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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2015–HA–0109]

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TRICARE; Mental Health and Substance Use Disorder Treatment

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This final rule modifies the TRICARE regulation to reduce administrative barriers to access to mental health benefit coverage and to improve access to substance use disorder (SUD) treatment for TRICARE beneficiaries, consistent with earlier Department of Defense and Institute of Medicine recommendations, current standards of practice in mental health and addiction medicine, and governing laws. This rule seeks to eliminate unnecessary quantitative and non-quantitative treatment limitations on SUD and mental health benefit coverage and align beneficiary cost-sharing for mental health and SUD benefits with those applicable to medical/surgical benefits, expand covered mental health and SUD treatment under TRICARE to include coverage of intensive outpatient programs and treatment of opioid use disorder and to streamline the requirements for mental health and SUD institutional providers to become TRICARE authorized providers, and to develop TRICARE reimbursement methodologies for newly recognized mental health and SUD intensive outpatient programs and opioid treatment programs.

DATES: This rule is effective [insert 30 days from date of publication in the *Federal Register*].

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Final Rule

1. The Need for the Regulatory Action

This final rule updates TRICARE mental health and substance use disorder benefits, consistent with earlier Department of Defense and Institute of Medicine recommendations, current standards of practice in mental health and addiction medicine, and our governing laws. The Department of Defense remains intently focused on supporting the mental health of our service members and their families, as this continues to be a top priority. The Department is also working to further de-stigmatize mental health treatment and expand the ways by which our beneficiaries can access authorized mental health services. This regulatory action eliminates unnecessary requirements that may be viewed as barriers to medically necessary and appropriate mental health services.

This rule has four main objectives: (a) to eliminate unnecessary quantitative and non-quantitative treatment limitations on SUD and mental health benefit coverage and align beneficiary cost-sharing for mental health and SUD benefits with those applicable to medical/surgical benefits; (b) to expand covered mental health and SUD treatment under TRICARE, to include coverage of intensive outpatient programs and treatment of opioid use disorder; (c) to streamline the requirements for mental health and SUD institutional providers to become TRICARE authorized providers; and (d) to develop TRICARE reimbursement methodologies for newly recognized mental health and SUD intensive outpatient programs and

opioid treatment programs.

(a) *Eliminating Unnecessary Quantitative and Non-Quantitative Treatment Limitations on SUD and Mental Health Benefit Coverage and Aligning Beneficiary Cost-Sharing for Mental Health and SUD Benefits with those Applicable to Medical/Surgical Benefits.*

The requirements of the Mental Health Parity Act (MHPA) of 1996 and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008, as well as the plan benefit provisions contained in the Patient Protection and Affordable Care Act (PPACA) do not apply to the TRICARE program. The provisions of MHPAEA and PPACA served as models for TRICARE in proposing changes to existing benefit coverage. These changes are intended to reduce administrative barriers to treatment and increase access to medically or psychologically necessary mental health care consistent with TRICARE statutory authority and program design.

Section 703 of the National Defense Authorization Act (NDAA) National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015, signed into law December 19, 2014, amended section 1079 of title 10 of the U.S.C. to remove prior existing statutory limits and requirements on TRICARE coverage of inpatient mental health services. This rule is necessary to conform the regulation to provisions in the enacted law. Specifically, TRICARE coverage is no longer subject to an annual limit on stays in inpatient mental health facilities of 30 days for adults and 45 days for children. In addition, TRICARE coverage is no longer subject to a 150-day annual limit for stays at Residential Treatment Centers (RTCs) for eligible beneficiaries.

In addition to the elimination of these statutory inpatient day limits and corresponding waiver provisions, the rule will also eliminate other unnecessary quantitative and non-quantitative treatment limitations, consistent with principles of mental health parity and our governing laws.

Additionally, this rulemaking will remove the categorical exclusion on treatment of gender dysphoria. This change will permit coverage of all non-surgical medically necessary and appropriate care in the treatment of gender dysphoria, consistent with the program requirements applicable for treatment of all mental or physical illnesses. Surgical care remains prohibited by statute at 10 U.S.C. 1079(a)(11), as discussed further below.

Finally, following the recent repeal (section 703 of the NDAA for FY 15) of the statutory authority (previously codified at 10 U.S.C. 1079(i)(2)) for separate beneficiary financial liability for mental health benefits, the rule revises the cost-sharing requirements for mental health and SUD benefits to be consistent with those that are applicable to TRICARE medical and surgical benefits.

(b) Expanding Coverage to Include Mental Health and SUD Intensive Outpatient Programs and Treatment of Opioid Use Disorder.

Previously, TRICARE benefits did not fully reflect the full range of contemporary SUD treatment approaches (i.e., outpatient counseling and intensive outpatient program (IOP)) that are now endorsed by the American Society of Addiction Medicine (ASAM), the Department of Health and Human Services (DHHS) Substance Abuse and Mental Health Services Administration (SAMHSA), and the VA/DoD Clinical Practice Guidelines (CPGs) for SUDs.

An amendment to the regulation was necessary to authorize TRICARE benefit coverage of medically and psychologically necessary services and supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of mental disorders. TRICARE coverage of medication assisted treatment (MAT) for opioid use disorder, extended through regulatory revisions, as published in the Federal Register on October 22, 2013 (78 FR 62427), was previously limited to MAT provided by a TRICARE authorized SUDRF. This revision of the TRICARE SUD

treatment benefit allows office-based opioid treatment (OBOT) by individual TRICARE-authorized physicians and adds coverage of qualified opioid treatment programs (OTPs) as TRICARE authorized institutional providers of SUD treatment for opioid use disorder.

(c) *Streamlining Requirements for Institutional Mental Health and SUD Providers to become TRICARE Authorized Providers.*

While TRICARE's comprehensive certification standards were once considered necessary to ensure quality and safety, these comprehensive certification requirements proved to be overly restrictive and at times inconsistent with current industry-based institutional provider standards and organization. There are currently several geographic areas that are inadequately served because providers in those regions did not meet TRICARE certification requirements, though they may have met the industry standard. This final rule will streamline TRICARE regulations to be consistent with industry standards for authorization of qualified institutional providers of mental health and SUD treatment. It is anticipated that these revisions will result in an increase in the number and geographic coverage areas of participating institutional providers of mental health and SUD treatment for TRICARE beneficiaries.

(d) *TRICARE Reimbursement Methodologies for Newly Recognized Mental Health and SUD Intensive Outpatient Programs and Opioid Treatment Programs.*

Along with recognition of several new categories of TRICARE authorized providers, this rule establishes reimbursement methodologies for these providers. Specifically, new reimbursement methodologies are instituted for IOPs for mental health and SUD treatment as well as OTPs, as these providers had not previously been recognized by TRICARE and thus appropriate reimbursement methodologies must be established. Existing reimbursement methodologies for SUDRFs, RTCs, and PHPs will continue to apply.

2. Legal Authority for the Regulatory Action

The legal authority for this final rule is 10 U.S.C., section 1073, which authorizes the Secretary of Defense to make decisions concerning TRICARE and to administer the medical and dental benefits provided in title 10 U.S.C., chapter 55. The Department is authorized to provide medically necessary and appropriate medical care for mental and physical illnesses, injuries and bodily malfunctions, including hospitalization, outpatient care, drugs, and treatment of mental health conditions under 10 U.S.C. 1077(a)(1) through (3) and (5). Although section 1077 identifies the types of health care to be provided in military treatment facilities (MTFs) to those authorized such care under section 1076, these same types of health care (with certain specified exceptions) are authorized for coverage within the civilian health care sector for ADFMs under section 1079 and for retirees and their dependents under section 1086. In general, the scope of TRICARE benefits covered within the civilian health care sector and the TRICARE authorized providers of those benefits are found at 32 CFR 199.4 and 199.6, respectively.

TRICARE beneficiary cost-sharing is governed by statute and regulation based upon both the beneficiary category and TRICARE option being utilized. With the recent repeal of the statutory authority (previously codified at 10 U.S.C. 1079(i)(2)) for separate beneficiary financial liability for mental health benefits, this final rule revises the cost-sharing requirements for mental health and SUD benefits to be consistent with those that are applicable to TRICARE medical and surgical benefits.

With respect to institutional provider reimbursement, pursuant to 10 U.S.C. 1079(i)(2), the Secretary is required to publish regulations establishing the amount to be paid to any provider of services, including hospitals, comprehensive outpatient rehabilitation facilities, and any other institutional facility providing services for which payment may be made. The amount of such payments shall be determined, to the extent practicable, in accordance with the same

reimbursement rules as apply to payments to providers of services of the same type under Medicare. TRICARE provider reimbursement methods are found at 32 CFR 199.14. When it is not practicable to adopt Medicare's methods or Medicare has no established reimbursement methodology (e.g. Medicare does not reimburse freestanding SUDRFs or PHPs that are not hospital-based or part of a Community Mental Health Clinic, while TRICARE does), TRICARE establishes its own rates through proposed and final rulemaking.

B. Summary of the Major Provisions of the Final Rule

1. Eliminating Unnecessary Quantitative and Non-Quantitative Treatment Limitations on SUD and Mental Health Benefit Coverage and Aligning Beneficiary Cost-Sharing for Mental Health and SUD Benefits with those Applicable to Medical/Surgical Benefits.

This final rule makes a number of comprehensive revisions to the TRICARE mental health and SUD treatment coverage. In an effort to further de-stigmatize SUD care, treatment of SUDs is no longer separately identified as a limited special benefit under 32 CFR 199.4(e) but rather has now been incorporated into the general mental health provisions in § 199.4(b) governing institutional benefits and § 199.4(c) governing professional service benefits. Further, this rule eliminates a number of mental health and SUD quantitative and non-quantitative treatment limitations, and corresponding waiver provisions, instead relying on determinations of medical necessity and appropriate utilization management tools, as are used for all other medical and surgical benefits. Proposed revisions include eliminating:

- All inpatient mental health day limits, following the statutory revisions to 10 U.S.C. 1079;
- The 60-day partial hospitalization and SUDRF residential treatment limitations;
- Annual and lifetime limitations on SUD treatment;

- Presumptive limitations on outpatient services including the six-hours per year limit on psychological testing; the limit of two sessions per week for outpatient therapy; and limits for family therapy (15 visits) and outpatient therapy (60 visits) provided in free-standing or hospital based SUDRFs;
- The limit of two smoking cessation quit attempts in a consecutive 12 month period and 18 face-to-face counseling sessions per attempt; and
- The regulatory prohibition that categorically excludes all treatment of gender dysphoria.

The rule also changes cost-sharing for mental health treatment for TRICARE Prime and Standard/Extra beneficiaries to align with the applicable cost-sharing provisions for other non-mental health inpatient and outpatient benefits. Additionally, revisions clearly identify services that will be cost-shared on an inpatient (e.g., inpatient admissions to a hospital, residential treatment center, SUDRF residential treatment program, or skilled nursing facility) versus outpatient (including partial hospitalization programs, intensive outpatient treatment services, and opioid treatment program services) cost-sharing basis to ensure consistency with the statutory requirements in 10 U.S.C. 1079 and 1086. In many cases, these modifications to cost-sharing will enhance TRICARE beneficiary access to care through lower out-of-pocket costs.

2. Expanding Coverage to Include Mental Health and SUD Intensive Outpatient Programs and Treatment of Opioid Use Disorder.

The regulatory language defines and authorizes new services by TRICARE authorized institutional and individual providers of SUD care outside of SUDRF settings at §199.2 and 199.6. Revisions to treatment benefits at § 199.4 and § 199.6 will allow intensive outpatient programs (IOPs) for mental health and SUD treatment; care in opioid treatment programs (OTPs); and outpatient SUD treatment (i.e., office-based opioid treatment, psychosocial treatment and family therapy) by individual TRICARE authorized providers.

3. Streamlining Requirements for Institutional Mental Health and SUD Providers to become TRICARE Authorized Providers.

Significant revisions to 32 CFR 199.6 eliminate the administratively burdensome provider certification process and streamline approval for institutional mental health and SUD providers to become TRICARE authorized providers. In multiple regions providers may meet industry standards but do not meet TRICARE certification requirements. Consequently, providers in these regions were unable to serve TRICARE beneficiaries. The applicable provisions for residential treatment centers, psychiatric and SUD partial hospitalization programs, and SUDRFs, have been rewritten in their entirety to address institutional provider eligibility, organization and administration, participation agreement requirements and any other requirements for approval as a TRICARE authorized provider. The requirement and formal process of certification will be eliminated. Similarly, new regulatory provisions for the newly recognized categories of institutional providers, namely IOPs and OTPs are instituted.

4. TRICARE Reimbursement Methodologies for Newly Recognized Mental Health and SUD Intensive Outpatient Programs and Opioid Treatment Programs.

Finally, amendments to 32 CFR 199.14, which specifies provider reimbursement methods, establish allowable all-inclusive per diem payment rates for psychiatric and SUD, PHP, IOP and OTP services.

C. Costs and Benefits

The amendment is not anticipated to have an annual effect on the economy of \$100 million or more. An independent government cost estimate found that this rule is estimated to have a net increase in costs of approximately \$58 million. The government's regulatory impact analysis based on this cost estimate can be found in the docket folder associated with this proposed rule [at DOD-2015-HA-0109]. To summarize, provisions to implement mental health parity account for

approximately \$36 million (62%) of the \$58 million net cost increase. While modifying mental health cost-sharing will increase costs, these revisions are required as the former statutory authority for mental health-specific cost sharing has been deleted from the statute (section 703 of the NDAA for FY15). As a result, the existing statutory cost-shares are utilized and this aligns mental health cost-shares with the current medical-surgical cost-shares. The largest cost increase (\$21.6 million) is attributable to lowering outpatient mental health cost-sharing for Non-Active Duty Dependent (NADD) TRICARE beneficiaries (from \$25 per visit to the medical/surgical outpatient cost-sharing of \$12 per visit).

Elimination of the statutory day limits for inpatient psychiatric and Residential Treatment Center (RTC) care for children (to comply with section 703 of the NDAA for FY15) will only minimally increase costs. This is because these previously published presumptive day limits were also subject to waivers and TRICARE had been reimbursing for medically necessary inpatient stays with waivers when continued medical necessity was supported. Eliminating the limit of two sessions per week for outpatient therapy is estimated to incur an increased cost (\$7.5 million), but this is based on the conservative assumption that the proportion of NADD beneficiaries who will pursue three psychotherapy sessions per week is comparable to the proportion of Active Duty Service Members (ADSMs) who do so (17%), even though ADSMs incur no cost-sharing and most receive psychotherapy within MTFs instead of civilian providers. Eliminating other limits (e.g., annual and lifetime limits on SUD treatment, smoking cessation program limits, and others as outlined above) will have a relatively minimal increase in costs. Overall, the benefit of removing these quantitative limits to mental health treatment will ensure that all beneficiaries receive the appropriate amount of care based on medical and psychological necessity.

Creating additional levels, providers, and types of mental health care (e.g., intensive outpatient programs, opioid treatment programs, non-surgical coverage for gender dysphoria,

and also allowing outpatient substance use treatment) will increase costs to the program by approximately \$19 million. Some of the cost increases will be offset through utilization of lower and less expensive levels of care (e.g., IOP versus residential or full day PHP) and prevention of relapse requiring more costly, intensive inpatient intervention. Previously, PHPs were the only step-down care from inpatient substance use disorder treatment covered by TRICARE. In many rural and sparsely-populated states, there are relatively few PHPs (on average 20 or fewer, with 4 states having fewer than 10 PHPs). IOPs in these rural states, on the other hand, are four times more plentiful than PHPs, and TRICARE coverage of IOP substance use disorder treatment will greatly increase beneficiary access to SUD treatment, particularly in these remote geographic areas. Coverage of outpatient SUD treatment by TRICARE authorized individual providers will facilitate early intervention for SUDs and help reduce relapse following more intensive treatment through the availability of outpatient aftercare from these professionals.

Additionally, TRICARE currently has an estimated 15,000 to 20,000 beneficiaries with opioid use disorder who, under the previous benefit, could not access medication-assisted treatment (MAT; e.g., buprenorphine or methadone). According to SAMHSA, there are approximately 1400 OTPs in the United States and 31,363 physicians with a DEA waiver to provide MAT for opioid use disorder, but none of these facilities or providers is TRICARE-authorized or eligible to be reimbursed by TRICARE under current regulation. Under these regulatory changes, TRICARE beneficiaries will have ready access to MAT on an outpatient basis as recommended by ASAM and clinical practice guidelines developed jointly by the Department of Veterans Affairs (VA) and DoD.

Streamlining requirements for institutional providers to become TRICARE authorized providers of mental health and SUD care will incur an estimated increased cost of \$3.2 million due to an anticipated increase in the number of institutional providers joining the TRICARE

network. To focus on RTC care as an example, TRICARE strives to provide a robust mental health treatment benefit to our child beneficiaries, but access to RTC care for children is significantly limited in many geographic areas by TRICARE's existing certification requirements. Less than one sixth of RTCs accredited by the Joint Commission are currently TRICARE certified, and only about one half of individual states have at least one TRICARE certified RTC. Revising TRICARE institutional provider authorization requirements for RTCs will make it much more likely that parents will seek RTC care for their children whose behavioral health condition is so severe as to require RTC services, and this change to the TRICARE behavioral health benefit is projected to increase utilization of RTC services by 20 percent. Ultimately, the net increase in costs associated with this final rule will greatly be outweighed by the enhanced mental health benefits, options and access available to beneficiaries.

D. Public Comments

On February 1, 2016 (81 FR 5061-5086), the Office of the Secretary of Defense published a proposed rule for a 60-day public comment period, and provided an opportunity to comment on implementing changes to TRICARE benefits. As a result of publication of the proposed rule, DoD received 290 comments. A large majority of commenters expressed overwhelming support for the rule change, while others expressed concerns about the cost and necessity of the proposed changes. We thank all those who provided comments. Specific matters raised by those who submitted comments are summarized below in the appropriate sections of the preamble.

II. Provisions of the Rule Regarding Eliminating Unnecessary Quantitative and Non-Quantitative Treatment Limitations on SUD and Mental Health Benefit Coverage and Aligning Beneficiary Cost-Sharing for Mental Health and SUD Benefits with Those Applicable to Medical/Surgical Benefits

A. Eliminating Unnecessary Quantitative and Non-Quantitative Treatment Limitations on SUD and Mental Health Benefit Coverage

1. Provisions of the Proposed Rule. This final rule will remove a number of unnecessary quantitative and non-quantitative limits for coverage of mental health and SUD care under the TRICARE Program, including:

- All inpatient mental health day (30 days maximum for adults and 45 days maximum for children at 32 CFR 199.4(b)(9)) and annual day limits (150 days at 32 CFR 199.4(b)(8)) for RTC care for beneficiaries 21 years and younger, following the statutory revisions to 10 U.S.C. 1079;
- The 60-day limitation on partial hospitalization (32 CFR 199.4(b)(10)(iv)) and SUDRF residential treatment (32 CFR 199.4(e)(4)(ii)(A));
- Annual (60 days in a benefit period) and lifetime (three treatment episodes – 32 CFR 199.4(e)(4)(ii)) limitations on SUD treatment;
- Presumptive limitations on outpatient services including the six-hour per year limit on psychological testing (32 CFR 199.4(c)(3)(ix)(A)(5)) and the limit of two sessions per week for outpatient therapy (32 CFR 199.4(c)(3)(ix)(B));
- Limits on family therapy (15 visits (32 CFR 199.4(e)(4)(ii)(C)) and outpatient therapy (60 visits - (32 CFR 199.4(e)(4)(ii)(B)) provided in free-standing or hospital based SUDRFs; and
- The limit of two smoking cessation quit attempts in a consecutive 12 month period and 18 face-to-face counseling sessions per attempt (32 CFR 199.4(e)(30)).

This rule will also allow coverage of outpatient treatment that is medically or psychologically necessary, including psychotherapy, family therapy and other covered diagnostic and therapeutic services, by a TRICARE authorized institutional provider or by authorized individual mental health providers without limits on the number of treatment sessions. All claims submitted for services under TRICARE remain subject to review for quality and appropriate

utilization in accordance with the Quality and Utilization Review Peer Review Organization Program, under 10 U.S.C. 1079(n) and 32 CFR 199.15.

The rule also removes certain regulatory exclusions for the treatment of gender dysphoria for TRICARE beneficiaries who are diagnosed by a TRICARE authorized provider, practicing within the scope of his or her license, to be suffering from a mental disorder, as defined in 32 CFR. 199.2. It is no longer justifiable to categorically exclude and not cover currently accepted medically and psychologically necessary treatments for gender dysphoria (such as psychotherapy, pharmacotherapy, and hormone replacement therapy) that are not otherwise excluded by statute. (Section 1079(a)(11) of title 10, U.S.C., excludes from CHAMPUS coverage surgery which improves physical appearance but is not expected to significantly restore functions, including mammary augmentation, face lifts, and sex gender changes.)

2. Analysis of Major Public Comments. Many commenters expressed strong support for the removal of presumptive quantitative limitations on mental health treatment benefits, such as elimination of inpatient mental health day limits, the previous six hours per year limit on psychological testing, the limit of two sessions per week for outpatient therapy, and the limit of two smoking cessation quit attempts in a consecutive 12 month period. One commenter specifically suggested a raised limit on the number of smoking cessation quit attempts in a consecutive 12 month period. There was also one specific expression of support for the inclusion of music therapy as an ancillary therapy. One commenter noted that individuals with substance use disorders should be allowed only one treatment episode, and subsequent to this, benefit coverage for SUD treatment should be suspended.

Response. We appreciate the overwhelming support for these proposed changes which will reduce unnecessary administrative barriers and ensure ready access to medically necessary care for our beneficiaries. In response to the general concerns regarding cost and necessity for the

proposed changes we would emphasize that while specific, presumptive quantitative treatment limitations have been eliminated, mental health and SUD care will still be reviewed for continued medical necessity and subject to utilization management review, as is all care under the TRICARE program. We believe this approach provides an appropriate balance between reducing administrative barriers to care while still ensuring appropriate utilization. Regarding allowance of only one treatment episode for SUD care, this is far less than the Department's previous allowance of three episodes of treatment for SUD care. The removal of these limitations recognizes that SUDs are chronic conditions with periodic phases of relapse and readmission, often requiring multiple interventions over several years to achieve full remission. With respect to the suggestion to raise the limit on smoking cessation quit attempts, the Department's approach of eliminating all presumptive quantitative limitations makes such a recommendation unnecessary. Finally, with respect to music therapy, we would note that while it is not recognized as a primary mental health or SUD treatment modality, it remains a covered ancillary therapy benefit solely when provided in the context of an approved inpatient, SUDRF, residential treatment, partial hospitalization, or intensive outpatient program treatment plan and under the clinical supervision of a qualified mental health professional.

Comment. Multiple national organizations sent comments requesting a definition of the term "qualitative" treatment limits as used in the proposed rule to be consistent with the MHPAEA, citing that the MHPAEA uses only the terms "quantitative" and "non-quantitative" treatment limits. While applauding TRICARE's removal of quantitative treatment limits (QTLs), some argued that the rule should go farther to achieve parity in accordance with the MHPAEA, and cited sections of regulation they perceived as non-quantitative treatment limitations (NQTLs) that are inconsistent with the MHPAEA, such as those: requiring utilization review, quality assurance and reauthorization for inpatient mental health services and partial

hospitalization at 199.4(a)(11) and (12); outlining medical necessity criteria for institutional providers of mental health treatment at 199.4(b); and, providing descriptions and requirements for mental health providers at 199.6(b) that were perceived as more detailed than those for medical/surgical settings. Several commenters also suggested that since compliance with the letter and the spirit of mental health parity rules has been inconsistent, that TRICARE issue clear guidance regarding enforcement of its requirements as well as establish a systemized way of collecting information from medical providers and enrollees about compliance. Several other commenters specifically requested that the final rule explicitly require issuers and plans to perform a compliance review of the plan or issuer's financial requirements regarding QTLs and NQTLs applied by the plan or issuer; and require plans and issuers to provide documentation that illustrates how the health plan has determined the financial requirements, QTLs and/or NQTLs are in compliance. Finally, one commenter noted that while they understood that TRICARE was not subject to the MHPAEA statute, they were not aware of any statutory prohibition which would preclude a complete modeling of its MH/SUD benefits with MHPAEA's qualitative, or NQTL, treatment limitation requirements.

Response. The Department appreciates the comments regarding "qualitative" or "non-quantitative" treatment limitations (NQTLs) and apologizes for any confusion created in the proposed rule by not following the same terminology used in the MHPAEA. In this final rule, the term "non-quantitative" has been substituted for "qualitative" for clarity and consistency. The Department believes that it is important to note that TRICARE is a program of medical benefits provided by the U.S. Government under public law to specified categories of individuals who are qualified for those benefits by virtue of their relationship to one of the seven Uniformed Services. In response to the public comments citing general challenges with plan disclosure requirements and problems with noncompliance and inconsistent application of

NQTLs by issuers and plans subject to the MHPAEA, the Department stresses that TRICARE is a statutory entitlement program; it is not health insurance and it is not administered through issuers or plans. As addressed in greater detail in the supplementary information background section of the proposed rule, TRICARE is not a group health plan subject to the MHPA of 1996, the MHPAEA of 2008, or the Health Care Reconciliation Act of 2010. Unlike private insurers, TRICARE is a federal entitlement program of uniform benefits, as outlined in law and regulations, for eligible beneficiaries. Benefit design is dictated by federal statute and regulation, as are patient deductibles and cost-sharing, provider reimbursement, and the rules and procedures regarding quality and utilization review. Further, federal regulations at 32 CFR 199.10 set forth the policies and procedures for appealing decisions. Therefore, while the provisions of these acts served as a model for TRICARE in proposing changes to existing benefit coverage so as to reduce unnecessary administrative barriers to treatment and increase access to medically necessary mental health care consistent with TRICARE statutory authority, the Department does not believe it is necessary or appropriate to incorporate into the TRICARE regulation suggested enforcement provisions applicable to issuers and plans.

We would also like to respond to the specific comments and recommendations we received that suggested additional revisions to existing TRICARE regulatory provisions could be made to achieve greater alignment and parity with medical/surgical benefits. First, one commenter suggested that the preauthorization, utilization review and quality assurance requirements for mental health care at § 199.4(a)(11) and (12) constitute NQTLs and should be eliminated. The Department emphasizes that all health care services for which reimbursement is sought under TRICARE are subject to review for quality of care and appropriateness of utilization as required by statute, 10 U.S.C. 1079(n). TRICARE's Quality and Utilization Review Peer Review Organization Program at 32 CFR 199.15 prescribes the objectives,

requirements and procedures for how TRICARE addresses quality assurance, reauthorization and other utilization review practices for all health care services, including medical and surgical care. With that said, the Department is committed to removing unnecessary quantitative and non-quantitative treatment limitations and simplifying our regulations where it makes sense. In reviewing the existing regulatory language in § 199.4(a)(11) and (12), we agree that the language is unnecessary and should be eliminated. With the remaining regulatory provisions that are applicable to all covered services, including both medical/surgical as well as mental health/SUD, there is no need to separately address quality and utilization review of mental health services. Therefore, within § 199.4, the parenthetical reference to utilization and quality review of mental health services in paragraph (a)(11) has been removed. Additionally, paragraph (a)(12) regarding utilization and quality review specifically for inpatient mental health and partial hospitalization has been removed and the paragraph reserved.

Additionally, the same commenter raised concerns that specific medical necessity criteria were included within the regulatory language under § 199.4 for mental health and SUD services while similar medical necessity criteria were not specified for medical/surgical services and settings. While the Department appreciates the comment, we have elected to retain this regulatory language as having these medical necessity criteria in regulation is instructive and informative for all stakeholders in administering the TRICARE benefit. Further, we do not believe these criteria are discriminatory or unnecessary but rather are reflective of the overarching statutory requirement that care be medically necessary and appropriate. These terms (“medically or psychologically necessary” and “appropriate medical care”) are further defined in regulation at § 199.2. These same requirements apply to TRICARE medical and surgical benefits. The language where included in § 199.4 is specifically tailored to address medically necessity in that context, particularly with respect to the different levels of care that are available

for the treatment of mental health and SUD that do not have a corresponding medical or surgical counterpart. The Department has also sought to strike an appropriate balance between eliminating unnecessary language and regulatory provisions while at the same time ensuring transparency in program administration.

Regarding comments that the Department set forth more elaborate descriptions and requirements for mental health institutional providers than for medical/surgical settings, a major objective of this rule has been to achieve significant streamlining of the descriptions and requirements for TRICARE authorization of institutional mental health care providers under §§ 199.6(b)(4)(vii) (RTCs), 199.6(b)(4)(xii) (PHPs), and 199.6(b)(4)(xiv) (SUDRFs) and we believe we have achieved that objective. The proposed revisions which are finalized in this rule have eliminated a large portion of the existing descriptions and requirements for existing mental health/SUD institutional providers. For each type of provider, the amended regulation includes a definition/general description of the type of institutional provider and eligibility requirements including licensing, accreditation, a written participation agreement and adherence to general TRICARE requirements. We have eliminated the elaborate descriptions that are contained in the existing regulations regarding such things as the organization of the facility and specific qualifications of the governing body (including the facility's Chief Executive Officer, Clinical Director, Medical Director and Medical or professional staff organization), staff composition, staff qualifications, admission process, assessments, treatment planning, discharge and transition planning, standards for physical plant and environment and a variety of other requirements that we believe are more appropriately satisfied through a national accreditation process. Similarly, we have also eliminated the requirements regarding capacity (30 percent) and length of time licensed and at full operational status (6 months) for OTPs, RTCs, PHPs, IOPs, and SUDRFs.

Furthermore, we would note the general requirement in § 199.6(a)(8)(i) that all

institutional providers must be participating providers under TRICARE. Hospitals (whether providing medical/surgical and/or mental health/SUD care) that are certified and participating under Medicare are deemed to meet TRICARE requirements and are not required to request TRICARE approval formally. (See § 199.6(b)(3).) Section 199.6 lists a variety of additional institutional providers, some of the medical/surgical variety (including, for example, skilled nursing facilities, freestanding ambulatory surgery centers, birthing centers, hospice programs, and home health agencies) and others that are mental health and SUD providers, which require specific approval to become TRICARE authorized institutional providers.

With respect to comments about specific requirements for inclusion in participation agreements, all institutional providers are required, under § 199.6(8)(i)(A), to be a participating provider under TRICARE, and the general provisions that must be included in the agreement are outlined in regulation at § 199.6(a)(13) and are equally applicable to medical/surgical and mental health/SUD institutional providers. In general, we believe the specific requirements outlined in § 199.6(b) are reflective of the general participation agreement requirements and simply tailored to the particular type of provider (so for instance, when requiring that the participating provider agree to accept the determined allowable amount, the regulatory provisions cross reference to the applicable reimbursement methodology for that type of provider). Again, we have sought to balance the competing interests of streamlining our regulations to the extent practicable with ease of reference for the reader, coupled with our commitment to ensuring transparency in program requirements. Further, these participation agreements ensure providers accept assignment on TRICARE claims, thereby protecting our beneficiaries from financial liability above their applicable deductibles and cost-shares, and ensure compliance with applicable program requirements in support of the provision of safe, quality care to our beneficiaries.

Additionally, while we wanted to address the general mental health parity comments here,

several of the specific requirements for mental health and SUD institutional providers contained in § 199.6 and referenced in public comments are more appropriately addressed below in the following sections.

Comment. Nineteen respondents expressed strong objection to the addition of benefit coverage for the diagnosis of gender dysphoria citing cost concerns and an inappropriate use of taxpayer funds. Several commenters expressed concerns about impact on military units and military readiness resulting from the treatment of transgender Service Members. Sixteen respondents commented in support of the proposed rule's addition of benefit coverage for psychological and medical care for gender dysphoria. Four respondents expressed objection to surgical coverage of gender dysphoria under the proposed rule. Two commenters expressed objection based on the conscience rights and first amendment liberties of those who work in the healthcare field and urged the retention of the regulatory exclusion as the diagnosis and treatment of gender dysphoria remains medically controversial. Conversely, several national organizations cited support for the addition of benefit coverage for the diagnosis of gender dysphoria but expressed significant objection to the exclusion of surgical treatment for gender dysphoria.

Response. The Department proposed to remove the exclusion on non-surgical treatment of gender dysphoria as it is no longer justifiable to categorically exclude and not cover current medical and psychologically necessary and appropriate proven treatments that are not otherwise excluded by law. Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, origin, sex, disability, or age (consistent with the scope of Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975). HHS recently released a final rule implementing Section 1557. That rule prohibits discrimination based on gender identity (incident to the Title IX ban on sex discrimination) in health programs. The rule by its terms applies only to HHS

programs, but the statute applies to all federal health programs, and DoD considers these portions (45 CFR 92.206, 92.207) of the HHS rule relevant guidance for purposes of administering TRICARE. Notably, the HHS regulation does not say plans must cover all gender transition related health care, just that they should not exclude all coverage for gender dysphoria, a mental health diagnosis established in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). DoD agrees that to the extent the Department has discretion, prevailing medical assessments and nondiscrimination principles call for removal of this categorical exclusion. With respect to the public comments regarding military readiness, we would note that this TRICARE rule does not control policies and practices regarding treatment of gender dysphoria in Active Duty Service Members. Additionally, there is nothing in this rule that requires providers to render care against their beliefs. Existing policies allow DoD providers who, as a matter of conscience or moral principle, do not wish to provide psychotherapy, psychopharmacological, or hormone treatment, to request excusal from any such involvement. Regarding commenters' concerns about the cost of non-surgical treatment of gender dysphoria, the Department does not believe cost estimates are at all substantial or out of line with treatment of other medical or psychological conditions covered by TRICARE and most health plans.

Surgical coverage of gender dysphoria was not included in the proposed rule, is not included in this final rule, and remains prohibited by statute at 10 U.S.C. 1079(a)(11). Several commenters argued the rule did not go far enough and others suggested the Department reconsider including coverage for transgender surgeries. Several argued the statutory exclusion was otherwise not applicable or ambiguous, must be interpreted in accordance with modern medical science and contemporary standards of care, and thus should not be read to exclude medically necessary surgical care to treat gender dysphoria. The pertinent statutory provision (10 U.S.C. 1079(a)(11)) states: "Surgery which improves physical appearance but is not expected to

significantly restore functions (including mammary augmentation, face lifts, and sex gender changes) may not be provided. . . .” The statute lists three exceptions – breast reconstructive surgery following a mastectomy, reconstructive surgery to correct serious deformities caused by congenital anomalies or accidental injuries, and neoplastic surgery. Some commenters believed that DoD could disregard the listing of “sex gender changes” in the parenthetical examples of surgery “which improves physical appearance but is not expected to significantly restore functions” because it is contrary to modern medical assessment and because they believe there is Supreme Court precedent¹ for disregarding a parenthetical example misaligned with the proposition for which it is listed as an example. However, in that Supreme Court case, the Court concluded that the parenthetical example at issue was “a drafting mistake”— “an example that Congress included inadvertently” – resulting from a failure to make conforming adjustments as changes in the draft legislation were made through the process.² That circumstance does not apply to the statutory provision at issue here. Commenters did not provide any other justification that allows DoD to disregard this unambiguous specification. While some commenters have argued that sex-gender changes should not be considered cosmetic, elective or unnecessary, and should be seen as surgery to significantly restore areas of social, psychological and physical functioning that may have been impaired by gender dysphoria, the statutory language itself is focused on restoring function of the body part upon which surgery is performed. As noted above, Congress has enacted several exceptions to the general prohibition on surgeries that are not expected to significantly restore functions. As a statutory entitlement program, the Department is constrained in its authority absent a legislative change. The final regulatory language is dictated by statute and is not meant to imply any Departmental position regarding the medical necessity of surgical treatment.

¹ Chickasaw Nation v. United States, 534 U.S. 84, 91 (2001).

² Id.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule except that sections making specific reference to mental health inpatient and partial hospitalization utilization review, quality assurance, and reauthorization requirements have been removed at § 199.4(a)(11) and (12).

B. Aligning Beneficiary Cost-Sharing for Mental Health and SUD Benefits with Those Applicable to Medical/Surgical Benefits

1. Provisions of the Proposed Rule. Following the recent repeal of statutory authority for separate beneficiary financial liability for mental health benefits, the rule eliminates any differential in cost-sharing between mental health and SUD benefits and medical/surgical benefits. The regulatory changes to 32 CFR 199.4(f) and 32 CFR 199.18 will reduce financial barriers to both outpatient and inpatient mental health and SUD benefits while, consistent with statutory requirements, minimize out-of-pocket risk for those beneficiaries.

With respect to TRICARE Prime co-payments, active duty family members (ADFM) enrolled in TRICARE Prime will continue to pay no copayment for inpatient or outpatient services. Retirees and all other non-active duty dependents enrolled in Prime will see the following changes:

- The co-pay for individual outpatient mental health visits will be reduced from \$25 to \$12.
- The co-pay for group outpatient mental health visits will be reduced from \$17 to \$12.
- The per diem charge of \$40 for mental health and SUD inpatient admissions will be reduced to the non-mental health per diem rate of \$11, with a minimum charge of \$25 per admission.

Regarding TRICARE Standard cost-sharing, ADFMs utilizing TRICARE Standard/Extra previously paid a higher per diem for mental health inpatient care than for other inpatient stays.

ADFM's will see the following change:

- The per diem cost-share for inpatient mental health services will be reduced from \$20/day to the daily charge (\$18/day for FY16) that would have been charged had the inpatient care been provided in a Uniformed Services hospital.

Retirees and their dependents who are not enrolled in Prime but use non-network providers (Standard) for mental health care are generally required to pay 25% of the allowable charges for inpatient care, and this will not change. Retirees and their dependents using Standard and Extra are currently responsible for their outpatient deductible and outpatient cost-sharing of 25% (Standard)/20% (Extra) of the CHAMPUS-determined allowable costs. This also will not change.

Cost-sharing for partial hospitalization programs (PHPs) will change from inpatient to outpatient to more accurately reflect the services being rendered, ensure consistency with the applicable statutes governing cost-sharing, and to further ensure parity between the surgical/medical and mental health benefit. Congress revoked the statutory authority granted to the Secretary to establish different cost-shares for mental health care. These factors provided the impetus for adoption of outpatient cost-sharing for PHPs. As noted above, ADFMs enrolled in TRICARE Prime/Prime Remote, do not pay co-pays for inpatient or outpatient services. For retirees and their dependents enrolled in Prime, the current inpatient per diem charge of \$40 for partial hospitalization program services will be reduced to an outpatient co-pay of \$12 per day of services. Realigning cost-sharing of partial hospitalization program services from inpatient to outpatient will impact ADFMs utilizing TRICARE Standard/Extra. Specifically, for ADFMs, the previous inpatient per diem charge of \$20/day (with a minimum \$25 charge per admission) for partial hospitalization program services will instead be subject to the applicable outpatient deductible and cost-sharing of 20% (Standard)/ 15% (Extra) of the PHP per diem rate. However,

these ADFMs will still retain the option of enrolling in TRICARE Prime/Prime Remote, where the cost-sharing is \$0 (i.e., no cost-sharing is applied). The financial liability of ADFMs under Extra and Standard will be further limited by the annual \$1000 catastrophic cap. Analyses conducted for the Regulatory Impact Analysis regarding this change indicated that only an estimated 50 to 80 additional non-Prime ADFMs may reach the catastrophic cap due to the higher PHP cost sharing.

2. Analysis of Major Public Comments. Numerous commenters agreed that differential cost-sharing requirements have served as a further disincentive for individuals seeking treatment, and agree that aligning cost-sharing requirements will reduce financial barriers for consumers on both inpatient and outpatient mental health and SUD benefits while minimizing out-of-pocket risks for beneficiaries. One commenter noted concern regarding having retirees and their dependents pay higher copays, given high unemployment and homelessness rates among Veterans.

Response. We appreciate all of the comments in support of this important change. With respect to retirees and their dependents paying higher copays, we believe this may have been a misunderstanding of general statutory and regulatory requirements regarding TRICARE cost-sharing, and what was specifically being proposed in the rule. In general, retirees and their dependents do pay more out-of-pocket costs than ADFMs. These requirements are outlined in statute and outside the scope of this rule. The intent of the rule itself is to provide parity in cost sharing between medical/surgical benefits and SUD/mental health benefits as applied to each beneficiary class. Previously retirees and their dependents enrolled in Prime paid higher copays for inpatient and outpatient mental health services than for inpatient and outpatient medical/surgical health services. However, under the final rule retirees and all other non-active duty dependents enrolled in Prime will see reductions in individual outpatient and group

outpatient mental health visits from a previous rate of \$25 and \$17 respectively, to a rate of \$12.

Our intent throughout is not to restrict access to care, but to provide equitable access to medically necessary care for all beneficiary groups.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made regarding beneficiary cost-sharing for mental health and SUD benefits.

III. Provisions of the Rule Regarding Expanding Coverage to Include Mental Health and SUD Intensive Outpatient Programs and Treatment of Opioid Use Disorder

A. Intensive Outpatient (IOP) Care for Psychiatric and Substance Use Disorders

1. Provisions of the Proposed Rule. Mental health and SUD IOP services were not previously identified as separate levels of care from partial hospitalization in TRICARE regulations. Although hospital-based and free-standing facilities that are TRICARE authorized to offer partial hospitalization services can provide less intensive IOP, covered at the half-day partial hospitalization rate, the previous TRICARE certification requirements for these programs restricted the typical mental health or SUD IOP from being recognized as a distinct covered benefit and TRICARE-authorized institutional provider type. SUD IOPs offer a validated level of care endorsed by ASAM, and the provision of mental health and SUD IOP services will better accommodate patients who require step-down services from an inpatient stay or a PHP. Explicit authorization of IOP is also anticipated to expand the number of TRICARE participating providers and improve access to care. IOP care institutional providers will be required to be accredited by an accrediting body approved by the Director, Defense Health Agency, and meet the requirements outlined in 32 CFR 199.6(b)(4)(xviii) to become TRICARE authorized.

2. Analysis of Major Public Comments. Several national organizations and many commenters expressed strong support for the authorization of new services for SUD care outside

of SUDRF settings, citing the need for additional treatment options consistent with the full range of the continuum of care. One national organization also requested clarification regarding application processes and contract amendments for existing TRICARE providers who serve patients in their PHP services but who would want to expand their services to include the new IOP level of care.

Response. The Department agrees and sought these revisions to ensure ready access to medically necessary treatment reflective of the full continuum of evidence-based care. The Department understands comprehensive SUD treatment must include access to various levels of care, ranging from acute detoxification to treatments that focus on stabilization and maintenance of treatment gains. While § 199.6 (b)(4)(xviii) establishes standards and requirements for intensive outpatient treatment programs for psychiatric and substance use disorders, further details regarding participation, billing, and accreditation standards will be outlined in the TRICARE manuals available online at <http://manuals.tricare.osd.mil>. With respect to institutional providers who would like to expand their services, we would note that the regulatory language regarding participation agreements specifically acknowledges that a single consolidated participation agreement is acceptable for all units of a TRICARE authorized facility granted that all programs meet the applicable requirements. Once implemented, interested facilities should work directly with the applicable managed care support contractor for their region to establish and/or modify their participation agreement.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made with respect to Intensive Outpatient (IOP) care for Psychiatric and Substance Use Disorders.

B. Treatment of Opioid Use Disorder

1. Provisions of the Proposed Rule. This rule expands treatment of opioid use disorder,

with the provision of medication assisted treatment (MAT), through both TRICARE authorized institutional and individual providers. In addition to SUD IOPs, this rule allows TRICARE coverage of opioid treatment programs (OTPs), with the inclusion of a definition of OTPs in 32 CFR 199.2 and the requirements for OTPs to become TRICARE authorized institutional providers outlined in 32 CFR 199.6(b)(4)(xix). Additionally, this rule allows coverage of OBOT, as defined in 32 CFR 199.2, and coverage of MAT on an outpatient basis as extended in 32 CFR 199.4(c)(3)(ix)(A)(9).

2. Analysis of Major Public Comments. A number of commenters, along with multiple national organizations sent comments in support of the addition of benefit coverage to include opioid treatment programs, noting opioid addiction is a significant national problem. One commenter stated that individuals with opioid use disorder should not be provided any form of treatment as this represented a waste of government funds. One national organization commented that there are actually approximately 1400 OTPs in existence. Also, several commenters requested that TRICARE clarify capacity requirements for OTPs and include the right to request a waiver to this requirement. One commenter queried how and if quality tracking of the newly authorized providers will be performed and by which department.

Response. Recent increases in prescription opioid misuse and heroin addiction make provision of MAT in OTPs and OBOT settings a timely and necessary addition to benefit coverage. We do not agree with the commenter who noted that treatment should be withheld for individuals with opioid use disorder, and we note that MAT is an effective, evidence-based treatment for opioid use disorder that should be provided by TRICARE as medically necessary and appropriate treatment. We appreciate the comment regarding the approximate number of OTPs in existence and are hopeful many of these facilities will elect to become TRICARE participating providers. With respect to the proposed regulatory requirement that OTPs are required to be

licensed and fully operational for a period of at least six months with a minimum patient census of at least 30 percent of capacity, we understand from several commenters that unlike inpatient and residential facilities, OTPs may not have a stated capacity as part of their licensure, and as a result, it may not be clear as to whether or not OTPs have met this requirement. We appreciate this issue being brought to our attention and have decided to remove the explicit capacity requirement for OTPs from the regulation. TRICARE will simply require OTPs to be licensed and operate in substantial compliance with state and federal regulations.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule and the only substantive change made regarding provisions for the treatment of opioid use disorder was removal of an explicit capacity requirement for OTPs contained in § 199.6(b)(xix)(A)(2)(ii).

C. Outpatient Substance Use Disorder Treatment by Individual Professional Providers

1. Provisions of the Proposed Rule. By previous regulation, reimbursement for office-based SUD outpatient treatment provided by TRICARE authorized individual mental health providers, as specified in 32 CFR 199.6, was not permitted. Such outpatient SUD treatment services were only authorized when provided by a TRICARE approved institutional provider (i.e., a hospital-based or free-standing SUDRF). However, although some accredited TRICARE-authorized SUDRFs provide office-based SUD outpatient treatment, institutional providers of SUD care primarily provide services to patients requiring a higher level of SUD care. To address this limitation in access, the Department proposed expanded coverage to include individual outpatient SUD care, including office-based outpatient treatment.

This rule covers services of TRICARE-authorized individual mental health providers, practicing within the scope of their licensure or certification, who offer medically or psychologically necessary SUD treatment services (including outpatient and family therapy)

outside of a SUDRF, to include MAT and treatment of opioid use disorder by a TRICARE authorized physician delivering OBOT on an outpatient basis.

2. Analysis of Major Public Comments. Again, national organizations and many commenters expressed strong support for the authorization of new services for SUD care outside of SUDRF settings, citing the need for additional treatment options consistent with the full range of the continuum of care and appropriate access to evidence-based care. Eight commenters requested additional SUD individual professional provider types be recognized by TRICARE as authorized to provide services. One commenter also noted that she was unable to provide services as she does not hold citizenship but suggested volunteers be allowed to provide services to beneficiaries.

Response. We agree that access to care is important for beneficiaries seeking SUD treatment. The Department made these revisions in acknowledgement of the importance of both the availability and convenience of access to evidence-based care in a range of settings to include TRICARE authorized, individual office-based providers.

TRICARE appreciates the contributions of peer counselors, and other non-medical individuals who desire to provide SUD and mental health services to beneficiaries as well as the skills and professional experience of the various substance use disorder and mental health providers in the field. We appreciate these comments but consider them beyond the scope of this rule as we did not propose any changes to the existing regulatory requirements for individual professional providers of care. TRICARE maintains a robust selection of TRICARE eligible providers by relying on currently recognized provider types. Qualified mental health providers are: Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and

supervised mental health counselors under a physician's supervision. However, we will review all recommendations provided and consider them in the development of future policy.

Additionally, the acceptance of volunteer services is beyond the scope of our proposed rule which addresses the cost-sharing of medically necessary services and supplies required in the diagnosis and treatment of an injury, illness or disease when rendered by a TRICARE authorized provider.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made to provisions regarding TRICARE coverage of outpatient SUD treatment by individual professional providers.

IV. Provisions of the Rule Regarding Streamlining Requirements for Institutional Mental Health and SUD Providers to become TRICARE Authorized Providers

1. Provisions of the Proposed Rule.

This rule simplifies the regulation to account for existing industry-wide accepted accreditation standards for TRICARE institutional providers of mental health care, including RTCs, freestanding PHPs, and freestanding SUDRFs. Requirements for TRICARE certification beyond industry-accepted accreditation, while once considered necessary to ensure quality and safety, eventually proved to be unnecessarily restrictive and inconsistent with current institutional provider standards and organization. Specifically, the final rule streamlines procedures and requirements for SUDRFs, RTCs, PHPs, IOPs and OTPs to qualify as TRICARE authorized providers, relying primarily on accreditation by a national body approved by the Director, as opposed to detailed, lengthy, stand-alone TRICARE requirements (e.g., the qualifications and authority of the clinical director, staff composition and qualifications, and standards for physical plant and environment, amongst others). In general, mental health and SUD institutional providers may become TRICARE authorized institutional providers if the facility is accredited by an accrediting organization approved by the Director and agrees to

execute a participation agreement with TRICARE, as outlined in the regulations. This streamlined approval process is a greatly simplified process from the previous, detailed certification process for current institutional providers.

Furthermore, given that there are now a growing number of accrediting bodies established for institutional providers of mental health care and industry standards that are widely accepted, the final rule eliminates by name references to specific accrediting bodies (e.g., The Joint Commission (TJC)). Instead, the specific mention of accrediting bodies is replaced with the term, “an accrediting organization, approved by Director.” This will allow the Defense Health Agency (DHA) flexibility in selecting and recognizing the authority of various accrediting bodies to assist in authorization of institutional providers of mental health care and SUD care. Rather than name all the approved accrediting bodies in regulation, DHA will identify specific accrediting bodies for various types of mental health care in TRICARE sub-regulatory policy found at <http://manuals.tricare.osd.mil>.

2. Analysis of Major Public Comments. Multiple national organizations and individuals noted strong support for changes in accreditation requirements as part of the streamlining of the process for TRICARE approval of institutional providers. Many of these comments sought to advocate for approval of the Commission on Accreditation of Rehabilitation Facilities as a TRICARE-approved accrediting organization. Also, a number of commenters sought to advocate for the Council on Accreditation, and several others advocated for Outdoor Behavioral Healthcare Accreditation, to be recognized as approved accrediting organizations. One commenter noted the positive impact this will have on community based providers, including enhancing local economies. Another commenter requested that the Department open TRICARE networks to any willing and able provider with appropriate credentials, indicating that paneling need not be made any more complicated. One commenter specifically discussed the

circumstances under which there were no network providers within one hour of place of residence to provide care. One commenter requested the Department clearly address coverage for eating disorder programs. Another commenter expressed concern that DoD should not propose new regulations that would make it difficult for providers to participate in TRICARE.

Concurrently, one national organization expressed concern that streamlining of accreditation requirements would negatively affect the quality of care received by beneficiaries, warned about the failure of accreditation agencies to ensure quality outcomes, and encouraged the Department to prioritize not only access but quality. That organization also suggested that TRICARE ensure public transparency and accountability by publishing inspection results of mental health facilities. The commenter also suggested that facilities with recent serious incidents should be subject to frequent reviews and increased reporting requirements around patient safety and quality measures. It was also suggested that TRICARE enforce current staffing standards for RTCs according to acuity and needs of patients, not only census. One organization questioned the Department's intent to rely primarily on national accreditation for authorization of RTCs and erroneously stated that the Department requires on-site inspection before a participation agreement is signed. They requested additional specific information and clarification concerning what degree TRICARE would continue to impose an additional layer of standards and processes and questioned how this would be implemented. Another commenter acknowledged TRICARE's right to conduct on-site surveys but indicated their hope was that on-site surveys would be done only in extraordinary circumstances and that the commitment to reliance on national accreditation would be sufficient in virtually every case. Finally, some commenters strongly objected to the requirement that participating institutional providers agree to permit "full access to patients" including interviewing patients during on-site quality assurance or accounting audits be granted.

Response. We agree that previous, “stand alone” standards for TRICARE certification are no longer necessary and standards must be streamlined. We concur with multiple commenters who believe the existing TRICARE certification standards now prove to be unnecessarily restrictive. Instead, relying primarily on industry-accepted accrediting bodies, including The Joint Commission and Commission on Accreditation of Rehabilitation Facilities, will encourage institutional provider participation in TRICARE thereby allowing beneficiaries greater access to medically necessary services. In order to avoid the necessity of updating the regulation every time a new industry-accepted accrediting organization is recognized by TRICARE, we have not included an itemized list of organizations in the regulation, rather indicating that a full list of accrediting organizations approved by the Director will be included in the TRICARE Policy Manual and promulgated following publication of this final rule.

We strongly believe that relying primarily on accreditation by a national accrediting body will not create an additional layer of standards and processes, nor will it reduce the overall quality of care beneficiaries receive. Over two decades ago, in the Final Rule: “Civilian Health and Medical Program of the Uniformed Services (CHAMPUS): Mental Health Services,” as published in 60 FR 12419, March 7, 1995, standards were developed to address identified problems of quality of care, fraud, and abuse in RTCs, SUDRFs, and PHPs at the time. There are now a number of industry-accepted accrediting bodies with mental health facility standards that meet or exceed the current TRICARE-established standards. Streamlining procedures to qualify as a TRICARE authorized institutional provider will not only increase access to approved care, but also decrease the overall cost to both the Department and institutional providers of certifying duplicative and now unnecessary quality standards first implemented by the 1995 Final Rule. With respect to eating disorders in particular, treatment services rendered in TRICARE-authorized free-standing or hospital facilities are covered as they are for other

mental health and SUD conditions. We believe this final rule will expand treatment options for the treatment of eating disorders with the inclusion of IOPs as well as the streamlining of requirements for institutional providers to become TRICARE authorized providers.

We also appreciate the public comments we received regarding quality of care and the need for ongoing oversight. TRICARE remains committed to provision of high quality mental health and SUD services and will continue to ensure high levels of quality care while expanding access. While the Department does intend to rely primarily on a facility's accreditation and willingness to become a TRICARE participating providers, all participating providers agree to grant the Department the right to conduct quality assurance audits on a scheduled or unscheduled (unannounced) basis as a condition of participation in TRICARE. To be clear, while we require provider to agree to grant the Department with the right to conduct audits, we do not intend to automatically conduct an on-site inspection or audit of every provider as a condition of participation. Further details regarding TRICARE's Quality and Utilization Peer Review Organization Program, which is based on specific statutory authority and follows many of the quality and utilization review requirements and procedures in effect for the Medicare Peer Review Organization, can be found in 32 CFR 199.15. Further, 32 CFR 199.9 sets forth provisions for invoking administrative remedies against providers in situations requiring administrative action to enforce provisions of law, regulation, and policy in order to ensure the quality of care for TRICARE beneficiaries. Given the past abuses and the vulnerability of this patient population, full access to patients is justified during on-site quality assurance and accounting audits and helps to ensure transparency and accountability of all parties. The Department has balanced the competing interests of expanded access and provision of high quality care through the provisions of this rule.

Comment. One commenter also made a number of specific recommendations regarding

the regulatory language in § 199.6 applicable to mental health and SUD institutional providers. We addressed the overarching mental health parity comments earlier. We will now address the additional specific comments about the proposed regulatory language.

Response. The commenter raised concerns with specific regulatory language regarding RTCs, namely “RTC is appropriate for patients whose predominant symptom presentation is essentially stabilized, although not resolved, and who have persistent dysfunction in major life areas.” The commenter indicated that the phrase “essentially stabilized” is a subjective term with no clear meaning and § 199.6(b)(4)(vii)(A)(I) should be revised. The Department would note that this is the existing standard for RTCs and in practice, it has not proven to be problematic but is rather geared to ensuring the appropriate level of care as part of medically necessary and appropriate care. This same commenter objected to the language in § 199.6(b)(4)(vii)(A)(I) that differentiates residential treatment from acute psychiatric care, partial hospitalization, a group home, therapeutic schools, facilities that treat patients with a primary diagnosis of substance use disorder or intellectual or developmental disability. Similar objections were raised to § 199.6(b)(4)(xiv)(A)(I) with respect to SUDRFs and included the recommendation that subparagraph (i) should be clarified as referring to a hospital/psychiatric hospital. The Department fully appreciates that different states may use different terms in licenses institutional providers. Regardless of the specific title of the license, as these vary by state, the facility or distinct part of the facility and license must be reviewed in order to determine the services that are actually being offered and whether the facility meets the requirements to be a TRICARE authorized RTC. These provisions are not new to the TRICARE regulation and are necessary to distinguish an RTC from acute psychiatric care, partial hospitalization, a professionally directed living arrangement, educational program, SUDRF, or facility offering long term, custodial care.

This commenter also recommended that the Department delete the first sentence in §

199.6(b)(4)(vii)(C)(2) and § 199.6(b)(4)(xiv)(C)(2) requiring that services be provided to “CHAMPUS beneficiaries in the same manner” that they are provided to other patients, indicating that the second sentence, which prohibits discrimination in admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment, was sufficient. Apart from stating that the second sentence in each of these provisions was sufficient, no other rationale was provided as to why the first sentence should be deleted. We believe these are important requirements, and even if somewhat duplicative, the inclusion of both provisions does no harm. Consequently, the Department has decided to leave the language as originally proposed.

Comment. Also, several national organizations requested that TRICARE allow providers 45 days rather than 30 to submit claims, acknowledging that the intent of most providers is to submit claims every 30 days, however, unforeseen delays do occur.

Response. In the case of continuous care, claims shall be submitted at least every 30 days, as this is consistent with industry billing standards and allows for efficiency and reduction of error in billing practices. While the public comments were made in response to the regulatory language regarding participation agreement requirements for TRICARE mental health and SUD institutional providers, this is an existing requirement that applies to all providers rendering continuous care, not just mental health and SUD institutional providers. As the specific provisions that were proposed in this rulemaking action were merely reflective of overarching TRICARE claims requirements (see, e.g., §§ 199.4(b)(1)(i) and 199.7(e)(1)), it would not be appropriate to revise the specific participation agreement provisions for institutional mental health and SUD providers in a manner that is inconsistent with other regulatory provisions that apply to the TRICARE program as a whole. While the overarching TRICARE claims requirements seek to lessen any potential adverse impact on a TRICARE beneficiary that could

result from a retroactive denial of care, we would also note the existing provisions in 32 CFR 199.4(h) regarding payment and liability for services and supplies retrospectively excluded by a Peer Review Organization by reason of being not medically necessary, at an inappropriate level, or other reason relative to reasonableness, necessity or appropriateness. Additional information regarding waiver of liability may be found in the TRICARE Policy Manual at Chapter 1, Section 4.1. In summary, we believe the requirement to submit claims every 30 days protects not only beneficiaries but also providers.

Comment. It was also requested that when providing cost data as required by TRICARE, that an entity with multiple service lines and treatment centers be allowed to submit a single consolidated audit of the organization's financial statements, and financial controls to meet this requirement.

Response. Both the existing and final regulation require participating institutional providers to permit access to the financial and organizational records of the provider and, when requested, to furnish cost data certified by an independent accounting firm or other agency authorized by the Director. Access to financial auditing/reporting continues to be important to the program in evaluating the quality and cost-effectiveness of care rendered by TRICARE-authorized providers. Additionally, cost data and financial reports/audits are utilized to calculate reimbursement rates in accordance with prescribed reimbursement methodology for certain institutional providers. For example, financial reports and audits would be essential for verification of charge/cost data used in the establishment of RTC-specific per diem rates. Entities are not prohibited from providing a single, consolidated audit of their organization's financial statements and controls to the extent that a consolidated audit provides the specificity required for evaluating the separate entities under consolidated reporting.

Comment: One commenter noted that the certification process regarding RTCs should be

on par with Medicaid certification.

Response: In general, under Medicaid, psychiatric residential treatment facilities must be accredited by The Joint Commission or any other accrediting organization with comparable standards recognized by the State. Similarly, this final rule streamlines the approval process for TRICARE authorized RTCs by relying principally on accreditation by nationally-accepted accrediting organizations.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made to provisions regarding streamlined requirements for institutional mental health and SUD providers to become TRICARE authorized providers.

V. Provisions of the Rule Regarding TRICARE Reimbursement Methodologies for Newly Recognized Mental Health and SUD Intensive Outpatient Programs and Opioid Treatment Programs

A. Intensive Outpatient Program Reimbursement

1. Provisions of the Proposed Rule. Under current regulatory provisions [32 CFR 199.14(a)(2)(ix)(C)], the maximum per diem payment amount for a full-day partial hospitalization program (minimum of six hours) is 40 percent of the average per diem amount per case established under the TRICARE mental health per diem reimbursement system for both high and low volume psychiatric hospitals and units.

Likewise, PHPs less than six hours (with a minimum of three hours) were paid a per diem rate at 75 percent of the rate for a full-day program. In analysis of the reimbursement methodology to be used for reimbursement of IOPs, it became apparent that the step-down in intensity, frequency and duration of treatment designated as half-day PHPs, were in fact, intensive outpatient services provided within a PHP authorized setting. While there is some variability in the intensity, frequency and duration of treatment under both programs (that is, less than six hours per day with a minimum of three hours for half-day PHPs; and two to five times

per week, two to five hours per day for IOPs), it appears that both the services rendered and the professional provider categories responsible for providing the services are quite similar. As a result of this observation/analysis, the IOP designation will be used in lieu of half-day PHP for treatment of less than six hours per day - with a minimum of two hours per day - rendered in a PHP authorized setting. While the minimum hours have been reduced from three to two hours per day for coverage/reimbursement, they are still within the acceptable range for IOP services typically provided in a PHP. Since intensive outpatient services can be provided in either a PHP or newly authorized IOP setting, and IOP services are essentially the same as half-day PHP services, it is only logical that IOP per diems be set at 75 percent of the full-day PHP per diem. This would be the case regardless of whether the IOP services were provided in a PHP or IOP.

2. Analysis of Major Public Comments. Two public commenters indicated that while the stated rationale for reimbursement of newly recognized mental health and SUD IOPs and OTPs seems reasonable, TRICARE must continue to reevaluate reimbursement over time in order to achieve the goal of increasing access to care. The same commenters also indicated that the all-inclusive per-diem payment rates appear to provide a predictable payment methodology, which makes it more possible for organizations to commit to providing services to TRICARE beneficiaries. Another commenter indicated they would support reasonable reimbursement rates if they at least meet or exceed the Medicare level of reimbursement for comparable interventions and patient service days, opining that reasonable reimbursement rates will encourage institutional providers to offer these services if they can do so without operating at a deficit. We appreciate these comments and agree. Further, as discussed at greater length in the proposed rule, by law, TRICARE reimbursement shall be determined, to the extent practicable, in accordance with the same rules as apply to payments to providers of services of the same type under Medicare. When Medicare has no established reimbursement methodology (e.g. Medicare does not reimburse

OTPs or freestanding SUDRFs or PHPs that are not hospital based or part of a Community Mental Health Clinic, while TRICARE does), TRICARE must establish its own rates through proposed and final rulemaking.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made to provisions regarding such IOP reimbursement.

B. Opioid Treatment Program Reimbursement and Cost-Sharing

1. Provisions of the Proposed Rule. As defined in this rule, OTPs are outpatient settings for opioid treatment that use a therapeutic maintenance drug for a drug addiction when medically or psychologically necessary and appropriate for the medical care of a beneficiary undergoing supervised treatment for a SUD. The program includes an initial assessment, along with integrated psychosocial and medical treatment and support services. Since OTPs are individually tailored programs of medication therapy, separate reimbursement methodologies are established based on the particular medication being administered for treatment of the SUD. By far the most common medication used in OTPs is methadone. Methadone care in OTPs includes initial medical intake/assessment, urinalysis and drug dispensing and screening as part of the bundled rate, as well as ongoing counseling services. Based on a preliminary review of industry billing practices, the weekly bundled per diem for administration of methadone will include a daily drug cost of \$3, along with a \$15 per day cost for integrated psychosocial and medical support services. The daily projected per diem costs (\$18/day) will be converted to a weekly per diem rate of \$126 (\$18/day x 7 days) and billed once a week to TRICARE using the Healthcare Common Procedure Coding System (HCPCS) code H0020, "Alcohol and/or drug services; methadone administration and/or service." The bundled per diem rate is how Medicaid and other third-party payers typically reimburse for methadone treatment in OTPs. The methadone rate for OTPs will be updated annually by the Medicare update factor used for

other mental health care services rendered (i.e. the Inpatient Prospective Payment System update factor) under TRICARE. The updated rates will be effective October 1 of each year, and will be published annually on the TRICARE website. Outpatient cost-sharing will be applied to a weekly per diem, since the copayment amounts for Prime NADDs and ADFMs under Extra and Standard will be near, or in some cases, above the daily charge for OTPs, essentially resulting in a non-benefit.

While the other two medications (buprenorphine and naltrexone) are more likely to be prescribed and administered in an OBOT setting, reimbursement methodologies for OTPs are being established for both medications to allow OTPs the full range of medications currently available for treatment of SUDs. Since the reimbursement of buprenorphine and naltrexone administered in OTPs are not conducive to the bundled per diem methodology due to variations in dosage and frequency of the drug and the non-drug services (e.g., administration fees and counseling services) will be reimbursed separately on a fee-for-service basis. We recognize that Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes are updated on a regular basis. The following referenced codes are current as of the writing of this final rule. If necessary, updated codes will be included in the TRICARE Policy Manual or TRICARE Reimbursement Manual. In the case of Buprenorphine, OTPs will bill TRICARE using the HCPCS code H0047, "Alcohol and/or other drug use services, not otherwise specified," for the medical intake/assessment, drug dispensing and monitoring and counseling, along with HCPCS code J8499, "Prescription drug, oral, non-chemotherapeutic, nos," for the prescribed medication. OTPs will include the National Drug Code for Buprenorphine, along with the dosage and acquisition cost on its claim. Prevailing rates will be established for drug related services (e.g., drug monitoring and counseling services) billed under HCPCS code H0047, while the drug itself will be reimbursed at 95 percent of the average

wholesale price. Outpatient cost-sharing will be applied on a per-visit basis. The preliminary weekly cost estimate for Buprenorphine OTPs is \$115 per week, assuming that the patient is stabilized and twice a week visits. This is based on an estimated drug cost of \$10 per day and an estimated non-drug cost of \$22.50 per visit $[(7 \times \$10) + (2 \times \$22.50) = \$115/\text{week}]$. These amounts mentioned above are both preliminary and estimates and are not intended to reflect final reimbursement rates.

Naltrexone, unlike methadone and buprenorphine, is not an agonist or partial agonist, but an inhibitor designed to block the brain's opiate receptors, diminishing the urges and cravings for alcohol, heroin, and prescription painkillers such as oxycodone. Due to the extreme cost of injectable naltrexone and the fact that it is only administered once a month, the drug, its administration fee, and ongoing counseling will be paid separately on a fee-for-service basis. OTPs will bill TRICARE using HCPCS code H0047 for counseling and other services. Prevailing rates will be established for drug related services (e.g., drug monitoring and counseling services) billed under HCPCS code H0047. The naltrexone injection will be billed using the HCPCS code J2315 with the number of milligrams used, while its administration fee will be billed using CPT code 96372. OTPs outpatient cost-sharing will be applied on a per-visit basis, which in this case would be once a month. The projected monthly amount for naltrexone is \$1,177 ($\$1,129$ for the injectable drug (J2315) + $\$25$ for the drug's administration fee (CPT 96372) + $\$22.50$ for other related services (H0047) = $\$1,176.50$). These amounts may be subject to change based on health care market forces, but are not expected to change significantly. The Director will have discretionary authority in establishing the reimbursement methodologies for new drugs and biologicals that may become available for the treatment of SUDs in OTPs. The type of reimbursement (e.g., fee-for-service versus bundled per diem payments) will be dependent in large part on the variability of the dosage and frequency of the medication being

administered.

2. Analysis of Major Public Comments. A number of commenters indicated that they believed the rates proposed for OTPs' services are near market rates and are acceptable. One commenter advised the Department of Defense to evaluate existing state Medicaid reimbursement models for the use of buprenorphine in OTPs, the most recent being through the New York State Office of Alcoholism and Substance Abuse services. The commenter felt that such references would provide additional guidance to the Department in establishing appropriate buprenorphine only rates for TRICARE beneficiaries.

One commenter felt that the proposed revisions assumed that patients being treated with buprenorphine in OTPs, once stabilized, would only visit OTPs twice a week. The commenter encouraged the Department to consider an induction rate for patients being treated with buprenorphine prior to stabilization requiring more than two visits per week-in some cases requiring daily visits to OTPs to achieve stabilization. Another commenter supported the rationale for a bundled weekly rate, but expressed concern with the projected weekly per diem price of \$126, especially for New York State providers, would not be financially sustainable.

Response. The review and analysis of Medicaid payment models were instrumental in the establishment of separate reimbursement methodologies based on the particular medication being administered for treatment of the substance use disorder. It was apparent from this initial analysis that separate fee-for-service reimbursement methodologies needed to be established for frequency of the drug and the non-drug services (e.g., administrative fees and counseling). As a result, prevailing rates will be established on a fee-for-service basis for all drug related services, while the drug itself will be reimbursed at the lesser of billed charges or 95 percent of the average wholesale price because Medicare has not yet established a reimbursement rate for buprenorphine in the Part B Drug Medicare Average Sales Price file. However, be assured that the Department

will continue to review and evaluate any innovative approaches [e.g., New York's Ambulatory Patient Group (APG) payment methodology for SUD] for reimbursement of OTPs that can effectively reduce costs and improve the quality of life for individuals with opioid use disorder. To this end, the proposed regulation included discretionary authority in establishing reimbursement methodologies for new drugs and biologicals that may become available for treatment of SUDs in OTPs.

This final rule does not set a limit of two visits per week for medication assisted treatment, and in fact, all existing quantitative limitations (regarding number of authorized visits, etc.) have been removed from the regulation. A separate induction rate is not required since buprenorphine treatment programs are reimbursed on a fee-for-services basis; i.e., the drug and non-drug services (administration fees and counseling services) will be reimbursed separately on a fee-for-service basis and bundled for payment on a weekly basis. The proposed rule merely included an example of how weekly services would be bundled and the example included two visits to OTPs. The bundled payments will vary depending on the dosage and frequency of the drug being administered and frequency of associated counseling services. As a result, the fee-for-service methodology will allow for additional visits to OTPs during the induction phase of the patient's treatment.

We appreciate the commenter's support for the bundled weekly rate for methadone treatment programs. The amount projected in the proposed rule, a weekly per diem rate of \$126 for methadone treatment programs, was based on a preliminary review of industry billing practices (i.e., bundled per diem rates that Medicaid and other third-party payers typically reimburse for methadone treatment in OTPs). However, other commenters did state the rates proposed for OTPs' services are near market rates and are acceptable. We agree that local/regional variation in costs for OTPs may occur, and therefore we will establish a national

weekly per-diem rate for methadone treatment which will be adjusted utilizing the existing adjustment process appropriate to the treatment setting (e.g., the CMAC locality-adjustment process for methadone treatment provided in freestanding OTPs and the OPSS wage-index adjustment formula for methadone treatment provided in hospital-based OTPs). It is important to note separate reimbursement of buprenorphine and naltrexone administered in OTPs will occur and will reflect the variation in dosage and frequency of the drug and the non-drug services. As a result, buprenorphine and naltrexone treatment programs will be reimbursed on a fee-for-service basis, on the basis of the CHAMPUS Maximum Allowable Charge (CMAC) methodology. A final national methadone weekly per diem rate will be established prior to implementation, which will reflect current bundled per diem rates that Medicaid and other third-party payers typically reimburse for methadone treatment in OTPs. The final reimbursement rates will be published in the TRICARE Reimbursement Manual found here: <http://manuals.tricare.osd.mil/>.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made to provisions regarding opioid treatment program reimbursement and cost-sharing.

C. Removal of the Federal Register Publication of TRICARE Hospital-Specific Rates and Fixed Daily Copayment Amounts

1. Provisions of the Proposed Rule. Under current regulatory provisions [32 CFR 199.4(f)(3)(ii)(B) and 32 CFR 199.14(a)(2)(iv)(C)(4)], annually updated psychiatric hospital regional per diems and fixed daily copayment amounts are to be published in the Federal Register at approximately the start of each fiscal year. While the initial intent of this regulatory requirement was to provide widespread notice of changes to regional psychiatric hospital per diems and fixed copayment amounts, its relevancy has been subsequently overshadowed by the public's online accessibility to the TRICARE manuals and reimbursement rates on the official

website of the Military Health System and the DHA (www.health.mil). As a result, the public has ready online access to psychiatric hospital regional per diems and fixed daily copayment amounts, as well as maximum rates for mental health rates, to include freestanding psychiatric PHPs in the TRICARE Reimbursement Manual or on the official website of the Military Health System and the DHA (www.health.mil). Because of the readily available online access to updated mental health rates and the ongoing administrative burden of publishing annual notices to the Federal Register, these regulatory requirements are removed and updates to psychiatric hospital regional per diems and fixed copayment amounts will be maintained on the Agency's official website. However, psychiatric hospitals and units with hospital-specific rates will continue to be notified individually of their rates due to confidentiality restrictions. The new per diem rates for IOPs and methadone OTPs will also be maintained and available to the public on the official website of the Military Health System and the DHA (www.health.mil).

2. Analysis of Major Public Comments. No public comments were received relating to this section of the rule.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, and no substantive changes were made to provisions regarding removal of the Federal Register publication of TRICARE hospital-specific rates and fixed daily copayment amounts.

D. Additional Regulatory Revisions

1. Provisions of the Proposed Rule. There are a number of additional proposed revisions that are more technical and administrative in nature that we would like to highlight here to ensure the public is made aware of these changes and their purpose. Within 32 CFR 199.2, the definition of "adequate medical documentation, mental health records" is revised to eliminate specific reference to Joint Commission standards and instead reference "standards of an accrediting organization approved by the Director" consistent with the changes in accreditation

requirements as part of the streamlining of TRICARE approval of institutional providers. The definition of “mental disorder” has been revised to include SUD. The definition of “Director” has been revised to incorporate the Director of the Defense Health Agency, consistent with DoD’s current organizational structure. Additionally, throughout the revisions, the term “Director” has been substituted for all other terms such as “Director, CHAMPUS” and “Director, TRICARE Management Activity.” A definition of “qualified mental health provider” has been added for easy reference (as it was previously discussed in 32 CFR 199.4 but not specifically defined); and, the definition of “Consultation” has been amended to include qualified mental health providers. Additionally, the elimination of quantitative limitations has also necessitated a number of revisions to other sections of the regulation that referenced these limits, including 32 CFR 199.4(e)(2), 32 CFR 199.7(e)(2) and 32 CFR 199.15(a)(6). Also, 32 CFR 199.14(a)(2)(iv)(C)(2) clarifies that the Medicare’s Inpatient Prospective Payment System update factor is used for TRICARE’s mental health rates.

2. Analysis of Major Public Comments. One commenter recommended that the definition of Case Management be revised to include the following phrase “including mental health and substance use disorder needs” and not just mental health needs. We have no objections to this proposed change and have amended the definition accordingly. Another commenter noted that the current definition of “mental disorder” in § 199.2 should be updated to reference the current version of the Diagnostic and Statistical Manual (DSM) to avoid confusion and correlate the definition with current practice definitions. We would note that the proposed rule removed the referenced definition of “mental disorder”, and replaced it with a definition of “mental disorder, to include substance use disorder.” We would also note that the newly proposed definition simply references the current edition of the DSM so as to avoid the need to update the regulatory definition every time the DSM is updated.

3. Provisions of the Final Rule. The final rule is consistent with the proposed rule, with the addition of the above recommended change to the definition of case management.

VI. Additional Comments

In addition to the four major areas of the proposed rule in which we received comments, we received a number of general comments that either do not apply to the major provision categories of the final rule outlined above or apply to multiple provision categories. Those comments are responded to as follows:

Comment: Twenty eight commenters requested benefit coverage for IOP and PHP stays for children under age thirteen.

Response: We thank those individuals who submitted these comments. The exclusion of benefit coverage for the medically necessary treatment to include IOP and PHP care for children under age thirteen was unintentional and occurred when we combined the requirements for mental health and SUD PHP and IOPs within § 199.6. The Department does acknowledge the States' need to impose specific mental health and SUD facility licensure requirements and does note that this may impact IOP and PHP stays for children under 13. However, we have amended the language of the final rule to eliminate any age limitations from the TRICARE definition of PHP and IOP care.

Comment: One commenter requested consistency with the Affordable Care Act and provision of coverage for dependents until age twenty six.

Response: Regarding coverage of adult children, in accordance with 10 U.S.C. 1110b, the TRICARE Young Adult program currently provides voluntary coverage for eligible adult children until age 26.

Comment: One commenter requested clarification regarding the scope of CFR 42.2 laws and asked whether a mental health outpatient program offering a single substance abuse class

was still bound by these regulations or if only the Health Insurance Portability and Accountability Act laws apply.

Response: Although we appreciate this comment, it is outside the scope of this rule and better addressed to the Department that promulgated that regulation, namely the Department of Health and Human Services.

Comment: One national organization commented that family therapy as required in SUD partial hospitalization services could become administratively burdensome for DoD and providers, as there are times when family therapy is contra-indicated with the SUD population for reasons such as trauma history and continued SUD in family members.

Response: DoD recognizes family therapy may be contraindicated for some beneficiaries and in these cases, it is not required. We appreciate the comment and have made additional revisions to § 199.4(b)(9)(vi) to make it clear that the decision as to whether family therapy is contraindicated for a specific patient may be made at the facility vice Director, Defense Health Agency level. If family therapy is clinically contraindicated, this should be noted and followed in the treatment plan.

Comment: Another commenter requested the allowance of electronic and video connections specifically for the provision of family therapy.

Response: We appreciate this suggestion and TRICARE supports the use of interactive audio/video connections between TRICARE certified providers and beneficiaries to provide clinical consultation and office-visits when appropriate and medically necessary. Geographically distant family therapy for children and adolescents in residential treatment centers is allowed where family members are distally separated from their children and the appointment takes place in accordance with existing TRICARE telemedicine and telemental health requirements as reflected in the TRICARE Policy Manual (Chapter 7, Section 22.1).

Comment: Another national organization requested the inclusion of long-acting injectable mental health and SUD medications as TRICARE pharmacy benefits.

Response: The TRICARE Pharmacy Program, codified at 10 U.S.C. 1074g and implemented via federal regulations at 32 CFR 199.21, provides TRICARE beneficiaries with access to a wide range of pharmaceutical agents, including self-administered and self-injectable medications. Alternatively, medications that are administered by a physician or other TRICARE authorized provider, including those drugs that are administered as an integral part of a procedure, are reimbursed under the TRICARE medical benefit program. Through these two complimentary programs, TRICARE beneficiaries have access to medically necessary prescription drugs, including long-acting injectable mental health and SUD medications.

Comment. One commenter indicated that the proposed rule does not address telehealth service delivery but acknowledged appreciation for the Department's efforts to expand its use within a complicated framework of federal and state laws. The commenter went on to indicate that the regulation is not the place to address the details, but including telehealth services in the list of covered services under various benefits could be helpful as indicators of where additional guidance is necessary. Another organization requested inclusion of a patient's home or designated location as an originating site for the receipt of telemedicine in the final rule language with regard to mental health and SUD services.

Response. We appreciate the comments and agree that the regulation is not the place to address the details of telemedicine. Further, the Department views telehealth, or telemedicine, as a method of delivery of medically necessary and appropriate care as opposed to a separate type of care altogether. The use of interactive audio/video technology is supported and allowed under existing TRICARE regulations and its use is delineated in the TRICARE Policy Manual. The

Department is actively examining current policy regarding provision of telemedicine and telehealth, and any changes will be addressed in subsequent policy manual revisions.

Comment: One national organization requested streamlining of the preauthorization process for patient admission. The organization also requested clarification of the professional services of the attending physicians.

Response: While we appreciate these comments, we believe they address sub-regulatory issues and processes as opposed to any regulatory approach proposed to be adopted by TRICARE. We are pleased that the preauthorization process is supported and plan to continue monitoring this process for any difficulties. Facilities and beneficiaries with case-specific questions should work with the regional managed care support contractor. While we are uncertain what type of clarification is requested regarding the professional services of attending physicians, we imagine these comments relate to reimbursement of those services. Professional mental health services are specifically addressed in both the existing, as well as, proposed language under § 199.4 for mental health and SUD institutional benefits and indicates that these services are billed separately only when rendered by an attending, TRICARE authorized mental health professional who is not an employee or, or under contract with, the applicable institutional provider for purposes of providing clinical patient care.

Comment: Several commenters specifically emphasized the importance of mental health SUD treatment for pediatric and adolescent patients. Some of these comments included emphasis on the integration of mental health and primary care where it makes sense and is feasible. Others encouraged DoD to continue exploring how to better meet the needs of military children. One national organization commented that the service continuum should include prevention, early identification, and comprehensive treatment services ranging from high fidelity wraparound services to individual and family therapy and medication management. Another commenter noted

that TRICARE needs to fully fund WRAP-around therapies for dependents, and noted that these services should be a treatment step before an RTC as well as considered as a transitional service whenever a child is discharged from an RTC. Similarly, another national organization encouraged TRICARE to continue to invest in its infrastructure for community-based services, reserving residential care for only its most extreme cases.

Response: The provision of appropriate health care and overall physical and mental well-being of military families and beneficiaries is one of the highest priorities of the Department. We strongly believe these changes will allow a comprehensive array of mental health services for all beneficiaries including children and adolescents, while maintaining quality standards. The Department agrees that care should be based on a continuum of services according to the needs of the individual. Within the MHS, the continuum of services begins with the medical treatment facility or purchased care physicians, pediatricians, nurses, and staff members who identify mental health needs and primary care managers provide direct or purchased care referrals for comprehensive treatment of beneficiaries. The final rule addresses the way that services for children and adolescents are delivered, through many levels of care according to the severity of condition, with the goal of maintaining the child or youth in his or her family or community where possible. Currently, TRICARE provides family, individual, group therapy, and medication management in diverse settings such as partial hospitalization, intensive outpatient, residential treatment centers, inpatient mental health and SUD treatment for children and adolescents. Further, managed care support contractors provide case management for comprehensive treatment with chronic and complex cases. While the full “wraparound services” model for children in many cases includes educational and non-clinical services that are beyond the scope of TRICARE coverage, this final rule seeks to increase access to medically necessary clinical care in all communities where military beneficiaries reside.

While not specifically addressed in this final rule, the Department appreciates the comment regarding exploration of the use of behavioral health integration programs and generally supports these concepts.

Comment: One commenter requested clarification on the determination of medical necessity and offered to share their guidelines with the Department as they found that a strong utilization review process based on the latest science to be essential to ensure appropriate and timely care.

Response: We appreciate the comment. The term medically or psychologically necessary is defined at 199.2. Further, 32 CFR 199.15 establishes the rules and procedures for the TRICARE Quality and Utilization Review Peer Review Organization program.

Comment: One commenter stated that qualified case managers should not be required to have a minimum of two years' case management experience before serving TRICARE beneficiaries.

Response: We appreciate this comment, and the "Case Manager" definition has been removed at § 199.2 entirely as it is largely unnecessary and industry now has a wide variety of accepted qualifications for individuals to perform as case managers.

Comment: One commenter requested that TRICARE expand to cover disabled veterans, and another commenter suggested that veterans should be allowed to utilize TRICARE.

Response: TRICARE entitlement is established by statute and outside of the scope of this rule. Similarly, compensation for and care and treatment of Service-connected disabilities by the Department of Veterans Affairs is governed by title 38, United States Code. The Department of Veterans Affairs is the principal healthcare system to address the healthcare needs of veterans with a Service-connected disability. Veterans who are also entitled to TRICARE may elect which benefit they are utilizing for a given episode of care.

Comment: One commenter suggested revising the referral process to include Licensed Professional Counselors (LPCs) and LCAS (Licensed Clinical Addiction Specialists (LCASs) with

the ability to accept non-primary care provider referred claims. Another commenter submitted an inquiry regarding TRICARE authorization for mental health counselors. Two commenters noted that the proposed rule failed to recognize SUD professionals, including Advanced Alcohol Drug Counselors, that are credentialed by a recognized body (e.g., the International Certification and Reciprocity Consortium (IR&RC)). One of these two commenters also recommended that a specific clause be added to the regulation to recognize the acceptability of an Advanced Register Nurse Practitioner in collaboration with a psychiatrist, as an acceptable treatment provider in inpatient settings.

Response: As mentioned under the analysis of major public comments under section III.C. above, TRICARE appreciates the contributions of peer counselors, and other non-medical individuals who desire to provide SUD and mental health services to beneficiaries as well as the skills and professional experience of the various substance use disorder and mental health providers in the field. We appreciate these comments but consider them beyond the scope of this rule as we did not propose any changes to the existing regulatory requirements for individual professional providers of care. For a further discussion on mental health counselors in particular, we would direct the public to the TRICARE Certified Mental Health Counselor final rule published in the Federal Register on July 17, 2014. With respect to the specific comment about Advanced Registered Nurse Practitioners, we are uncertain what is specifically being requested but would note that all mental health services must be provided by TRICARE authorized individual professional providers of mental health services. TRICARE specifically recognized certified psychiatric nurse specialists (CPNS). The TRICARE Policy Manual provides additional details, including a list of American Nurses Credentialing Center certifications that meet TRICARE requirements.

Comment: One commenter requested the addition of mobile crisis stabilization services

and other mental health care safety nets under the provisions of TRICARE because outcomes and econometric analysis shows their effectiveness in reducing the need for inpatient hospitalization.

Response: We appreciate these comments, but they are beyond the scope of this rule. Mobile crisis services are currently provided as part of covered services for many institutional providers, and these services do not warrant the creation of a new, stand-alone provider type under TRICARE. However, we have reviewed all recommendations provided and will consider them in the development of future policy.

Comment: One commenter requested that TRICARE provide coverage of neurofeedback therapy.

Response: While this comment falls outside the scope of this rule, we would note that TRICARE covers proven care as determined by the hierarchy of reliable evidence in 32 CFR 199.14(g)(15). TRICARE periodically reviews the available reliable evidence to determine whether a given treatment or procedure meets the criteria to be considered proven safe and effective. In the event we find sufficient reliable evidence to determine a given procedure is proven, the TRICARE Policy Manual is updated.

Comment: One commenter expressed concern regarding “the reclassification of the electric shock machine.”

Response: The classification of medical devices is outside the purview of the Department. We are uncertain regarding the specific type of therapy the commenter is referring to, but we know that aversion therapy is currently excluded, and will continue to be excluded, from coverage. Specifically, the programmed use of physical measures, such as electric shock, alcohol, or other drugs as negative reinforcement (aversion therapy) is not a covered benefit, even if recommended by a physician. If by “electric shock machine” the commenter is referring to electroconvulsive therapy (ECT), the use of ECT as an evidence-based treatment for the treatment of major

depressive disorder remains a covered benefit under TRICARE.

Comment: One national organization requested the Department consider recognizing residential/transition brain injury treatment programs as TRICARE authorized providers as either residential treatment centers or Other Special Institutional Providers. That organization also proposed an expansion of the definition of IOP to include rehabilitation programs that provide services to Service members and veterans with brain injury. Finally, the commenter also recommended the Department consider extending TRICARE coverage for cognitive rehabilitation therapy (CRT).

Response: We appreciate these comments. TRICARE does not normally engage in agency rule-making for specific interventions, such as Cognitive Rehabilitation Therapy (CRT). CRT, as billed on a residential or IOP basis, has not been established as safe and effective and therefore does not currently meet regulatory requirements (32 CFR, Part 199.4(g)(15)(i)) and is excluded from coverage. However, we would note that TRICARE covers medically necessary and appropriate care, including rehabilitative services, as provided by TRICARE-authorized physicians, psychologists, physical therapists, occupational therapists, and speech therapists, as well as recognized institutional providers. While residential and transition brain injury programs are not currently recognized as a separate category of institutional providers, with respect to CRT, the Department does provide TRICARE coverage for interventions when provided as part of otherwise covered occupational therapy, physical therapy, and speech and language pathology services. As medicine is ever evolving, the Department will continue to monitor medical research and advances in this area for future revisions to the TRICARE program. Further, in conjunction with the CDC, NIH, and VA, the Department continues to collaborate on the development and improvement of traumatic brain injury (TBI) related diagnostic tools and therapeutic interventions that will allow for improved rehabilitation and reintegration of military and civilian TBI survivors.

VII. Summary of Regulatory Modifications

Overall, the final rule is consistent with the proposed rule. Several important changes are noted, in that we have amended the final rule to: remove the definition of “Case Manager” from § 199.2; remove the parenthetical reference to utilization and quality review of mental health services in § 199.4(a)(11) and remove and reserve § 199.4(a)(12) regarding utilization and quality review specifically for inpatient mental health and partial hospitalization; ensure medically necessary treatment coverage for dependents under age thirteen for IOP and PHP care; clarify in § 199.4(b)(9)(vi) that while family therapy is a required component of PHP services, an exception may be made when the Clinical Director, or designee, determines that family therapy is clinically contraindicated for a particular patient; and, remove the 30 percent capacity and full operational status for a period of at least 6 months requirements for TRICARE authorization of OTPs, IOPs, RTCs, PHPs, and SUDRFs.

VIII. Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Subsequently, the Department completed an Independent Government Cost Estimate and the results are referenced in C. Cost and Benefits. This rule has been designated “significant regulatory action,” although not economically significant, under section

3(f) of Executive Order 12866. Accordingly, this final rule has been reviewed by the Office of Management and Budget (OMB).

Congressional Review Act, 5 U.S.C. 804(2)

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts.

This final rule is not a major rule under the Congressional Review Act.

Public Law 96-354, "Regulatory Flexibility Act" (RFA), (5 U.S.C. 601)

The Regulatory Flexibility Act requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This final rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this final rule is not subject to the requirements of the RFA.

Public Law 104-4, Sec. 202, "Unfunded Mandates Reform Act"

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$140 million. This rule will not mandate any requirements for state, local, or tribal governments or the private sector.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rulemaking does not contain a "collection of information" requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. chapter 35).

Executive Order 13132, "Federalism"

This final rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government.

Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel, Substance use disorder treatment.

For the reasons stated in the preamble, the Department of Defense amends 32 CFR part 199 as set forth below:

PART 199 – CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55

2. Section 199.2(b) is amended by:

a. Revising the definitions of “Adequate medical documentation, mental health records” and “Case management”;

b. Removing the definition of “Case managers”;

c. Revising the definitions of “Consultation” and “Director”;

d. Adding definitions for “Intensive outpatient program (IOP)” and “Medication assisted treatment (MAT)” in alphabetical order;

e. Removing the definition of "Mental disorder";

f. Adding definitions for “Mental disorder, to include substance use disorder”, “Office-

based opioid treatment” and “Opioid Treatment Program” in alphabetical order;

g. Revising the definitions of “Other special institutional providers” and “Partial hospitalization”;

h. Adding a definition for “Qualified mental health provider” in alphabetical order;

i. Revising the definition of “Residential treatment center (RTC)”;

j. Adding a definition for “Substance use disorder rehabilitation facility (SUDRF)” in alphabetical order; and

k. Revising the definition of “Treatment plan”. The revisions and additions read as follows:

§ 199.2 Definitions

* * * * *

(b) * * *

Adequate medical documentation, mental health records. Adequate medical documentation provides the means for measuring the type, frequency, and duration of active treatment mechanisms employed and progress under the treatment plan. Under CHAMPUS, it is required that adequate and sufficient clinical records be kept by the provider to substantiate that specific care was actually and appropriately furnished, was medically or psychologically necessary (as defined by this part), and to identify the individual(s) who provided the care. Each service provided or billed must be documented in the records. In determining whether medical records are adequate, the records will be reviewed under the generally acceptable standards (e.g., the standards of an accrediting organization approved by the Director, and the provider’s state or local licensing requirements) and other requirements specified by this part. The psychiatric and psychological evaluations, physician orders, the treatment plan, integrated progress notes (and

physician progress notes if separate from the integrated progress notes), and the discharge summary are the more critical elements of the mental health record. However, nursing and staff notes, no matter how complete, are not a substitute for the documentation of services by the individual professional provider who furnished treatment to the beneficiary. In general, the documentation requirements of a professional provider are not less in the outpatient setting than the inpatient setting. Furthermore, even though a hospital that provides psychiatric care may be accredited under The Joint Commission (TJC) manual for hospitals rather than the behavioral health standards manual, the critical elements of the mental health record listed above are required for CHAMPUS claims.

* * * * *

Case management. Case management is a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs, including mental health and substance use disorder needs, using communication and available resources to promote quality, cost effective outcomes.

* * * * *

Consultation. A deliberation with a specialist physician, dentist, or qualified mental health provider requested by the attending physician primarily responsible for the medical care of the patient, with respect to the diagnosis or treatment in any particular case. A consulting physician or dentist or qualified mental health provider may perform a limited examination of a given system or one requiring a complete diagnostic history and examination. To qualify as a consultation, a written report to the attending physician of the findings of the consultant is required.

NOTE: Staff consultations required by rules and regulations of the medical staff of a hospital or

other institutional provider do not qualify as consultation.

* * * * *

Director. The Director of the Defense Health Agency, Director, TRICARE Management Activity, or Director, Office of CHAMPUS. Any references to the Director, Office of CHAMPUS, or OCHAMPUS, or TRICARE Management Activity, shall mean the Director, Defense Health Agency (DHA). Any reference to Director shall also include any person designated by the Director to carry out a particular authority. In addition, any authority of the Director may be exercised by the Assistant Secretary of Defense (Health Affairs).

* * * * *

Intensive outpatient program (IOP). A treatment setting capable of providing an organized day or evening program that includes assessment, treatment, case management and rehabilitation for individuals not requiring 24-hour care for mental health disorders, to include substance use disorders, as appropriate for the individual patient. The program structure is regularly scheduled, individualized and shares monitoring and support with the patient's family and support system.

* * * * *

Medication assisted treatment (MAT). MAT for diagnosed opioid use disorder is a holistic modality for recovery and treatment that employs evidence-based therapy, including psychosocial treatments and psychopharmacology, and FDA-approved medications as indicated for the management of withdrawal symptoms and maintenance.

* * * * *

Mental disorder, to include substance use disorder. For purposes of the payment of CHAMPUS benefits, a mental disorder is a nervous or mental condition that involves a clinically significant behavioral or psychological syndrome or pattern that is associated with a painful symptom, such as distress, and that impairs a patient's ability to function in one or more

major life activities. A substance use disorder is a mental condition that involves a maladaptive pattern of substance use leading to clinically significant impairment or distress; impaired control over substance use; social impairment; and risky use of a substance(s). Additionally, the mental disorder must be one of those conditions listed in the current edition of the Diagnostic and Statistical Manual of Mental Disorders. “Conditions Not Attributable to a Mental Disorder,” or V codes, are not considered diagnosable mental disorders. Co-occurring mental and substance use disorders are common and assessment should proceed as soon as it is possible to distinguish the substance related symptoms from other independent conditions.

* * * * *

Office-based opioid treatment. TRICARE authorized providers acting within the scope of their licensure or certification to prescribe outpatient supplies of the medication to assist in withdrawal management (detoxification) and/or maintenance of opioid use disorder, as regulated by 42 CFR part 8, addressing office-based opioid treatment (OBOT).

* * * * *

Opioid Treatment Program. Opioid Treatment Programs (OTPs) are service settings for opioid treatment, either free standing or hospital based, that adhere to the Department of Health and Human Services’ regulations at 42 CFR part 8 and use medications indicated and approved by the Food and Drug Administration. Treatment in OTPs provides a comprehensive, individually tailored program of medication therapy integrated with psychosocial and medical treatment and support services that address factors affecting each patient, as certified by the Center for Substance Abuse Treatment (CSAT) of the Department of Health and Human Services’ Substance Abuse and Mental Health Services Administration. Treatment in OTPs can include management of withdrawal symptoms (detoxification) from opioids and medically supervised withdrawal from maintenance medications. Patients receiving care for substance use

and co-occurring disorders care can be referred to, or otherwise concurrently enrolled in, OTPs.

* * * * *

Other special institutional providers. Certain specialized medical treatment facilities, either inpatient or outpatient, other than those specifically defined, that provide courses of treatment prescribed by a doctor of medicine or osteopathy; when the patient is under the supervision of a doctor of medicine or osteopathy during the entire course of the inpatient admission or the outpatient treatment; when the type and level of care and services rendered by the institution are otherwise authorized in this part; when the facility meets all licensing or other certification requirements that are extant in the jurisdiction in which the facility is located geographically; which is accredited by the Joint Commission or other accrediting organization approved by the Director if an appropriate accreditation program for the given type of facility is available; and which is not a nursing home, intermediate facility, halfway house, home for the aged, or other institution of similar purpose.

* * * * *

Partial hospitalization. A treatment setting capable of providing an interdisciplinary program of medically monitored therapeutic services, to include management of withdrawal symptoms, as medically indicated. Services may include day, evening, night and weekend treatment programs which employ an integrated, comprehensive and complementary schedule of recognized treatment approaches. Partial hospitalization is a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic environment. Partial hospitalization is an appropriate setting for crisis stabilization, treatment of partially stabilized mental disorders, to include substance disorders, and a transition from an inpatient program when medically necessary.

* * * * *

Qualified mental health provider. Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and supervised mental health counselors under a physician's supervision.

* * * * *

Residential treatment center (RTC). A facility (or distinct part of a facility) which meets the criteria in § 199.6(b)(4)(vii).

* * * * *

Substance use disorder rehabilitation facility (SUDRF). A facility or a distinct part of a facility that meets the criteria in § 199.6(b)(4)(xiv).

* * * * *

Treatment plan. A detailed description of the medical care being rendered or expected to be rendered a CHAMPUS beneficiary seeking approval for inpatient and other benefits for which preauthorization is required as set forth in § 199.4(b). Medical care described in the plan must meet the requirements of medical and psychological necessity. A treatment plan must include, at a minimum, a diagnosis (either current International Statistical Classification of Diseases and Related Health Problems (ICD) or current Diagnostic and Statistical Manual of Mental Disorders (DSM)); detailed reports of prior treatment, medical history, family history, social history, and physical examination; diagnostic test results; consultant's reports (if any); proposed treatment by type (such as surgical, medical, and psychiatric); a description of who is or will be providing treatment (by discipline or specialty); anticipated frequency, medications, and specific goals of treatment; type of inpatient facility required and why (including length of time the related inpatient stay will be required); and prognosis. If the treatment plan involves the transfer

of a CHAMPUS patient from a hospital or another inpatient facility, medical records related to that inpatient stay also are required as a part of the treatment plan documentation.

* * * * *

3. Section 199.4 is amended by:

- a. Revising paragraphs (a)(1)(i) and (a)(11);
- b. Removing and reserving paragraph (a)(12);
- c. Adding paragraphs (a)(14), (b)(1)(vi), (b)(2)(xix) and (xx), and (b)(3)(xvi) and (xvii);
- d. Removing paragraphs (b)(4)(viii) and (ix);
- e. Removing and reserving paragraphs (b)(6)(iii) and (iv);
- f. Revising paragraph (b)(7) introductory text;
- g. Revising paragraphs (b)(8), (9), and (10);
- h. Adding paragraph (b)(11);
- i. Revising paragraph (c)(3)(ix);
- j. Removing and reserving paragraphs (e)(4) and (e)(7);
- k. Revising paragraph (e)(8)(ii)(A);
- l. Adding paragraph (e)(8)(ii)(D);
- m. Removing and reserving paragraph (e)(8)(iv)(P);
- n. Revising paragraphs (e)(8)(iv)(Q) and (R);
- o. Revising paragraph (e)(11) introductory text
- p. Revising paragraph (e)(13)(i)(B);
- q. Removing paragraph (e)(30)(iii);
- r. Revising paragraph (f)(2)(ii) introductory text;
- s. Removing paragraph (f)(2)(ii)(D);
- t. Removing and reserving paragraph (f)(2)(v);

- u. Revising paragraph (f)(3)(ii);
- v. Removing paragraph (f)(3)(iv);
- w. Revising paragraphs (g)(1) and (g)(29);
- x. Removing and reserving paragraph (g)(72); and
- y. Revising paragraph (g)(73).

The revisions and additions read as follows:

§ 199.4 Basic program benefits.

(a) * * *

(1)(i) Scope of benefits. Subject to all applicable definitions, conditions, limitations, or exclusions specified in this part, the CHAMPUS Basic Program will pay for medically or psychologically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care and well-baby care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians, other authorized individual professional providers, and professional ambulance service, prescription drugs, authorized medical supplies, and rental or purchase of durable medical equipment.

* * * * *

(11) Quality and Utilization Review Peer Review Organization program. All benefits under the CHAMPUS program are subject to review under the CHAMPUS Quality and Utilization Review Peer Review Organization program pursuant to Sec 199.15.

* * * * *

(14) Confidentiality of substance use disorder treatment. Release of any patient identifying information, including that required to adjudicate a claim, must comply with the provisions of

section 543 of the Public Health Service Act, as amended, (42 U.S.C. 290dd-2), and implementing regulations at 42 CFR part 2, which governs the release of medical and other information from the records of patients undergoing treatment of substance use disorder. If the patient refuses to authorize the release of medical records which are, in the opinion of the Director, Defense Health Agency, or a designee, necessary to determine benefits on a claim for treatment of substance use disorder, the claim will be denied.

(b) * * *

(1) * * *

(vi) *Substance use disorder treatment exclusions.* (A) The programmed use of physical measures, such as electric shock, alcohol, or other drugs as negative reinforcement (aversion therapy) is not covered, even if recommended by a physician.

(B) *Domiciliary settings.* Domiciliary facilities generally referred to as halfway or quarterway houses are not authorized providers and charges for services provided by these facilities are not covered.

(2) * * *

(xix) *Medication assisted treatment.* Covered drugs and medicines for the treatment of substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.

(xx) *Withdrawal management (detoxification).* For a beneficiary undergoing treatment for a substance use disorder, this includes management of a patient's withdrawal symptoms (detoxification).

(3) * * *

(xvi) *Medication assisted treatment.* Covered drugs and medicines for the treatment of

substance use disorder include the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing supervised treatment for a substance use disorder.

(xvii) *Withdrawal management (detoxification)*. For a beneficiary undergoing treatment for a substance use disorder, this includes management of a patient's withdrawal symptoms (detoxification).

* * * * *

(7) *Emergency inpatient hospital services*. In the case of a medical emergency, benefits can be extended for medically necessary inpatient services and supplies provided to a beneficiary by a hospital, including hospitals that do not meet CHAMPUS standards or comply with the nondiscrimination requirements under title VI of the Civil Rights Act and other nondiscrimination laws applicable to recipients of federal financial assistance, or satisfy other conditions herein set forth. In a medical emergency, medically necessary inpatient services and supplies are those that are necessary to prevent the death or serious impairment of the health of the patient, and that, because of the threat to the life or health of the patient, necessitate, the use of the most accessible hospital available and equipped to furnish such services. Emergency services are covered when medically necessary for the active medical treatment of the acute phases of substance withdrawal (detoxification), for stabilization and for treatment of medical complications for substance use disorder. The availability of benefits depends upon the following three separate findings and continues only as long as the emergency exists, as determined by medical review. If the case qualified as an emergency at the time of admission to an unauthorized institutional provider and the emergency subsequently is determined no longer to exist, benefits will be extended up through the date of notice to the beneficiary and provider that CHAMPUS benefits no longer are payable in that hospital.

* * * * *

(8) Residential treatment for substance use disorder—(i) *In general*. Rehabilitative care, to include withdrawal management (detoxification), in an inpatient residential setting of an authorized hospital or substance use disorder rehabilitative facility, whether free-standing or hospital-based, is covered on a residential basis. The medical necessity for the management of withdrawal symptoms must be documented. Any withdrawal management (detoxification) services provided by the substance use disorder rehabilitation facility must be under general medical supervision.

(ii) *Criteria for determining medical or psychological necessity of residential treatment for substance use disorder*. Residential treatment for substance use disorder will be considered necessary only if all of the following conditions are present:

(A) The patient has been diagnosed with a substance use disorder.

(B) The patient is experiencing withdrawal symptoms or potential symptoms severe enough to require inpatient care and physician management, or who have less severe symptoms that require 24-hour inpatient monitoring or the patient's addiction-related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas.

(iii) *Services and supplies*. The following services and supplies are included in the per diem rate approved for an authorized residential treatment for substance use disorder.

(A) *Room and board*. Includes use of the residential treatment program facilities such as food service (including special diets), laundry services, supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

(B) *Patient assessment*. Includes the assessment of each individual accepted by the facility,

and must, at a minimum, consist of a physical examination; psychiatric examination; psychological assessment; assessment of physiological, biological and cognitive processes; case management assessment; developmental assessment; family history and assessment; social history and assessment; educational or vocational history and assessment; environmental assessment; and recreational/activities assessment. Assessments conducted within 30 days prior to admission to a residential treatment program for substance use disorder (SUD) may be used if approved and deemed adequate to permit treatment planning by the residential treatment program for SUD.

(C) *Psychological testing.* Psychological testing is provided based on medical and psychological necessity.

(D) *Treatment services.* All services, supplies, equipment and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: residential treatment programs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but are actively working toward licensure or certification may provide services within the all-inclusive per diem rate, but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) *Case management required.* The facility must provide case management that helps to assure arrangement of community based support services, referral of suspected child or elder abuse or domestic violence to the appropriate state agencies, and effective after care arrangements, at a minimum.

(v) *Professional mental health benefits.* Professional mental health benefits are billed

separately from the residential treatment program per diem rate only when rendered by an attending, TRICARE authorized mental health professional who is not an employee of, or under contract with, the program for purposes of providing clinical patient care.

(vi) *Non-mental health related medical services.* Separate billing will be allowed for otherwise covered non-mental health related services.

(9) *Psychiatric and substance use disorder partial hospitalization services—(i) In general.* Partial hospitalization services are those services furnished by a TRICARE authorized partial hospitalization program and authorized mental health providers for the active treatment of a mental disorder. All services must follow a medical model and vest patient care under the general direction of a licensed TRICARE authorized physician employed by the partial hospitalization program to ensure medication and physical needs of all the patients are considered. The primary or attending provider must be a TRICARE authorized mental health provider (see paragraph (c)(3)(ix) of this section), operating within the scope of his/her license. These categories include physicians, clinical psychologists, certified psychiatric nurse specialists, clinical social workers, marriage and family counselors, TRICARE certified mental health counselors, pastoral counselors, and supervised mental health counselors. All categories practice independently except pastoral counselors and supervised mental health counselors who must practice under the supervision of TRICARE authorized physicians. Partial hospitalization services and interventions are provided at a high degree of intensity and restrictiveness of care, with medical supervision and medication management. Partial hospitalization services are covered as a basic program benefit only if they are provided in accordance with paragraph (b)(9) of this section. Such programs must enter into a participation agreement with TRICARE; and be accredited and in substantial compliance with the specified standards of an accreditation organization approved by the Director.

(ii) *Criteria for determining medical or psychological necessity of psychiatric and SUD partial hospitalization services.* Partial hospitalization services will be considered necessary only if all of the following conditions are present:

(A) The patient is suffering significant impairment from a mental disorder (as defined in § 199.2) which interferes with age appropriate functioning or the patient is in need of rehabilitative services for the management of withdrawal symptoms from alcohol, sedative-hypnotics, opioids, or stimulants that require medically-monitored ambulatory detoxification, with direct access to medical services and clinically intensive programming of rehabilitative care based on individual treatment plans.

(B) The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively on an outpatient basis, to include outpatient treatment program, outpatient office visits, or intensive outpatient services (but is able, with appropriate support, to maintain a basic level of functioning to permit partial hospitalization services and presents no substantial imminent risk of harm to self or others). These patients require medical support; however, they do not require a 24-hour medical environment.

(C) The patient is in need of crisis stabilization, acute symptom reduction, treatment of partially stabilized mental health disorders, or services as a transition from an inpatient program.

(D) The admission into the partial hospitalization program is based on the development of an individualized diagnosis and treatment plan expected to be effective for that patient and permit treatment at a less intensive level.

(iii) *Services and supplies.* The following services and supplies are included in the per diem rate approved for an authorized partial hospitalization program:

(A) *Board*. Includes use of the partial hospital facilities such as food service, supervised therapeutically constructed recreational and social activities, and other general services as considered appropriate by the Director, or a designee.

(B) *Patient assessment*. Includes the assessment of each individual accepted by the facility, and must, at a minimum, consist of a physical examination; psychiatric examination; psychological assessment; assessment of physiological, biological and cognitive processes; case management assessment; developmental assessment; family history and assessment; social history and assessment; educational or vocational history and assessment; environmental assessment; and recreational/activities assessment. Assessments conducted within 30 days prior to admission to a partial program may be used if approved and deemed adequate to permit treatment planning by the partial hospital program.

(C) *Psychological testing. Treatment services*. All services, supplies, equipment and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: partial hospitalization programs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate, but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the partial hospitalization program.]

(iv) *Case management required*. The facility must provide case management that helps to assure the patient appropriate living arrangements after treatment hours, transportation to and from the facility, arrangement of community based support services, referral of suspected child or elder abuse or domestic violence to the appropriate state agencies, and effective after

care arrangements, at a minimum.

(v) *Educational services required.* Programs treating children and adolescents must ensure the provision of a state certified educational component which assures that patients do not fall behind in educational placement while receiving partial hospital treatment. CHAMPUS will not fund the cost of educational services separately from the per diem rate. The hours devoted to education do not count toward the therapeutic intensive outpatient program or full day program.

(vi) *Family therapy required.* The facility must ensure the provision of an active family therapy treatment component, which assures that each patient and family participate at least weekly in family therapy provided by the institution and rendered by a TRICARE authorized individual professional provider of mental health services. There is no acceptable substitute for family therapy. An exception to this requirement may be granted on a case-by-case basis by the Clinical Director, or designee, only if family therapy is clinically contraindicated.

(vii) *Professional mental health benefits.* Professional mental health benefits are billed separately from the partial hospitalization per diem rate only when rendered by an attending, TRICARE authorized mental health professional who is not an employee of, or under contract with, the partial hospitalization program for purposes of providing clinical patient care.

(viii) *Non-mental health related medical services.* Separate billing will be allowed for otherwise covered, non-mental health related medical services.

(10) *Intensive psychiatric and substance use disorder outpatient services—(i) In general.* Intensive outpatient services are those services furnished by a TRICARE authorized intensive outpatient program and qualified mental health provider(s) for the active treatment of a mental disorder, to include substance use disorder.

(ii) *Criteria for determining medical or psychological necessity of intensive outpatient*

services. In determining the medical or psychological necessity of intensive outpatient services, the evaluation conducted by the Director, or designee, shall consider the appropriate level of care, based on the patient's clinical needs and characteristics matched to a service's structure and intensity. In addition to the criteria set for this paragraph (b)(10) of this section, additional evaluation standards, consistent with such criteria, may be adopted by the Director, or designee. Treatment in an intensive outpatient setting shall not be considered necessary unless the patient requires care that is more intensive than an outpatient treatment program or outpatient office visits and less intensive than inpatient psychiatric care or a partial hospital program. Intensive outpatient services will be considered necessary only if the following conditions are present:

(A) The patient is suffering significant impairment from a mental disorder, to include a substance use disorder (as defined in § 199.2), which interferes with age appropriate functioning. Patients receiving a higher intensity of treatment may be experiencing moderate to severe instability, exacerbation of severe/persistent disorder, or dangerousness with some risk of confinement. Patients receiving a lower intensity of treatment may be experiencing mild instability with limited dangerousness and low risk for confinement.

(B) The patient is unable to maintain himself or herself in the community, with appropriate support, at a sufficient level of functioning to permit an adequate course of therapy exclusively in an outpatient treatment program or an outpatient office basis (but is able, with appropriate support, to maintain a basic level of functioning to permit a level of intensive outpatient treatment and presents no substantial imminent risk of harm to self or others).

(C) The patient is in need of stabilization, symptom reduction, and prevention of relapse for chronic mental illness. The goal of maintenance of his or her functioning within the community cannot be met by outpatient office visits, but requires active treatment in a stable, staff-supported environment;

(D) The admission into the intensive outpatient program is based on the development of an individualized diagnosis and treatment plan expected to be effective for that patient and permit treatment at a less intensive level.

(iii) *Services and supplies.* The following services and supplies are included in the per diem rate approved for an authorized intensive outpatient program.

(A) *Patient assessment.* Includes the assessment of each individual accepted by the facility.

(B) *Treatment services.* All services, supplies, equipment, and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual qualified mental health provider. [Exception: Intensive outpatient programs that employ individuals with master's or doctoral level degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but are actively working toward licensure or certification, may provide services within the all-inclusive per diem rate but such individuals must work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) *Case management.* When appropriate, and with the consent of the person served, the facility should coordinate the care, treatment, or services, including providing coordinated treatment with other services.

(v) *Professional mental health benefits.* Professional mental health benefits are billed separately from the intensive outpatient per diem rate only when rendered by an attending, TRICARE authorized qualified mental health provider who is not an employee of, or under contract with, the program for purposes of providing clinical patient care.

(vi) *Non-mental health related medical services.* Separate billing will be allowed for otherwise covered, non-mental health related medical services.

(11) *Opioid treatment programs*—(i) *In general*. Outpatient treatment and management of withdrawal symptoms for substance use disorder provided at a TRICARE authorized opioid treatment program are covered. If the patient is medically in need of management of withdrawal symptoms, but does not require the personnel or facilities of a general hospital setting, services for management of withdrawal symptoms are covered. The medical necessity for the management of withdrawal symptoms must be documented. Any services to manage withdrawal symptoms provided by the opioid treatment program must be under general medical supervision.

(ii) Criteria for determining medical or psychological necessity of an opioid treatment program are set forth in 42 CFR part 8.

(iii) *Services and supplies*. The following services and supplies are included in the reimbursement approved for an authorized opioid treatment program.

(A) *Patient assessment*. Includes the assessment of each individual accepted by the facility.

(B) *Treatment services*. All services, supplies, equipment, and space necessary to fulfill the requirements of each patient's individualized diagnosis and treatment plan. All mental health services must be provided by a TRICARE authorized individual professional provider of mental health services. [Exception: opioid treatment programs that employ individuals with degrees in a mental health discipline who do not meet the licensure, certification, and experience requirements for a qualified mental health provider but work under the clinical supervision of a fully qualified mental health provider employed by the facility.]

(iv) *Case management*. Care, treatment, or services should be coordinated among providers and between settings, independent of whether they are provided directly by the organization or by an organization or by an outside source, so that the individual's needs are addressed in a seamless, synchronized, and timely manner.

(c) * * *

(3) * * *

(ix) *Treatment of mental disorders, to include substance use disorder.* In order to qualify for CHAMPUS mental health benefits, the patient must be diagnosed by a TRICARE authorized qualified mental health professional practicing within the scope of his or her license to be suffering from a mental disorder, as defined in § 199.2

(A) *Covered diagnostic and therapeutic services.* CHAMPUS benefits are payable for the following services when rendered in the diagnosis or treatment of a covered mental disorder by a TRICARE authorized qualified mental health provider practicing within the scope of his or her license. Qualified mental health providers are: Psychiatrists or other physicians; clinical psychologists, certified psychiatric nurse specialists, certified clinical social workers, certified marriage and family therapists, TRICARE certified mental health counselors, pastoral counselors under a physician's supervision, and supervised mental health counselors under a physician's supervision.

(1) *Individual psychotherapy, adult or child.* A covered individual psychotherapy session is no more than 60 minutes in length. An individual psychotherapy session of up to 120 minutes in length is payable for crisis intervention.

(2) *Group psychotherapy.* A covered group psychotherapy session is no more than 90 minutes in length.

(3) *Family or conjoint psychotherapy.* A covered family or conjoint psychotherapy session is no more than 90 minutes in length. A family or conjoint psychotherapy session of up to 180 minutes in length is payable for crisis intervention.

(4) *Psychoanalysis.* Psychoanalysis is covered when provided by a graduate or candidate of a psychoanalytic training institution recognized by the American Psychoanalytic Association

and when preauthorized by the Director, or a designee.

(5) *Psychological testing and assessment.* Psychological testing and assessment is covered when medically or psychologically necessary. Psychological testing and assessment performed as part of an assessment for academic placement are not covered.

(6) *Administration of psychotropic drugs.* When prescribed by an authorized provider qualified by licensure to prescribe drugs.

(7) *Electroconvulsive treatment.* When provided in accordance with guidelines issued by the Director.

(8) *Collateral visits.* Covered collateral visits are those that are medically or psychologically necessary for the treatment of the patient.

(9) *Medication assisted treatment.* Medication assisted treatment, combining pharmacotherapy and holistic care, to include provision in office-based opioid treatment by an authorized TRICARE provider, is covered. The practice of an individual physician in office-based treatment is regulated by the Department of Health and Human Services' 42 CFR 8.12, the Center for Substance Abuse Treatment (CSAT), and the Drug Enforcement Administration (DEA), along with individual state and local regulations.

(B) *Therapeutic settings—(1) Outpatient psychotherapy.* Outpatient psychotherapy generally is covered for individual, family, conjoint, collateral, and/or group sessions.

(2) *Inpatient psychotherapy.* Coverage of inpatient psychotherapy is based on medical or psychological necessity for the services identified in the patient's treatment plan.

(C) *Covered ancillary therapies.* Includes art, music, dance, occupational, and other ancillary therapies, when included by the attending provider in an approved inpatient, SUDRF, residential treatment, partial hospital, or intensive outpatient program treatment plan and under the clinical supervision of a qualified mental health professional. These ancillary therapies are not

separately reimbursed professional services but are included within the institutional reimbursement.

(D) *Review of claims for treatment of mental disorder.* The Director shall establish and maintain procedures for review, including professional review, of the services provided for the treatment of mental disorders.

* * * * *

(e) * * *

(8) * * *

(ii) * * *

(A) For purposes of CHAMPUS, dental congenital anomalies such as absent tooth buds or malocclusion specifically are excluded.

* * * * *

(D) Any procedures related to sex gender changes, except as provided in paragraph (g)(29) of this section, are excluded.

* * * * *

(iv) * * *

(Q)) Penile implant procedure for psychological impotency or as related to sex gender changes, as prohibited by section 1079 of title 10, United States Code.

(R) Insertion of prosthetic testicles as related to sex gender changes, as prohibited by section 1079 of title 10, United States Code.

* * * * *

(11) *Drug abuse.* Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, TRICARE benefits cannot

be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means. Drugs, including the substitution of a therapeutic drug with addictive potential for a drug of addiction, prescribed to beneficiaries undergoing medically supervised treatment for a substance use disorder as authorized under paragraphs (b) and (c) of this section are not considered to be in support of, or to maintain, an existing or potential drug abuse situation and are allowed. The Director may prescribe appropriate policies to implement this prescription drug benefit for those undergoing medically supervised treatment for a substance use disorder.

* * * *

* (13) * * *

(i) * * *

(B) *Home care is not suitable.* Institutionalization of a child because a parent (or parents) is unable to provide a safe and nurturing environment due to a mental or substance use disorder, or because someone in the home has a contagious disease, are examples of why domiciliary care is being provided because the home setting is unsuitable.

* * * *

(f) * * *

(2) * * *

(ii) *Inpatient cost-sharing.* Dependents of members of the Uniformed Services are responsible for the payment of the first \$25 of the allowable institutional costs incurred with each covered inpatient admission to a hospital or other authorized institutional provider (refer to § 199.6, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility), or the amount the

beneficiary or sponsor would have been charged had the inpatient care been provided in a Uniformed Service hospital, whichever is greater.

Note: The Secretary of Defense (after consulting with the Secretary of Health and Human Services and the Secretary of Transportation) prescribes the fair charges for inpatient hospital care provided through Uniformed Services medical facilities. This determination is made each fiscal year.

* * * * *

(3) * * *

(ii) *Inpatient cost-sharing.* Inpatient admissions to a hospital or other authorized institutional provider (refer to § 199.6, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility) shall be cost-shared on an inpatient basis. The cost-sharing for inpatient services subject to the TRICARE DRG-based payment system and the TRICARE per diem system shall be the lesser of the respective per diem copayment amount multiplied by the total number of days in the hospital (except for the day of discharge under the DRG payment system), or 25 percent of the hospital's billed charges. For other inpatient services, the cost-share shall be 25% of the CHAMPUS-determined allowable charges.

* * * * *

(g) * * *

(1) *Not medically or psychologically necessary.* Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness (including mental disorder, to include substance use disorder) or injury, for the diagnosis and treatment of pregnancy or well-baby care except as provided in the following paragraph.

* * * * *

(29) *Sex gender changes.* Services and supplies related to sex gender change, also referred to as sex reassignment surgery, as prohibited by section 1079 of title 10, United States Code. This exclusion does not apply to surgery and related medically necessary services performed to correct sex gender confusion/intersex conditions (that is, ambiguous genitalia) which has been documented to be present at birth.

* * * * *

(73) *Economic interest in connection with mental health admissions.* Inpatient mental health services (including both acute care and RTC services) are excluded for care received when a patient is referred to a provider of such services by a physician (or other health care professional with authority to admit) who has an economic interest in the facility to which the patient is referred, unless a waiver is granted. Requests for waiver shall be considered under the same procedure and based on the same criteria as used for obtaining preadmission authorization (or continued stay authorization for emergency admissions), with the only additional requirement being that the economic interest be disclosed as part of the request. This exclusion does not apply to services under the Extended Care Health Option (ECHO) in § 199.5 or provided as partial hospital care. If a situation arises where a decision is made to exclude CHAMPUS payment solely on the basis of the provider's economic interest, the normal CHAMPUS appeals process will be available.

* * * * *

4. Section 199.6 is amended by revising paragraphs (b)(4)(iv)(B) and (D), (b)(4)(vii), (b)(4)(xii), and (b)(4)(xiv), and adding paragraphs (b)(4)(xviii) and (xix) to read as follows:

§ 199.6 TRICARE-authorized providers.

(b) * * *

(4) * * *

(iv) * * *

(B) In order for the services of a psychiatric hospital to be covered, the hospital shall comply with the provisions outlined in paragraph (b)(4)(i) of this section. All psychiatric hospitals shall be accredited under an accrediting organization approved by the Director, in order for their services to be cost-shared under CHAMPUS. In the case of those psychiatric hospitals that are not accredited because they have not been in operation a sufficient period of time to be eligible to request an accreditation survey, the Director, or a designee, may grant temporary approval if the hospital is certified and participating under Title XVIII of the Social Security Act (Medicare, Part A). This temporary approval expires 12 months from the date on which the psychiatric hospital first becomes eligible to request an accreditation survey by an accrediting organization approved by the Director.

* * * * *

(D) Although psychiatric hospitals are accredited under an accrediting organization approved by Director, their medical records must be maintained in accordance with accrediting organization's current standards manual, along with the requirements set forth in § 199.7(b)(3). The hospital is responsible for assuring that patient services and all treatment are accurately documented and completed in a timely manner.

* * * * *

(vii) *Residential treatment centers.* This paragraph (b)(4)(vii) establishes the definition of and eligibility standards and requirements for residential treatment centers (RTCs).

(A) *Organization and administration—(1) Definition.* A Residential Treatment Center (RTC) is a facility or a distinct part of a facility that provides to beneficiaries under 21 years of age a medically supervised, interdisciplinary program of mental health treatment. An RTC is

appropriate for patients whose predominant symptom presentation is essentially stabilized, although not resolved, and who have persistent dysfunction in major life areas. Residential treatment may be complemented by family therapy and case management for community based resources. Discharge planning should support transitional care for the patient and family, to include resources available in the geographic area where the patient will be residing. The extent and pervasiveness of the patient's problems require a protected and highly structured therapeutic environment. Residential treatment is differentiated from:

(i) Acute psychiatric care, which requires medical treatment and 24-hour availability of a full range of diagnostic and therapeutic services to establish and implement an effective plan of care which will reverse life-threatening and/or severely incapacitating symptoms;

(ii) Partial hospitalization, which provides a less than 24-hour-per-day, seven-day-per-week treatment program for patients who continue to exhibit psychiatric problems but can function with support in some of the major life areas;

(iii) A group home, which is a professionally directed living arrangement with the availability of psychiatric consultation and treatment for patients with significant family dysfunction and/or chronic but stable psychiatric disturbances;

(iv) Therapeutic school, which is an educational program supplemented by psychological and psychiatric services;

(v) Facilities that treat patients with a primary diagnosis of substance use disorder; and

(vi) Facilities providing care for patients with a primary diagnosis of mental retardation or developmental disability.

(2) *Eligibility.* (i) In order to qualify as a TRICARE authorized provider, every RTC must meet the minimum basic standards set forth in paragraphs (b)(4)(vii)(A) through (C) of this section, and as well as such additional elaborative criteria and standards as the Director

determines are necessary to implement the basic standards.

(ii) To qualify as a TRICARE authorized provider, the facility is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The facility is currently accredited by an accrediting organization approved by the Director.

(iv) The facility has a written participation agreement with OCHAMPUS. The RTC is not a CHAMPUS-authorized provider and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(vii), for the services of an RTC to be authorized, the RTC shall have entered into a Participation Agreement with OCHAMPUS. The period of a participation agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a Participation Agreement. Retroactive approval is not given. In addition, the Participation Agreement shall include provisions that the RTC shall, at a minimum:

(1) Render residential treatment center inpatient services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(2) Accept payment for its services based upon the methodology provided in § 199.14(f) or such other method as determined by the Director;

(3) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in § 199.4, and charges for services and

supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director, to collect those amounts, which represents the beneficiary's liability, as defined in § 199.4;

(5) Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the RTC agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(7) Certify that:

(i) It is and will remain in compliance with the TRICARE standards and provisions of paragraph (b)(4)(vii) of this section establishing standards for Residential Treatment Centers; and

(ii) It will maintain compliance with the CHAMPUS Standards for Residential Treatment Centers Serving Children and Adolescents with Mental Disorders, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The RTC shall inform OCHAMPUS in writing of the designated individual;

(9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director, OCHAMPUS;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and

other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis.

This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of the RTC which would confirm compliance with the participation agreement and designation as a TRICARE authorized RTC;

(ii) Conducting such audits of RTC records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the RTC and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required;

(v) Audits conducted by the United States Government Accountability Office.

(C) *Other requirements applicable to RTCs.* (1) Even though an RTC may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the RTC also meeting all conditions set forth in § 199.4 especially all requirements of § 199.4(b)(4).

(2) The RTC shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides inpatient services to all other patients. The RTC may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The RTC shall assure that all certifications and information provided to the Director, incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized status will be denied or terminated, and the RTC will be ineligible for consideration for authorized provider status for a two year period.

* * * * *

(xii) *Psychiatric and substance use disorder partial hospitalization programs.* This paragraph (b)(4)(xii) establishes the definition of and eligibility standards and requirements for psychiatric and substance use disorder partial hospitalization programs.

(A) *Organization and administration—(1) Definition.* Partial hospitalization is defined as a time-limited, ambulatory, active treatment program that offers therapeutically intensive, coordinated, and structured clinical services within a stable therapeutic milieu. Partial hospitalization programs serve patients who exhibit psychiatric symptoms, disturbances of conduct, and decompensating conditions affecting mental health. Partial hospitalization is appropriate for those whose psychiatric and addiction-related symptoms or concomitant physical and emotional/behavioral problems can be managed outside the hospital for defined periods of time with support in one or more of the major life areas. A partial hospitalization program for the treatment of substance use disorders is an addiction-focused service that provides active treatment to children and adolescents, or adults aged 18 and over.

(2) *Eligibility.* (i) To qualify as a TRICARE authorized provider, every partial hospitalization program must meet minimum basic standards set forth in paragraphs (b)(4)(xii)(A) through (D) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each

partial hospitalization program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing program. Approval of a hospital by TRICARE is sufficient for its partial hospitalization program to be an authorized TRICARE provider. Such hospital-based partial hospitalization programs are not required to be separately authorized by TRICARE.

(ii) To be approved as a TRICARE authorized provider, the facility is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The facility is required to be currently accredited by an accrediting organization approved by the Director. Each PHP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The facility is required to have a written participation agreement with OCHAMPUS. The PHP is not a CHAMPUS-authorized provider and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements.* In addition to other requirements set forth in this paragraph (b)(4)(xii), in order for the services of a PHP to be authorized, the PHP shall have entered into a Participation Agreement with OCHAMPUS. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. The PHP shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the PHP until the date the participation agreement is signed by the Director. In addition to review of a facility's application and supporting documentation, an on-site inspection by OCHAMPUS authorized personnel may be required prior to signing a

participation agreement. The Participation Agreement shall include at least the following requirements:

(1) Render partial hospitalization program services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation.

(2) Accept payment for its services based upon the methodology provided in § 199.14, or such other method as determined by the Director;

(3) Accept the CHAMPUS all-inclusive per diem rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that represent the beneficiary's liability, as defined in § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in § 199.4;

(5) Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Submit claims for services provided to CHAMPUS beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the PHP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by CHAMPUS;

(7) Certify that:

(i) It is and will remain in compliance with the TRICARE standards and provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and substance use disorder partial hospitalization programs; and

(ii) It will maintain compliance with the CHAMPUS Standards for Psychiatric Substance

Use Disorder Partial Hospitalization Programs, as issued by the Director, except for any such standards regarding which the facility notifies the Director, or designee, that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The PHP shall inform the Director, or designee, in writing of the designated individual;

(9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost-effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of the PHP which would confirm compliance with the participation agreement and designation as a TRICARE authorized PHP provider;

(ii) Conducting such audits of PHP records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the PHP and interviewing employees,

members of the staff, contractors, board members, volunteers, and patients, as required;

(v) Audits conducted by the United States General Account Office.

(C) *Other requirements applicable to PHPs.* (1) Even though a PHP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the PHP also meeting all conditions set forth in § 199.4.

(2) The PHP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The PHP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that is has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the PHP will be ineligible for consideration for authorized provider status for a two year period.

* * * * *

(xiv) *Substance use disorder rehabilitation facilities.* This paragraph (b)(4)(xiv) establishes the definition of eligibility standards and requirements for residential substance use disorder rehabilitation facilities (SUDRF).

(A) *Organization and administration—(1) Definition.* A SUDRF is a residential or rehabilitation facility, or distinct part of a facility, that provides medically monitored, interdisciplinary addiction-focused treatment to beneficiaries who have psychoactive substance use disorders. Qualified health care professionals provide 24-hour, seven-day-per-week, assessment, treatment, and evaluation. A SUDRF is appropriate for patients whose addiction-

related symptoms, or concomitant physical and emotional/behavioral problems reflect persistent dysfunction in several major life areas. Residential or inpatient rehabilitation is differentiated from:

(i) Acute psychoactive substance use treatment and from treatment of acute biomedical/emotional/behavioral problems; which problems are either life-threatening and/or severely incapacitating and often occur within the context of a discrete episode of addiction-related biomedical or psychiatric dysfunction;

(ii) A partial hospitalization center, which serves patients who exhibit emotional/behavioral dysfunction but who can function in the community for defined periods of time with support in one or more of the major life areas;

(iii) A group home, sober-living environment, halfway house, or three-quarter way house;

(iv) Therapeutic schools, which are educational programs supplemented by addiction-focused services;

(v) Facilities that treat patients with primary psychiatric diagnoses other than psychoactive substance use or dependence; and

(vi) Facilities that care for patients with the primary diagnosis of mental retardation or developmental disability.

(2) *Eligibility.* (i) In order to become a TRICARE authorized provider, every SUDRF must meet minimum basic standards set forth in paragraphs (b)(4)(xiv)(A) through (C) of this section, as well as such additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards.

(ii) To be approved as a TRICARE authorized provider, the SUDRF is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The SUDRF is currently accredited by an accrediting organization approved by

the Director. Each SUDRF must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The SUDRF has a written participation agreement with OCHAMPUS. The SUDRF is not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements.* In addition to other requirements set forth in this paragraph (b)(4)(xiv), in order for the services of an inpatient rehabilitation center for the treatment of substance use disorders to be authorized, the center shall have entered into a Participation Agreement with OCHAMPUS. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. The SUDRF shall not be considered to be a CHAMPUS authorized provider and CHAMPUS payments shall not be made for services provided by the SUDRF until the date the participation agreement is signed by the Director. In addition to review of the SUDRF's application and supporting documentation, an on-site visit by OCHAMPUS representatives may be part of the authorization process. In addition, such a Participation Agreement may not be signed until an SUDRF has been licensed and operational for at least six months. The Participation Agreement shall include at least the following requirements:

(1) Render applicable services to eligible CHAMPUS beneficiaries in need of such services, in accordance with the participation agreement and CHAMPUS regulation;

(2) Accept payment for its services based upon the methodology provided in § 199.14, or such other method as determined by the Director;

(3) Accept the CHAMPUS-determined rate as payment in full and collect from the CHAMPUS beneficiary or the family of the CHAMPUS beneficiary only those amounts that

represent the beneficiary's liability, as defined in § 199.4, and charges for services and supplies that are not a benefit of CHAMPUS;

(4) Make all reasonable efforts acceptable to the Director to collect those amounts which represent the beneficiary's liability, as defined in § 199.4;

(5) Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to CHAMPUS;

(6) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified to by an independent accounting firm or other agency as authorized by the Director;

(7) Certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xiv) of the section establishing standards for substance use disorder rehabilitation facilities; and

(ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director and notified the Director of any matter regarding which the facility is not in compliance with such standards; and

(iii) It will maintain compliance with the CHAMPUS Standards for Substance Use Disorder Rehabilitation Facilities, as issued by the Director, except for any such standards regarding which the facility notifies the Director that it is not in compliance.

(8) Designate an individual who will act as liaison for CHAMPUS inquiries. The SUDRF shall inform OCHAMPUS in writing of the designated individual;

(9) Furnish OCHAMPUS, as requested by OCHAMPUS, with cost data certified by an independent accounting firm or other agency as authorized by the Director;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review,

claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis.

This right to audit/review included, but is not limited to:

(i) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(ii) Conducting such audits of center records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the SUDRF and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(v) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to substance use disorder rehabilitation facilities.

(1) Even though a SUDRF may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the SUDRF also meeting all conditions set forth in §

199.4.

(2) The center shall provide inpatient services to CHAMPUS beneficiaries in the same manner it provides services to all other patients. The center may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The substance use disorder facility shall assure that all certifications and information provided to the Director, incident to the process of obtaining and retaining authorized provider status, is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the facility will be ineligible for consideration for authorized provider status for a two year period.

* * * * *

(xviii) *Intensive outpatient programs.* This paragraph (b)(4)(xviii) establishes standards and requirements for intensive outpatient treatment programs for psychiatric and substance use disorder.

(A) *Organization and administration—(1) Definition.* Intensive outpatient treatment (IOP) programs are defined in § 199.2. IOP services consist of a comprehensive and complimentary schedule of recognized treatment approaches that may include day, evening, night, and weekend services consisting of individual and group counseling or therapy, and family counseling or therapy as clinically indicated for children and adolescents, or adults aged 18 and over, and may include case management to link patients and their families with community based support systems.

(2) *Eligibility.* (i) In order to qualify as a TRICARE authorized provider, every intensive outpatient program must meet the minimum basic standards set forth in paragraphs

(b)(4)(xviii)(A) through (C) of this section, as well as additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. Each intensive outpatient program must be either a distinct part of an otherwise-authorized institutional provider or a free-standing psychiatric or substance use disorder intensive outpatient program. Approval of a hospital by TRICARE is sufficient for its IOP to be an authorized TRICARE provider. Such hospital-based intensive outpatient programs are not required to be separately authorized by TRICARE.

(ii) To qualify as a TRICARE authorized provider, the IOP is required to be licensed and operate in substantial compliance with state and federal regulations.

(iii) The IOP is currently accredited by an accrediting organization approved by the Director. Each IOP authorized to treat substance use disorder must be accredited to provide the level of required treatment by an accreditation body approved by the Director.

(iv) The facility has a written participation agreement with TRICARE. The IOP is not considered a TRICARE authorized provider and TRICARE benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) *Participation agreement requirements.* In addition to other requirements set forth in paragraph (b)(4)(xii) of this section, in order for the services of an IOP to be authorized, the IOP shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of the TRICARE authorized facility granted that all programs meet the requirements of this part. The period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation

agreement. The Participation Agreement shall include at least the following requirements:

(1) Render intensive outpatient program services to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.

(2) Accept payment for its services based upon the methodology provided in § 199.14, or such other method as determined by the Director;

(3) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in § 199.4, and charges for services and supplies that are not a benefit of TRICARE;

(4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in § 199.4;

(5) Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;

(6) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, the IOP agrees not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;

(7) Free-standing intensive outpatient programs shall certify that:

(i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for psychiatric and SUD IOPs;

(ii) It has conducted a self-assessment of the facility's compliance with the CHAMPUS Standards for Intensive Outpatient Programs, as issued by the Director, and notified the Director of any matter regarding which the facility is not in compliance with such standards; and

(iii) It will maintain compliance with the TRICARE standards for IOPs, as issued by the

Director, except for any such standards regarding which the facility notifies the Director, or a designee that it is not in compliance.

(8) Designate an individual who will act as liaison for TRICARE inquiries. The IOP shall inform TRICARE, or a designee in writing of the designated individual;

(9) Furnish OCHAMPUS with cost data, as requested by OCHAMPUS, certified by an independent accounting firm or other agency as authorized by the Director.

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, preauthorization, concurrent care review, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not CHAMPUS beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review included, but is not limited to:

(i) Examination of fiscal and all other records of the center which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(ii) Conducting such audits of center records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided CHAMPUS beneficiaries;

(iii) Examining reports of evaluations and inspection conducted by federal, state and local government, and private agencies and organizations;

(iv) Conducting on-site inspections of the facilities of the IOP and interviewing employees, members of the staff, contractors, board members, volunteers, and patients, as required.

(v) Audits conducted by the United States Government Accountability Office.

(C) Other requirements applicable to Intensive Outpatient Programs (IOP). (1) Even though an IOP may qualify as a TRICARE authorized provider and may have entered into a participation agreement with CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon the IOP also meeting all conditions set forth in § 199.4.

(2) The IOP may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices, placement in special or separate wings or rooms, or provisions of special or limited treatment.

(3) The IOP shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and the IOP will be ineligible for consideration for authorized provider status for a two year period.

(xix) *Opioid Treatment Programs (OTPs)*. This paragraph (b)(4)(xix) establishes standards and requirements for Opioid Treatment Programs.

(A) *Organization and administration*. (1) *Definition*. Opioid Treatment Programs (OTPs) are defined in § 199.2. Opioid Treatment Programs (OTPs) are organized, ambulatory, addiction treatment services for patients with an opioid use disorder. OTPs have the capacity to provide daily direct administration of medications without the prescribing of medications. Medication supplies for patients to take outside of OTPs originate from within OTPs. OTPs

offer medication assisted treatment, patient-centered, recovery-oriented individualized treatment through addiction counseling, mental health therapy, case management, and health education.

(2) *Eligibility.* (i) Every free-standing Opioid Treatment Program must be accredited by an accrediting organization recognized by Director, under the current standards of an accrediting organization, as well as meet additional elaborative criteria and standards as the Director determines are necessary to implement the basic standards. OTPs adhere to requirements of the Department of Health and Human Services' 42 CFR part 8, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment, and the Drug Enforcement Agency. OTPs must be either a distinct part of an otherwise authorized institutional provider or a free-standing program. Approval of hospitals by TRICARE is sufficient for their OTPs to be authorized TRICARE providers. Such hospital-based OTPs, if certified under 42 CFR section 8, are not required to be separately authorized by TRICARE.

(ii) To qualify as a TRICARE authorized provider, OTPs are required to be licensed and fully operational for a period of at least six months and operate in substantial compliance with state and federal regulations.

(iii) OTPs have a written participation agreement with OCHAMPUS. OTPs are not considered a TRICARE authorized provider, and CHAMPUS benefits are not paid for services provided until the date upon which a participation agreement is signed by the Director.

(B) Participation agreement requirements. In addition to other requirements set forth in this paragraph (b)(4)(xix), in order for the services of OTPs to be authorized, OTPs shall have entered into a Participation Agreement with TRICARE. A single consolidated participation agreement is acceptable for all units of a TRICARE authorized facility. The

period of a Participation Agreement shall be specified in the agreement, and will generally be for not more than five years. In addition to review of a facility's application and supporting documentation, an on-site inspection by DHA authorized personnel may be required prior to signing a participation agreement. The Participation Agreement shall include at least the following requirements:

- (1) Render services from OTPs to eligible TRICARE beneficiaries in need of such services, in accordance with the participation agreement and TRICARE regulation.
- (2) Accept payment for its services based upon the methodology provided in § 199.14, or such other method as determined by the Director;
- (3) Collect from the TRICARE beneficiary or the family of the TRICARE beneficiary only those amounts that represent the beneficiary's liability, as defined in § 199.4, and charges for services and supplies that are not a benefit of TRICARE;
- (4) Make all reasonable efforts acceptable to the Director to collect those amounts, which represent the beneficiary's liability, as defined in § 199.4;
- (5) Comply with the provisions of § 199.8, and submit claims first to all health insurance coverage to which the beneficiary is entitled that is primary to TRICARE;
- (6) Submit claims for services provided to TRICARE beneficiaries at least every 30 days (except to the extent a delay is necessitated by efforts to first collect from other health insurance). If claims are not submitted at least every 30 days, OTPs agree not to bill the beneficiary or the beneficiary's family for any amounts disallowed by TRICARE;
- (7) Free-standing opioid treatment programs shall certify that:
 - (i) It is and will remain in compliance with the provisions of paragraph (b)(4)(xii) of this section establishing standards for opioid treatment programs;
 - (ii) It will maintain compliance with the TRICARE standards for OTPs, as issued by the

Director, except for any such standards regarding which the facility notifies the Director, or a designee, that it is not in compliance.

(8) Designate an individual who will act as liaison for TRICARE inquiries. OTPs shall inform TRICARE, or a designee, in writing of the designated individual;

(9) Furnish TRICARE, or a designee, with cost data, as requested by TRICARE, certified by an independent accounting firm or other agency as authorized by the Director;

(10) Comply with all requirements of this section applicable to institutional providers generally concerning accreditation requirements, claims processing, beneficiary liability, double coverage, utilization and quality review, and other matters;

(11) Grant the Director, or designee, the right to conduct quality assurance audits or accounting audits with full access to patients and records (including records relating to patients who are not TRICARE beneficiaries) to determine the quality and cost effectiveness of care rendered. The audits may be conducted on a scheduled or unscheduled (unannounced) basis. This right to audit/review includes, but is not limited to:

(i) Examination of fiscal and all other records of OTPs which would confirm compliance with the participation agreement and designation as an authorized TRICARE provider;

(ii) Conducting such audits of OTPs' records including clinical, financial, and census records, as may be necessary to determine the nature of the services being provided, and the basis for charges and claims against the United States for services provided TRICARE beneficiaries;

(iii) Examining reports of evaluations and inspections conducted by federal, state and local government, and private agencies and organizations.

(C) *Other requirements applicable to OTPs.* (1) Even though OTPs may qualify as a TRICARE authorized provider and may have entered into a participation agreement with

CHAMPUS, payment by CHAMPUS for particular services provided is contingent upon OTPs also meeting all conditions set forth in § 199.4.

(2) OTPs may not discriminate against CHAMPUS beneficiaries in any manner, including admission practices or provisions of special or limited treatment.

(3) OTPs shall assure that all certifications and information provided to the Director incident to the process of obtaining and retaining authorized provider status is accurate and that it has no material errors or omissions. In the case of any misrepresentations, whether by inaccurate information being provided or material facts withheld, authorized provider status will be denied or terminated, and OTPs will be ineligible for consideration for authorized provider status for a two year period.

* * * * *

§ 199.7 [Amended]

- 5. Section 199.7 is amended by removing and reserving paragraph (e)(2).
- 6. Section 199.14 is amended by revising paragraphs (a)(2)(iv)(C)(2) and (4) and (a)(2)(ix) to read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * * (2)

* * *

(iv) * * *

(C) * * *

(2) Except as provided in paragraph (a)(2)(iv)(C)(3) of this section, for subsequent federal fiscal years, each per diem shall be updated by the Medicare Inpatient Prospective Payment System update factor.

* * * * *

(4) Hospitals and units with hospital-specific rates will be notified of their respective rates prior to the beginning of each Federal fiscal year. New hospitals shall be notified at such time as the hospital rate is determined. The actual amount of each regional per diem that will apply in any Federal fiscal year shall be posted to the Agency's official website at the start of that fiscal year.

* * * * *

(ix) *Payment for psychiatric and substance use disorder rehabilitation partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services—(A) Per diem payments.* Psychiatric and substance use disorder partial hospitalization services, intensive outpatient psychiatric and substance use disorder services and opioid treatment services authorized by § 199.4(b)(9), (b)(10), and (b)(11), respectively, and provided by institutional providers authorized under § 199.6(b)(4)(xii), (b)(4)(xviii) and (b)(4)(xix), respectively, are reimbursed on the basis of prospectively determined, all-inclusive per diem rates pursuant to the provisions of paragraphs (a)(2)(ix)(A)(1) through (3) of this section, with the exception of hospital-based psychiatric and substance use disorder and opioid services which are reimbursed in accordance with provisions of paragraph (a)(6)(ii) of this section and freestanding opioid treatment programs when reimbursed on a fee-for-service basis as specified in paragraph (a)(2)(ix)(A)(3)(ii) of this section. The per diem payment amount must be accepted as payment in full, subject to the outpatient cost-sharing provisions under § 199.4(f), for institutional services provided, including board, routine nursing services, group therapy, ancillary services (e.g., music, dance, and occupational and other such therapies), psychological testing and assessment, overhead and any other services for which the customary practice among similar providers is included in the institutional charges, except for

those services which may be billed separately under paragraph (a)(2)(ix)(B) of this section. Per diem payment will not be allowed for leave days during which treatment is not provided.

(1) *Partial hospitalization programs.* For any full-day partial hospitalization program (minimum of 6 hours), the maximum per diem payment amount is 40 percent of the average inpatient per diem amount per case established under the TRICARE mental health per diem reimbursement system during the fiscal year for both high and low volume psychiatric hospitals and units [as defined in paragraph (a)(2) of this section]. Intensive outpatient services provided in a PHP setting lasting less than 6 hours, with a minimum of 2 hours, will be paid as provided in paragraph (a)(2)(ix)(A)(2) of this section. PHP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(2) *Intensive outpatient programs.* For intensive outpatient programs (IOPs) (minimum of 2 hours), the maximum per diem amount is 75 percent of the rate for a full-day partial hospitalization program as established in paragraph (a)(2)(ix)(A)(1) of this section. IOP per diem rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(3) *Opioid treatment programs.* Opioid treatment programs (OTPs) authorized by § 199.4(b)(11) and provided by providers authorized under § 199.6(b)(4)(xix) will be reimbursed based on the variability in the dosage and frequency of the drug being administered and in related supportive services.

(i) *Weekly all-inclusive per diem rate.* Methadone OTPs will be reimbursed the lower of the billed charge or the weekly all-inclusive per diem rate (the weekly national all-inclusive rate adjusted for locality), including the cost of the drug and related services (i.e., the costs related to the initial intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and support services). The bundled weekly per diem

payments will be accepted as payment in full, subject to the outpatient cost-sharing provisions under § 199.4(f). The methadone per diem rate for OTPs will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(ii) *Exceptions to per diem reimbursement.* When providing other medications which are more likely to be prescribed and administered in an office-based opioid treatment setting, but which are still available for treatment of substance use disorders in an outpatient treatment program setting, OTPs will be reimbursed on a fee-for-service basis (i.e., separate payments will be allowed for both the medication and accompanying support services), subject to the outpatient cost-sharing provisions under § 199.4(f). OTPs' rates will be updated annually by the Medicare update factor used for their Inpatient Prospective Payment System.

(iii) *Discretionary authority.* The Director, TRICARE, will have discretionary authority in establishing the reimbursement methodologies for new drugs and biologicals that may become available for the treatment of substance use disorders in OTPs. The type of reimbursement (e.g., fee-for-service versus bundled per diem payments) will be dependent on the variability of the dosage and frequency of the medication being administered, as well as the support services.

(B) *Services which may be billed separately.* Psychotherapy sessions and non-mental health related medical services not normally included in the evaluation and assessment of PHP, IOP or OTPs, provided by authorized independent professional providers who are not employed by, or under contract with, PHP, IOP or OTPs for the purposes of providing clinical patient care are not included in the per diem rate and may be billed separately. This includes ambulance services when medically necessary for emergency transport.

* * * * *

§ 199.15 [Amended]

7. Section 199.15 is amended in paragraph (a)(6) by removing “, such as inpatient mental

health services in excess of 30 days in any year” in the last sentence.

8. Section 199.18 is amended by:

- a. Revising paragraph (d)(2)(ii);
- b. Removing and reserving paragraph (d)(3)(ii); and
- c. Revising paragraphs (e)(2) and (3).

The revisions read as follows:

§ 199.18 Uniform HMO Benefit.

* * * * *

(d) * * *

(2) * * *

(ii) The per visit fee provided in paragraph (d)(2)(i) of this section shall also apply to partial hospitalization services, intensive outpatient treatment, and opioid treatment program services. The per visit fee shall be applied on a per day basis on days services are received, with the exception of opioid treatment program services reimbursed in accordance with § 199.14(a)(2)(ix)(A)(3)(i) which per visit fee will apply on a weekly basis.

* * * * *

(e) * * *

(2) *Structure of cost-sharing.* For inpatient admissions, there is a nominal copayment for retired members, dependents of retired members, and survivors. This nominal copayment shall apply to an inpatient admission to any hospital or other authorized institutional provider, including inpatient admission to a residential treatment center, substance use disorder rehabilitation facility residential treatment program, or skilled nursing facility.

(3) *Amount of inpatient cost-sharing requirements.* In fiscal year 2001, the inpatient cost-sharing requirements for retirees and their dependents for acute care admissions and other

inpatient admissions is a per diem charge of \$11, with a minimum charge of \$25 per admission.

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Dated: August 29, 2016.

Aaron Siegel

Alternate OSD Federal Register Liaison Officer

Department of Defense

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