ALLIANCE DEFENDING FREEDOM
FOR FAITH. FOR JUSTICE.

April 3, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services,
U.S. Department of Health and Human Services
Attention: CMS-9903-P
P.O. Box 8016
Baltimore, MD 21244-8016

VIA REGULATIONS.GOV

RE: Coverage of Certain Preventive Services Under the Affordable Care Act CMS–9903–P; RIN 0938–AU94; CMS-2023-0016-0001

Dear Administrator Brooks-LaSure,

We write in opposition to the proposed rule, Coverage of Certain Preventive Services Under the Affordable Care Act, 88 Fed. Reg. 7,236 (Feb. 2, 2023) (the proposed rule). We ask that the Departments of HHS, Labor, and the Treasury (the agencies) withdraw the proposed rule and leave the existing regulations in place.

Alliance Defending Freedom (ADF) is an alliance-building legal organization that advocates for the right of all people to freely live out their faith. It pursues its mission through litigation, training, strategy, and funding. ADF has handled many legal matters involving the agencies' application of the women's preventive services requirement to cover contraceptives (the contraceptive mandate), and its interaction with the Religious Freedom Restoration Act (RFRA), the First Amendment, federal healthcare conscience rights, and other legal principles. Several ADF cases are discussed in the proposed rule, including *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). The vast majority of plaintiffs in these cases were successful.

There is no need to engage in this rulemaking because the rules finalized in 2018 and upheld by the Supreme Court in 2020 have effectively resolved the situation. *See Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania,* 140 S. Ct. 2367 (2020). The proposed rule and the suggestions in it will lead to more litigation because they will violate the legal rights and religious and moral consciences of persons and groups throughout the country. This will cause more lawsuits that the agencies will lose and will resolve fewer lawsuits, which the agencies already won the first time around. That outcome is not a legitimate reason to reverse a regulatory position.

I. The "alternative approach" to oblige issuers to provide contraception to persons covered by a religiously objecting plan is illegal and should be rejected.

The agencies quickly described an "alternative approach" to the religious exemptions to the contraceptive mandate. In the approach, where there is a religious objection by a plan sponsor, "the health insurance issuer would still be required to fulfill its separate and independent obligation to provide contraceptive coverage." Proposed rule at 7,248. "The Departments seek comment on all aspects of this alternative approach." *Id.* This approach is legally flawed and would increase litigation risk for the agencies for several reasons.

A. The "alternative approach" hijacks religious entities' plans.

The alternative approach would violate RFRA. It would hijack religious objectors' health plans and coverage to provide for contraceptives and abortifacients to which they object. The issuer they hired to provide coverage would be the entity providing objectionable contraceptive and abortifacient items to persons covered by that plan. The issuer's obligation to provide those items to those persons would inextricably derive from the religious objector's arrangement of the health coverage through that issuer. In short, the coverage would be part of the plan as a matter of religious ethics and common sense. That will be true even if the agencies declare through some legal fiction that the obligation, coverage, and payments are somehow separate.

After twelve years of public discussion and litigation, it is clear that "seamlessness" and "separation" are incompatible. The agencies' goal of "seamless" coverage is absent from this statute, and in any event it cannot be achieved while keeping the coverage "separate" from the plan sponsors who object. The agencies essentially admit this when they describe the proposal to keep the religious exemptions (not the alternative approach) as being "[c]ritically . . . independent" and "completely separate" from religious plans. The agencies notably fail to use those same descriptors for the alternative approach, since it is neither independent nor separate from objectors' plan arrangements. When the coverage is not separate, it is simple to conclude that the mandate substantially burdens the employer's exercise of religion. That mandate will be enjoined under RFRA.

B. The "alternative approach" is not supported by a compelling government interest.

The alternative approach would violate RFRA's compelling interest test. The agencies already stated there is no compelling interest under RFRA to impose a

mandate like the alternative approach, nor to impose the mandate on religious objectors in any way. 83 Fed. Reg. at 57,546. The fact that the agencies may disagree with that conclusion now, five years later, cannot reinstate a compelling interest where none existed. A compelling interest must be one "of the highest order" and exists "only in rare cases." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah,* 508 U.S. 520, 546-47 (1993). Compelling interests do not toggle in and out of existence like quarks. The election of a president from a different party cannot make an interest compelling, especially when it derives from an obscure guidance not mandated by the statute in question.

The other flaws in the agencies' compelling interest would continue to exist under this alternative approach. The agencies still propose to do nothing to give contraception, seamless or otherwise, to millions of women in grandfathered plans, in comparison to what the agencies estimate is a much smaller number of women in religious plans. The agencies propose to pay for contraceptives for women in religious plans by diverting marketplace user fees, but the agencies admittedly are not extending that arrangement to women in grandfathered plans.

The agencies offer no plausible rationale why the user fees scheme, if it is legally sound, cannot be applied to benefit women in grandfathered plans, nor why the women in those plans have less of a need than women in religious plans. Marketplace user fees have no greater relationship to religious employer-based plans provided than they have to grandfathered employer-based plans. In choosing to not extend this benefit to the latter, the agencies are once again leaving their interest unpursued on a far grander scale than in religious plans. That flaw continues to negate the agencies' compelling interest under RFRA.

C. The "alternative approach" would also violate the First Amendment.

For the similar reasons, any attempt by the agencies to impose the alternative approach would be unlawful under the First Amendment's Free Exercise Clause. *See Fulton v. City of Philadelphia*, 141 S. Ct. 1868 (2021); *Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021) (*per curiam*). HHS must prove that it has a compelling interest in applying the mandates to the religious objectors—"the particular claimant[s] whose sincere exercise of religion is being substantially burdened." *Burwell v. Hobby Lobby Stores, Inc*., 573 U.S. 682, 726 (2014) (quoting *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-31 (2006)). No broadly stated interest "in ensuring nondiscriminatory access to healthcare" is enough. *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1148 (D.N.D. 2021).

If it pursues the alternative approach, the agencies would be improperly targeting religious entities while leaving millions of other women in grandfathered plans without the same treatment. *Masterpiece Cakeshop, Ltd. v. Colo. C.R. Comm'n*, 138 S. Ct. 1719, 1730 (2018) ("The treatment of the conscience-based objections at issue in these three cases contrasts with the Commission's treatment of Phillips' objection."). The approach would be neither neutral nor generally applicable under Free Exercise Clause jurisprudence. The government would be leaving millions of women without user-fee-subsidized contraception while insisting it has an interest "of the highest order" to hijack religious entities' plans to make sure their women get the contraception.

D. The "alternative approach" is not the least restrictive means of achieving the government's purported interest.

This proposed rule also proves that there is a less restrictive means of advancing the government's alleged interest: that the federal government pay for contraceptives itself through actually separate channel. Note that the least restrictive means test does not ask what the *executive branch* can do under its existing statutes—it asks what the *federal government* could do. Congress *could* pass legislation that buys contraception for women who do not get it from their health plans. See, for example, Title X of the Public Health Service Act. The fact that Congress has not passed such legislation in no way negates this option as a less restrictive means under RFRA. On the contrary, the agencies' primary approach set forth in this proposed rule to set up a new contraceptive arrangement by diverting marketplace user fees is a concession that less restrictive means exist.

E. The "alternative approach" would be illegal as imposed on entities protected by court injunctions.

It would be contempt of court for the agencies to impose the alternative approach on religious entities protected by court injunctions. Most of those injunctions specify that the agencies cannot use the women's preventive services statute to impose a contraceptive mandate on those protected by the injunction. The alternative approach would impose an obligation that funnels objectionable contraception through their health coverage arrangements. That would violate the injunctions.

Moreover, several of those injunctions apply to organizations that religious entities can join to receive protection from the injunction, including Catholic Benefits Association and Christian Employers Alliance. The agencies cannot violate the injunctions for those organizations, and therefore its alternative approach will not likely advance the government's interests in a significant way.

F. There is no logical outgrowth from the proposed rule to impose this "alternative approach" in the final rule.

There is no logical outgrowth from the proposed rule to impose the alternative approach in the final rule. The agencies failed to set forth proposed regulation language on how the alternative approach would work. The agencies express uncertainty about several important questions concerning what the effect of this approach would be on religious entities. As a result, the public has not been afforded adequate notice of what the alternative approach would do, how it would work, what its legal basis would be, how it would fare under RFRA and or the First Amendment, and how it would impact regulated entities. Given this lack of attention, the public has not been given a meaningful opportunity to comment on the alternative approach.

The comments the agencies receive on this alternative approach cannot demonstrate that the government gave the public adequate notice. Instead, those comments only show that the agencies partially described an approach and raised many questions in the public's mind. They do not show that the agencies provided full and necessary information about the approach. Of course the public can comment generally on a partial idea. In fact, the more vague and amorphous an idea is, the more possible things commenters can say and ask about it. But the APA requires that the agencies give the public an opportunity to comment on all of the important aspects of a proposed rule, such as its regulatory text, its operational details, its legal implications, and its regulatory impacts, costs, and benefits. The proposed rule does not meet that threshold for the alternative approach. If the agencies wish to pursue the alternative approach, they would need to issue a new proposed rule setting it forth in full detail and opening another comment period.

II. Repeal of the moral exemptions is illegal, unnecessary, and inconsistent with administration policy.

The proposed rule's repeal of the moral exemptions to the mandate is not legally sound, despite the agencies' assertions. Nor is it necessary to achieve the agencies' goals. It also conflicts with broader administration policy that otherwise acknowledges the legitimacy and importance of business corporations pursuing social goals.

A. Eliminating the moral exemptions violates the First Amendment.

The proposed elimination of the moral exemptions to the contraceptive mandate is illegal. *First*, it violates the First Amendment right to freedom of speech

and association with respect to non-profit organizations. The First Amendment guarantees the right of Americans to form non-profit advocacy organizations. March for Life is a typical example. As explained in the successful lawsuit we filed against the agencies on this issue, see *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015), March for Life is a non-religious non-profit organization formed to promote the sanctity of each human life from the moment of conception—that is, from the fertilization of sperm and ovum, which is when a unique human life comes into existence.

The First Amendment freedoms of speech and association protect the right to form and operate such an organization. If the agencies exercise their purported discretion to force such organizations to perform acts that directly contradict their advocacy mission and their reason for associating, the agencies are violating the First Amendment rights of those groups. *See Hurley v. Irish–Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557 (1995). Such groups will be forced to contradict their message by complying with the mandate or, alternatively, they will be forced to cease operations and therefore stop speaking and associating.

In upholding the moral exemptions rule in *Little Sisters of the Poor* in 2020, the Supreme Court determined that there is no legal requirement that the agencies impose the contraceptive mandate at all, much less that they impose it on morally objecting entities. Absent such a legal requirement, the agencies cannot justify the infringement of these First Amendment rights of non-profit organizations that object to compliance with this mandate.

This is especially true when the agencies have already acknowledged the primacy of these First Amendment rights in their 2017 and 2018 moral exemptions rules. For over five years, the agencies have taken the position that it is wrong to coerce non-profit organizations that morally oppose the contraceptive. This conclusion does not dissolve simply by stating that the agencies have changed their minds. Constitutional rights do not change based on the outcome of an election.

Second, eliminating the moral exemptions will constitute unlawful viewpoint discrimination between moral and religious views. Under the proposed rule (setting aside the alternative approach), if companies oppose coverage of contraceptives on religious grounds they may be exempt. But if they oppose contraceptives on grounds that are exactly the same, but are based on non-religious moral convictions, they will not be exempt. Discriminating against an organization that takes exactly the same position as another—but merely has a different ideological motive for its position—is an unlawful targeting of its viewpoint.

The agencies conceded their hostility to the viewpoint of moral organizations that object to early-abortion causing drugs when they said that for morally objecting employers, "in light of the Supreme Court's decision in *Dobbs* . . . it is necessary to provide women" contraceptives funded "directly through their plan." This demonstrates that it is the pro-life position of morally objecting organizations that the agencies are targeting. Targeting pro-life positions is illegitimate under the First Amendment, even when purporting to regulate the practice of healthcare. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361 (2018). Likewise, nothing about *Dobbs* or its aftermath makes direct provision of contraceptives "necessary" for morally objecting employers but not for religiously employers or grandfathered plans that have no principled objection at all.

B. Eliminating the moral exemptions serves no rational government interest.

Eliminating the moral exemptions also serves no rational government interest. The agencies themselves conceded this in their 2017 and 2018 rules. The government's goal in the contraceptive mandate is to provide coverage of contraceptives to women who want and will use that coverage. By definition, women working at morally objecting non-profit entities don't want and won't use the coverage.

The court in the *March for Life* case held that imposing the contraceptive mandate on a non-profit organization like March for Life "makes no rational sense." 128 F. Supp. 3d at 128 (D.D.C. 2015). Where a group exists and hires people to oppose abortion, including certain items in the contraceptive mandate, no interest of the government is advanced by imposing the mandate on that group. The only "goal" the government pursues in that case is to suppress the existence of a viewpoint that the government disfavors. That is not a permissible goal.

The agencies claim they would still be achieving a rational goal because maybe some beneficiaries of morally exempt plans might be able to obtain contraception if the mandate is imposed on such entities. That is not a legitimate conclusion, however, for two reasons. *First*, the organization has the First Amendment right to only hire people who do not undermine their mission, and therefore they have a First Amendment right to only maintain in their employment people whose plan beneficiaries will not use the plan for objectionable purposes. In other words, they have a First Amendment right to fire employees if the employee's plan beneficiaries use their health plan for abortifacient contraceptives. So the government cannot constitutionally pursue this goal through that organization.

Second, there is no reasonable likelihood that the people working for these groups will actually have dependents who use this coverage to get contraception. The notion that the government will achieve such a goal within this tiny population hostile to the government's viewpoint is speculative and absurd. An organization that makes these strongly held views central to its mission will not likely have employees whose dependents will use contraceptives provided under that plan. The agencies' rationale is arbitrary and capricious and lacks reasoned decision-making under the Administrative Procedure Act (APA).

C. The government cannot finalize its proposal based on flawed assumptions about the number of moral objectors that exist.

The agencies would be relying on flawed assumptions if they finalize the repeal of the moral exemptions based on the notion that there may not be enough of such objectors to justify keeping it. That rationale is flawed for three reasons.

First, the existing number of objectors under the moral exemptions presents the wrong denominator to measure the impact of the rule. New people are born in the United States every day. New non-profit and for-profit organizations are formed and dissolved every day. Existing organizations change their corporate goals and missions every day. There was a day in U.S. history when the organization March for Life did not exist, and then a day later when it did exist. Asking how many organizations exist today who use the moral exemptions is not an adequate measure of the impact of the proposed rule. Even if there were zero organizations using the moral exemptions today, another ten companies could form tomorrow that want to use the exemptions. For this reason it was rational for the agencies to assume there are some organizations using the exemptions.

Polls support the likelihood that at least a few entities use the moral exemption. Polls have suggested that fewer Americans identify as religious, and that a steady percentage of Americans identify as pro-life. This implies more Americans are adopting non-religious pro-life views. There are several prominent pro-life organizations that do not seem to identify as religious. They have names such as Secular Pro-Life, Progressive Anti-Abortion Uprising, Pro-Life San Francisco, the Equal Rights Institute, Feminists for Life, and Democrats for Life of America. Whether they use the moral exemptions is not known by this commenter. The point is that people with their views are increasingly common, and those people have the right to conscientiously object to buying insurance coverage for items they believe can destroy a human life.

Second, there is no reason to think there is reliable data on the number of entities using the moral exemptions. For very good reasons, the agencies did not

require exempt entities to submit documentation to claim the exemption. Citizens should not have to register with the government to be exempt from a mandate that violates their conscience about the sanctity of human life. Registration would likely subject them to unwarranted public scrutiny under FOIA, and to the risk of government employees abusing or improperly disclosing their information.

But absence of data is not data of absence. The agencies cannot assume that because they don't know how many entities use the moral exemptions, there are none who use them, and therefore that rescinding the exemptions causes no harm. Nor can the agencies assume that because this proposed rule was posted in the federal register, any entities using the moral exemptions would submit a comment to identify themselves. The politically charged nature of this controversy is a deterrent to some entities identifying themselves publicly as taking this position. Moreover, the fear of the agencies compiling records against them and engaging in retaliation or cancellation is also a deterrent. Consequently, it would be improper for the agencies to assume that no entities are using the moral exemption other than those that identify themselves in these public comments.

Third, even though the agencies should assume some entities are using the exemptions, it is reasonable to assume the number of those entities is statistically small as in comparison to the employer sponsored insurance field overall. Perhaps tens, or a low number of hundreds, of women of childbearing age might be covered in such plans. Many or most of them might not object to the exemption, and might support it. The number of entities using the moral exemptions is likely to be sufficiently large that the coercion of their consciences is unjustified and causes legal liability to the agencies, and sufficiently small compared to the market so that the alleged benefits of coercing those entities is not large enough to justify the agencies' proposed rescission of the exemptions.

If the agencies finalize the elimination of the moral exemptions, they may find out the hard way that entities were using it or want to use it, by answering lawsuits in federal court as they did in the *March for Life* case.

D. The agencies' justification for removing the moral exemptions is inadequate and fails to adequately consider alternatives.

The agencies do not have a sufficient justification for rescinding the moral exemptions, and have not adequately explored alternatives.

For the reasons explained above and in the *March for Life* ruling, no plausible government interest is served in eliminating the exemption for non-profit entities. As to for-profit entities, the number of entities using the exemptions now

and in the future has a very small statistical effect on coverage nationwide, or compared with the number of women impacted by the agencies' continual failure to address grandfathered plans.

For related reasons, the agencies' reliance on RFRA's inapplicability for targeting moral employers is inadequate. Although RFRA does protect religious plans, it does not protect grandfathered plans as such. Yet the government is not heeding the alleged necessity it has identified to assist the millions of women in those plans. The contours of religious liberty claims are therefore not a legitimate rationale to explain the agencies' proposed course of action.

The government's citation to *Dobbs* is also an invalid reason to target morally objecting plans. Nothing in *Dobbs* or in the post-*Dobbs* situation supports a distinction between the alleged need to impose "direct" coverage on morally objecting plans when the government has chosen not to it on religious or grandfathered plans, especially since the latter cover millions more women.

These basic facts show there is no need for the regulation under ordinary regulatory standards. *See* OMB Circular A-4. The agencies lack any need to rescind the moral exemptions because the government has eschewed its alleged need in parallel plans that cover many more women. This lack of proportion is irrational, and evinces hostility to the viewpoint of morally objecting entities.

Finalizing the proposed rule to eliminate the moral exemptions would be even more irrational in light of the agencies' plan to use marketplace user fee adjustments to provide free contraceptives to women in religious plans. There is no rationale why the agencies cannot simply apply that approach to morally exempt plans instead of eliminating the moral exemption. There is nothing about religious plans that makes the agencies' goal of seamlessness or directness less "necessary" than it would be for moral plans. The fact that religious entities can sue under RFRA and morally objecting entities cannot is not such a reason, because that reason has nothing to do with the alleged interest in seamlessness. Nor can the price of applying the user fees adjustments to morally exempt entities support eliminating the moral exemptions, since statistically that price will likely be negligible compared to the approximately $50 million the agencies estimate it will cost to apply user fees adjustments for persons covered by religious entities. Adding morally exempt plans to the user fees adjustments will likely result in a very small cost because: (1) there seem to be far fewer such plans; (2) those plans seem to be held by small employers; and (3) as to non-profit entities and the owners and decision-makers in for-profit companies, there will be few if any users who want contraceptives so as to pursue those reimbursements.

This point also illustrates the agencies' failure to consider and rebut alternatives to eliminating the moral exemption, namely: (1) not eliminate it because so few people are affected, to protect the deep convictions of the companies using it; (2) not eliminate it and apply the user fees adjustments to persons in morally exempt plans the same way they would be applied to persons in religiously exempt plans; (3) announce enforcement discretion, under which morally objecting entities will not have to comply with the mandate; or (4) keep the moral exemptions for non-profit entities, especially considering their First Amendment rights and the lack of any likely advancement that mandate would achieve towards the government's goal of providing coverage to women who want it. The agencies have not considered these alternatives adequately because they have not considered the disproportionality of their focus on this small number of plans compared to the religious and grandfathered plans where the agencies are pursuing similar alternatives.

Reducing litigation is not a rationale that supports the proposal to rescind the moral exemptions. There are no lawsuits against the agencies from persons who are in morally exempt plans and have been denied coverage as a result. States challenging the exemptions lost in in *Little Sisters of the Poor* three years ago and have made no significant litigation progress since. In contrast, whenever the agencies have imposed this mandate they have faced a far larger number of lawsuits and much less success.

There is also no evidence that the moral exemptions are actually depriving particular women of contraceptive coverage that they want. If that were happening, it should be no trouble for the pro-mandate states to actually provide proof—even one example—of such a woman. They have failed to do so. They have even failed to show that women in religious plans are using public funds to gain contraceptives outside their employer-based coverage. And those states have provided zero evidence of any cost or harmful result from the moral exemptions specifically. Those states have produced zero evidence proving that women covered by morally objecting plans exist in their states, or have needed to seek coverage from state funded programs. This is partly because nearly all of those states have contraceptive mandates in state law. Those state laws make it practically impossible for the moral exemption to impact persons in those states because morally objecting entities tend to be small and therefore are extremely unlikely to self-insure to avoid state contraceptive mandates.

E. Eliminating the moral exemptions is inconsistent with the government's ESG efforts.

Eliminating the moral exemptions contradicts this administration's emphasis of corporate environmental, social, and governance efforts (ESG). In other policies, the administration is aggressively promoting the view that companies should take moral positions—often or usually on non-religious grounds—to advance what the companies see as environmental or social policy goals, and diversity, equity, and inclusion in governance. See, for example, Prudence and Loyalty in Selecting Plan Investments and Exercising Shareholder Rights, 87 Fed. Reg. 73,822 (Dec. 1, 2022); Enhanced Disclosures by Certain Investment Advisers and Investment Companies About Environmental, Social, and Governance Investment Practices, 87 Fed. Reg. 36,654 (June 17, 2022).

But in this proposed rule, the agencies would eliminate moral exemptions entirely as to the contraceptive mandate while possibly leaving religious exemptions in place. The agencies offer the rationale that it is acceptable to eliminate moral exemptions because companies' views on this issue are unacceptable to the government. But that is inconsistent with the administration's support for companies to advance other moral goals that go beyond profit-seeking.

Moreover, the agencies' approach here is viewpoint discriminatory. The administration would be discriminating against companies that adopt this particular moral view on some or all contraceptives, while favoring and rewarding companies for taking other moral views in furtherance of ESG.

F. The agencies' reasons for disagreeing with enactment of the moral exemptions are flawed.

The agencies claim that the Church Amendments' protection for moral objectors should not be analogized to the moral exemptions because Congress did not apply the provisions of Church "to private entities that typically do not accept funds from or do business with the government."

This reasoning is flawed. In the Church Amendments, there was no statute or regulation that violated conscience to which the Church Amendments provided relief. In the Church Amendments, Congress took the situation of the courts legalizing abortion and added conscience protections, but did so only to the extent Congress was constitutionally authorized to do so—using Spending Clause authority by applying the protections to federally funded entities. The final outcome was that more conscience protection existed, and it is highly relevant here that Congress included moral objections in that package.

Here, the ACA added no conscience violation to remedy, because it contains no contraceptive mandate. It was the agencies that created a conscience violation by creating an unnecessary contraceptive mandate and imposing it on entities not receiving federal funding. Initially the agencies refused to respect conscientious objections, but in 2017 and 2018 they did the right thing and fully protected rights of conscience. Those exemptions naturally applied beyond federally funded entities because the mandate itself applied beyond federally funded entities. The parallel that the agencies drew to the Church Amendments in 2018 was therefore fully appropriate: where a conscience violation exists, how does Congress respond? In the Church Amendments, Congress applied moral exemptions to the full extent of its authority. Because it did not create the conscience violations, the Spending Clause was the authority Congress could maximize. Here, where the agencies imposed a conscience violation based on its authority over private employers, the Church Amendments teach that the agencies should respect moral and religious conscience for all those employers. If the agencies believe Spending Clause authority is a limit on the agencies' actions, the agencies should limit the contraceptive mandate itself to federal funding recipients. Since they are not proposing to do that, it is not legitimate to categorically exclude moral protections from entities just because the underlying contraceptive mandate is not limited to federally funded entities.

The agencies also failed to account for *Welsh* v. *United States,* 398 U.S. 333 (1970), which was another explicit reason the agencies gave for enacting moral exemptions. There the Court would not allow the government to exempt a religious objector to the military draft but not exempt a "'sincere and meaningful belief which occupies in the life of its possessor a place parallel to that filled by the God of those admittedly qualifying for the exemption.'" *Id.* at 339 (quoting *United States v. Seeger*, 380 U.S. 163, 176 (1969)). The agencies propose to do here what the Court said the government cannot do in a much more urgent situation.

The agencies' refusal to comply with *Welsh* and *Seeger* would be exacerbated by the existence of the grandfathering exemption, which exempts plans that encompass millions of women but have no principled objection at all. Rescinding the moral exemptions here would be like imposing a military draft with religious exemptions, adding an exemption for people whose last names begin with A through G, and then vigorously punishing a handful of sincere, secular pacifists.

III. The agencies should not define contraceptives as "emergency services" or eliminate protections for that reason.

The agencies "seek comment on the circumstances under which contraceptive services would constitute emergency services, as well as whether to continue to apply the protections." To the extent the agencies are suggesting that by defining

contraceptives as emergency services they can override any of the religious or moral exemptions, they are mistaken.

Under the applicable statute at 42 U.S.C. § 300gg-13, the mandate can only include "preventive" services, not emergency services. There is no basis to interpret that statutory provision as including emergency services, much less to force religious or moral objectors to comply with the contraceptive mandate on that basis. The U.S. District Court for the Northern District of Texas recently issued preliminary and permanent injunctions against HHS for attempting to create a new abortion mandate under the aegis of emergency services. *Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525 (N.D. Tex. Aug. 23, 2022 and Jan. 13, 2023). Any attempt to shoehorn the contraceptive mandate into a newly discovered "emergency" mandate will subject the agencies to similar legal liability.

IV. The marketplace user fees diversion scheme is illegal.

The agencies' plan to expand diversion of marketplace user fees in the proposed rule, and the agencies' existing use of that fee structure, are illegal. Entities that are deprived of an exemption based on this proposed rule will be able to challenge the rule as being contrary to law.

As HHS has previously explained, Section 1311 of the ACA allows an exchange to charge user fees "to support its operations." 42 U.S.C. § 18031(d)(5)(A). *See* 78 Fed. Reg. 15,409, 15,412 (Mar. 11, 2013). But these user fees have nothing to do with supporting the operations of federal (or state) exchange. The persons receiving free contraception under this scheme are in employer-based plans, not marketplace plans. Paying for women in employer-based plans to have free contraception, and giving insurance companies and contraceptive distributors 15% profits on top of that, does not support the operations of marketplaces. Therefore, the diversion of those funds is not authorized by Section 1311.

Agencies can only act if Congress has authorized them to act in that way. *See, e.g.*, *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) ("Agencies have only those powers given to them by Congress"); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). No federal statute authorizes HHS or other agencies to create and run a reimbursable system of free contraception as set forth in the proposed rule. HHS is authorized to not impose the contraceptive mandate, and the agencies may exempt entities from such a mandate. But they are not authorized to create a system of contraceptive distribution funded by marketplace user fees. Especially in the context of a statute such as the ACA, which sets up a host of healthcare programs and payment mechanisms, the "statutory silence" wherein the agencies are given no authority to create a contraception fund with marketplace user fees

can only be interpreted to exclude the agencies' authority to do so. *Cf. Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 223 (2009).

The agencies' rationale for diverting these fees for a similar purpose on a smaller scale in 2013 is inadequate. There the agencies claimed that the fees could be diverted to advance "the goals of the Affordable Care Act," "improving the health of the population, reducing health care costs, providing access to health coverage," and "the governmental interests in promoting public health and in promoting gender equality." 78 Fed. Reg. 8,456, 8,465 (Feb. 6, 2013). By this rationale, the agencies could divert user fees to set up a system to freely distribute any drug, device, or service to any citizen with no connection to the marketplaces, simply to advance the generic goal of "promoting public health." That rationale has no limiting principle and will not sustain the legality of this scheme. Section 1311 and the ACA do not authorize the agencies to create new programs to give away goods and services and then to fund those programs by diversion of user fees collected for the purpose of supporting the operation of the exchange.

Nothing in OMB Circular No. A25-R supports this system. That circular advises that each provision of goods or resources by the government be "self-sustaining." But it does not provide independent authority for delivery of those goods or services in the first place. Nor could it, since the circular is a creation of the President, not of Congress, and only Congress can authorize agencies to act. *West Virginia*, 142 S. Ct. at 2609. Similarly, 31 U.S.C. § 9701 does not independently authorize the government to provide goods and services, but merely authorizes the collection of fees if the government is otherwise authorized to do such business.

The use of unappropriated user fees to create a new unauthorized program likely violates the Appropriations Clause of the Constitution. "The Appropriations Clause is . . . a bulwark of the Constitution's separation of powers among the three branches of the National Government. It is particularly important as a restraint on Executive Branch officers." *U.S. Dep't of Navy v. Fed. Lab. Rels. Auth.*, 665 F.3d 1339, 1347 (D.C. Cir. 2012) (Kavanaugh, J.) The agencies' lack of statutory authority to divert user fees to create a new program is exacerbated by the fact that only Congress is empowered to fund new programs, yet HHS will be operating this new program with funds over which Congress has no appropriations authority. Where Congress allows user fees for a specific purpose, agencies transgress Congress' appropriations authority by using those fees collection arrangements to fund an unauthorized purpose.

This flaw in the proposed rule creates legal liability for the agencies in connection with any elimination of exemptions from the status quo. This includes the proposal to repeal moral exemptions and deny them access to the user fees

scheme. The agencies might be able to diminish this liability if they leave the moral exemptions in place, however (and either apply the user fees arrangement to those plans or not), because entities using the moral exemption might be less likely to bring suit if they are still exempt.

The Supreme Court is poised to rule in cases against the U.S. Department of Education's attempt to forgive half a trillion dollars in student loans. See, for example, *Biden v. Nebraska*, S. Ct. Docket No. 22-506. As discussed at oral argument, the Court will likely rule on the question of whether and when a statute authorizes an agency to create a new program. Given the lack of statutory authority for the proposed scheme here, even as compared to the law at issue in those cases, the agencies should not finalize this proposed rule at least until after the Supreme Court rules in the student loan cases. If the Court strikes down the agency's action there, the agencies here should refrain from withdrawing any existing exemption under these rules.

V. The underlying contraceptive mandate is illegal under the APA.

The agencies' proposed repeal or negation of exemptions is illegal because the underlying contraceptive mandate violates the APA. The APA requires that agency rules undergo notice and comment. 5 U.S.C. § 553. The mandate is unquestionably a rule under the APA. But although regulations about *exemptions* to the mandate have undergone notice and comment, the underlying contraceptive mandate itself has never undergone notice and comment consistent with the APA. HRSA's "guidelines" have only ever been promulgated by posting them on their website and updating them repeatedly through a non-governmental organization.

The Supreme Court has acknowledged this embarrassing fact. *Little Sisters of the Poor*, 140 S. Ct. at 2382 n. 8 ("HRSA has altered its Guidelines multiple times since 2011, always proceeding without notice and comment."). This leaves the agencies with no room to argue that somehow the contraceptive mandate had undergone notice and comment. The U.S. District Court for the Eastern District of Texas, on similar grounds, granted a preliminary injunction against HRSA based on its failure to use the notice and comment process to promulgate the contraceptive mandate. *Tice-Harouff v. Johnson*, No. 6:22-CV-201-JDK, 2022 WL 3350375, at *11 (E.D. Tex. Aug. 12, 2022). HHS subsequently consented to a permanent court order and did not appeal.

The failure to subject the contraceptive mandate to notice and comment rulemaking also caused the government to fail to engage in reasoned decision-making. It is obvious based on years of controversy that such public participation would have led to robust debates of significant issues. By refusing to conduct notice

and comment rulemaking in issuing or revising the contraceptive mandate, HHS denied the public the opportunity to comment on questions such as: whether the thing that contraception prevents (pregnancy) is a disease or illness that qualifies the items as a preventive service under the statute; whether each specific method in the mandate is appropriately included, such as most recently male condoms, which the agency claimed it had no authority to mandate for a decade; whether and to what extent some methods can destroy newly formed human embryos, and therefore are not (or not merely) contraceptive but abortive in violation of other ACA provisions and conscience laws; and many other important policy questions. HHS unlawfully deprived the public of the opportunity to raise all of these questions. Imposing this mandate on any objecting entity will create a new and ongoing injury based on that underlying illegal action.

The contraceptive mandate also violates the Vesting Clause of the Constitution, often referred to as the non-delegation doctrine. The Supreme Court noted in *Little Sisters of the Poor* that under the statute "HRSA has virtually unbridled discretion," and the Court left the non-delegation question unanswered by observing that it simply had not been raised in that case. 140 S. Ct. at 2380, 2382. That objection will likely be raised if the agencies impose this mandate on currently exempt entities. Entities will also likely raise claims that the mandate violates the Appointments Clause. *See, e.g.*, *Kelley v. Azar*, No. 4:20-CV-00283-O, 2021 WL 4025804 (N.D. Tex. Feb. 25, 2021) (denying HHS's motion to dismiss Appointments Clause and Vesting Clause claims). The agencies failed to discuss these legal issues in the proposed rule.

VI. If the final rule rescinds or weakens exemptions, it cannot be applicable for most plans until January 2024.

Under the preventive services mandate, 42 U.S.C. § 300gg-13(b), newly imposed coverage obligations cannot go into effect until the next plan year that begins one year after their promulgation. The agencies have embraced this one-year delay period since the beginning of the mandate. 75 Fed. Reg. 41,726, 41,729 n.4 (July 19, 2010). The agencies repeated this one-year period of delayed applicability in footnote two of this proposed rule, and the agencies gave no indication that it would not be followed if these rules are finalized.

As a result, any finalization that rescinds or weakens exemptions—whether in the repeal of the moral exemptions or an adoption of the alternative approach to the religious exemptions—cannot go into effect until the plan year beginning one year after the finalization of those rules. For plans that operate on a calendar year, that will likely mean these rules cannot go into effect until the January 2024 plan year.

The agencies have no basis to sidestep this effective date. Five years have passed since the existing rules were finalized in 2018. The agencies did not propose these rules on an interim final basis or assert good cause for the need to eliminate ordinary timelines. They also did not give the public any notice in this proposed rule that the final rules would not follow the one-year delay, nor did they give a rationale for handling the mandate differently than it was handled in the past. If the agencies wish to apply these final rules sooner, they will need to resubmit the proposed rules for a new comment period so that the public may comment on the agencies' explanation of why the one-year delay will not be followed.

Notably, in the past where *exemptions* were added the one-year delay in § 300gg-13(b) did not apply. This was correct because the delay only applies when a new recommendation or guideline is added requiring coverage, because a new coverage obligation takes time to implement. This one-year delay is not designed for a decision to remove a coverage requirement, which is what an exemption does. Since rescinding an exemption imposes a new obligation that is not currently present, it is subject to the one-year delay to ensure time for implementation. Therefore, the one-year delay would apply to rescinding the moral exemptions or imposing the alternative approach to the religious exemptions.

VII. There is a history of failure to enforce the preventive services guidelines with respect to fertility awareness-based methods of family planning.

The agencies asked for comment on "information regarding potential noncompliance with these requirements" including the requirement to cover instruction on fertility awareness-based methods (FABM) of family planning. It is common practice for issuers to refuse to comply with their obligation under the women's preventive services guidelines to cover FABM instruction. This may be due to issuers not knowing of the requirement, or to the agencies' inconsistent inclusion of mention of that requirement in their guidance letters. More information about this is included in other public comments (*see, e.g.*, tracking number let-1jo5-xz94).

The agencies should, as the proposed rule preamble suggests, engage in "additional oversight and enforcement actions . . . to ensure health plans and issuers are complying with" their obligation to cover FABM instruction specifically. General attempts to inform issuers of their overall obligations to cover women's preventive services or contraception have proven insufficient. Those general attempts tend to emphasize non-FABM methods, so that the requirement to cover instruction on FABM methods gets lost in the message. Outreach and enforcement specifically with respect to FABM coverage is needed.

VIII. The agencies should not add the non-statutory phrase "evidence-informed" to the regulatory requirements.

The agencies should not add the phrase "evidence-informed" to 45 C.F.R. § 147.130(a)(iv). It is not in the applicable statutory paragraph, 42 U.S.C. § 300gg-13(a)(4). Notably, Congress did include "evidence-based" under (a)(1) and "evidence-informed" under (a)(3). Where Congress uses a phrase in one sentence and omits it from another sentence of the same statutory section, those uses and omissions are deemed intentional by the courts.

The reason to omit the language is to avoid narrowing the authorization for the provisions and to avoid confusion. The agencies have committed both errors in proposing this language when they stated, "these proposed rules would help ensure that plans and issuers are required to cover recommended preventive items and services, without cost sharing, only when evidence supports the items' or services' value as preventive care." That rationale causes confusion for insurers because it raises the question whether there are some items that explicitly fall into the mandate that plans nevertheless need not cover because someone considers them not "evidence-informed." Given the agencies' own stated concern to reduce insurer non-compliance, it is inconsistent for the agencies to add this language because it invites noncompliance with a mandate otherwise clearly listed in the guidelines.

In addition, the broad authority that allows the agencies to include religious and moral exemptions is potentially undermined if the phrase "evidence-informed" is added where Congress did not add it. Congress intended to let the agencies craft the mandate so as to encompass concerns that are not based solely on scientific evidence—including concerns of religious liberty and moral conscience. Adding this phrase creates legal liability because it suggests the agencies are backhandedly repealing all of the exemptions based on someone's interpretation of what constitutes "evidence-informed" guidelines.

The agencies' attempt to clarify this in footnote 91 is insufficient. If, as the agencies claim, Congress meant "evidence-based" means a decision "solely" based on scientific evidence, and "evidence-informed" means a decision considering scientific evidence and other standards, then Congress must have meant to give the agency even more leeway in using *neither phrase* under the paragraph applicable to this mandate. By adding this language the agencies would be denying that Congress gave them even more leeway than for example it gave them under subparagraph (a)(3). That conclusion is not supported by the statutory text and is therefore contrary to the agency's statutory authority.

For all these reasons, the agencies should abandon the proposed rule.

Respectfully submitted,

/s/ *Matthew S. Bowman*

Matthew S. Bowman
Senior Counsel
Alliance Defending Freedom