

April 3, 2023

U.S. Departments of Treasury, Labor, and Health and Human Services
c/o Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9903-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: [CMS-9903-P] Coverage of Certain Preventive Services Under the Affordable Care Act

Submitted Electronically via <https://www.regulations.gov>

FROM: Edmund F. Haislmaier, Preston A. Wells, Jr. Senior Research Fellow, Center for Health and Welfare Policy, The Heritage Foundation

In the preamble to this proposed rule, the Departments note that they, “have engaged in several rounds of rulemaking and other initiatives that solicited public input in an effort to address the claims of those religious employers, institutions of higher education, and health insurance issuers that object to providing coverage for contraceptive services while also ensuring women’s access to seamless coverage for contraceptive services.”¹

Statutory and regulatory context

The context for this proposed rule, and the Departments’ related prior rulemaking, is as follows:

- The Patient Protection and Affordable Care Act of 2010 (PPACA) amended the Public Health Service Act (PHSA) to include a new section 2713 that requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage of preventive services without cost sharing. The types of services that are required to be covered are described in subsection (a), paragraphs (1) through (5). Separately, section 1562 of the PPACA incorporated section 2713 of the PHSA into the

¹ U.S. Departments of Treasury, Labor, and Health and Human Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” Notice of Proposed Rulemaking, February 2, 2023, at 88 FR 7242.

Employee Retirement Income Security Act of 1974 and into the Internal Revenue Code of 1986.²

- Section 2713(a)(4) specifies: “with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.”
- Section 1251 of the PPACA exempts so called grandfathered plans from the requirements of certain provisions of the PHSA, including section 2713.³
- The Departments published an interim final rule on July 19, 2010, implementing the provisions of section 2713, but without the guidelines specified in paragraph (a)(4).⁴
- The Health Resources and Services Administration (HRSA) issued the applicable guidelines on August 1, 2011, and the Departments published a final rule on February 15, 2012, amending the CFR to implement the requirement that plans comply with those guidelines.⁵
- The HRSA guidelines require coverage of “the full range of U.S. Food and Drug Administration (FDA)- approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures.”⁶
- In response to employers and plans that objected on moral or religious grounds to providing some, or all, of the required contraceptive items and services specified in the HRSA guidelines, the Departments first promulgated regulations regarding “exceptions and accommodations” in 2013.⁷ Since then, the Departments regulatory construct for such “exceptions and accommodations” has been the subject of litigation and regulatory revisions, the most recent of which are proffered in this proposed rule.

Implications

² Section 2713 of the Public Health Service Act as added by Public Law 111-148 § 1001(5) and as incorporated by § 1562(e) and (f) of Public Law 111-148 into § 715 of the Employee Retirement Income Security Act of 1974 and into § 9815 of the Internal Revenue Code of 1986, respectively. Codified at: 42 U.S. Code § 300gg-13(a); 29 U.S. Code § 1185d, and; 26 U.S. Code § 9815.

³ Public Law 111-148 § 1251.

⁴ U.S. Departments of Treasury, Labor, and Health and Human Services, “Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act,” July 19, 2010, at 75 FR 41726-41760.

⁵ U.S. Departments of Treasury, Labor, and Health and Human Services, “Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act,” Final Rules, February 15, 2012, at 77 FR 8725-8730.

⁶ Health Resources & Services Administration, “Women’s Preventive Services Guidelines,” at <https://www.hrsa.gov/womens-guidelines>.

⁷ U.S. Departments of Treasury, Labor, and Health and Human Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” Proposed Rules, February 6, 2013, at 78 FR 8456-8476.

Section 2713 of the PHSA does not enumerate specific items or services that must be covered. Instead, the statute enumerates four subject matter categories, and for each category it: 1) identifies the mechanism that the Executive Branch is to use in determining the list of specific items and services for which coverage is required, and 2) names the specific Executive Branch sub-unit to which the task is assigned.

Thus, while the Departments' rulemaking with respect to section 2713 of the PHSA is within the scope of authority delegated by Congress to the Departments in the statute, the specific requirement that plans cover contraceptive items and services for women is not expressly included in the statute. The statute simply requires that plans cover "such additional preventive care and screenings...provided for in comprehensive guidelines supported by the Health Resources and Services Administration."

This statutory context entails three important implications for the Departments' rulemaking.

First, under the authority delegated to the Departments by section 2713(a)(4) of the PHSA, the Departments have discretion to include, or exclude, specific items or services from the list of required coverages.

Second, the Departments implicitly have authority under section 2713 to establish limits on, or exceptions to, required coverages. Indeed, in their implementation of both paragraph (4) and the other paragraphs of section 2713(a), the Departments have established in regulation and guidance limits or exceptions in connection with issues of frequency, applicable patient populations, the imposition of cost sharing with respect to non-preferred providers or drugs, plan medical management practices, etc.

Third, because there is no *statutory* requirement for coverage of contraceptive items and services, the Departments' decision to require such coverage, along with the subsidiary decisions as to the scope of such coverage and any limits or exceptions thereto, are all derived from Executive Branch *policy preferences*. Any particulars of the Departments' rulemaking that seek to achieve results that conform to Executive Branch policy preferences are secondary and subordinate to statute.

Two statutory problems with the Departments' basic "accommodation" construct

As noted, the Departments first promulgated regulations regarding "exceptions and accommodations" to the contraceptive coverage requirement in 2013.

Those regulations addressed various issues related to providing exemptions for entities and health plans with religious or moral objections to providing, paying for, or facilitating some or all such contraceptive items or services. They also specified mechanisms by which women enrolled in such plans could separately obtain alternative contraceptive coverage. The first set of issues has been the primary focus of subsequent litigation and revisions to the regulations, while the provisions addressing the mechanics of obtaining alternative coverage have largely been a secondary consideration.

While the Departments have revised elements of those regulations several times since 2013, the underlying regulatory construct of the Departments’ “accommodation” for providing and funding alternative coverage, which that the Departments first developed and promulgated in their 2013 rule, has remained in place with little change since then. This proposed rule also retains that same basic construct.

However, the Departments’ underlying “accommodation” construct is flawed because it incorporates two errors of statutory interpretation that the Departments made in 2013 and which they have not subsequently corrected.

Conflating “cost-sharing” with “premiums”

The first flaw in the Departments’ “accommodation” construct is that it erroneously extends the statutory prohibition on imposing “cost sharing” on enrollees to also include an additional prohibition on charging enrollees any “premium” or “fee” for alternative contraceptive coverage.

Specifically, the Departments regulations state:

- In 26 CFR § 54.9815–2713A(b)(2), and in 29 CFR § 2590.715–2713A(b)(2):
... the third-party administrator will provide or arrange payments for contraceptive services, using one of the following methods—
 - (i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or
 - (ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.
- In 26 CFR § 54.9815–2713A(c)(2)(ii), and in 29 CFR § 2590.715-2713A(c)(2)(ii), and in 45 CFR § 147.131(d)(2)(ii):

With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

The proposed rule would retain, without change, all the above provisions, which include the identical phrasing “any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.”

The problem with that phrasing is that it conflates two separate issues that the Departments faced when devising their “accommodation” construct.

The first issue was ensuring that any alternative coverage complied with the statutory requirement that no cost-sharing be imposed on participants or beneficiaries.

The second issue was ensuring that any entity or plan that objected to providing, funding, or facilitating contraceptive services, would not be directly or indirectly charged for the alternative coverage.

While that phrasing does achieve both of those objectives, its *also* has the effect of imposing on any third-party administrator or health insurance issuer providing alternative coverage an additional requirement. Specifically, in that phrasing the prohibition on imposing any “premium, fee, or other charge, or any portion thereof, directly or indirectly,” applies *not only* to “eligible organizations” and “group health plans” *but also* to “plan participants or beneficiaries.”

That additional prohibition on charging enrollees any “premium” or “fee” in the above cited provisions is not supported by the statute. It is also not imposed anywhere else in the Departments’ regulations implementing the same statute with respect to the provision of *any other* required preventive service, nor is it imposed with respect to the provision of contraceptive coverage by *non-objecting* plans, plan sponsors, or issuers.

Put simply, there is no statutory justification for the Departments prohibiting health plans or health insurance issuers from charging premiums or fees to enrollees for alternative coverage of required preventive services. The statute states only that a plan or issuer “shall not impose any cost sharing requirements.”

Furthermore, the Departments indicate elsewhere that they agree with the foregoing statutory interpretation.

Specifically, in the initial regulations implementing the broader preventive services mandate, published July 19, 2010, the Departments correctly interpreted the statutory text as meaning that a plan or issuer “may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services.”⁸ Those regulations do not mention premiums or fees and remain unchanged. In fact, the Departments expected that compliance with section 2713 would result in additional claims costs to plans. The Departments further assumed that plans would pass on some, or all, of those additional costs to their enrollees

⁸ U.S. Departments of Treasury, Labor, and Health and Human Services, “Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act,” July 19, 2010, at 75 FR 41726-41760. See also: 26 CFR § 54.9815–2713T(a)(1), 29 CFR § 2590.715–2713(a)(1), and 45 CFR § 147.130(a)(1).

in the form of higher premiums. Indeed, as part of their regulatory impact analysis, the Departments even provided their estimates for how much premiums might increase as a result.⁹

Thus, to clarify the responsibilities of affected parties, the Departments now need to revise the above cited regulatory provisions to correct this error before finalizing this proposed rule.

The solution is to separate, and clearly delineate, the two distinct requirements and their relevant applications. That can easily be accomplished by revising the language to read as follows:

In 26 CFR § 54.9815–2713A(c)(2)(ii), and in 29 CFR § 2590.715-2713A(c)(2)(ii), and in 45 CFR § 147.131(d)(2)(ii):

...may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) on plan participants or beneficiaries, nor may the issuer impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization or the group health plan.

In 26 CFR § 54.9815–2713A(b)(2)(i) and (ii), and in 29 CFR § 2590.715–2713A(b)(2) (i) and (ii):

...without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) on plan participants or beneficiaries, and without imposing any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization or group health plan.

Such revisions would correctly reflect the statute. They would also have the practical effect of providing additional options for affected enrollees in exempt plans to obtain alternative contraceptive coverage for which they could be charged a premium or fee—as they could be for coverage of any other preventive service for which enrollee cost-sharing may not be imposed.

Misapplication of user fees

The second flaw in the Departments’ “accommodation” construct is that it relies on an improper application of the user fee statute to provide funding for alternative contraception coverage.

The background is that Section 1311 of the PPACA directed the establishment of state “Health Benefit Exchanges” and authorized and funded federal grants to states for the purposes of planning and establishing such exchanges.¹⁰ However, the statute also required that the new exchanges be financially self-sustaining.¹¹ Congress assumed that states would willingly set up exchanges and fund their operating costs, but most states declined to do so. Consequently, the federal government currently operates, in whole or part, the exchanges in 33 states.

Because Congress has never appropriated any funding for federally operated exchanges, the

⁹ Ibid., 75 FR 41736-41738.

¹⁰ Public Law 111-148 § 1311, codified at 42 USC § 18031.

¹¹ Ibid., subsection (d)(5)(A).

Department of Health and Human Services (HHS) resorted to imposing user fees on the health insurance issuers participating in those exchanges.¹² In justifying that decision, the Department cited authority under three statutory provisions:

1. Section 1311(d)(5)(A) of the PPACA, which envisions states (though not the federal government) charging health insurance issuers user fees to support exchange operations. [Codified at 42 USC § 18031(d)(5)(A)]
2. Section 1321(c) of the PPACA, which stipulates that if a state fails to establish or operate an exchange that meets requirements, “the Secretary shall (directly or through agreement with a not-for-profit entity) establish and operate such Exchange within the State and the Secretary shall take such actions as are necessary to implement such other requirements.” [Codified at 42 USC § 18041(c)]
3. 31 USC § 9701, which authorizes federal agencies to charge user fees for items or services provided to identifiable recipients.

As previously explained, the Departments’ regulations regarding “exceptions and accommodations” with respect to contraceptive coverage, erroneously stipulate that enrollees and beneficiaries in exempt plans are not to be charged premiums for alternative contraceptive coverage. Based on that erroneous construct, HHS then decided to compensate third-party administrators and health insurance issuers for their costs in providing such alternative coverage by amending its exchange user fee regulations to permit health insurance issuers participating in federally-facilitated exchanges to claim a reduction in user fees equal to those costs plus an administrative allowance, and to also permit applicable third-party administrators to obtain reimbursement from user-fee paying health insurance issuers on a pass-through basis.¹³

In this proposed rule, the Departments estimate that the total reduction in exchange user fees to fund alternative contraceptive coverage will be \$79.46 million per year for the next five years.¹⁴

The application of user fees by federal agencies is governed by statute (31 USC § 9701) and by Office of Management and Budget (OMB) Circular No. A-25 Revised.¹⁵

The statute requires that any user fees be “fair” and based on “the value of the service or thing to the recipient.”¹⁶

¹² U.S. Department of Health and Human Services, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014,” Proposed Rule, December 7, 2012, at 77 FR 73181-73182, and U.S. Department of Health and Human Services, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014,” Final Rule, March 11, 2013, at 78 FR 15520-15521, which added 45 CFR § 156.50(c).

¹³ 45 CFR § 156.50(d).

¹⁴ For source of calculation see, U.S. Departments of Treasury, Labor, and Health and Human Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” Notice of Proposed Rulemaking, February 2, 2023, footnote 166 at 88 FR 7263.

¹⁵ U.S. Office of Management and Budget, “Circular No. A-25 Revised,” at <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>.

¹⁶ 31 U.S. Code § 9701(b)(1) and (2)(B).

Relevant provisions of OMB Circular No. A-25 include the following:

6. General policy: A user charge...will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public...

a. Special benefits

1. Determining when special benefits exist. When a service (or privilege) provides special benefits to an identifiable recipient beyond those that accrue to the general public...For example, a special benefit will be considered to accrue and a user charge will be imposed when a Government service:

(a) enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) than those that accrue to the general public (e.g., receiving a patent, insurance, or guarantee provision, or a license to carry on a specific activity or business or various kinds of public land use)

...

(c) is performed at the request of or for the convenience of the recipient, and is beyond the services regularly received by other members of the same industry or group or by the general public

...

b. Charges to the direct recipient. Charges will be made to the direct recipient of the special benefit even though all or part of the special benefits may then be passed to others.

In sum, the parameters for federal agencies imposing user fees are that such fees are to be assessed:

- For “special benefits” that are “beyond those received by the general public.”
- On “the direct recipient of the special benefit even though all or part of the special benefits may then be passed to others.”
- Based on “the value of the service or thing to the recipient.”

When HHS first proposed to assess user fees on participating health insurance issuers “to support the operation of federally facilitated exchanges” the Department implicitly recognized and accepted those parameters in its justification, stating that:

Participating issuers will receive two special benefits not available to the general public when they offer plans through a Federally-facilitated Exchange: (1) The certification of their plans as QHPs, and (2) the ability to sell health insurance

coverage through a Federally-facilitated Exchange to individuals determined eligible for enrollment in a QHP. These special benefits are provided to participating issuers based on the following Federal operations in connection with the operation of Federally-facilitated Exchanges:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Administration of advance payments of the premium tax credit and cost-sharing reductions;
- Enrollment processes;
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification); and
- Administration of a SHOP Exchange.

Activities performed by the Federal government that do not provide issuers participating in a Federally-facilitated Exchange with a special benefit will not be covered by this user fee.¹⁷

Yet, just three months later, the Department proposed amending its exchange user fee regulations to incorporate offsets for the costs of providing alternative contraceptive coverage, and justified those amendments as follows:

Consistent with Office of Management and Budget (OMB) Circular No. A25–R, the proposed revised FFE user fee calculation (which would result in an adjustment of the FFE user fee) would facilitate the proposed accommodation of self-insured plans established or maintained by eligible organizations by ensuring that plan participants and beneficiaries have separate individual health insurance policies for contraceptive coverage at no additional cost such that eligible organizations are not required to administer or fund such coverage.¹⁸

While the Department did reference Circular No. A-25, it offered no explanation for its assertion that its regulatory amendments were consistent with the parameters of Circular No. A-25. Neither did the Department offer any explanation for how such offsets were consistent with the purpose and special benefits it previously identified in justifying the imposition of exchange user fees. The Department simply stated that the offsets “would facilitate the proposed accommodation.”

There are several problems with this construct that HHS devised for funding alternative

¹⁷ U.S. Department of Health and Human Services, “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014,” Proposed Rule, December 7, 2012, at 77 FR 73181.

¹⁸ U.S. Departments of Treasury, Labor, and Health and Human Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” Proposed Rule, February 6, 2013, at 78 FR 8465.

contraceptive coverage through reductions in exchange user fees:

1. As previously explained, this construct is premised on the, erroneous and statutorily unsupported, requirement that the alternative coverage is to be provided at *no cost* to the covered individuals. However, because the statute permits any plan or policy that covers any, or all, required preventive services under section 2713 to charge enrollees premiums, there is no need for the government to fund such coverage. Put simply, the Department's regulatory construct for funding alternative contraceptive coverage through offsets to federal exchange user fees is unnecessary.
2. The arrangement opens the door to rampant fraud and abuse. Under the proposed rule, a woman is entitled to free contraceptives based merely on her say so. Specifically, the only confirmation required by the rule is that a woman provide "an attestation" that her employer does not provide full contraceptive coverage.¹⁹ Nowhere in the rule or in the sample attestation provided by the Departments is she required to substantiate or even claim that her employer is not providing contraceptive coverage due to a religious objection.²⁰ Moreover, the provider is not required to ask anything about the reasons why the employer is not providing coverage and "would have discretion on choosing what confirmation method to accept."²¹ This allows unscrupulous persons to simply lie about their coverage status to get contraceptives to which they are not entitled.

Furthermore, as discussed in the next section below, there are potentially millions of women in grandfathered plans not receiving fully compliant contraceptive coverage who could thus walk into a local Planned Parenthood and truthfully sign an attestation (or make a statement) saying their employer does not provide full contraceptive coverage and walk out with free contraceptives. The proposed rule invites precisely such a result.

Indeed, there is in fact a strong financial incentive for both providers and issuers to ignore or even encourage such fraud or abuse because issuers would receive full reimbursement and a 15% administrative allowance for every claim,²² while providers would receive full payments for services (even if inflated) and an estimated 38.5% in administrative costs on top.²³

The Departments' estimate of total costs of \$79.46 million per year is certainly a gross underestimation. The Departments have decades of experience with fraud and abuse in government programs including under the ACA. It would be the height of arbitrariness and capriciousness for the Departments to not firmly close this glaring loophole, and to not account for obvious behavioral effects in their cost estimate.

¹⁹ See proposed rule § 54.9815–2713A(a)(3)(ii); § 2590.715–2713A(a)(3)(ii); § 147.131(a)(3)(ii) at 88 FR 7271, 7274, and 7277, respectively.

²⁰ *Ibid.*, § 54.9815–2713A(e)(2); § 2590.715–2713A(e)(2); § 147.131(d)(2).

²¹ U.S. Departments of Treasury, Labor, and Health and Human Services, "Coverage of Certain Preventive Services Under the Affordable Care Act," Notice of Proposed Rulemaking, February 2, 2023, at 88 FR 7253 and 7257.

²² *Ibid.*, footnote 166 at 88 FR 7263.

²³ *Ibid.*

Self-attestation is unacceptable under these circumstances. At the very least, the Departments must require independent documentary evidence, including a written claim denial or written plan exclusions, as well as independent written evidence that the lack of full contraceptive coverage stems from the religious beliefs of the employer and not from being enrolled in a grandfathered plan.

3. A plausible argument could be made that the Department’s facilitation of alternative contraceptive coverage constitutes a “special benefit” provided by the Department. However, not only has the Department not made that argument, but an inherent implication of that argument is that the correct action by the Department should be to charge an additional, or separate, user fee to the identified recipients of that “special benefit” (i.e., either the entities providing, or the enrollees receiving, the alternative coverage). Yet, in fact, not only is the Department *not charging* those recipients user fees, but it is instead providing those recipients with *subsidies* equal to their costs for that “special benefit.”
4. Another implication of 31 USC § 9701 and Circular No. A-25 is that the collection and expenditure of funds from user fees by a federal agency are to effectively operate on a “zero-sum” basis. Consequently, in the case of the user fees imposed by the Department on plans in federally facilitated exchanges, the reductions in user fees claimed by some of those plans must, of necessity, be recouped from the user fees paid by plans not claiming reductions. As noted, the user fees on plans sold through federally facilitated exchanges are passed on by those plans to their customers in the form of increased premiums.
5. Under 31 USC § 9701 and Circular No. A-25, federal user fees may be imposed and collected for the purpose of recouping the cost to the government of providing identified recipients with one or more identified special benefits. The statute and Circular No. A-25 *do not* permit an agency to impose and collect user fees for one set of special benefits to fund *subsidizing* the provision of a *different* special benefit.
6. In fact, under the Department’s “accommodation” construct, the individuals receiving alternative contraceptive coverage do not pay (either directly or indirectly) any of the user fees charged to plans in federally facilitated exchanges, as those individuals are not enrolled in plans offered through federally facilitated exchanges. At the same time, the enrollees in exchange plans who do pay (indirectly) the user fees (a portion of which the Department is applying to fund the alternative coverage), all automatically receive, and pay for, the required contraceptive coverage, which must be included in all exchange plans. Thus, exchange enrollees receive no “value” for the portion of the exchange user fees that they pay which are used by the Department to fund separate contraceptive coverage for individuals who *do not* purchase coverage through the exchanges.²⁴

In sum, the Department’s diversion of a portion of the revenues collected from user fees imposed

²⁴ The only possible exception to the mutually exclusive composition of the two groups would be if a health insurance insurer offering plans through one or more federally facilitated exchanges were to claim an exemption from offering contraceptive coverage in such plans. In such circumstances, the affected issuer (and enrollees) would still be required to pay the user fees levied on plans offered through federally facilitated exchanges.

on plans offered in federally facilitated exchanges to fund subsidies for the provision of alternative contraceptive coverage for enrollees in other plans contravenes both the user fee statute at 31 USC § 9701 and the parameters established in OMB Circular No. A-25.

Issues with the scope of application

In the preamble to this proposed rule, the Departments justify their rulemaking by asserting a need to ensure that enrollees in those plans claiming an exemption from the contraceptive mandate based on religious or moral objections be able to obtain alternative contraceptive coverage. The Departments buttress that justification with additional assertions framed in unequivocal language, including:²⁵

Access to contraception is an essential component of women’s health care...

Ensuring access to contraception at no cost (other than the premium or contribution paid for health coverage) is a national public health imperative...

The November 2018 final rules...did not give sufficient consideration to women’s significant interests in access to contraceptive services.

The exemptions also ignore the government interest in promoting coverage for contraceptive services and assuring access to contraception.

Improving access to contraceptive services is critical to narrowing disparities in reproductive health access and outcomes, as well as longer-term outcomes.

Access to contraceptive services has wide-ranging economic effects for women, from increased educational attainment to increases in labor force participation and lifetime earnings.

This proposed approach would further the government’s interest in protecting women’s health and their right to make reproductive decisions.

The November 2018 final rules failed to adequately account for women’s legal entitlement to access preventive care, critically including contraceptive services, without cost sharing as Congress intended... and the government’s interest in ensuring women have access to this coverage.

Yet, having thus asserted that contraception is “an essential component of women’s health care,” access to which is “a national public health imperative,” and that there is a “government interest in promoting coverage for contraceptive services,” to which women have a “legal entitlement,” several pages later, the Departments blithely state:

²⁵ U.S. Departments of Treasury, Labor, and Health and Human Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” Notice of Proposed Rulemaking, February 2, 2023, at 88 FR 7240-7243.

The Departments acknowledge that grandfathered health plans are not required to comply with section 2713 of the PHS Act, including the implementing regulations. However, because there are relatively few grandfathered plans and coverage still in existence, and these plans and issuers providing grandfathered coverage may voluntarily, or as required by State law, provide contraceptive coverage, the Departments are not proposing to apply the proposed individual contraceptive arrangement to women enrolled in grandfathered plans.²⁶

Thus, the Departments advance sharply different positions with respect to the two sets of health plans claiming exemptions. On the one hand, the Departments are very insistent on the supposed need to provide alternative contraceptive coverage to enrollees in plans claiming a *regulatory* exemption. Yet on the other hand, the Departments are casually dismissive of any presumed need to provide alternative coverage (for contraception or for other preventive services) to enrollees in plans claiming a *statutory* exemption.

The Departments' disparate treatment of the two sets of plans and affected enrollees is even more striking given the substantial difference in their size.

The Departments estimate that under their regulatory exemption for objecting plans there would be at least 126,400 women eligible for alternative contraceptive coverage.²⁷ Yet, in the above cited paragraph in which the Departments state that they "are not proposing to apply the proposed individual contraceptive arrangement to women enrolled in grandfathered plans," they include a footnote referencing their, much larger, estimate of the number of affected individuals in that group.²⁸ Specifically, the Departments estimated that, in 2020, there were 413,545 grandfathered plans with 23.7 million enrollees.²⁹ Based on that estimate, it can be extrapolated that there are about 6.5 million affected female enrollees in grandfathered plans who may have either no contraceptive coverage, or coverage that is less comprehensive than that required under the HRSA guidelines.³⁰

The Departments' different treatment of the two groups cannot be explained by a lack of data, as the Departments admit to not having firm and reliable data on the number of plans, number of affected enrollees, or extent of coverage, for either the statutorily exempt plans or the regulatorily exempt plans.

²⁶ Ibid., at 88 FR 7253.

²⁷ Ibid., at 88 FR 7261.

²⁸ Ibid., footnote 127 at 88 FR 7253.

²⁹ U.S. Departments of Treasury, Labor, and Health and Human Services, "Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage," Final Rule, December 15, 2020, at 85 FR 81108.

³⁰ The extrapolation is as follows: Employer group plans cover workers and their dependents, almost all of whom are under age 65. With respect to contraceptive coverage for women, the Departments state that "The references to 'women' in these proposed rules should be considered to include any individual potentially capable of becoming pregnant." [footnote 3 at 88 FR 7237] Based on that standard, the relevant population subset consists of females primarily between the ages of 15 and 50. Calculations using Census data find that females between ages 15 and 50 account for 27.45 percent of the population of non-institutionalized persons under age 65. [U.S. Census Bureau, "Age and Sex Composition in the United States: 2020," <https://www.census.gov/data/tables/2020/demo/age-and-sex/2020-age-sex-composition.html>] Applying the assumption that the demographic composition of the Departments' estimated 23.7 million grandfathered plan enrollees mirrors that of the total population, yields an estimate of around 6.5 million pregnancy-capable females enrolled in grandfathered group plans.

Nor can it be assumed that statutorily exempt plans cover all, or even any, of the required contraceptive services. Indeed, there are grandfathered plans that maintain their grandfathered status to deliberately avoid the contraceptive coverage mandate (and possibly for other reasons as well). Furthermore, due to their statutory exemption, grandfathered plans may, or may not, cover one or more of the other preventive services required under section 2713 of the PHSA, and may, or may not, impose enrollee cost sharing in connection with such other preventive services.

Furthermore, the fact that Congress explicitly exempted grandfathered plans from *some* of the PPACA's insurance reform provisions, including section 2713 of the PHSA, but not others, means that there is no statutory support for the Departments' insistence that women enrolled in plans claiming a regulatory exemption from the contraceptive coverage mandate be able to obtain alternative contraceptive coverage. Had Congress been concerned that some individuals might not benefit from the required preventive services, it could have applied section 2713 to grandfathered plans, just as it explicitly applied other sections of the PHSA to grandfathered plans.³¹

In sum, the Departments' disparate treatment of the two sets of plans claiming exemptions is arbitrary and capricious.

Stand-alone coverage

In their original proposed rules, the Departments recognized that states could authorize health insurers to issue individual market contraceptive-only coverage policies, and the Departments proposed regulations to recognize such policies as a form of "excepted benefit" coverage under the provisions of section 2791(c)(2) of the PHSA (and the parallel provisions in section 734 of ERISA and section 9833 of the Internal Revenue Code) in accordance with the authority to do so granted the Departments under those statutes.³²

However, in promulgating their final regulations, the Departments discarded those proposed provisions stating that, "the accommodations established under these final regulations do not require the issuance of a separate excepted benefits individual health insurance policy covering contraceptive services."³³

In this proposed rule, as part of their discussion of regulatory alternatives, the Departments revisited the option of separate contraceptive coverage policies, stating:

With respect to individuals enrolled in coverage through entities that have a religious objection to contraceptive coverage, the Departments considered an approach under which contraceptive coverage would be available through

³¹ See: 42 USC §18011(a)(3) and (4), which apply to grandfathered plans the provisions of sections 2708, 2711, 2712, 2714, 2715, and 2718 of the PHSA.

³² U.S. Departments of Treasury, Labor, and Health and Human Services, "Coverage of Certain Preventive Services Under the Affordable Care Act," Proposed Rules, February 6, 2013, at 78 FR 8467-8468 and 8473-8475.

³³ U.S. Departments of Treasury, Labor, and Health and Human Services, "Coverage of Certain Preventive Services Under the Affordable Care Act," Final Rules, July 2, 2013, at 78 FR 39874 and 39876.

separate individual insurance policies that cover only contraceptives and in which participants, beneficiaries, and enrollees would have to separately enroll if they desired contraceptive coverage. The Departments decided against this option for a number of reasons. The Departments are concerned that issuers would not offer these products to a sufficient extent to ensure access nationwide... Additionally, some State regulators might not have authority or capacity to approve single benefit insurance policies (other than dental or vision or disease-specific excepted benefits policies) within a relatively short period of time after Federal rules would permit these policies. Cost-free contraception policies would also not satisfy some State laws conditioning policy approval on a “reasonable premium” or the existence of valid contracts because the prospective policyholder would not provide consideration in exchange for the coverage.³⁴

The Departments foregoing reasons for rejecting this option are all erroneous. Specifically:

1. There are no statutory grounds for the Departments rejecting this option because it might not “ensure access nationwide.”
2. There is no statutory basis for the Departments’ justification that states might not be able to approve such policies “within a relatively short period of time.”
3. There is no statutory basis for the Departments’ assertion that federal regulations would be needed to “permit these policies.” Under the relevant federal statutes (PHSA, ERISA and IRC), any legitimate federal regulations, such as those initially proposed by the Departments, would *only* be for the purpose of clarifying the application, or non-application, of federal law (as specified in those same statutes) to such insurance products. Those statutes delegate to the Departments the authority to *recognize* and *classify* in regulation a new category of limited benefit policies, but not the authority to *authorize* such policies.
4. As previously explained, there is no statutory basis for the requirement that contraceptive policies be issued to enrollees on a “cost-free” basis.
5. Except when explicitly preempted by federal law, states retain plenary powers to establish and enforce state insurance laws, including those governing financial requirements, contractual terms and insurer marketing practices. Because there are no federal laws that preempt state laws governing premiums charged for limited-benefit policies, there is no obstacle to the application of such state laws to limited-benefit contraceptive coverage policies.

Furthermore, and as previously noted, the Departments appear to be unconcerned that another, and much larger, group of grandfathered plans and enrollees, may not have separate coverage either for contraceptive items and services or for other items and services required under section 2713 of the PHSA. The Departments have never attempted to arrange separate coverage for such

³⁴ U.S. Departments of Treasury, Labor, and Health and Human Services, “Coverage of Certain Preventive Services Under the Affordable Care Act,” Notice of Proposed Rulemaking, February 2, 2023, at 88 FR 7265.

affected individuals. The Departments also give no indication of recognizing that states could authorize the issuance of limited-benefit insurance products to fill gaps in the coverage of preventive services under grandfathered major medical plans.

In sum, the Departments are acting in an arbitrary and capricious manner when they summarily dismiss the alternative of enrollees directly purchasing separate contraceptive coverage.

Conclusion

This proposed rule would modify the Departments' existing construct for providing alternative contraceptive coverage to enrollees in health plans claiming religious or moral exemptions from the requirement to cover contraceptive items and services.

However, in several of its particulars, that construct is either erroneous or flawed.

First, there is no statutory justification for the Departments current regulatory requirement, which this proposed rule would maintain, that health insurance issuers or third-party administrators providing such alternative coverage not charge enrollees premiums or fees for the alternative coverage.

Furthermore, and consistent with the provisions of the applicable statute (section 2713 of the PHSA), the Departments have never proposed applying that "no premium or fee on enrollees" condition to: 1) the provision of required contraceptive coverage by health plans *not claiming* a regulatory exemption; 2) the provision of *any other coverages* required by that same statute, or; 3) any supplemental coverage that may be offered to enrollees in "grandfathered" plans that are statutorily exempted (by section 1251 of the PPACA) from compliance with all provisions of section 2713 of the PHSA.

Because the Departments' requirement that alternative contraceptive coverage be provided to enrollees in exempt plans with no premium or fee charged to the enrollee is not supported by the statute, and because the Departments apply that requirement only with respect to enrollees in plans claiming a religious or moral exemption to the contraceptive coverage mandate, but not with respect to enrollees in other, equivalent circumstances, the Departments are engaging in arbitrary and capricious rulemaking.

Second, the Department's diversion of a portion of the revenues collected from user fees imposed on plans offered in federally facilitated exchanges to fund subsidies for the provision of alternative contraceptive coverage for enrollees in other plans contravenes both the user fee statute at 31 USC § 9701 and the parameters established in OMB Circular No. A-25. The statute and Circular No. A-25 *do not* permit an agency to impose and collect user fees on the recipients of one set of "special benefits" for the purpose of *subsidizing* the provision of a *different* "special benefit" to a *different* set of recipients.

Third, in their rulemaking the Departments have taken sharply different positions with respect to the two categories of health plans claiming exemptions. On the one hand, the Departments are very insistent on the supposed need to provide alternative contraceptive coverage to enrollees in

plans claiming a *regulatory* exemption. Yet on the other hand, the Departments are casually dismissive of any presumed need to provide alternative coverage (for contraception or other preventive services) to enrollees in plans claiming a *statutory* exemption.

The Departments' disparate treatment of the two categories of health plans claiming exemptions is arbitrary and capricious.

Fourth, the Departments state that they considered, but rejected, the option that enrollees in plans claiming an exemption could obtain separate, supplemental coverage, on their own initiative and at their own expense. Because none of the justifications offered by the Departments for that decision are statutorily supported, that decision by the Departments was arbitrary and capricious.

For all the foregoing reasons, the Departments should withdraw this proposed rule and should initiate new rulemaking to repeal or revise their current regulations to conform them to the applicable statutes, as set forth in this analysis.