January 27, 2025

Via Federal eRulemaking Portal

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4208–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: **HHS Proposed Rule, "Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Enhancing Coverage of Preventive Services Under the Affordable Care Act" RIN: 0938-AV40**

Dear Acting Administrator Wu:

I am a scholar at the Ethics and Public Policy Center (EPPC), a member of EPPC's Administrative State Accountability Project (ASAP), and a former attorney in the U.S. Department of Justice's Civil Rights Division. I write to offer public comment regarding the Department of Health and Human Services' (HHS) proposed rule, "Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Enhancing Coverage of Preventive Services Under the Affordable Care Act" (Proposed Rule).[1]

I write in response to one particular aspect of the Proposed Rule, its proposed modifications to 42 C.F.R. § 442.112(a)(8).[2] The Proposed Rule would reorganize the section slightly and add a new § 422.112(a)(8)(ii) to clarify that § 422.112(a)(8)'s "equitable access" requirements apply to "[a]rtificial intelligence or automated systems" and that covered entities must therefore take care that such systems, "if utilized, [are] used in such a manner that preserves equitable access to [Medicare Advantage] services."

I take no position on the merits of this proposal, but instead call HHS's attention to § 422.112(a)(8)'s list of protected bases, reorganized here from § 422.112(a)(8)(i)-(vii) to § 422.112(a)(8)(i)(A)-(G). One of these provisions, 42 C.F.R. § 422.122(a)(8)(E), states that Medicare

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[1] 89 Fed. Reg. 99340 (Dec. 10, 2024), https://www.federalregister.gov/documents/2024/12/10/2024-27939/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.
[2] *Id*. at 99560.

Advantage organizations must "promote equitable access to . . . [p]eople who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex."[3]

As HHS reviews this Proposed Rule, I ask HHS to review the proposed new § 422.112(a)(8)(E) to make sure it complies with President Trump's January 20, 2025, Executive Order, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government."[4] I specifically direct you to the following aspects of the President's Executive Order:

- Section 2(f) recognizes that "Gender ideology is internally inconsistent, in that it diminishes sex as an identifiable or useful category but nevertheless maintains that it is possible for a person to be born in the wrong sexed body."

- Section 2(g) recognizes that "'Gender identity' reflects a fully internal and subjective sense of self, disconnected from biological reality and sex and existing on an infinite continuum, that does not provide a meaningful basis for identification and cannot be recognized as a replacement for sex."

- Section 3(a) instructs the Secretary of HHS to "provide to the U.S. Government, external partners, and the public clear guidance expanding on the sex-based definitions set forth in this order."

- Section 3(b) states that federal agencies "shall enforce laws governing sex-based rights, protections, opportunities, and accommodations to protect men and women as biologically distinct sexes."

- Section 3(c) states that, "[w]hen administering or enforcing sex-based distinctions," federal agencies "shall use the term 'sex' and not 'gender' in all applicable Federal policies and documents."

- Section 3(f) instructs the Attorney General to "immediately issue guidance to agencies to correct the misapplication of the Supreme Court's decision in *Bostock v. Clayton County* (2020) to sex-based distinctions in agency activities.

To my knowledge, the Secretary of HHS has not yet issued the guidance described in Section 3(a) and the Attorney General has not yet issued the guidance described in Section 3(f). As HHS looks to finalize this Proposed Rule, HHS should look to see whether the Secretary of HHS and Attorney General have promulgated guidance in response to President Trump's Executive Order. If they have, HHS must take those guidance documents into account.

More broadly, I encourage HHS to review the identified provisions of the President's Executive Order on Gender Ideology into account, along with any guidance or other relevant documents issued pursuant to the President's Executive Order, as it considers proposed changes to 42 C.F.R. § 422.122(a)(8)(E).

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[3] Proposed 42 C.F.R. § 422.122(a)(8)(E), at 89 Fed. Reg. at 99560.
[4] https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/.

Conclusion

For the reasons stated above, I urge the Department to carefully examine the proposed changes to 42 C.F.R. § 422.122(a)(8)(E) in the Proposed Rule in light of President Trump's January 20, 2025, Executive Order. "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government." I hope this public comment helps you better carry out your important responsibilities and ensure that the regulations finalized by HHS reflect the President's priorities and directives.

Sincerely,

Eric Kniffin, J.D.
Fellow
Administrative State Accountability Project
Ethics & Public Policy Center