

Secretary Xavier Becerra, Department of Health and Human Services
Acting Secretary Julie Su, Department of Labor
Secretary Janet L. Yellen, Department of the Treasury
Washington, DC

Re: Coverage of Certain Preventive Services Under the Affordable Care Act; RIN 1545-BQ35, RIN 1210-AC13, & RIN 0938-AU94

Submitted electronically at regulations.gov

April 3, 2023

Dear Secretaries Becerra and Walsh and Acting Secretary Su,

The forty-five undersigned organizations write to you in response to the Department of Health and Human Services, Department of Labor, and Department of the Treasury (“the Departments”) proposed rulemaking, *Coverage of Certain Preventive Services Under the Affordable Care Act* (RIN 1545-BQ35, RIN 1210-AC13, and RIN 0938-AU94.) We appreciate that the Departments are now considering the impact of these regulations on people who need contraception. We support the rescission of the exemption based on moral objections to contraception, and believe the Departments should have also reconsidered the existing religious exemption in light of its impact on people who need contraception. We devote much of this comment to the Departments’ proposed Individual Contraceptive Arrangement (ICA). We concur that such an arrangement is necessary when someone’s coverage excludes contraception, and raise a number of concerns and potential solutions for its planning and implementation. We also address the need for oversight and enforcement of the Affordable Care Act (ACA) contraceptive coverage requirement, including accommodation- and ICA-specific oversight and enforcement issues. We encourage the Departments to incorporate these recommendations into the final rule and to finalize the rule as soon as possible to expand contraceptive access and mitigate the harms experienced by those who currently lack coverage.

We appreciate that the Departments are now considering the impact of these regulations on people who need contraception, as directed by the Supreme Court in *Zubik v. Burwell*.

The Departments correctly state in the preamble to the proposed rule that the impact of exemptions on people who need contraception was at the core of the Supreme Court’s decision in *Burwell v. Hobby Lobby*, its direction to the parties and lower courts in *Zubik*, and the issues remanded in *Little Sisters of the Poor v. Pennsylvania*. We agree with the Departments’ conclusion that the existing regulations do not adequately attend to individuals’ contraceptive needs and thus warrant reexamination.

The Departments should revise the ACA contraceptive coverage regulations, independent of the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*.

The *Dobbs* decision has rendered abortion inaccessible for millions of people across the U.S. Moreover, the *Dobbs* decision has impacted contraceptive access, including emboldening providers to refuse care, sowing confusion about the legality and availability of contraception, and increasing demand for contraception.^{1,2,3} As

¹ Zernike K. Medical Impact of Roe Reversal Goes Beyond Abortion Clinics, Doctors Say - The New York Times. The New York Times. <https://www.nytimes.com/2022/09/10/us/abortion-bans-medical-care-women.html>. Published September 10, 2022. Accessed October 9, 2022.

² Shorman J. Kansas City area health system stops providing Plan B in Missouri because of abortion ban. The Kansas City Star. <https://www.kansascity.com/news/politics-government/article262988028.html>. Published July 1, 2022. Accessed October 9, 2022.

³ Langmaid V. Contraception demand up after Roe reversal, doctors say. CNN. Published July 6, 2022. Accessed October 9, 2022. <https://www.cnn.com/2022/07/06/health/contraceptives-demand-after-roe/index.html>

the Departments state, *Dobbs* has “placed a heightened importance on access to contraceptive services.” However, improved access to contraception does not, and cannot, replace access to abortion. And barriers to contraceptive access -- including challenges that result from the existing regulation -- predate *Dobbs*. The Departments’ assessment that the 2018 Final Rule “did not give sufficient consideration to women’s significant interests in access to contraceptive services” stands on its own as justification for revisiting it.

We support the rescission of the moral exemption and oppose any alternative to rescission.

The Departments propose to rescind the moral exemption, which was not legally required in the first place. First, RFRA does not require any exemption for non-religious moral objections and there is no other statute that requires such an exemption. Second, very few entities are likely to seek a moral exemption. We agree with this reasoning and support the rescission. We oppose all of the alternatives to rescinding the moral exemption that the Departments suggest, as all are more burdensome than the seamless access provided by insurance coverage as required by the ACA.

We oppose the sweeping religious exemption currently in place.

We continue to oppose the sweeping religious exemption in the 2018 Final Rule, which unjustifiably expanded the exemption to apply to *all* nonprofit and for-profit employers and private colleges and universities. At the same time, the 2018 Final Rule “did not give sufficient consideration” to people’s “significant interests in access to contraceptive services.”⁴ The Departments should reconsider the religious exemption, and at minimum, limit its sweeping scope. To do so, the Departments should strike the exemption for not-closely-held for-profits and reissue a definition of closely-held for-profit that was eliminated in the 2018 Final Rule.

The Departments’ technical updates to the accommodation are much needed, and the Departments should consider making the accommodation required once again.

The Departments’ proposed technical updates to the accommodation are welcome adjustments that align the regulatory text with the Departments’ clear intent in prior rulemakings and provide critical consumer protections. We support the updates that clarify the application of the rule to student health insurance (proposed cross-reference to 45 CFR 147.132(a)(1)(iii) and proposed rule of construction at 45 CFR 147.131).⁵ Additionally, we support: the removal of the transitional rule provision which no longer has relevance; the retention of the generally applicable rule of revocation; the amendments to refer to all Food and Drug Administration (FDA)-approved, -cleared, or -granted contraceptives; and the addition of the reference to section 414(e) of the Internal Revenue Code when referring to Church Plans.

We also support the Departments’ proposal to continue to apply certain legal protections to the accommodation, particularly those that are vitally important in the context of contraceptive care. We support the Departments’ updated cross-reference to section 9822 of the Internal Revenue Code, section 722 of the Employee Retirement Income Security Act (ERISA), and section 2799A-7 of the Public Health Service Act, which ensures that people in the accommodation are able to access obstetric or gynecologic care without referral. Further, we support the Departments’ proposal to continue to require issuers to make payments as part of the accommodation consistent with the protections for emergency services, given the variety of circumstances in which contraception constitutes an emergency service, including sexual assault, or diagnosis of a condition where pregnancy presents an unacceptable health risk.

⁴ NPRM at 7241. In fact, the Constitution requires that the government weigh the effect that granting an exemption would have on other significant interests and may not grant exemptions that detrimentally affect others. *Cutter v. Wilkinson*, 544 U.S. 709, 720, 722, 726 (2005).

⁵ For brevity, references to the proposed regulation only include Part 45 of the Code of Federal Regulations.

These protections are critically important to people in need of contraception, and it is vital that the Departments include all of them in the final rule. Beyond this, even more people would benefit from these protections if the accommodation were no longer optional. We are cognizant that the Departments would not have created the ICA if they believed there was a path forward with a required accommodation, but encourage the Departments to reconsider this possibility.

The Departments must make the ICA work well in practice.

We appreciate the goals underlying the ICA, to create an alternative pathway to obtaining contraceptive services at no cost for those enrolled in a health plan excluding that coverage. The ICA is only necessary because of the various exceptions that the Departments and courts have permitted, and those who will potentially use the ICA would otherwise be entitled to access all contraceptive services through their health plan. Indeed, it is unfortunate that there are so many opportunities to deny people critical preventive health care.

We support the Department's proposal to create the ICA and many of the specific details included in the proposed rule. However, for the ICA to be an effective substitute for seamless contraceptive coverage, the Departments will need to take additional steps to ensure that the ICA helps as many people as possible; that it is as streamlined as possible for consumers, providers, and issuers; that it is broadly publicized; that it includes a robust range of providers; and that it is implemented effectively.

- **Eligibility for consumers should be as broad as possible.**

As detailed in the proposed rule, the ICA is meant to be a solution for people whose health coverage excludes no-cost contraceptive services and supplies. To fulfill that role, the ICA must broadly define eligibility for consumers and providers. Extending broad eligibility for the ICA would be in line with the purpose of the ACA and would also help to ensure that there are enough people using the ICA to make participation a worthwhile investment of time and resources for issuers and providers.

First, the Departments should make clear that the ICA includes anyone who does not have coverage of contraceptives without cost-sharing because of an objection by an employer, school, issuer, or individual, including those whose lack of coverage is the result of an injunction, a settlement agreement, or because they are enrolled in a Church Plan.

Second, the Departments note that the ICA as proposed would exclude enrollees in plans that are using the optional accommodation. We agree with the Departments' assessment that few such individuals would purposefully use the ICA, because the optional accommodation should be seamless. However, we also agree that there may be confusion among both consumers and providers between the optional accommodation and the ICA. Moreover, there is little public information about whether the optional accommodation has been operating as intended. For these reasons, we recommend either making these individuals eligible for the ICA or otherwise guaranteeing that individuals, providers, and issuers are held harmless if a consumer uses the ICA rather than the accommodation.

Third, the Departments comment in the proposed rule that they have not made enrollees in grandfathered plans eligible for the ICA, 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." However, as the Departments acknowledge in a footnote, millions of enrollees remain in grandfathered plans — an estimated 23.7 million in 2020. This represents a broken promise and a failure of the ACA. The Departments should take steps (beyond this proposed rule) to address this failure. In the meantime, the Departments should make enrollees in grandfathered plans eligible for the ICA, as one way of mitigating this ongoing harm.

Ultimately, we recommend that the Departments go even further: the final rule should allow *anyone* who does not have no-cost contraceptive coverage to be eligible for the ICA. That would include, among others, the millions of people who are uninsured, those covered through Medicare, and those with short-term health insurance exempt from ACA contraceptive coverage requirements.

- **The range of providers should be as broad as possible.**

The Departments propose to define the term “provider of contraceptive services” as “any health care provider (including a clinician, pharmacy, or other facility) acting within the scope of that provider’s license, certification, or authority under applicable law to provide contraceptive services.” We appreciate the Departments’ creation of a broad definition that captures a range of provider types, including pharmacies. We also appreciate the Departments’ clarification that this definition is intended to encompass any provider or facility authorized to provide any contraceptive services, including when provided via telehealth or mail. This distinction is especially important given the increased availability and utilization of telehealth, and given the impact of the *Dobbs* decision and other efforts to limit access to reproductive health care.

Broadly defining who can participate as a provider under an ICA is helpful but not sufficient. Indeed, in order for the ICA to be meaningful for patients and in order for the Departments to achieve their aims, patients must be able to access provider services in a timely, affordable, and accessible way. The Departments should build a robust set of providers to participate in the proposed ICA, looking beyond those who typically provide contraception, like Title X clinics and obstetrics and gynecology practices. This might include, but is not limited to, hospitals, Federally Qualified Health Centers, state and local health departments, and primary care practices, including those operated by nurse practitioners and other qualified providers. It should also encompass nationwide pharmacy chains, mail-order pharmacies, and online services that prescribe contraception.

- **The ICA must be as easy as possible for everyone involved.**

The Departments have emphasized numerous times — including in this proposed rule, previous rulemakings on this topic, and in various legal challenges — that contraceptive coverage should be as seamless as possible to fulfill the goals of the ACA’s preventive services provision. Making the ICA as seamless as possible is legally required under the ACA and other federal laws prohibiting discrimination in benefits.⁶ Section 1554 of the ACA prohibits any regulation that creates unreasonable barriers to care or impedes timely access to services.⁷ Additionally, Section 1557 prohibits sex discrimination in certain health programs and activities, which would include discrimination based on contraceptive use.⁸ Among other steps, the Departments should ensure that consumers never have cost sharing for contraception; that consumers, providers, and issuers are held harmless for unintentional errors; that consumers can easily make use of the ICA; and that providers and issuers can easily enter into agreements.

⁶ See Title VII (Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (codified as amended in scattered sections of 2 U.S.C., 28 U.S.C., & 42 U.S.C.), and Title IX (20 U.S.C. 1681 (1972)).

⁷ 42 U.S.C. § 18114.

⁸ *Id.* § 18116.

- ***Care under the ICA should always be at no cost to the consumer.***

By eliminating cost sharing, the ACA has proven to be effective in improving access to contraception, among other preventive services, partially rectifying disparities that preceded its implementation.^{9,10,11} Those using the ICA, whose employers and universities have effectively stood in the way of them accessing needed contraception, deserve those same benefits. The success of the ICA is contingent on ensuring that consumers can get contraception at no cost directly at the point of service. Furthermore, in publicization and dissemination of ICA information it should be very clear that providers must agree to provide contraceptive care at no cost to ICA participants at point of service as the basic threshold for participation, and any provider agreements with issuers should reiterate this requirement.

- ***The Departments should hold ICA participants harmless.***

The ICA is a compelling, but untested, access policy that will require flexibility and some experimentation. In order to be willing to participate, no ICA participants should fear repercussions for good faith participation.

The proposed regulations at 45 CFR 156.50(d)(9) to (11) and elsewhere state that if a provider or issuer relies on good faith representation of eligibility, for either the ICA or the accommodation, then they can still meet the documentation requirements if the eligibility is later determined to be incorrect. We strongly support these provisions, and recommend the Administration continue to make clear that it will not pursue any retaliatory action against providers or issuers for any aspect of the ICA if they are participating in good faith. In addition, we recommend communicating to contraceptive users that they will not be penalized at any point in the ICA process if they have misunderstood a requirement during a good faith attempt to access care to which they believed they were entitled.

Under the “hold harmless” framework, providers should be reimbursed for the contraceptive care they provide, even if it is later found that the individual was not actually eligible to use the ICA. This is analogous to presumptive eligibility (PE) in Medicaid, where qualified entities who make a determination that a patient is eligible for PE will be reimbursed for services provided during the PE period, even if the individual is later found not eligible for full-scope Medicaid.

- ***The Departments should require that patient attestation alone is sufficient to receive services.***

The proposed rule describes that an individual can confirm that they are eligible for the ICA by providing an attestation or documentation of their lack of contraceptive coverage, like a summary of benefits and coverage, and that providers would have discretion in choosing what confirmation method to accept. We urge the Departments to require providers to accept an attestation alone. Even if the Departments require information about coverage coverage or exclusions in plan documents, some consumers may not know until they are visiting a provider that they lack coverage, and may be unable to access documentation when they need it.

⁹ See, e.g., Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 Health Servs. Research 1331, 1347-48 (2000); Dahlia K. Remler & Jessica Greene, *Cost-Sharing: A Blunt Instrument*, 30 Annual Rev. Pub. Health 293, 296 (2009)

¹⁰ Partnership for Prevention, *Preventive Care: A National Profile on Use, Disparities, and Health Benefits* 8 (2007), <http://www.rwjf.org/content/dam/farm/reports/reports/2007/rwjf13325>; see also Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 New Eng. J. Med. 2635, 2641 (2003)

¹¹ See IMS Inst. for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* (2014).

In the Medicaid context, PE uses a simplified method of determining income as compared to traditional eligibility calculations.¹² As a best practice, only the minimum amount of information necessary for input into the Medicaid Management Information System is required for the PE application, such as name, address, birthdate, and an attestation regarding income and immigration status. The ICA should similarly use the simplest method possible for determining eligibility: patient attestation. Another option could be for issuers to include the phrase “No BC” in relevant plan names, which could then appear on an individual’s insurance card; this would make it seamless to present a regular insurance card to a provider, who could easily verify likely eligibility for the ICA.

The commenters appreciate that the Department provide example attestation language at 45 CFR 147.131(d)(2). However, the commenters are concerned that this example language would be difficult for most patients to understand and encourage the Departments to revise the language to meet health literacy standards, as well as enforce Section 1557’s language access requirements where appropriate.

- *The Departments should streamline processes for providers and issuers.*

Without more detail about how the ICA process should be operationalized, we have concerns about the administrative burdens it would impose on providers, particularly on safety-net providers with limited experience or relationships with private payers.

The proposed rule makes no mention of how ICAs would interact with existing insurance contracts, the process for credentialing providers, or entering into new contracts with issuers. We suggest that an existing contract with an issuer of a Marketplace plan could function as an ICA for the purposes of this rule with minimal additional paperwork on the part of the provider and the issuer. Should that issuer participate in a Marketplace other than the federally facilitated exchange (FFE), its user fee reductions could be exchanged with another issuer, as is currently permitted in the accommodation process. Those providers without existing contracts with appropriate issuers, who are only seeking to engage in an ICA, should be able to bypass the issuers existing contracting and credentialing process, which can be arduous and take months to complete. Safety net providers, like Title X family planning providers, often have fewer insurance contracts and less staff time available to manage the administrative work of contracting, billing, and chasing denied claims than their private practice counterparts. Because Title X-funded health centers primarily provide care to individuals with low incomes, it is imperative that their particular needs be considered in the development of the ICA process.

While the proposed rule states providers who have entered into an ICA may seek reimbursement from a participating issuer, little information is provided on how providers will know which plan to enter into an agreement with and what plan to bill. Providers may not have the bandwidth to go through the administrative complexities of entering into an ICA. We urge the Departments to make this process as simple as possible by allowing providers to enter into agreements with any issuer participating in the federal marketplace. The Departments should issue guidance clarifying that the parameters of the arrangements should remain as broad as possible.

As defined in the proposed rule, both providers and pharmacies would need to enter into ICAs for eligible individuals to have access to the contraceptive method of their choice at no cost. Once a patient is able to identify a provider participating in an ICA and get an appointment, depending on the type of contraception the patient chooses, they often would need to identify a pharmacy that also has an ICA in order to fill the

¹² 42 C.F.R. §§ 435.1102(a) (children), 435.1103(a) (pregnant women), 435.1110(a) (hospitals); see also CMS, Medicaid and CHIP FAQs: Implementing Hospital Presumptive Eligibility Programs (Jan. 2014) (Q & A 12), <https://www.medicaid.gov/state-resource-center/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/faqs-by-topic-hospital-pe-01-23-14.pdf> (“[F]ull MAGI-based eligibility determinations cannot be used to determine [presumptive eligibility].”).

prescription. We encourage the Departments to identify ways to reduce barriers, like issuing a public list of participating pharmacies.

- **The ICA must be proactively and broadly publicized.**

The Departments have an obligation to take a leadership role in the ICA rollout, including broadly publicizing and disseminating information about the ICA to potential users both through its own platforms as well as in collaboration with community-based organizations, and actively recruiting a large network of providers, including chain pharmacies. The current proposed rule only discusses participating providers as a source of information to consumers about the existence of the ICA. That is clearly insufficient, and we outline potential additional actions are needed.

First, the Departments should create and disseminate public education materials informing consumers of the existence of the ICA as a means to obtain no-cost contraception when their insurance does not cover it. These materials should be available in multiple languages and at an elementary reading level, and provide consumers with resources such as a hotline or FAQs to help address questions they may have.

Second, the Departments should provide pharmacy education materials, to be distributed to all major retail and online pharmacies as well as networks of independent pharmacies, including information about the ICA and where pharmacies can direct consumers for more information about the ICA. These could include posters to be displayed in pharmacy break rooms and other mechanisms for sharing new information with the pharmacy community, including presenting at conferences.

Third, the Departments should provide educational materials about the ICA for the full range of providers who offer contraceptive care, helping them to understand what the ICA is, why and how to participate, and, how to educate their patients about the availability of the ICA and what information they need to participate. (See page 8 for additional thoughts about a potential tool kit for providers.)

- **The Departments must actively recruit and incentivize payers and providers.**

In developing this network, the Departments should aim to include providers who can accept new patients, are geographically widespread, and who offer quality contraceptive care, including person-centered counseling and the full range of contraception, including postpartum. Specifically, there must be obstetrician-gynecologists and other delivery providers, including from anesthesiology departments, available to offer contraceptives like LARCs and tubal ligation immediately postpartum to individuals in an ICA. The Departments should consider whether these providers may need additional incentives or flexibilities when entering into an ICA.

Ideally, all eligible providers would participate in the ICA, so that patients do not need to search for specific ICA providers. This will require adequately incentivizing participation. A scenario where only some contraceptive providers participate in the ICA would create logistically impossible situations. For example, if a patient desires a postpartum tubal ligation, but their obstetrician-gynecologist does not participate in the ICA, it is unclear how the patient could arrange for a separate ICA-participating provider to perform their tubal ligation immediately after delivering.

It is critical that providers receive adequate reimbursement to incentivize participation in the ICA. The Department seeks comment on whether a provider's reimbursement should be equal to their actual costs of furnishing contraceptive services or whether HHS should instead establish a standard methodology to calculate costs. We recommend to the Departments that contraception payment should be reimbursed in accordance with established rates in the Medicare Physician Fee Schedule. Sufficient reimbursement at established Medicare rates would encourage widespread provider participation and provide critical funds that enable safety-net providers to participate. Where relevant gaps exist in the fee schedule, the Departments

should establish reimbursement at rates that at minimum cover the cost of the contraceptive, associated care, and practice expenses.

Reimbursement for providers also must be timely. The proposed rule requires that the provider is paid within 60 days of the issuer receiving the adjustment to their user fee. However, the user fee adjustment takes place in the benefit year following the year that the contraceptive services are provided. That means that an issuer must reimburse the provider within fourteen months of the provision of services, which may pose financial burdens on the provider—especially for safety-net providers and those that are the only provider in a geographic area that participates in the ICA. The Departments note that an issuer could pay upfront for the cost of services provided during that benefit year rather than in the following benefit year. We encourage the Departments to require this upfront payment model, which could be based on the average cost of services from the previous year, to lessen financial burdens on providers.

- **The Departments must support providers implementation of the ICA.**

The Departments should provide a roadmap or toolkit for providers who are interested in entering into ICAs. We encourage the Departments to seek input from providers, and especially safety net providers, on the development of such resources.

Potential toolkit topics could include the benefits of entering into an ICA and outline the requirements for doing so. It should also provide step by step instructions for entering into an ICA, beginning with best practices for contacting issuers. A model agreement for providers and issuers could also be a helpful resource. The agreement should outline the required components to ease the burden on providers.

In order to increase public awareness of the ICA, the Departments should provide a template notice that providers of contraceptive services, including pharmacies, can print and display in their reception and lobby areas as well as share on their websites. The language on the template notice should be clear, concise, and easy to understand. For example, “If your health plan does not cover birth control, we can provide it to you here at no cost. Talk to your clinician or the front desk staff.” The Departments should clarify that such notices, as they pertain to the receipt of benefits or services from a covered entity’s health program or activity, must comply with Section 1557 and its implementing regulations. In addition, the Departments should consider other consumer education resources – like mailers or social media content – that providers can make available to their patients and include these in the toolkit.

Lastly, we appreciate the invitation to provide comments on whether or not to publish the names of providers participating in the ICA. The concern for provider safety is valid, as is the concern that publishing a directory could disincentivize providers from participating. However, seeking contraceptive care under the ICA would be untenable if patients are unable to locate a participating provider. Moreover, there must be a system by which providers who do not elect to participate in ICAs can help their patients find a provider that does. The Departments should make available and regularly update an online resource that contains the contact information for providers that participate in ICAs. This resource should be accessible to the public in order to best facilitate connections to needed care. To address concerns around provider safety, the Departments could consider including an “opt out” option for providers.

The Departments must issue guidance and take immediate enforcement action to bring the insurance industry into compliance with the ACA contraceptive coverage requirement.

We are pleased that the Departments make note of the accounts of health plan noncompliance with the ACA in the preamble to the proposed rule, and are considering “what changes to existing regulations or guidance may be needed.” Additional guidance and enforcement are essential to bring plans into compliance and to ensure that patients have access to the contraception they are entitled to. A number of recent reports document

clear, systemic, on-going violations of the ACA contraceptive coverage requirement.^{13,14,15} At least 34 products, many of them newly introduced, face exclusions or cost-sharing.¹⁶ Most of the insurers and pharmacy benefit managers (PBMs) reported denying an average of at least 40% of exception requests for contraceptive products. These practices prevent patients from accessing the contraception that is best for them, in violation of the ACA's contraception coverage requirement.¹⁷ The Departments should issue additional guidance and take enforcement action.

Rather than continuing attempts to make a cost-sharing exceptions process function for all contraceptive products, the Departments should adjust the mechanism by which they ensure that every person gets the specific contraceptive they need without barriers or delays. Specifically, the Departments should require coverage in plan formularies of each therapeutically unique contraceptive. The FDA maintains a comprehensive, authoritative list of products and therapeutic equivalents: the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." Tying the updated contraceptive coverage requirement to the Orange Book would be relatively simple to implement because this list is already in common use by health plans, PBMs, and state and federal agencies.¹⁸ This strikes a balance of ensuring that patients have access to contraceptives without cost-sharing and still allowing issuers to manage costs. While this will address many denials without accessing the required cost-sharing exceptions process, this process will still be needed for patients where one formulation is medically necessary over the covered formulation (e.g., an adverse reaction to an inactive ingredient).

The Departments should also take this opportunity to clarify that over-the-counter (OTC) contraceptives are required to be covered by the ACA, such as levonorgestrel emergency contraception and external condoms. Given that Health Services and Resources Administration (HRSA) has deliberately removed the "as prescribed" requirement from its earlier guidance, the Departments should correspondingly amend its guidance to clearly prohibit plans from requiring a prescription for coverage of OTC contraceptives.

The Departments must vigilantly oversee and enforce every aspect of the contraceptive coverage requirement, including health plan compliance, the accommodation, and the ICA.

The Departments' intention with this proposed rulemaking is to ensure that everyone enrolled in a health plan that would have to comply with the ACA but for regulatory exemptions has access to contraception without out-of-pocket costs. The current landscape is complicated for consumers, providers, and health insurance plans to navigate, and the ICA will be additionally complicated. It is the Departments' duty to ensure that,

¹³ Nat'l Women's Law Ctr., *The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement Is Working for All* (Oct. 2021) *available at* <https://nwlc.org/resource/the-affordable-care-acts-birth-control-benefit-progress-on-implementation-and-continuing-challenges/>.

¹⁴ Power to Decide, *When Your Birth Control Isn't Covered: Health Plan Non-Compliance with the Federal Contraceptive Coverage Requirement* (May 2022) *available at* <https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf>.

¹⁵ Staff of H. Comm. On Oversight and Reform, 117th Cong., *Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance* (Oct. 2022) *available at* <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>.

¹⁶ *Id.*

¹⁷ Ctrs. for Medicare & Medicaid Servs., *FAQs About Affordable Care Act Implementation (Set 51)* (Jan. 10, 2022), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>; Ctrs. for Medicare & Medicaid Servs., *FAQs About Affordable Care Act Implementation Part 54* (Jul. 28, 2022), <https://www.cms.gov/files/document/faqs-part-54.pdf>.

¹⁸ The term "therapeutic equivalent" is defined by the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the Orange Book)", see: <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>

despite these challenges, people get the care they need. Only regular, detailed oversight and enforcement of the contraceptive coverage requirement will achieve this goal.

The Departments must ensure that the contraceptive coverage requirement is functioning as intended for people who are in coverage that is not exempted and for people in the accommodation. For people in coverage that is not exempted, there is simply no excuse when they incur cost-sharing simply because their health plan does not comply with the law. Moreover, because plan non-compliance with the ACA is rampant across all segments of the private insurance market, there is reason to believe issuers apply the same non-compliant limitations to people in the accommodation. Through oversight and enforcement, the Departments can similarly make certain that people in the accommodation are never denied the contraception to which they are entitled and never have to make use of the ICA.

To improve access to contraception and ensure the viability of both the accommodation and the ICA, the Departments should take on a match-making role between issuers and entities that want to make use of the accommodation and between issuers and providers in the ICA. When an entity opts in to the accommodation, the Departments should ensure that they are able to connect with a participating issuer that participates, and should adopt a similar process for the ICA. These relationships are essential to ensure the functioning of both the accommodation and the ICA.

As part of their oversight and enforcement efforts, the Departments should collect non-identifiable data about use of the ICA, accommodation, and exemption, and utilize that information to improve implementation. We particularly encourage the Departments to plan how they will track the number and composition of providers participating in the ICA, and how to assess whether these are adequate to meet community needs. To ensure geographic diversity and availability of providers in contraceptive care deserts, the Departments could examine provider data by zip code and population within a 25-mile radius, to focus recruitment efforts in areas with the lowest access. The Departments should pay particular attention to trends in differences in contraceptives accessed across participating issuers and providers as well as geographic gaps in access to any or all contraceptives. We encourage the Departments to also compare data from the ICA against claims data from employer-sponsored health plans to determine differences in contraceptives used, types of providers participating, or other areas for improvement.¹⁹ The Departments should collect this data at least annually and make it publicly available on their websites.

The undersigned organizations appreciate that the Departments have revisited these regulations and proposed a new route to access contraception without cost for people impacted by the exemptions. We strongly urge the Departments to incorporate all of our recommendations into the final rule.

Sincerely,

AIDS United
American Academy of Pediatrics
American Atheists
American College of Obstetricians and Gynecologists
American Humanist Association
American Medical Student Association
American Public Health Association

¹⁹ Claims data on reproductive health care from employer-sponsored plans is currently publicly available in this report from the Health Care Costs Institute, but is delayed by several years: <https://healthcostinstitute.org/hcci-research/hcci-sexual-and-reproductive-health-report>. We encourage the Departments to find alternative sources of claims data to have a real-time view of ICA implementation.

Americans United for Separation of Church and State
Association of Maternal & Child Health Programs
Association of Women's Health, Obstetric and Neonatal Nurses
Big Cities Health Coalition
Catholics for Choice
Center for Biological Diversity
Center for Reproductive Rights
Coalition to Expand Contraceptive Access
Community Catalyst
Contraceptive Access Initiative (CAI)
Guttmacher Institute
Healthy Teen Network
Ibis Reproductive Health
Ipas Partners for Reproductive Justice
Jacobs Institute of Women's Health
NARAL Pro-Choice America
National Association of Nurse Practitioners in Women's Health (NPWH)
National Birth Equity Collaborative
National Center for Lesbian Rights
National Coalition of STD Directors
National Council of Jewish Women
National Family Planning & Reproductive Health Association
National Health Law Program
National Latina Institute for Reproductive Justice
National Medical Association
National Network to End Domestic Violence
National Partnership for Women & Families
National Women's Health Network
National Women's Law Center
Physicians for Reproductive Health
Planned Parenthood Federation of America
Power to Decide
Reproductive Health Access Project
SIECUS: Sex Ed for Social Change
Society for Adolescent Health and Medicine
The Leadership Conference on Civil and Human Rights
UCSF Bixby Center for Global Reproductive Health
Union for Reform Judaism