

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 64

January 22, 2024

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act (ACA). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs> and <http://www.cms.gov/cciiio/resources/fact-sheets-and-faqs/index.html>), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

Coverage of Preventive Services

Public Health Service (PHS) Act section 2713 and its implementing regulations relating to coverage of preventive services¹ require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without the imposition of any cost-sharing requirements, the following items or services:

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;^{2,3}
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;⁴

¹ See 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; and 45 CFR 147.130.

² The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of title II of Division H of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2025.

³ On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in the case *Braidwood Management Inc. v. Becerra*, Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023) holding that the USPSTF’s members served in violation of the Appointments Clause of Article II of the United States Constitution, and enjoined and vacated federal action taken to enforce the requirements of section 2713(a) of the PHS Act. The federal defendants appealed, and the U.S. Court of Appeals for the Fifth Circuit issued a partial stay pending appeal.

⁴ In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and its implementing regulations, plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, such additional preventive care and screenings not described in PHS Act section 2713(a)(1) as provided for in comprehensive guidelines supported by HRSA.⁵

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer⁶ may use reasonable medical management techniques to determine any such coverage limitations. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service.⁷ Additionally, plans and issuers subject to PHS Act section 2713 must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately.⁸

Coverage of Contraceptives and Contraceptive Care Pursuant to HRSA-supported Guidelines

The HRSA-supported Women’s Preventive Services Guidelines (HRSA-supported Guidelines), as updated on December 30, 2021, recommend that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes.⁹ The HRSA-supported Guidelines also provide that contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (e.g., management, evaluation, and changes, including the removal, continuation, and discontinuation of contraceptives). The HRSA-supported Guidelines further recommend that the full range of U.S. Food and Drug Administration (FDA)-approved, -cleared, or -granted contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care. The full range of contraceptives includes those listed in the FDA’s Birth Control Guide as posted on December 22, 2021: (1) sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all

current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use). 85 FR 71142 (Nov. 6, 2020). *See also* FAQs Part 58 (March 29, 2023), Q4, available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-58.pdf> and <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf>.

⁵ For accommodations and religious and moral exemptions with respect to coverage of certain recommended contraceptive services, *see* 26 CFR 54.9815-2713A; 29 CFR 2590.715-2713A; 45 CFR 147.131 through 147.133.

⁶ References to plans and issuers throughout these FAQs refer to plans and issuers that are subject to PHS Act section 2713 and not exempt from the requirement to cover contraceptive services and products without cost sharing.

⁷ *See* 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4).

⁸ *See* 85 FR 71142, 71174 (Nov. 6, 2020) (discussing examples provided in Coverage of Certain Preventive Services Under the Affordable Care Act (“2015 Final Regulations”), 80 FR 41318 (July 14, 2015)); *see also* 2015 Final Regulations, 80 FR 41318, 41319 (July 14, 2015) (discussing previous guidance).

⁹ Women’s Preventive Services Guidelines, available at <https://www.hrsa.gov/womens-guidelines#:~:text=Contraception>.

durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), (7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and any additional contraceptives approved, cleared, or granted by the FDA.¹⁰

The Departments are committed to ensuring consumers have access to all contraceptive benefits to which they are entitled under federal law. The President has issued several executive orders directing the Secretaries of the Treasury, Labor, and HHS (the Secretaries) to take steps to strengthen the implementation of the ACA and improve the accessibility, affordability, and comprehensiveness of health care and health coverage.¹¹ Most recently, on June 23, 2023, the President issued Executive Order 14101, “Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services” (E.O. 14101).¹² Section 2 of E.O. 14101 directs the Secretaries to consider issuing guidance to further improve Americans’ ability to access contraception, without out-of-pocket expenses, under the ACA and to consider additional actions to promote increased access to over-the-counter contraception, including emergency contraception.

The Departments have interpreted PHS Act section 2713 and its implementing regulations, in conjunction with the HRSA-supported Guidelines, to require plans and issuers to cover without cost sharing any contraceptive services and FDA-approved, -cleared, or -granted contraceptive products that an individual’s attending provider determined to be medically appropriate for the individual.¹³ On January 10, 2022, the Departments issued FAQs that summarized previously issued FAQs that stated the Departments’ interpretation of the requirement to cover contraceptives and contraceptive care.¹⁴ Most recently, on July 28, 2022, the Departments issued

¹⁰ See *id.* The entire HRSA-supported Guidelines regarding contraception is available at

<https://www.hrsa.gov/womens-guidelines#:~:text=Contraception>.

¹¹ See Executive Order (E.O.) 14009, “Strengthening Medicaid and the Affordable Care Act,” available at 86 FR 7793 (January 28, 2021) and E.O. 14070, “Continuing To Strengthen Americans’ Access to Affordable, Quality Health Coverage,” available at 87 FR 20689 (April 5, 2022). Additionally, E.O. 14076, “Protecting Access to Reproductive Healthcare Services,” available at 87 FR 42053 (July 13, 2022), requires the Secretary of HHS to identify potential actions to protect and expand access to the full range of reproductive health care services, including actions to enhance family planning services such as access to emergency contraception.

¹² 88 FR 41815.

¹³ See FAQs About Affordable Care Act Implementation Part 54 (July 28, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-54.pdf> and <https://www.cms.gov/files/document/faqs-part-54.pdf> (FAQs Part 54).

¹⁴ See FAQs Part 51, which summarizes FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12 (FAQs Part XII); FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf (FAQs Part XXVI); and FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women’s Health and Cancer Rights Act Implementation (Apr. 20, 2016), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-31.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf (FAQs Part

FAQs (FAQs Part 54)¹⁵ that reiterated prior guidance explaining that the Departments interpret 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130 to require that plans and issuers, among other requirements, (1) cover without cost sharing at least one form of contraception in each of the categories listed in the HRSA-supported Guidelines; and (2) cover without cost sharing any contraceptive services and FDA-approved, -cleared, or -granted products that an individual and their attending provider have determined to be medically appropriate for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-supported Guidelines. The latter requirement extends to newer contraceptive products as they are approved, cleared, or granted by the FDA, whether or not such products are identified in the categories listed in the current HRSA-supported Guidelines.¹⁶ With respect to those newer contraceptive products and services not included in the categories listed in the HRSA-supported Guidelines, plans and issuers may use reasonable medical management techniques to determine which specific products or services to cover without cost sharing only if at least one of multiple, substantially similar products or services are available and medically appropriate for the individual.¹⁷

Consistent with existing regulations and guidance, plans and issuers may use reasonable medical management techniques only within a specified category of contraception (or, with respect to contraceptive categories not described in the HRSA-supported Guidelines, within a group of substantially similar services or products) and only to the extent the HRSA-supported Guidelines do not specify the frequency, method, treatment, or setting for the provision of a recommended preventive item or service that is a contraceptive service or FDA-approved, -cleared, or -granted product.¹⁸ However, prior FAQs clarified that the use of such medical management techniques will generally not be considered reasonable unless the plan or issuer (1) has an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider (or other individual acting as the individual's authorized representative); and (2) covers without cost sharing a contraceptive service or FDA-approved, -cleared, or -granted contraceptive product determined to be medically necessary with respect to an individual as determined by the individual's attending provider (including if there is only one service or product that is medically appropriate for the individual, as determined by their attending provider).¹⁹

31). FAQs Part XXVI, Q5, make clear that a plan or issuer cannot limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity, or recorded gender.

¹⁵ See FAQs Part 54.

¹⁶ This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive product or service. See FAQs Part 54, Q2 and Q3.

¹⁷ See FAQs Part 54, Q3. This FAQ also states that, if an individual's attending provider recommends a particular service or FDA-approved, -cleared, or -granted product not included in a category described in the HRSA-supported Guidelines based on a determination of medical necessity with respect to that individual, the plan or issuer generally must cover that service or product without cost sharing, must defer to the determination of the attending provider, and must make available an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome so the individual or their provider (or other individual acting as the individual's authorized representative) can obtain coverage for the medically necessary service or product without cost sharing.

¹⁸ See 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4); and FAQs Part 54, Q8.

¹⁹ See FAQs Part 54, Q3, Q8, and Q9.

Despite repeated clarification of what the Departments consider to be reasonable medical management techniques, the Departments are aware of reports that plans and issuers continue to impose widespread barriers to contraceptive coverage, causing individuals to experience difficulty accessing the coverage without cost sharing that they are entitled to under PHS Act section 2713 and its implementing regulations. In FAQs Part 54, the Departments described several examples of potentially unreasonable medical management techniques used by plans and issuers.²⁰ Examples of potentially unreasonable medical management techniques and other problematic practices include actions by plans and issuers that:

- Require individuals to satisfy step therapy protocols (a medical management technique also known as “fail first”) using numerous other services or FDA-approved, -cleared, or -granted contraceptive products within the same category of contraception before the plan or issuer will approve coverage for the contraceptive service or FDA-approved, -cleared, or -granted contraceptive product that is medically necessary for the individual, as determined by the individual’s attending health care provider;
- Apply age-related restrictions for a contraceptive service or product that is medically necessary for the individual, as determined by the individual’s attending health care provider;
- Impose unduly burdensome administrative requirements as part of an exceptions process, such as onerous documentation requirements or multiple levels of processes (such as one to cover an excluded drug that is medically necessary and another to remove cost-sharing requirements), that result in denials of coverage or imposition of a cost-sharing requirement for contraceptive services or products that are medically necessary for the individual, as determined by the individual’s attending health care provider; and
- Require cost sharing for services provided that are integral to the preventive service provided (regardless of whether the items and services are billed separately), such as anesthesia, pregnancy tests needed before the provision of certain forms of contraceptives, or other pre- and post-operative items and services integral to the furnishing of sterilization surgeries including tubal ligation.²¹

The Departments are also aware of investigations that have documented potentially unreasonable medical management techniques used by plans and issuers. For instance, the U.S. House of Representatives Committee on Oversight and Reform (Committee) published a report in October 2022 documenting the findings of its investigation into contraceptive coverage for individuals enrolled in private health coverage.²² The Committee identified at least 34 different contraceptive items, particularly contraceptive drugs and drug-led devices,²³ that were

²⁰ See FAQs Part 54, Q8.

²¹ See FAQs Part 54, Q1.

²² U.S. House of Representatives Committee on Oversight and Reform, “Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance” (October 25, 2022), available at <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>.

²³ In this guidance, a drug-led device refers to a combination product, as defined under 21 CFR 3.2(e), that is comprised of a drug and a device, and for which the drug component provides the primary mode of action. The primary mode of action of a combination product is the single mode of action (that is, the action provided by the drug, device, or biological product) that provides the most important therapeutic action of the combination product. See 21 U.S.C.A. § 353(g)(1)(C) and 21 CFR 3.2(m).

commonly excluded from coverage or for which cost-sharing requirements often were applied, and noted that insurers denied an average of 40 percent of exception requests related to contraceptive coverage, with one company denying more than 80 percent of requests in a year.

In light of these reports of continued barriers and difficulty accessing contraceptive coverage without cost sharing, the Departments are issuing the following FAQs to provide further guidance on a therapeutic equivalence approach, which plans and issuers may adopt (in combination with an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome) to comply with the requirements under PHS Act section 2713 regarding the coverage of contraceptive drugs and drug-led devices.

Q1: Other than what has been described in previous guidance, how can plans and issuers ensure compliance with the requirement to cover the full-range of FDA-approved contraceptive drugs and drug-led devices²⁴ without cost sharing under PHS Act section 2713 and its implementing regulations?

As described earlier in these FAQs, the Departments have previously issued guidance interpreting the regulations implementing PHS Act section 2713 in regard to the coverage of contraception. Plans and issuers may continue to meet the requirements of section 2713 and its implementing regulations by implementing the standards described in prior guidance. Alternatively, to comply with the requirements in PHS Act section 2713 and its implementing regulations with respect to FDA-approved contraceptive drugs and drug-led devices, a plan or issuer may provide coverage consistent with the therapeutic equivalence approach outlined in these FAQs.

Specifically, with respect to FDA-approved contraceptive drugs and drug-led devices, if a plan or issuer utilizes medical management techniques within a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category), the Departments will generally consider such medical management techniques to be reasonable if the plan or issuer covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost sharing. Even then, a plan's or issuer's medical management techniques would generally be considered reasonable only if the plan or issuer provides an exceptions process that allows an individual to access without cost sharing the specific contraceptive drug or drug-led device (that is a therapeutic equivalent to the product that is covered without cost sharing) that is determined to be medically necessary with respect to the individual, as determined by the individual's attending provider.²⁵

²⁴ Under PHS Act section 2713 and its implementing regulations, in conjunction with the HRSA-supported Guidelines, plans and issuers are required to cover without cost sharing the full range of FDA-approved, -cleared, or -granted contraceptives. The Departments refer to only "FDA-approved" contraceptive drugs and drug-led devices in these FAQs to reflect that the FDA approves, but does not "clear" or "grant," contraceptive drugs and drug-led devices.

²⁵ See FAQs Part 54, Q8.

Q2: How will the Departments determine whether a contraceptive drug or drug-led device is therapeutically equivalent to another drug or drug-led device?

The Departments will consider a contraceptive drug or drug-led device to be therapeutically equivalent to another drug or drug-led device if the drug products or drug-led devices are identified as therapeutic equivalents (that is, designated with a code with the first letter “A”) in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).²⁶ The Departments will consider a drug or drug-led device for which the Orange Book has not identified any therapeutic equivalents to have no therapeutic equivalent. For example, as of the date of publication of these FAQs, under the category of “intrauterine devices with progestin (all durations and doses),” there are four FDA-approved products available; however, none of the four products are listed in the Orange Book as therapeutic equivalents to each other, so the Departments would treat each of these products as having no therapeutic equivalent.

For additional information regarding the FDA’s therapeutic equivalence evaluations, please refer to the FDA’s information regarding the Orange Book, available at <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

The following example illustrates the coverage approach described in Q1.

Example: Within the category of “oral contraceptives (combined pill),” a plan covers all FDA-approved oral contraceptives (combined pill) products without cost sharing, other than those for which there is a therapeutic equivalent that is covered without cost sharing. Specifically, the plan covers Pill A, Pill B, and generic Pill D without cost sharing. Neither Pill A nor Pill B has a therapeutic equivalent product according to the Orange Book. Pill W, Pill X, and Pill Y, as well

²⁶ 21 CFR 314.3(b), 44 FR 2932 (January 12, 1979) and 45 FR 72582 (October 31, 1980). The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. The FDA believes that drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product when administered to the patient under the conditions specified in the labeling. Specifically, the FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations in 21 CFR Part 210, 21 CFR Part 211, and 21 CFR Part 212. The concept of therapeutic equivalence applies only to drug products containing the identical active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition (e.g., meperidine hydrochloride vs. morphine sulfate for the treatment of pain). Note that while therapeutic equivalence evaluations are provided for approved multisource prescription drug products, this should not be understood to require the exclusion of coverage of preventive products available over-the-counter, without a prescription. The Departments are considering the comments received in response to the Request for Information regarding the coverage of preventive products available over-the-counter without cost sharing and without a prescription to determine if and what additional actions the Departments may take regarding such products. See 88 FR 68519 (Oct. 4, 2023).

as Pill Z (which is a more expensive brand name product) are all classified in the Orange Book as therapeutic equivalents to Pill D and are not covered by the plan without cost sharing. However, the plan provides an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on an individual or their provider (or other individual acting as the individual's authorized representative). The plan's exceptions process allows an individual to receive coverage without cost sharing for a therapeutic equivalent to Pill D (i.e., Pill W, Pill X, Pill Y, or Pill Z) if the therapeutic equivalent product is determined to be medically necessary with respect to the individual, as determined by the individual's attending provider.

Conclusion: The plan's medical management techniques with respect to the category of "oral contraceptives (combined pill)" are generally reasonable. However, the plan's medical management techniques could be considered unreasonable if the plan imposes additional medical management techniques that are problematic, such those highlighted earlier in these FAQs.

Q3: Does the approach to reasonable medical management with regard to therapeutically equivalent products described in Q1 and Q2 apply to all forms of contraception required to be covered under PHS Act section 2713?

No. Forms of contraception that are not FDA-approved drugs or drug-led devices are not listed in the Orange Book. Therefore, the therapeutic equivalence approach described in Q1 and Q2 does not apply to such other forms of contraception.

Q4: If a plan or issuer covers without cost sharing all FDA-approved contraceptive drugs or contraceptive drug-led devices other than those for which there is a covered therapeutic equivalent, is the plan or issuer still expected to maintain an exceptions process as previously described in guidance?

Yes. The Departments generally do not consider medical management techniques to be reasonable absent the availability of an exceptions process. Therefore, all plans and issuers are expected to have an exceptions process available to ensure that individuals can access coverage without cost sharing for a contraceptive service or FDA-approved, -cleared, or -granted contraceptive product (including another contraceptive drug or drug-led device for which there is a covered therapeutic equivalent) that is medically necessary for the individual, as determined by the individual's attending provider, and that is otherwise not covered without cost sharing.²⁷

The availability of an exceptions process as described in prior guidance remains a critical resource for individuals to have access to the full range of contraceptives and contraceptive care, as recommended by the HRSA-supported Guidelines and as individuals are entitled to, without cost sharing, under PHS Act section 2713 and its implementing regulations.

Nonetheless, the Departments expect that plans and issuers that opt to provide coverage consistent with the therapeutic equivalence approach described in Q1 and Q2 will experience a significant reduction in the frequency with which the exceptions process would be utilized by (or

²⁷ See FAQs Part 54, Q3, Q8, and Q9.

necessary for) individuals to access contraceptive drugs and drug-led devices that are medically necessary, as determined by the individual's attending provider.

Q5: Can plans and issuers continue to satisfy the requirements under PHS Act section 2713 with respect to coverage of the full range of FDA-approved, -cleared, or -granted products—including with respect to contraceptive drugs and drug-led devices—by following the Departments' prior guidance?

Yes. Plans and issuers may continue to satisfy the requirements under PHS Act section 2713 and its implementing regulations by implementing the standards described in prior guidance, including by making available an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider (or other individual acting as the individual's authorized representative). However, given reports of continued barriers to accessing contraception, the Departments remain concerned that many exceptions processes do not meet the criteria outlined in the Departments' prior guidance. Therefore, with respect to FDA-approved contraceptive drugs and drug-led devices, a plan or issuer could provide coverage consistent with the Departments' prior guidance or, alternatively, consistent with the therapeutic equivalence approach outlined in these FAQs to comply with the requirements in PHS Act section 2713 and its implementing regulations. Regardless of approach, plans and issuers are expected to have an exceptions process available to ensure that individuals can access coverage without cost sharing for a contraceptive service or FDA-approved, -cleared, or -granted contraceptive product (including another contraceptive drug or drug-led device for which there is a covered therapeutic equivalent) that is medically necessary for the individual, as determined by the individual's attending provider. Under the therapeutic equivalence approach, the circumstances under which an exceptions process would apply should be less frequent.

Under the therapeutic equivalence approach outlined in these FAQs with respect to FDA-approved contraceptive drugs and drug-led devices, if a plan or issuer utilizes medical management techniques within a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category), the Departments will generally consider such medical management techniques to be reasonable if the plan or issuer covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost sharing. Even then, a plan's or issuer's medical management techniques would generally be considered reasonable only if the plan or issuer provides an exceptions process that allows an individual to access without cost sharing the specific contraceptive drug or drug-led device (that is, a therapeutic equivalent to the product that is covered without cost sharing) that is determined to be medically necessary with respect to the individual, as determined by the individual's attending provider.

To ensure consumers have access to all contraceptive benefits to which they are entitled to under federal law, plans and issuers following the prior guidance should carefully review the Departments' previously issued FAQs and all medical management techniques that they apply to contraceptive products and services to ensure that they are reasonable.

Q6: What should an individual do if the individual has concerns regarding, or has difficulty with, accessing contraceptive coverage under their group health plan or group or individual health insurance coverage?

Individuals who have concerns about their plan’s or issuer’s compliance with the contraceptive coverage requirements may contact the appropriate federal or state agency:

Consumers covered by a private-sector, employer-sponsored group health plan	Contact the Department of Labor (DOL) at www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa or call toll free at 1-866-444-3272
Consumers covered by fully-insured coverage	Go to https://content.naic.org/state-insurance-departments to find contact information for the appropriate State Department of Insurance
Consumers with concerns that their State Department of Insurance is not enforcing the contraceptive coverage requirements	Contact HHS at contraception_complaints@cms.hhs.gov
Consumers covered by non-federal, public-sector employer-sponsored plan (such as state or local government employee plan)	Contact HHS at contraception_complaints@cms.hhs.gov or call toll free at 1-888-393-2789
Consumers covered by the Federal Employees Health Benefits (FEHB) Program ²⁸	Contact the Office of Personnel Management (OPM) at contraception@opm.gov

If an individual is uncertain whether their health coverage is fully insured or self-insured, they can contact the entity that administers the plan or coverage, or consult plan or coverage documentation for more information. Individuals may also reach out to HHS or DOL by using the contact information above for help finding the appropriate agency to contact.

²⁸ These consumers receive coverage through health benefits plans offered by FEHB carriers having contracts with OPM pursuant to 5 U.S.C. 8902.