ETHICS AND PUBLIC POLICY CENTER

November 1, 2024

Secretary Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201
Via regulations.gov

Re: EPPC Scholars Comment Opposing Interim Final Rule, "Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principes, and Award Requirements for Federal Awards," 89 Fed. Reg. 80,055 (Oct. 2, 2024), Docket ID HHS_FRDOC_0001; RIN ____

Dear Secretary Becerra:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write in strong opposition to the Interim Final Rule (IFR), "Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principes, and Award Requirements for Federal Awards." 89 Fed. Reg. 80,055 (Oct. 2, 2024).

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Despite its generic-sounding name, the IFR is yet another example of the Biden-Harris administration's efforts to use the regulatory process to unlawfully rewrite federal sex discrimination laws. HHS ignores its obligations to give the public advance notice and opportunity to submit comment and claims it has no need to take public comment on the substantive aspects of its proposal. HHS should withdraw the IFR.

I. The Interim Final Rule is procedurally deficient and therefore unlawful under the Administrative Procedure Act.

As explained below, HHS has failed to undertake the notice-and-comment process and the reasoned decision-making process required under the APA. 5 U.S.C. § 500 et seq.

A. HHS fails to explain why this rulemaking addresses an identified problem.

Federal administrative agencies are required to engage in "reasoned decision-making."[1] This obligation requires a federal agency to identify the problem it intends to address.[2] To justify replacing current regulations, an agency must provide specific evidence as to how the current regulations are

[1] *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015).
[2] Exec. Order No. 12866 § 1(b) (establishing the principles of regulation, including that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.").

causing harms or burdens and how the IFR would remedy the alleged defects *without* causing equal or greater harms and burdens.[3] Here, HHS has failed to meet that standard.

The closest HHS comes to discussing the purpose of this rulemaking is in the background section, where it describes the reasons why OMB updated its model Uniform Guidance in 2024. HHS states that OMB's rulemaking had "the goals of increasing accessibility and equity with respect to Federal funding opportunities." 89 Fed. Reg. at 80,055. HHS claims that the changes OMB made "further streamline, clarify and update the guidance." *Id.* Finally, HHS describes what it calls the "three primary objectives" that OMB gave for passing the 2024 revisions to 2 CFR part 200: "(1) to reduce agency and recipient burden; (2) to clarify sections that recipients or agencies may have interpreted in different ways; and (3) to rewrite applicable sections in plain language, improving flow and addressing inconsistent use of terms." *Id.*

Elsewhere, HHS merely offers broad unsupported claims about benefits that would flow from the IFR. It says that "we have determined that the government-wide adoption of the Uniform Guidance is of substantial benefit to the regulated community" and asserts that the "Uniform Guidance promotes uniformity, understanding, compliance, and a uniform body of regulations across federal departments and agencies." 89 Fed. Reg. at 80,057.

These statements do not satisfy HHS's obligations to engage in reasoned decision-making.[4] If such broad and unsubstantiated promises about "benefit to the regulated community" were enough to get HHS past this hurdle, then the APA requirement would be meaningless. To the extent HHS is relying on OMB's claims, the IFR is bereft of any statement as to whether HHS believes that it would advance any of these interests by introducing this IFR now. More fundamentally, HHS does not even claim that there are existing problems that HHS would solve or at least improve by adopting certain OMB regulations and moving certain existing HHS regulations.

HHS also undercuts the rationale behind OMB's guidance to streamline regulations because HHS proposed its own modifications to the guidance. 89 Fed. Reg. at 80,055-56.

In short, HHS has failed to identify the problem it is trying to solve, let alone described the significance of that problem and how adopting the OMB guidance with the proposed modifications would address that problem. HHS has therefore failed to meet its obligations under EO 12866 § 1(b) by failing to describe in detail the problem the IFR will solve.

B. HHS did not have "good cause" to bypass the Administrative Procedure Act's advance notice and comment requirements.

While the Administrative Procedure Act (APA) generally requires agencies to follow certain procedures when promulgating rules, the statute's "good cause" exception permits agencies to forgo Section 553's notice and comment requirement if "the agency for good cause finds" that compliance would be "impracticable, unnecessary, or contrary to the public interest" and bypass its 30-day publication requirement if good cause exists. 5 U.S.C. § 553(b)(B). The APA requires the agency to publish such good cause "with the rule." *Id*. at (d)(3). Here, HHS claims good cause to issue its IFR.

[3] *Michigan*, 576 U.S. at 779 (regulation is irrational if it disregards the relationship between its costs and benefits); *Alltelcorp v. FCC*, 838 F.2d 551, 561 (D.C. Cir. 1988) ("a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist").
[4] *Michigan v. EPA*, 576 U.S. 743, 750 (2015).

IFRs short circuit the democratic public notice and comment rulemaking process required by the Administrative Procedures Act (APA). As such, IFRs are not commonly issued, and exceptions to the normal rulemaking process should not be used lightly.

Here, HHS's rationale falls far short of the good cause threshold to issue an IFR. HHS claims it has "good cause under 5 U.S.C. § 533(b)(B and (d)(3) to dispense with the opportunity for advance notice and for public comment and good cause to publish this rule with an effective date of October 1, 2024, for the eight provision noted in the preamble and reiterated below, and an effective date of October 1, 2025, for the remainder of the provisions." 89 Fed. Reg. at 80,056. After acknowledging the relevant law, HHS summarily states that "advance notice and opportunity for public comment are unnecessary." *Id.*

Regarding adoption of OMB's 2024 Guidance (with modifications), HHS discusses the history of OMB model guidance over the years and HHS's adoption or lack thereof.

- *2013 OMB Guidance*: HHS joined some agencies in claiming "good cause" to adopt OMB's 2013 guidance via IFR with certain agency-specific modifications. The agencies claimed public comment was "unnecessary" because "OMB had already provided the public with an opportunity to comment through its advanced notice of proposed guidance as well as a notice of proposed guidance." *Id.* at 80,057 & n.1 (citing 79 Fed. Reg. at 75,877).[5]

- *2020 OMB Guidance*: HHS did *not* adopt OMB's 2020 guidance by IFR or normal rulemaking process. *Id.* at 80057.

- *2024 OMB Guidanc*e: HHS issued this IFR.

But what HHS and other agencies have done in the past on other rules (even if similar) is not an explanation for why there is good cause to forego public notice and comment on *this rule*. Nothing in the 2024 OMB Guidance requires HHS to adopt it in whole or in part. Indeed, HHS opted not to adopt the 2020 OMB Guidance.

HHS admits that "HHS itself did not seek and respond to these multiple rounds of comment," yet claims good cause to forego advance notice and public comment because *OMB* received public input and comments on its 2020 and 2023 proposed guidance. 89 Fed. Reg. at 80,057. HHS says that advance notice and public comment for HHS's adoption (with some modification) of those regulations is "unnecessary," "duplicative," and "inefficient." *Id*. As discussed below, the public was able to comment on the *proposed* OMB guidances, but it did not have an opportunity to comment on the *final* OMB guidances. Further, even if OMB solicited, reviewed, and responded to comment, *HHS* did not solicit, review, or respond to the public comments. It is unlikely that OMB staff have the expertise to understand all the nuances of how its guidance will apply in the health and human services space. Indeed, HHS itself acknowledges in the IFR the need to make modifications to the OMB guidance for its federal awards. *Id.* at 80,056. And even though OMB solicited comments, HHS recipients were not on notice that HHS would adopt those regulations and may not have provided comment because it was not an HHS-specific rule or applied directly to them.

[5] The agencies claimed that adopting OMB's 2013 guidance was "necessary in order to incorporate into regulation and thus bring into effect the Uniform Guidance as required by OMB. Implementation of this guidance will reduce administrative burden and risk of waste, fraud, and abuse for the approximately $600 billion per year awarded in Federal financial assistance. The result will be more Federal dollars reprogrammed to support the mission, new entities able to compete and win awards, and ultimately a stronger framework to provide key services to American citizens and support the basic research that underpins the United States economy." 79 Fed. Reg. 75,871, 75,872. In contrast, for this IFR, HHS makes no such similar claims of necessity.

HHS also claims that its failure to adopt OMB's 2020 Guidance, the Department is "lagging behind the rest of the grant making agencies, causing confusion and additional administrative burden for HHS recipients." *Id.* at 80,057. It is unclear whether HHS intends this statement to further support its good cause claim. Regardless, it does not. HHS fails to point to any real-world examples of confusion or identify the additional administrative burden HHS recipients face, or how immediate adoption of the 2024 OMB rule will alleviate that confusion and minimize the administrative burden. More importantly, the agency's failure to adopt the 2020 Guidance *for four years* is not a justification to forego public notice and comment.

Regarding HHS's decision to recodify the provision in 45 CFR § 75.300 (as finalized by HHS's Grants Rule) to new 2 CFR § 300.300, HHS likewise claims it does not need advance notice and opportunity to comment because "there are only minor modifications" being made to the provisions and "HHS recipients should already be in compliance with these provisions." But current compliance does not give HHS good cause to forego notice and comment when it chooses to recodify existing provisions.

Next, HHS reliance *Priests for Life v. U.S. Department of Health & Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), does not alleviate HHS of its responsibilities under the APA. *Priests for Life* is distinguishable in major aspects, but HHS merely cites the case without elaborating why it believes the case is on point and allows HHS to skip notice-and-comment as required by the APA here. This is not reasoned decision-making as required by the APA.

1. The public has not had the opportunity to comment on the final regulations that HHS seeks to adopt here.

HHS's main argument is that the public has already had an opportunity to comment on the OMB Guidance and HHS Grants Rule. But this is not true. The public only had an opportunity to comment on the *proposed rules*, not the final rules. Scholars from EPPC's HHS Accountability Project offered public comment on both proposals, which led to some positive changes in the final regulations by OMB and HHS.[6] But there were significant differences between both proposed regulations and their final regulations, including provisions that raise concerns, lack of clarity and warrant additional public comment.

For example, regarding just one regulation (2 CFR § 200.300) in the 2024 OMB Guidance that establishes statutory and national policy requirements for federal awards, OMB made three major changes based on concerns raised by commenters, including EPPC scholars. As one of us described these changes for *National Review*:

> First, OMB retained the references to protecting free speech and religious liberty in the final regulation. OMB explained that it was doing so "to eliminate any confusion and allay concerns that OMB was singling out certain protections." OMB further clarified that all awards must be implemented "in full accordance" with applicable constitutional, statutory, and regulatory provisions, including the free-exercise clause of the First Amendment, the Religious Freedom Restoration Act, and other provisions protecting religious liberty. As such, the regulation "will not affect" the ability of faith-based organizations to participate in agencies' programs.
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> Second, OMB clarified that the prohibition against discrimination based on sexual orientation and gender identity applies only "if the statute's prohibition on sex discrimination encompasses

[6] EPPC Comment on OMB Proposed "Guidance for Grants and Agreements" (Dec. 4, 2023), https://eppc.org/wp-content/uploads/2023/12/EPPC-Comment-on-OMB-Proposed-Guidance.pdf; EPPC Scholars Comment Opposing HHS OCR's "Health and Human Services Grants Regulation" (Sept. 23, 2023), https://eppc.org/wp-content/uploads/2023/09/EPPC-Comment-Opposing-HHS-Grants-NPRM.pdf.

> discrimination based on sexual orientation and gender identity." Significantly, this provision "does not impose any new nondiscrimination requirements."
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> Third, the final provision was revised to reference "heightened constitutional scrutiny that may apply under the Constitution's Equal Protection guarantee for government action that provides differential treatment based on protected characteristics." Here, OMB dropped the specific references to sexual orientation and gender identity; instead, it refers to "all characteristics" that might require "heightened constitutional scrutiny under equal protection principles." OMB also dropped the reference to the 14th Amendment, which commenters pointed out does not apply to the federal government. Avoiding the embarrassing error, OMB confirmed that it is instead "referring to the Fifth Amendment's equal protection guarantee, which does apply to the Federal government."[7]

These changes between OMB's proposed guidance and final guidance are just the changes made to one of the many regulations in OMB's 2024 Guidance. While these changes marked an improvement over OMB's proposal, as discussed below the final text still contains significant ambiguities regarding its application and would benefit from more clarity.

The final HHS Grants Rule is also different in important regards from the proposed rule that was presented to the public for comment. Most significantly, the proposed rule raised important religious liberty concerns that were raised in public comments. But instead of addressing those concerns in the final rule, HHS merely outlined a new process for addressing religious liberty concerns. That process is detailed in 45 C.F.R. 75.300(e) and described in the preamble to the final rule. Significantly, this new process has not itself been subject to public comment and raises many important questions.

Additionally, HHS declined to respond to concerns raised in public comments about how broadly the Department may interpret discrimination "on the basis of sex." HHS merely said, "The Department agrees that the final rule protects against discrimination based on sex characteristics, but does not believe it is necessary to specify this in regulatory text." 89 Fed. Reg. at 36,689.

These changes are significant and have not yet been subject to public comment.

2. The same text raises different issues when proposed by a different agency.

Additionally, while HHS did review the public comments on the HHS Grants proposed rule, the public has not had the opportunity to comment on how the OMB Guidance might apply to HHS, and there is no indication that HHS has reviewed all of the comments that the public submitted to OMB on that rulemaking. HHS fails to explain how OMB's solicitation and review of public comments, satisfies *HHS's* obligations under the APA.

3. The same rule raises different issues when it is raised at a later time.

Furthermore, even if OMB and HHS had adopted the proposed regulations without change, the same regulations raise different issues when raised at a later time. As Heraclitus noted over 2,500 years ago, "No man ever steps in the same river twice, for it's not the same river and he's not the same man."

That is especially true here, as the OMB Guidance and HHS Grants Rule advance the Biden-Harris Administration's aggressive interpretation of *Bostock*. As shown in more detail below, *see infra* Section II, many courts have ruled *against* the Administration's interpretation of *Bostock* and many of

[7] Rachel N. Morrison, *When Public Comment Matters*, National Review (Apr. 8, 2024), https://www.nationalreview.com/corner/when-public-comment-matters/.

these decisions have come down since the end of the comment period (or the publication of the final rules) on these rules.

HHS must allow the public the opportunity to comment on the legality and prudence of its regulations in light of these significant legal developments. HHS must then consider the harms and illegality of these regulations in light of these public comments before finalizing its proposed changes.

C. HHS should not dissuade the public from providing comment and must consider comments on the substance of each regulation at issue.

The IFR states HHS "will consider and address comments on HHS's plan and timeline for implementation, including the provision of two effective dates," as well as "comments under this interim final rule regarding the plan and timeline for adopting the Uniform Guidance described herein." *Id.* at 80058. But HHS "will not respond to comments regarding OMB's 2020 or 2024 modifications to 2 CFR part 200, or on existing HHS specific provisions merely being moved to 2 CFR part 300, as those provisions have already been subject to public input and comment and the latter have been finalized in existing promulgated rules," or "comments related to the content of the HHS-specific modifications at 2 CFR 300, as these provisions are existing HHS regulations that have been promulgated and maintained at 45 CFR part 75, not new requirements for the HHS applicant and recipient community." *Id.*

As we explained above, the final text of the regulations, which is not identical to the proposed OMB Guidance and HHS Grants Rule, has *not* received public comment. HHS's attempt to dissuade the public from commenting on all aspects, especially the substantive provisions and obligations, of this IFR is inappropriate and violates the APA. **At minimum, HHS should reopen a comment period and solicit and accept comments on the substantive aspects of its proposal.**

D. HHS purports that some changes in the IFR are effective *before* the IFR was even published.

We also note that HHS claims "good cause" to make the OMB portions of the IFR effective on October 1, 2024, even though the IFR itself was not published in the federal register until the following day, on October 2, 2024. 89 Fed. Reg. at 80,056. We are unaware of any legal authority that allows a federal agency to change federal regulations in the past. We call on HHS to explain and defend this undemocratic practice.

E. HHS did not give the public a full thirty days to comment and has given the public conflicting information about how and where to provide comment.

In addition to the faults identified above, HHS has not made good on its promise to give the public thirty days to comment. *See id.* at 80055. After the IFR was officially published in the Federal Register, no comment box or button was made available on the Federal Register or regulations.gov (where the IFR directs the public to submit comment).

On October 17, more than halfway through the comment period, one of us emailed Johanna Nestor, the contact person indicated on the first page of the IFR, to alert HHS to this issue and to seek clarity about how comments may be submitted. The same day, a comment button was made available on regulations.gov. **At a minimum, HHS should reopen the IFR comment period so that the public has the full 30 days to submit comment.**

Furthermore, even though the IFR states that comments "must be received by HHS electronically through *www.regulations.gov*," 89 Fed. Reg. at 80,055, the Federal Register now has a comment box accepting comments. It is unclear whether HHS will accept any comments submitted on the Federal

Register. But it would be inappropriate to allow comment submission via the Federal Register yet not review any such comments. **HHS should clarify whether it is or is not accepting comments via the Federal Register, and if it is not, reopen the comment period without a Federal Register comment box option.**

F. HHS admits it failed to consult with State, Local, and Tribal governments.

HHS acknowledges that it has not consulted with state or local governments. Executive Order 13121 outlines an agency's obligations when a proposed rulemaking has federalism implications. *See* 89 Fed. Reg. at 80,058. HHS acknowledges that OMB "consulted with appropriate State and local officials prior to finalizing its most recent update." *Id*. at 80,059. HHS offers two dueling explanations for its failure to do likewise. First, HHS claims that OMB erred when it judged that its Uniform Guidance had federalism implications: "this interim final rule does not impose such costs or have any Federalism implications." *Id*. Second, HHS seems to suggest that no additional consultation is necessary because OMB has already performed an analysis.

HHS's arguments are unpersuasive. First, HHS does not explain why OMB misjudged the federalism implications of its Uniform Guidance. Second, as indicated before, the same regulatory text has different implications when it is adopted by a different agency at a different time. **Prior to finalizing the rule, HHS should conduct a federalism consultation.**

HHS acknowledges that it has not consulted and coordinated with Tribal governments concerning the impacts of this rule as required under Executive Order 13175. President Biden also required tribal consultation in his January 26, 2021, Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships. HHS claims it not required to do so because "OMB held a Tribal consultation to solicit feedback from Tribal representatives and HHS is adopting OMB's uniform guidance with minimally impactful changes to tribes." 89 Fed. Reg. at 80,059.

We do not see anything in E.O. 13175 or President Biden's Memorandum that allows HHS to use these circumstances to shirk its obligation to conduct a tribal consultation. **Prior to finalizing the rule, HHS should conduct a tribal consultation on the specific aspects of this rule.**

II. HHS's interpretation of *Bostock* is implausible on its face and is even less defensible in light of recent caselaw and Congress's refusal to expand nondiscrimination law.

In the OMB Guidance, OMB clarified in the preamble that agencies must implement 2 CFR § 200.300 on statutory and national policy requirements "consistent with their legal authority and the particular statutes and regulations governing each of their Federal financial assistance programs" and that the regulation "does not impose any new legal requirements"— agencies must implement their programs consist with "other, *existing* legal requirements that apply of their own force." 89 Fed. Reg. 30,046, 30,075 (Apr. 22, 2024).

In the IFR, HHS adopts 2 CFR § 200.300, but then proposes to expand on those statutory and national policy requirements by adding a new regulation 2 CFR § 300.300, which recodifies regulatory text from the final HHS Grants Rule. New 2 CFR § 300.300 explains that "[i]n addition to 2 CFR 200.300(a), the following requirements apply," including a prohibition against discrimination, application of Supreme Court decisions, interpretation that sex discrimination prohibits sexual orientation and gender identity discrimination under *Bostock*'s reasoning, and application of religious freedom and conscience protections. 89 Fed. Reg. at 80,062-63.

The addition of 2 CFR § 300.300 is a significant change from the OMB Guidance which states that recipients must not "unlawfully discriminate based on sexual orientation or gender identity *if the*

statute's prohibition on sex discrimination encompasses discrimination based on sexual orientation and gender identity consistent with the Supreme Court's reasoning in *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020)." 2 CFR § 200.300(b) (emphasis added).

The text in 2 CFR § 200.300 appears to prohibit *only* discrimination based on sexual orientation or gender identity to the extent the sex discrimination statute *itself* prohibits discrimination on those bases consistent with *Bostock*. (OMB does not clarify which statutes it believes would satisfy this requirement.) Going further than OMB's regulation, HHS's addition would automatically make *every* statutory prohibition against sex discrimination that HHS enforces a prohibition against sexual orientation and gender identity, regardless of whether the statute itself prohibits discrimination on those bases. In short, 2 CFR § 300.300 is inconsistent with OMB's regulation, *Bostock*, and Congressional direction.

A. *Bostock* is a limited decision.

First, *Bostock* did not create a new protected category. The Court held that under Title VII, "an employer who fires someone simply for being homosexual or transgender has discharged or otherwise discriminated against that individual 'because of such individual's sex.'"[8] While the Court used the terms "sexual orientation" and "transgender status" (not "gender identity") throughout its opinion,[9] it made clear that it was the employees' sex, not their sexual orientation or transgender status, that must be the "but-for cause" of an employer's adverse action.[10] As the Court explained, Title VII is violated "[i]f the employer intentionally relies in part on an individual employee's sex when deciding to discharge the employee—put differently if changing the employee's sex would have yielded a different choice by the employer."[11] For example:

> [T]ake an employer who fires a transgender person who was identified as a male at birth but who now identifies as a female. If the employer retains an otherwise identical employee who was identified as female at birth, the employer intentionally penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth.[12]

Second, the Court used the term "transgender status" not "gender identity," which is arguably a broader concept and is fundamentally incompatible with "sex." Indeed, *Bostock* was premised on the assumption that "sex" refers "only to biological distinctions between male and female."[13] *Bostock* assumed sex is biological and binary and premised its holding on the assumption that "sex" refers only to the "biological distinctions between male and female."[14] Sex as a biological binary is incompatible with the notion that each person can self-proclaim a "gender identity" that is fluid or along a spectrum.

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[8] *Bostock v. Clayton Cnty.,* 590 U.S. 644, 681 (2020).

[9] The *Bostock* majority uses the term "gender identity" only once, as then only as a descriptor of what the employees in the case argued and an argument that was not relevant for the Court's decision:

> The employees . . . submit[] that, even in 1964, the term [sex] . . . captur[ed] more than anatomy and reaching at least some norms concerning gender identity and sexual orientation. But because nothing in our approach to these cases turns on the outcome of the parties' debate, and because the employees concede the point for argument's sake, we proceed on the assumption that "sex" signified what the employers suggest, referring only to biological distinctions between male and female.

Id. at 656.

[10] *Id.* at 660.

[11] *Id.* at 659-60.

[12] *Id.* at 660.

[13] *Id.* at 656.

[14] *Id*. at 656.

Third, the Court's decision was limited to hiring and firing under Title VII. The Court explicitly did not address the "broader scope" of conduct, such as "bathrooms, locker rooms, or anything else of the kind."[15] Responding to concerns that its decision would "sweep beyond Title VII to other federal or state laws that prohibit sex discrimination," the Court explained that it would "not prejudge" any such concerns because "none of th[o]se other laws [we]re before [them]."[16] As one federal district court explained, *Bostock*'s holding was cabined to "homosexuality and transgender *status*"; it does not extend to "correlated *conduct*—specifically, the sex-specific: (1) dress; (2) bathroom; (3) pronoun; and (4) healthcare practices."[17] Yet HHS is attempting to do the exact opposite here.

To the extent that the *Bostock* Court addressed sexual orientation and transgender status, its decision was limited to hiring and firing and was based on consideration of the employee's sex.[18] HHS's broad prohibitions against sexual orientation and gender identity discrimination beyond the hiring and firing context and without regard to an employee's sex is inconsistent with the Supreme Court's reasoning in *Bostock.*

B. Congress has not directed HHS to prohibit discrimination based on sexual orientation or gender identity.

Congress has not made sexual orientation or gender identity protected bases under civil rights laws, nor has it redefined sex discrimination prohibitions to extend to sexual orientation and gender identity despite multiple unsuccessful attempts to do so.[19] Yet HHS is attempting rewrite sex discrimination laws passed by elective representatives in Congress to include sexual orientation and gender identity discrimination. This exceeds HHS's Constitutional or statutory authority and raises major concerns under the clear-notice cannon and major questions doctrine.

Further, HHS cannot rely on direction from the Equal Employment Opportunity Commission (EEOC). Congress also refused to give the EEOC substantive rulemaking authority under Title VII, meaning that none of the EEOC's Title VII guidances, especially those that go beyond Title VII's text and the Supreme Court's direction in *Bostock*, have the force and effect of law. Indeed, as discussed below, these guidances and other expansive interpretations of sex discrimination (including by HHS) have been enjoined by federal courts for going beyond Title VII, *Bostock*, and the EEOC's authority.

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[15] *Id*. at 655, 681.
[16] *Id.* at 681.
[17] *Texas v. EEOC*, No. 21-194, at *4 (N.D. Tex. Oct. 1, 2022).
[18] *See* 590 U.S. at 661 ("to discriminate on [homosexuality or transgender status] grounds requires an employer to intentionally treat individual employees differently because of their sex").
[19] *See, e.g.*, S.788 - 116th Congress (2019-2020): Equality Act, S.788, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/senate-bill/788; S.393 - 117th Congress (2021-2022): Equality Act, S.393, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/393; Text - H.R.15 - 118th Congress (2023-2024): Equality Act, H.R.15, 118th Cong. (2023), https://www.congress.gov/bill/118th-congress/house-bill/15/text.

One of the programs identified by the HHS Grants Rule, was amended to expand the scope of the program to address sexual orientation or gender identity. *See* 34 U.S.C. § 12291; 45 C.F.R. Pt. 1370. Notably, this amendment did not modify the program's prohibition against sex discrimination. *See* 42 U.S.C. § 10406. This further demonstrates that Congress does not understand sex to include sexual orientation or gender identity and knows how to pass laws including sexual orientation or gender identity protections when it so chooses.

C. HHS has not accounted for legal developments since the comment periods ended on related OMB and HHS rulemaking.

In our public comments on the OMB Guidance and HHS Grants proposed rule, we challenged the Biden-Harris Administration's interpretation of *Bostock*.[20] Since those comments were submitted and the comment period have closed, the Biden-Harris administration's and HHS's expansive interpretation and application of *Bostock* has been enjoined or vacated by numerous federal courts in different contexts.

Section 1557 Guidance and Rule. Section 1557 of the Affordable Care Act prohibits discrimination in federally funded healthcare programs and activities on the grounds prohibited under Title IX (i.e., sex). 20 U.S.C. §§ 1681 et seq. Relying on *Bostock*, HHS issued guidance and a final rule claiming that Section 1557 prohibits discrimination based on gender identity and sexual orientation.[21] This guidance and rule have been enjoined by federal courts.[22]

Title IX Rule. Title IX prohibits discrimination on the basis of sex in federally funded educational programs and activities. 20 U.S.C. §§ 1681 et seq. The Biden-Harris Department of Education claimed in a final rule that Title IX's prohibition against sex discrimination extends to gender identity and sexual orientation discrimination.[23] This rule is enjoined by many federal courts.[24]

EEOC Bostock Guidance. On the one-year anniversary of *Bostock*, the EEOC Chair unilaterally issued guidance purportedly on what *Bostock* means for gender identity and sexual orientation discrimination in employment, including applications to employee conduct like dress, sex-specific bathrooms, and self-selected pronouns.[25] Although the EEOC claimed its guidance was "intended only to

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[20] *See* EPPC Comment on OMB Proposed "Guidance for Grants and Agreements" (Dec. 4, 2023), https://eppc.org/wp-content/uploads/2023/12/EPPC-Comment-on-OMB-Proposed-Guidance.pdf; EPPC Scholars Comment Opposing HHS OCR's "Health and Human Services Grants Regulation" (Sept. 23, 2023), https://eppc.org/wp-content/uploads/2023/09/EPPC-Comment-Opposing-HHS-Grants-NPRM.pdf.

[21] Office for Civil Rights, HHS, HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (Mar. 2, 2022), https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf; HHS, Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024), https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities.

[22] *See Texas v. Becerra*, No. 24-211 (E.D. Tex. July 3, 2024); *Tennessee v. Becerra*, No. 24-161 (S.D. Miss. July 3, 2024); *Florida v. HHS*, No. 24-1080 (M.D. Fla. July 3, 2024); *Christian Emps. All. v. EEOC*, No. 21-195 (D. N.D. Mar. 4, 2024).

[23] Dep't of Educ., Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance, 89 Fed. Reg. 33,474 (Apr. 29, 2024), https://www.govinfo.gov/content/pkg/FR-2024-04-29/pdf/2024-07915.pdf.

[24] *See Alabama v. Cardona*, No. 24-12444 (11th Cir. Aug. 22, 2024); *Texas v. United States*, No. 24-86 (N.D. Tex. July 11, 2024); *Carroll Indep. Sch. Dist. v. U.S. Dep't of Educ.*, No. 24-461 (N.D. Tex. July 11, 2024); *Tennessee v. Cardona*, No. 24-72 (E.D. Ky. June 7, 2024), *app. for partial stay denied*, No. 24A78, 603 U.S. ___ (2024); *Louisiana v. U.S. Dep't of Educ.*, No. 24-563 (W.D. La. June 13, 2024), *app. for partial stay denied*, No. 24A79, 603 U.S. ___ (2024); *Oklahoma v. Cardona*, No. 24-461 (W.D. Okla. July 31, 2024); *Arkansas v. U.S. Dep't of Educ.*, No. 24-636 (E.D. Mo. July 24, 2024); *Kansas v. U.S. Dep't of Educ.*, No. 24-4041 (D. Kan. July 2, 2024); *Texas v. Cardona*, No. 23-604 (N.D. Tex. Aug. 5, 2024) (amended order granting motion for summary judgment).

[25] EEOC, *Protections Against Employment Discrimination Based on Sexual Orientation or Gender Identity* (June 14, 2021), https://www.eeoc.gov/laws/guidance/protections-against-employment-discrimination-based-sexual-orientation-or-gender.

provide clarity to the public regarding existing requirement under law,"[26] federal courts have disagreed. Within months of the guidance being released, two federal courts held the guidance was unlawful.[27]

EEOC Harassment Guidance. EEOC issued harassment guidance that does "not have the force and effect of law and are not meant to bind the public in any way" but is meant to "provide clarity to the public regarding existing requirements under the law or agency policies."[28] Going far beyond *Bostock*, the guidance states that "[s]ex-based discrimination under Title VII includes employment discrimination based on … gender identity[,] … including how that identity is expressed."[29] Examples of harassment include: "outing (disclosure of an individual's sexual orientation or gender identity without permission)," "repeated and intentional use of a name or pronoun inconsistent with the individual's known gender identity (misgendering)," and "the denial of access to a bathroom or other sex-segregated facility consistent with the individual's gender identity."[30] This guidance has been enjoined by a federal court.[31]

Failure to consider these decisions and relevant caselaw developments is not reasoned decision-making in violation of the APA. **HHS should hold this rulemaking and suspend the operation of the IFR until litigation on these regulations concludes and courts resolve the scope of *Bostock*'s holding and application to existing sex discrimination laws.**

III. HHS should consider substantive comments because the IFR raises important concerns that the public has the right to inquire about.

In light of all the comments above, we ask HHS to respond to substantive comment and provide clarity on the following points:

- What act of Congress or what legal authority does HHS claim gives it the power to expand sex discrimination prohibitions beyond the text and Supreme Court direction in *Bostock*?
- Does HHS agree with OMB's statement in its guidance that 2 CFR § 200.300 "does not impose any new legal requirements"?
- In HHS's view are there any sex discrimination statutes that by their own terms do not prohibit discrimination based on sexual orientation or gender identity? If not, why does 2 CFR § 200.300(b) have limiting language?
- How does HHS square the conflicting standards under 2 CFR § 200.300(b) and proposed 2 CFR § 300.300? Does one provision trump the other?
- OMB's 2 CFR § 200.300(c) directs agencies to "take account of the heightened constitutional scrutiny that may apply under the Constitution's Equal Protection guarantee." In HHS's view, what protected characteristics require "heighted constitutional scrutiny"? Does HHS contend that it has performed the accounting that OMB's regulation calls for?

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[26] *Id.*
[27] *See Texas v. EEOC*, 633 F. Supp. 3d 824, 831 (N.D. Tex. 2022) (The EEOC "misread[] *Bostock* by melding 'status' and 'conduct' into one catchall protected class covering all conduct correlated to 'sexual orientation' and 'gender identity. Justice Gorsuch expressly did not do that."); *Tennessee v. U.S. Dep't of Educ*., 615 F. Supp. 3d 807 (E.D. Tenn. 2022).
[28] EEOC, Enforcement Guidance on Harassment in the Workplace (Apr. 29, 2024), https://www.eeoc.gov/laws/guidance/enforcement-guidance-harassment-workplace.
[29] *Id.*
[30] *Id.*
[31] *See Cath. Benefits Assoc. v. Burrows*, No. 24-142 (D. N.D. Sept. 23, 2024).

- Does HHS believe that the Supreme Court's decision in *Skrmetti* this term, on whether *Bostock* applies to the Fourteenth Amendment or gender identity receives heightened constitutional scrutiny under the Fourteen Amendment, could impact how HHS interprets the Constitution's Equal Protection guarantee? Regardless, and especially if HHS believes the answer is yes, **HHS should hold finalization of the IFR until after the Supreme Court's decision in *Skrmetti* as that case may shed further light on the proper interpretation and application on *Bostock* and the equal protection guarantee.**
- Does HHS believe that the court decisions enjoining agency regulations involving a broad application of *Bostock* and expansive interpretation of sex discrimination have any impact on this IFR? **HHS should clarify that it will enforce its regulations in compliance with the injunctions issued in federal court against HHS's *Bostock* guidance and Section 1557 regulations.**
- Does HHS believe that using biologically accurate pronouns is discriminatory? How does the requirement avoid violating the First Amendment and being government-compelled speech?
- Does HHS believe that males who identify as women are required to have access to female-specific spaces such as bathrooms and housing facilities? Does this requirement apply to children? Will adult males who identify as women have access to private spaces for young girls?
- How does HHS square its gender identity nondiscrimination requirement with the statutory requirement to prohibit sex discrimination and ensure equal opportunities, safety, and privacy for females?
- How does HHS square its requirements with parental rights?
- How does HHS's requirements interact with laws protection religious freedom and conscience rights? How will HHS ensure that it complies with the First Amendment, the Religious Freedom Restoration Act, Title VII's religious nondiscrimination and accommodation protections, Title VII's religious organization exemption, and federal healthcare conscience protection laws?
- How has HHS accounted for the harm to beneficiaries, including children, when its requirements will lead to the exodus of faith-based providers that have "traditional" religious beliefs about marriage, gender, and sexuality that may be determined inconsistent with the obligations under the IFR?
- How will HHS apply statutory protections for religious freedom in the programs these regulations apply to?
- Will the IFR preempt any state laws? If not, HHS should clarify that its rule does not have any preemptive effect?
- The HHS Grants final rule acknowledged that it received comments concerned about the rule's implications for religious liberty and free speech rights. However, the Department did not answer those concerns with specificity, but instead "notes that it remains committed to fully complying with the First Amendment, Free Exercise and Establishment Clause." 89 Fed. Reg. at 36,696. What is the significance of this and similar language in the final rule? What rights does HHS believe that grant recipients have as related to the nondiscrimination provisions in the final rule? How can grant recipients understand their rights and where should they go to understand how HHS interprets those rights and its own obligations in light of those rights?
- The new religious liberty process outlined in 45 CFR § 75.300(e) states that HHS will consider whether to grant exemptions on a case-by-case basis. Does HHS concede that this case-by-case exemption process renders its regulations subject to strict scrutiny under *Fulton v. City of*

Philadelphia, 593 U.S. 522 (2021)? If HHS does not concede this point, on what basis does HHS find *Fulton* distinguishable?

- In the HHS Grants Rule, HHS claims that its decision to refuse to state clearly its obligations under RFRA and the First Amendment and instead to evaluate "requests for assurance of a religious freedom- or conscience-based exemption that are evaluated on a case-by-case basis" will "help[] ensure that the Department complies with its legal obligations." 89 Fed. Reg. at 36,703. How does HHS justify its insistence on a case-by-case approach by its decision to accept a religious organization's sincere religious objection to its contraption mandate based on the entity's submission of a one-page form that says, in part, "I certify that, on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered; the organization is organized and operates as a nonprofit entity; and the organization holds itself out as a religious organization"?[32]
- Similarly, how does HHS defend its insistence on a case-by-case approach in light of cases where courts have found in favor of religious employers and religious healthcare institutions for reasons that do not require inquiries into entity-specific facts? *See, e.g.*, *Hobby Lobby v. Sebelius*, 573 U.S. 682, 728 (2014) (the "most straightforward way" of advancing HHS's interest would be for the government to pay for the services at issue directly); *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 693 (N.D. Tex. 2016) ("the government has numerous less restrictive means available to provide access and coverage for transition and abortion procedures").
- Does HHS's broad definition of "on the basis of sex" have implications for abortion?
- On what basis does HHS claim that the HHS Grants final rule is merely "interpretive"? Can HHS justify this characterization by comparing it to other rulemaking deemed "interpretive" or, as it appears, this this merely a transparent effort to avoid accountability through the judicial process?
- One of the thirteen statutes that HHS purports to "interpret" in the HHS Grants Rule is Head Start. HHS's efforts to redefine discrimination "on the basis of sex" is especially troubling in this context and has important implications for children's rights and parents' rights. Please clarify whether the HHS Grants Rule requires covered preschools to expose young children to pro-LGBTQ materials. To the extent that HHS contends that a covered preschool must expose staff and children to materials that advance gender ideology, what rights do parents have to be informed about and to shield their children from such materials?

[32] HHS, CMS-10459-Certification, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cms-10459-certification.pdf.

V. Conclusion

HHS should withdraw the IFR. Alternatively, at a minimum, HHS should reopen the comment period with an explicit invitation to comment on the full substance of HHS's proposal and a pledge that HHS will in fact consider substantive comments.

Sincerely,

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