and definition of the factors used to design or apply the nonquantitative treatment limitation. The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of all of the factors considered, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor; and

(B) A description of each evidentiary standard (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section.

(3) Description of how factors are used in the design and application of the nonquantitative treatment limitation. The comparative analysis must include a description of how each factor identified and defined pursuant to paragraph (c)(2) of this section is used in the

design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviation(s) or variation(s).

(4) Demonstration of comparability and stringency as written. The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard, and the evaluation of relevant data as required under § 146.136(c)(4)(iv)(A), to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure

manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reason(s) for any deviation(s) or variation(s) in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviation(s) or variation(s), including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) Demonstration of comparability and stringency in operation. The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer ensures that, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the

nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation; and

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(ii) Identification of the relevant data collected and evaluated as required under § 146.136(c)(4)(iv)(A);

(iii) An evaluation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including the relevant data as required under § 146.136(c)(4)(iv)(A);

(iv) A detailed explanation of material differences in outcomes evaluated pursuant to paragraph (c)(5)(iii) of this section that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits and the bases for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(v) A discussion of any measures that have been or are being implemented by the plan or issuer to mitigate any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer is taking under § 146.136(c)(4)(iv)(B)(*1*) to address material differences to ensure compliance with § 146.136(c)(4)(i) and (ii).

(6) Findings and conclusions. The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is not (or might not be) in compliance with the requirements of § 146.136(c)(4), including any actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iv) The date of the analysis and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of each nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) Requirements related to submission of comparative analyses to the Secretary upon request—(1) Initial request by the Secretary for comparative analysis. A group health plan or health insurance issuer offering group health insurance coverage must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within

10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) Additional information required after a comparative analysis is deemed to be insufficient. In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to review the comparative analysis required in paragraph (b) of this section, the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1) of this section. Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) Initial determination of noncompliance, required action, and corrective action plan. In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 146.136(c)(4) or this section, the plan or issuer must respond to the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (b) of this section that demonstrate compliance with § 146.136(c)(4) and this section, not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) Requirement to notify participants and beneficiaries of final determination of noncompliance—(i) In general. If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 146.136(c)(4) or this section with respect to such plan or coverage. Such notice must be provided

within 7 calendar days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, and any service provider involved in the claims process.

(ii) Content of notice. The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: "Attention! The Department of Health and Human Services has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.";

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed;

(C) A summary of the Secretary's final determination that the plan or issuer is not in compliance with § 146.136(c)(4) or this section, including any provisions or practices identified as being in violation of MHPAEA, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 146.136(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has indicated that those actions, if completed, will result in compliance; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(*1*) The plan's or issuer's phone number and an email or web portal address; and

(*2*) The Center for Medicare and Medicaid Services' phone number and email or web portal address.

(iii) Manner of notice. The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an Internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) Requests for a copy of a comparative analysis. In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) Rule of construction. Nothing in this section or § 146.136 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 146.136 or this section.

(g) Applicability. The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 146.136(e), to the

extent the plan or issuer is not exempt under § 146.136(f) or (g), for plan years beginning on or after January 1, 2025.

(h) Severability. If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

9. Amend § 146.180 by:

a. Revising paragraph (a)(2);

b. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8);

c. Adding new paragraph (a)(3);

d. Revising newly redesignated paragraphs (a)(5) and (a)(7)(i) and paragraph (f)(1); and

e. Adding paragraph (f)(4)(iii).

The revisions and additions read as follows:

§146.180 Treatment of non-Federal governmental plans.

(a) * * *

(2) General rule. For plans years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, except as provided in paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(3) Sunset of election option related to parity in mental health and substance use disorder benefits. A sponsor of a non-Federal governmental plan may not newly elect to exempt its

plan(s) from the requirements described in paragraph (a)(1)(v) of this section on or after December 29, 2022.

* * * * *

(5) Examples – (i) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1 of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(ii) Example 2. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to 5 plan years, October 1, 2009 through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraphs (a)(1)(i) through (iii) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

* * * * *

(7) * * *

(i) Subject to paragraph (a)(7)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

* * * * *

(f) * * *

(1) Election renewal. A plan sponsor may renew an election under this section through subsequent elections. Notwithstanding the previous sentence and except as provided in paragraph (f)(4)(iii) of this section, an election with respect to the requirements described in paragraph (a)(1)(v) of this section expiring on or after June 27, 2023, may not be renewed. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

* * * * *

(4) * * *

(iii) In the case of a plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to the requirements described in paragraph (a)(1)(v) of this section in effect as of December 29, 2022, that expires on or after June 27, 2023, the plan may extend such election until the date on which the term of the last such agreement expires.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

10. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

11. Revise § 147.160 to read as follows:

§ 147.160 Parity in mental health and substance use disorder benefits.

(a) In general. The provisions of §§ 146.136 and 146.137 of this subchapter apply to individual health insurance coverage offered by a health insurance issuer in the same manner and

to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) Applicability date. The provisions of this section apply for policy years beginning on or after January 1, 2026. Until the applicability date in the preceding sentence, issuers are required to continue to comply with 45 CFR 147.160, revised as of October 1, 2021. This section applies to non-grandfathered and grandfathered health plans as defined in § 147.140.

[FR Doc. 2023-15945 Filed: 7/31/2023 8:45 am; Publication Date: 8/3/2023]