#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

**45 CFR Part 84** 

RIN 0945-AA27

Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance

**AGENCY:** Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department) issues this Notice of Proposed Rulemaking (NPRM) to revise 45 CFR 84.4(g) in the regulation implementing section 504 of the Rehabilitation Act of 1973 (section 504) as it applies to recipients of HHS funding (entitled "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance," 89 FR 40066 ("2024 Final Rule")), published on May 9, 2024. This rule clarifies that the Department interprets the statutory exclusion of "gender identity disorders not resulting from physical impairments" from the definitions of "individual with a disability" and "disability" set forth at 29 U.S.C. 705(9) & (20)(F)(i), 42 U.S.C. 12211(b), to encompass "gender dysphoria not resulting from a physical impairment" for purposes of part 84. This clarification is necessary to resolve ambiguity introduced in the preamble to the 2024 Final Rule and to ensure compliance with the best reading of the plain language of the governing statute.

#### **DATES:**

Comments: Submit comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]

**ADDRESSES:** You may submit comments to this proposed rule, identified by RIN Number 0945 -AA27, by any of the following methods. Please do not submit duplicate comments.

Federal eRulemaking Portal: You may submit electronic comments at <a href="https://regulations.gov">https://regulations.gov</a> by searching for the Docket ID number XXXXX. Follow the instructions for submitting electronic comments. If you are submitting comments electronically, the department strongly encourages you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), the Department strongly encourages you to convert the PDF to "print-to-PDF" format, or to use some other commonly used searchable text format. Please do not submit the PDF in scanned format. Using a print-to-PDF allows the Department to electronically search and copy certain portions of your submissions to assist in the rulemaking process.

**Regular, Express, or Overnight Mail:** You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Disability NPRM, RIN 0945-AA27, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

All comments received by the methods and due date specified above, or officially post marked by the due date above, will be posted without change to content to <a href="https://www.regulations.gov">https://www.regulations.gov</a>, including any personal information provided, and such posting may occur after the closing of the comment period.

However, the Department may redact certain non-substantive content from comments before posting, including threats, hate speech, profanity, graphic images, or individually identifiable information about an individual third-party other than the commenter. In addition, comments or material designated as confidential or not to be disclosed to the public will not be accepted. Comments may be redacted or rejected as described above without notice to the commenter, and the Department will not consider in rulemaking any redacted or rejected content that would not be made available to the public as part of the administrative record. Because of the large number of

public comments normally received on Federal Register documents, the Office for Civil Rights is not able to provide individual acknowledgements of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays.

Please note that comments submitted by fax or email and those submitted or postmarked after the comment period will not be accepted.

*Docket:* For a plain language summary of the proposed rule and complete access to background documents or posted comments, go to <a href="https://www.regulations.gov">https://www.regulations.gov</a> and search for Docket ID number <a href="https://www.regulations.gov">XXXXXX</a>.

## FOR FURTHER INFORMATION CONTACT:

John Thompson, Office for Civil Rights, Department of Health and Human Services at (202) 545-4884 or (800) 537-7697 (TDD), or via email at 504@hhs.gov.

## **SUPPLEMENTARY INFORMATION:**

#### **Table of Contents**

### I. Background

- a. Statutory Framework
- b. Medical Diagnostic History of "Gender Dysphoria"
- c. Fourth Circuit Interpretation and Litigation

# II. Legal Authority

# III. Reasons for the Proposed Rulemaking

#### IV. Alternatives Considered

## V. Executive Order 12866 and Related Executive Orders on Regulatory Review

- a. Executive Order 12866 Determination
- b. Executive Order 12250 on Leadership and Coordination of Nondiscrimination
- c. Regulatory Flexibility Analysis Initial Small Entity Analysis
- d. Executive Order 13132: Federalism

e. Executive Order 13175: Tribal Consultation

f. Paperwork Reduction Act

g. Executive Order 14192: Deregulation

## VI. Request for Comment

#### **Background**

#### **Statutory Framework**

Section 504 of the Rehabilitation Act of 1973, codified at 29 U.S.C. 794, prohibits discrimination on the basis of disability in federally assisted and federally conducted programs and activities. Specifically, 29 U.S.C. 794(a) provides: "No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency[.]" The HHS Office for Civil Rights (OCR) enforces section 504 as well as other statutes that prohibit discrimination on the basis of disability. Although the Rehabilitation Act predates the Americans with Disabilities Act of 1990 (ADA), Congress subsequently amended the Rehabilitation Act, through the Rehabilitation Act Amendments of 1992 (Pub. L. 102-569, sec. 102, 106 Stat 4344), to align key definitions in the Rehabilitation Act with key definitions in the ADA. Under these amendments, the term "individual with a disability" "does not include an individual on the basis of . . . transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders." 29 U.S.C. 705(20)(F)(i).

Congress amended the Rehabilitation Act again, in the ADA Amendments Act of 2008 (Pub. L. 110-325, sec. 7, 122 Stat 3553), to further align the Rehabilitation Act definitions with the ADA. Specifically, 29 U.S.C. 705(9)(B) states: "The term 'disability' means . . . for purposes of [section 504], the meaning given it in section 12102 of [the ADA]." In addition, the definition of "individual with a disability" at 29 U.S.C. 705(20)(B) was revised for purposes of section 504 to mean "any person who has a disability as defined in section 12102 of [the ADA]." Under the

ADA, 42 U.S.C. 12102(1), "disability" means: "(A) a physical or mental impairment that substantially limits one or more major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment." The ADA, at 42 U.S.C. 12211(b), explicitly excludes certain conditions from the definition of "disability." Specifically, 42 U.S.C. 12211(b)(1) states that, "under this Chapter," on Equal Opportunity for Individuals with Disabilities,"[t]he term 'disability' shall not include (1) transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders[.]" Thus, any regulatory interpretation of section 504 must adhere to these identical statutory exclusions from the definitions of "individual with a disability" and "disability."

# Relevant Medical Diagnostic History of "Gender Dysphoria"

At the time Congress passed the ADA, the American Psychiatric Association's Diagnostic and Statistical Manual (DSM), third edition (1987) ("DSM-III-R") described a set of disorders as "gender identity disorders." DSM-III-R at 71-78. This set of disorders included "Gender Identity Disorder of Childhood," "Transsexualism," "Gender Identity Disorder of Adolescence or Adulthood, Nontranssexual Type (GIDAANT)," and "Gender Identity Disorder Not Otherwise Specified." *Id.* As described in DSM-III-R, the "essential feature of the disorders included in this subclass [Gender Identity Disorders] is an incongruence between assigned sex (i.e., the sex that is recorded on the birth certificate) and gender identity." *Id.* at 71.

The descriptions for each of the disorders within the DSM-III-R's set of "Gender Identity Disorders" tracked this essential feature. "Gender Identity Disorder of Childhood" was marked by "persistent and intense distress in a child about his or her assigned sex and the desire to be, or insistence that he or she is, of the other sex." *Id.* at 71. An "essential feature[]" of "transsexualism" included "a persistent discomfort and sense of inappropriateness about one's assigned sex in a person who has reached puberty." *Id.* at 74. GIDAANT similarly included "a persistent or recurrent discomfort and sense of inappropriateness about one's assigned sex[.]" *Id.* at 76. Finally, "Gender

Identity Disorder Not Otherwise Specified" served as a catch-all for "[d]isorders in gender identity that are not classifiable as a specific Gender Identity Disorder." *Id.* at 77. The conditions were associated with symptoms such as anxiety and depression. *Id.* at 72, 74, 76.

The DSM-III-R was in effect at the time Congress passed the exclusionary language at issue. Later, the diagnostic framework in the DSM-III-R was revised in the DSM fourth edition (1994) ("DSM-IV") to describe a singular condition, "Gender Identity Disorder." DSM-IV at 532-38. The DSM-IV's description of "Gender Identity Disorder" included a diagnostic criterion that the condition "causes clinically significant distress or impairment in social, occupational, or other important areas of functioning." DSM-IV at 538.

In 2013, the American Psychiatric Association revised its terminology in the DSM fifth edition ("DSM-5"), replacing the section on "Gender Identity Disorder" with a section on "Gender Dysphoria." DSM-5 at 451-59. In DSM-5, "[g]ender dysphoria refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." *Id.* at 451. The DSM-5 explained that the terminology change was because "[t]he current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se." *Id.* 

The diagnostic criteria for "gender dysphoria" remained functionally similar to the criteria for gender identity disorder(s) in previous versions of the DSM. To qualify for a diagnosis of gender dysphoria under DSM-5, a person must exhibit a "marked incongruence between one's experienced/expressed gender and assigned gender" "of at least six months' duration," as manifested through specific urges or convictions. *Id.* at 452. "The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." *Id.* at 452-53. Importantly, the American Psychiatric Association explicitly

intersex condition." DSM-IV at 537, 538.

<sup>&</sup>lt;sup>1</sup> The DSM-IV also included a category for "Gender Identity Disorder Not Otherwise Specified" that was "included for coding disorders in gender identity that are not classifiable as a specific Gender Identity Disorder," and which could be used, for example, "for individuals who have a gender identity problem with a concurrent congenital

acknowledged that this was not the creation of a new diagnosis, but rather a reframing of the same condition: "This diagnosis is a revision of DSM-IV's criteria for gender identity disorder and is intended to *better characterize* the experiences of affected children, adolescents, and adults."<sup>2</sup>

## Fourth Circuit Interpretation and Litigation

The Rehabilitation Act and the ADA expressly exclude "gender identity disorders not resulting from physical impairments" from the definition of "disability." As noted above, this exclusion was enacted in the ADA in 1990 and has never been amended by Congress.

While this seems straightforward, in recent years, Federal district courts have split on whether "Gender Dysphoria" falls within the ADA's exclusion for gender identity disorders not resulting from physical impairments.<sup>3</sup> The Fourth Circuit's decision in *Williams v. Kincaid*, 45 F.4th 759 (4th Cir. 2022), *cert. denied*, 600 U.S. \_\_\_\_ (2023), represents the only appellate review of this issue on the merits under the ADA and the Rehabilitation Act.

In *Williams* the court concluded, in a 2-1 decision, that gender dysphoria is not excluded from the ADA's definition of "disability." *Williams*, 45 F.4th at 769, 773-74. The majority reasoned that gender dysphoria, as clinically classified, is distinct from "gender identity disorders not resulting from physical impairments" excluded by the ADA in 42 U.S.C. § 12211(b)(1). *Id.* Specifically, the court emphasized that gender dysphoria involves clinically significant distress and functional impairments, and that, thus, the diagnostic criteria under the DSM-5 differ from those of the gender identity disorders referenced in the DSM-III-R when the ADA was enacted in

<sup>&</sup>lt;sup>2</sup> Am. Psychiatric Ass'n, *Gender Dysphoria* (2013), <a href="https://www.psychiatry.org/file%20library/psychiatrists/practice/dsm/apa\_dsm-5-gender-dysphoria.pdf">https://www.psychiatry.org/file%20library/psychiatrists/practice/dsm/apa\_dsm-5-gender-dysphoria.pdf</a> (emphasis added).

<sup>&</sup>lt;sup>3</sup> See, e.g., the following cases determining that gender dysphoria is subject to the ADA's gender identity disorder exclusion: Duncan v. Jack Henry & Assocs., Inc., 617 F. Supp. 3d 1011, 1055–57 (W.D. Mo. 2022); Lange v. Houston Cnty., 608 F. Supp. 3d 1340, 1361–63 (M.D. Ga. 2022); Doe v. Northrop Grumman Sys. Corp., 418 F. Supp. 3d 921, 930 (N.D. Ala. 2019); Parker v. Strawser Constr. Inc., 307 F. Supp. 3d 744, 754–55 (S.D. Ohio 2018); Gulley-Fernandez v. Wis. Dep't of Corr., No. 15-CV-995, 2015 WL 7777997, at \*3 (E.D. Wis. Dec. 1, 2015); but see Guthrie v. Noel, No. 1:20-CV-02351, 2023 WL 8115928, at \*13 (M.D. Pa. Sept. 11, 2023); Kozak v. CSX Transportation, Inc., No. 20-CV-184S, 2023 WL 4906148, at \*4–7 (W.D.N.Y. Aug. 1, 2023); Doe v. Mass. Dep't of Corr., No. 17-12255-RGS, 2018 WL 2994403, at \*6–7 (D. Mass. Jun. 14, 2018); Blatt v. Cabela's Retail, Inc., No. 5:14-cv-04822, 2017 WL 2178123, at \*3–4 (E.D. Pa. May 18, 2017).

1990. *Williams*, 45 F.4th at 767-68. The majority interpreted the ADA in light of what it viewed as evolving medical concepts.

The Supreme Court subsequently denied certiorari in *Kincaid v. Williams*, 600 U.S., \_\_\_\_143, S. Ct. 2414 (2023), leaving the Fourth Circuit's judgment intact. As a result, *Williams* remains binding precedent within Maryland, North Carolina, South Carolina, Virginia, and West Virginia, but it does not constitute controlling authority elsewhere. \*\*See Maryland v. Balt. Radio Show, Inc., 338 U.S. 912, 919 (1950) (Frankfurter, J., respecting denial of certiorari) (noting that denial of certiorari "does not remotely imply approval . . . of what was said by [the lower court]").

#### Relevant Regulatory History and Related Lawsuits.

On May 9, 2024, the Department issued the 2024 Final Rule modifying its regulations implementing section 504. As relevant here, the preamble to the 2024 Final Rule discussed whether "gender dysphoria may constitute a disability under section 504." 89 FR at 40069. The 2024 Final Rule concluded, in its preamble, that "gender dysphoria does not fall with the statutory exclusions for gender identity disorders." *Id.* The codified regulatory text merely cross-referenced the statutory exclusion in 29 U.S.C. 705(20)(F). *See* 45 C.F.R. 84.4(g).

The 2024 Final Rule, including its preamble language, spawned litigation. In *Texas v. Becerra*, No. 5:24-cv-00225 (N.D. Tex.), seventeen States filed suit challenging the 2024 Final Rule, arguing, among other things, that the preamble's reference to gender dysphoria unlawfully expands the definition of "disability" beyond the scope authorized by 29 U.S.C. 705(20)(F) and 42 U.S.C. § 12211(b).<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> The factual basis of *Kincaid*'s 2022 holding has since been called into doubt. The majority opinion relied in part on the applicability of the seventh edition of the World Professional Association for Transgender Health Standards of Care ("WPATH Standards") to interpret the gender identify disorder exclusion. *Kincaid*, 45 F.4th at 764, 769; *id*. at 782 (Quattlebaum, J., dissenting) (recognizing the majority's reliance on WPATH Standards). Since that opinion, the basis for the WPATH standards have been undermined. *See Eknes Tucker v. Governor*, 114 F.4th 1241, 1261 (11th Cir. 2024) (Lagoa, J., concurring in denial of rehearing *en banc*) ("recent revelations indicate that WPATH's lodestar is ideology, not science"); *see also* Statement of Interest of the United States, *Fuller v. Georgia Dep't of Corr.*, N.D. Ga., 25-cv-246, Apr. 25, 2025.

<sup>&</sup>lt;sup>5</sup> Litigation also has been filed in the Western District of Louisiana similarly challenging the section 504 preamble reference to gender dysphoria. *Rapides Parish Sch. Bd. v. U.S. Dep't of Health & Hum. Servs., et al*, 1:25-cv-70 (W.D. La.).

In response to the litigation, the Department published a notice in the Federal Register (90 FR 15412 (Apr. 11, 2025)). The notice highlights the Department's concern that "there has been significant confusion about the preamble language referencing gender dysphoria in the" 2024 Final Rule. *Id.* at 15412. The notice stated: "It is well-established that where, as here, the language included in the regulatory text itself is clear, statements made in the preamble to a final rule published in the Federal Register, lack the force and effect of law and are not enforceable."

This NPRM reaffirms the statutory exclusion of 29 U.S.C. 705(20)(F) in unambiguous terms for section 504 coverage and makes clear that the Department interprets the exclusionary language "gender identity disorders not resulting from physical impairments" to encompass gender dysphoria that does not result from physical impairment.

### **Legal Authority**

The Department has legal authority under the Rehabilitation Act to promulgate regulations "as may be necessary to carry out [section 504]." 29 U.S.C. 794(a). Indeed, since 1977, the year the Department (then, the Department of Health Education and Welfare) issued the implementing regulation for section 504 Part 84, the Department has exercised this authority to interpret the requirements of 29 U.S.C. 794(a) and provide certainty to recipients of Department financial assistance that they are in compliance with section 504. For example, in *Alexander v. Choate*, the Supreme Court relied on the general nondiscrimination requirements in HHS' section 504 implementing regulations in Part 84 when determining whether limitations on Medicaid benefits amounted to discrimination under section 504.6

As stated in *Loper Bright v. Raimondo*, "when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring the agency acts within it." While courts must respect that Congress delegated authority to HHS to implement regulations for section 504 and interpret the nondiscrimination requirements of the

-

<sup>&</sup>lt;sup>6</sup> See Alexander v. Choate, 469 U.S. 287, 304 (1985).

<sup>&</sup>lt;sup>7</sup> Loper Bright Enters. v. Raimondo, 603 U.S. 369, 413 (2024).

statute, the preamble to the 2024 Final Rule went beyond the statutory limits when it interpreted the definition of disability in a manner that included a condition excluded by Congress.

Administrative agencies must act within the limits of authority delegated to them by Congress. As the Supreme Court has made clear, "[a]n agency literally has no power to act . . . unless and until Congress confers power upon it." *Louisiana Public Service Commission v. FCC*, 476 U.S. 355, 374 (1986). Agencies may not expand their authority or reframe statutory provisions based on policy preferences. *See Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) (stating that agencies cannot through rulemaking "conjure up a [right] that has not been authorized by Congress. Agencies may play the sorcerer's apprentice but not the sorcerer himself").

The definition of "individual with a disability" in section 504 and the definition of "disability" that applies to both section 504 and the ADA do not cover "transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders." 29 U.S.C. 705(9) & (20)(F)(i), 42 U.S.C. 12211(b)(1). As neither section 504 nor the ADA define "gender identity disorders," the term must be given the "ordinary meaning" it had at the time of its adoption. *See Niz-Chavez v. Garland*, 593 U.S. 155, 160 (2021) ("When called on to resolve a dispute over a statute's meaning, this Court normally seeks to afford the law's terms their ordinary meaning at the time Congress adopted them."). Given the history of the terms "gender identity disorders" and "gender dysphoria" referenced above, under the ordinary meaning of the term as used in the DSM-III-R, gender identity disorder, as a category, includes gender dysphoria.

In the 1990s, gender identity disorders were understood to be a family of conditions which shared the same "essential feature": an individual experiencing "incongruence between assigned sex (i.e., the sex that is recorded on the birth certificate) and gender." DSM-III-R at 71. The DSM-III-R noted that an individual with even mild incongruence could feel "discomfort and a sense of inappropriateness about the [ir] assigned sex." *Id.* at 77. The distress resulting from the discomfort could also manifest as "[a]nxiety and depression." *Id.* at 76. Not all individuals with gender

incongruence can fit squarely within a subcategory due to a variation of symptoms. However, even if an individual does not fit within a specific subcategory, the individual would have a "Gender Identity Disorder Not Otherwise Specified" *Id.* at 77-78.

A later update of the DSM published in 1994 clarified that distress was part and parcel of a gender identity disorder. To make a gender identity disorder diagnosis, "there must be evidence of clinically significant *distress* or impairment in social, occupational, or other important areas of functioning." DSM-IV at 533 (emphasis added).

The DSM-5 switched from using the term "gender identity disorders" to "gender dysphoria." But the difference is merely linguistic. Gender dysphoria specifically "refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." DSM-5 at 451. To be diagnosed with gender dysphoria, an individual must show the hallmark of a gender identity disorder—gender incongruence. *See* DSM-5 at 452-53. Then, because of that incongruence, they must also have "clinically significant distress or impairment." *See id.* In other words, gender dysphoria is gender identity disorder where the person has specifically had "clinically significant distress."

While the American Psychiatric Association and the medical profession may have changed how they conceptualize gender identity disorders by focusing on the distress rather than on the incongruence, they do not have the authority to redefine the meaning of statutes. *See id.* at 451 (explaining that change in conceptualizing gender identity disorders); As Judge Quattlebaum wrote in his opinion in *Williams*, "linguistic drift cannot alter the meaning of the words in the ADA when it was enacted." *Williams*, 45 F.4th at 780; *see also Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024) ("[E]very statute's meaning is fixed at the time of enactment." (quotation omitted)).

The exclusions from the definition of "disability" applicable to the ADA and section 504 and from the definition of "individual with a disability" applicable in section 504, cannot be circumvented through renaming or redefining the conditions that are excluded in the law. Gender

identity disorders were understood to encompass conditions where the person was suffering from gender incongruence and the accompanying distress. Gender dysphoria falls squarely within this framework.

Here, the Rehabilitation Act and the ADA expressly exclude "gender identity disorders not resulting from physical impairments" from the definitions of "disability" and "individual with a disability." 29 U.S.C. 705(9) & (20)(F)(i); 42 U.S.C. 12211(b)(1). OCR does not have the authority to broaden or narrow these statutory exclusions through agency rulemaking. Deviation from the statute Congress enacted would be legally vulnerable under the Administrative Procedure Act, which requires federal courts to "hold unlawful and set aside" agency actions taken "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. 706(2)(C).

While Williams framed its analysis in terms of evolving medical classifications, such reliance on post-enactment developments in the DSM-5 raises serious concerns under established canons of statutory construction. Instead, one must look to the DSM-III-R, in place in 1990, which provides that, even in mild cases, gender identity disorders involve "discomfort and a sense of the inappropriateness about the assigned sex." DSM-III-R at 71. It even lists such distress as the first diagnostic criteria for gender identity disorder. *Id.* at 73, 77. This language makes clear that gender identity disorders, as understood in 1990, included distress and discomfort from identifying as a gender different from the sex assigned at birth and thus encompasses "gender dysphoria." See at 2417 (Alito, J. dissenting from denial of certiorari) (noting that the "broad brush used by Congress" in crafting the language of Section 12211(b)(1) suggests Congressional intent to "prohibit the ADA's application to conditions that are sufficiently similar to the more specific categories of conditions" identified). Several federal courts agree with this interpretation. See, e.g., Parker v. Strawser Constr., Inc., 307 F. Supp. 3d 744, 754 (S.D. Ohio 2018) (surveying cases and finding that "[t]he majority of federal cases have concluded" that the ADA excludes from its protection "both disabling and non-disabling gender identity disorders that do not result from a physical impairment"); *Duncan v. Jack Henry Assocs., Inc.*, 617 F. Supp. 3d 1011, 1056-57 (W.D. Mo. 2022) (concluding that ADA's exclusion of gender identity disorders "encompass[ed] Plaintiff's diagnosis of gender dysphoria"); *Lange v. Houston Cnty., Georgia*, 608 F. Supp. 3d 1340, 1361-63 (M.D. Ga. 2022) (holding that gender dysphoria not resulting from physical impairment is subject to the gender identity disorder exclusion); *Doe v. Northrop Grumman Sys. Corp.*, 418 F. Supp. 3d 921, 930 (N.D. Ala. 2019) (same).

Accordingly, under a review of the definition of disability as written in 29 U.S.C. 705(20)(A) and (F)(i), independent of HHS' 2024 Final Rule and preamble, many courts have reached the conclusion that the best reading of the statute is that "disability" does not include gender dysphoria not resulting from physical impairments. Even if a court considers there to be ambiguity as to whether gender identity disorders not resulting from physical impairments includes gender dysphoria not resulting from physical impairments, "there is a best reading all the same—'the reading the court would have reached' if no agency were involved." This proposed rulemaking rectifies the overreach committed by the 2024 Final Rule preamble and recognizes the the interpretation of "disability" set by Congress and the courts as required by the Administrative Procedures Act.9

#### **Reasons for the Proposed Rulemaking**

The Department is issuing this NPRM to address a targeted but consequential gap in regulatory clarity created by the 2024 Final Rule's preamble. Although the operative regulation at 45 CFR 84.4(g) cross-references the statutory exclusion for "gender identity disorders not resulting from physical impairments," the preamble's general discussion of gender dysphoria introduced interpretative confusion regarding how the exclusion applies to that condition. The Department has determined that this ambiguity warrants regulatory resolution.

<sup>&</sup>lt;sup>8</sup>Loper Bright Enters. v. Raimondo, 603 U.S. 369, 400 (2024).

<sup>&</sup>lt;sup>9</sup> See 5 U.S.C. § 706.

When Congress clearly excluded "gender identity disorders not resulting from physical impairments," federal agencies and courts are bound to apply that exclusion as written, unless and until Congress amends the underlying statute. Here, the Rehabilitation Act and the ADA expressly exclude "gender identity disorders not resulting from physical impairments" from the definitions of "disability" and "individual with a disability." 29 U.S.C. 705(9) & (20)(F)(i); 42 U.S.C. 12211(b)(1). OCR does not have the authority to broaden or narrow these statutory exclusions through agency rulemaking. This is in part because the Administrative Procedure Act requires federal courts to "hold unlawful and set aside" agency actions taken "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. 706(2)(C). Therefore, to remedy the ambiguity and reduce litigation risk, we are issuing this proposed rule to clarify that, where "gender identity disorders not resulting from physical impairments" is used in part 84, it encompasses "gender dysphoria not resulting from physical impairments," because the statutory text states as much.

The Department maintains that the preamble language of the 2024 Final Rule lacks the force and effect of law and is not enforceable. However, we recognize that this proposed rule comes to a different conclusion on whether "gender dysphoria" not resulting from physical impairment may be a disability under section 504 compared to that preamble.

The Department is issuing this rule because it has reevaluated the relevant statutory language and determined that the term "gender dysphoria not resulting from physical impairments" is encompassed in the term "gender identity disorder not resulting from physical impairments," as that term is used in the ADA and in section 504, based on the plain language of the statutory exclusions from the definitions of "disability" and "individual with a disability" in the context of existing medical terminology at the time of the ADA's enactment. The discussion in the preamble of the 2024 final rule focused almost exclusively on the *Williams* majority opinion and its determination that the current definition of gender dysphoria is not interchangeable with the definition of gender identity disorder from 1990. 45 F.4th 759. After careful consideration, the

Department recognizes that the evolving medical classifications of gender disorders cannot change the meaning of the statutory language.

Because the preamble lacks the force and effect of law and is not enforceable, the Department expects that any reliance interests are minimal. To the extent anyone relied on that language, however, they have no legitimate reliance interests in maintaining that language, and indeed would be harmed by its continuation. Since the preamble language is not enforceable and lacks the force of law, no one can use it to their benefit. Meanwhile, individuals may unintentionally believe that the preamble language can override statutory language. By fixing the incorrect language in the preamble, the Department is ensuing that no one incorrectly relies on the mistaken interpretation to their detriment.

#### **Alternatives Considered**

While the Department believes that rulemaking to clarify that the definitions of "disability" and "individual with a disability" in Section 504 exclude "gender dysphoria not resulting from physical impairments" is the most prudent course of action, we considered a host of alternatives.

The first alternative to rulemaking considered was to simply leave the existing preamble language in place and maintain the Department's position that the preamble language is not binding or legally enforceable, as stated in the April 11, 2025 notice in the Federal Register. While this approach would result in less rulemaking for the Department and may ultimately result in the same outcome as this rulemaking in hypothetical future litigation, it would do little to rectify the ambiguity surrounding the definition of "disability" caused by the preamble to the 2024 Final Rule. The Department believes that the 2024 Final Rule Preamble has generated significant confusion and that the only way to rectify such confusion is to modify the text.

The second alternative considered was to issue guidance further explaining to the public that the Department interpreted the exclusion for "gender identity disorders not resulting from

-

<sup>&</sup>lt;sup>10</sup> 90 FR 15412 (Apr. 11, 2025).

physical impairments" to include "gender dysphoria not resulting from physical impairments." Similar to the first alternative, the Department determined that guidance alone would be insufficient to rectify the existing confusion, and the public would question why contradictory preamble language still existed.

The final alternative considered was a full repeal of the 2024 Final Rule. While this method would have eliminated the confusion caused by the preamble language, such an approach would be broader than necessary to address the issue presented by the preamble on whether "disability" included or excluded "gender dysphoria not resulting from physical impairment.".

The Department requests comments on these alternatives considered.

# Executive Order 12866 and Related Executive Orders on Regulatory Review

#### **Executive Order 12866 Determination**

Pursuant to Executive Order 12866, this rulemaking has been designated as a significant regulatory action under subsection 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

#### **Executive Order 12250 on Leadership and Coordination of Nondiscrimination**

Pursuant to Executive Order 12250, the Attorney General has the responsibility to "coordinate the implementation and enforcement by Executive agencies of . . . "[a]ny other provision of Federal statutory law which provides, in whole or in part, that no person in the United States shall, on the ground of race, color, national origin, handicap, religion, or sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance." Executive Order 12250 at § 1-201(d), 45 FR 72995 (Nov. 2, 1980). The NPRM was reviewed and approved by the Attorney General.

#### RFA – Initial Small Entity Analysis

The Regulatory Flexibility Act (RFA), Public Law 96-354, applies to rules for which an agency publishes a general notice of proposed rulemaking (NPRM) pursuant to 5 U.S.C. 553(b).<sup>11</sup>

-

<sup>&</sup>lt;sup>11</sup> See generally 5 U.S.C. 601, et. seq.

Because this proposed rule would clarify a single limited aspect of the definitions of "disability" and "individual with a disability" under section 504, any associated costs to recipients, including small entities, would be negligible. Recipients would not have to purchase new equipment, alter benefits, or change their practices in any way based on this clarification. The Department certifies that this proposed rule would not have a significant effect on small entities.

#### **Executive Order 13132: Federalism**

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications. The Department has determined that this proposed rule does not impose such costs or have any Federalism implications.

#### **Executive Order 13175: Tribal Consultation**

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Because this rulemaking would only clarify whether "gender dysphoria not resulting from physical impairment" may be included in the definitions of "disability" and "individual with a disability" and will not have a significant effect on Tribal finances or the relationship between the Federal Government and Indian Tribes, the Department has determined that this rulemaking would not have Tribal implications that require consultation under Executive Order 13175.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. ch. 3506; 5 CFR part 1320 appendix A.1), the Department has reviewed this proposed rule and has determined that there are no new or modified collections of information contained therein.

#### **Executive Order 14192: Deregulation**

Under Executive Order 14192, Unleashing Prosperity Through Deregulation, executive agencies are required to limit the costs of planned regulations, including by repealing existing regulations for each newly promulgated regulation and/or prioritizing regulations with minimal costs or burdens. This proposed rule will not impose new costs or burdens on recipients as it will result in a clarification made necessary by the preamble language of the 2024 Final Rule that called into question whether gender dysphoria could be considered a disability.

#### **Request for Comment**

The Department seeks comment on all issues raised by the proposed rule. Additionally, the Department seeks comments on any reliance interests that recipients of financial assistance from HHS, people with disabilities, or other entities may have related to the gender dysphoria discussion in the preamble of the 2024 Final Rule. The Department is especially interested in comments indicating that an entity has changed its policies, practices, or procedures to account for the 2024 Final Rule gender dysphoria preamble language and how this rulemaking would affect the entity. The Department also seeks comments on the regulatory alternatives it considered in Section IV of this notice of proposed rulemaking and the Department's decision to pursue this rulemaking.

#### List of Subjects in 45 CFR Part 84

Adoption and foster care, Civil rights, Childcare, Child welfare, Colleges and universities, Communications, Disabled, Discrimination, Emergency medical services, Equal access to justice, Federal financial assistance, Grant programs, Grant programs—health, Grant programs—social programs, Health, Health care, Health care access, Health facilities, Health programs and activities, Individuals with disabilities, Integration, Long term care, Medical care, Medical equipment, Medical facilities, Nondiscrimination, Public health.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR Subtitle A, Subchapter A, Part 84 as set forth below:

45 CFR PART 84 —NONDISCRIMINATION ON THE BASIS OF DISABILITY IN

PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE.

1. The authority citation for part 84 continues to read as follows:

Authority: 29 U.S.C. 794

Subpart G is also issued under 21 U.S.C. 1174; 42 U.S.C. 4581.

2. Amend § 84.4 by revising subsection (g) to read as follows:

§ 84.4 Disability

(g) Exclusions. The term "disability" does not include the conditions set forth at 29

U.S.C. 705(20)(F), including "transvestism, transsexualism, pedophilia, exhibitionism,

voyeurism, gender identity disorders not resulting from physical impairments, or other

sexual behavior disorders" under Section 705(20)(F)(i). For the purpose of part 84, the

term "gender identity disorders not resulting from physical impairments" includes gender

dysphoria not resulting from physical impairments.

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

[FR Doc. 2025-23484 Filed: 12/18/2025 8:45 am; Publication Date: 12/19/2025]