

Publications

Tri-Agencies Issue FAQs on Contraceptive Coverage

ATTORNEYS & PROFESSIONALS

Kathryn Bjornstad Amin

kamin@groom.com

202-861-2604

Lisa Campbell

lcampbell@groom.com

202-861-6612

Tamara Killion

tkillion@groom.com

202-861-6328

Patrick D. O'Neil

poneil@groom.com

202-861-6601

Ryan C. Temme

rtemme@groom.com

202-861-6659

PUBLISHED

02/07/2024

SOURCE

Groom Publication

SERVICES

Employers & Sponsors

- Health & Welfare Programs

Health Services

- Federal Insurance Regulation
- State Insurance Regulation

On January 22, the Departments of Labor, Treasury, and Health and Human Services (“Tri-Agencies”) [issued a set of Frequently Asked Questions](#) (“ACA FAQs Part 64”) clarifying the contraceptive-related services that plans and issuers must provide under the Public Health Service Act (“PHSA”) section 2713 and its implementing regulations relating to coverage of preventive services with no cost-sharing.

The Affordable Care Act (“ACA”) enacted PHSA section 2713 to require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover certain items and services without cost-sharing, including preventive care and screenings for women provided for by guidelines supported by the Health Resources and Services Administration (“HRSA”).

GROOM INSIGHT: Although a case before the Fifth Circuit Court of Appeals, *Braidwood Mgmt. Inc. v. Becerra*, could upend certain preventive services requirements under the ACA, this case does not apply to contraceptive coverage requirements.

The HRSA-supported guidelines recommend that adolescent and adult women have access to the full range of contraceptive care included in the Food and Drug Administration (“FDA”)-approved, -cleared, or -granted contraceptives, effective family planning practices, and sterilization procedures. The full range of contraceptives includes each form of contraception listed in the FDA’s Birth Control Guide (with the exception of sterilization surgery for men), including: (1) sterilization surgery for women; (2) implantable rods; (3) copper intrauterine devices; (4) intrauterine devices with progestin; (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); (17) emergency contraception (ulipristal acetate); and (18) any additional contraceptives approved, cleared, or granted by the FDA.

GROOM INSIGHT: Because most plans and issuers rely on pharmacy benefit managers (“PBMs”) for administering benefits for many contraceptive categories required under the HRSA guidance, plans and issuers should conduct a thorough review of all contraceptive benefits to ensure that the benefits meet the coverage requirements, the limitations on cost-sharing, and the need for exceptions process, to the extent the contraceptive is subject to either cost share or some form of medical management, like prior authorization or step therapy.

Previous Tri-Agency Guidance

The Tri-Agencies [previously issued FAQs](#) in July 2022 (“ACA FAQs Part 54”) to reiterate prior guidance interpreting the preventive services rule, clarifying that plans and issuers must cover without cost-sharing: (1) at least one form of contraception in each category of the HRSA-supported guidelines; and (2) any contraceptive services and FDA-approved, -cleared, or -granted products determined to be medically appropriate for the individual, regardless of whether those services or products are specifically identified in the categories listed in the HRSA-supported guidelines.

The previous FAQs listed examples of unreasonable medical management techniques, including step therapy protocols, age-related restrictions for medically necessary contraceptives, onerous administrative requirements, and cost-sharing for services integral to the application of a preventive service. The Tri-Agencies also specified that, in order for medical management technique to be reasonable, the plan or issuer must provide an “easily accessible, transparent, and sufficiently expedient” exception process that defers to the treating providers’ clinical judgment.

New Tri-Agency FAQs

The new FAQs clarify that plans and issuers can ensure compliance with contraceptive coverage requirements under PHSA section 2713 by implementing the standards from prior guidance or by using a therapeutic equivalence approach. The therapeutic equivalence approach entails the plan or issuer utilizing medical management techniques within a specific category of contraceptives from the HRSA-supported guidelines. The Tri-Agencies state in the FAQs that this is a reasonable medical management technique if the plan or issuer covers all FDA-approved contraceptive drugs and drug-led devices in each category of contraception without cost-sharing, except for those that have at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost-sharing. However, the FAQs specify that, under this approach, the plan or issuer would still need to provide an exceptions process through which an individual could access the specific contraceptive where medically necessary. The FAQs specify that a contraceptive drug or drug-led device is a therapeutic equivalent if it is identified as a therapeutic equivalent in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”).

GROOM INSIGHT: For plans and issuers that seek to impose cost-sharing or medical management techniques on certain contraceptives without a therapeutic equivalent, we anticipate greater scrutiny of the plan/issuer’s exceptions process, both in terms of how it is communicated to participants and providers, as well as the scope of deference given to the treating provider regarding the medical appropriateness of the particular contraceptive.

The Tri-Agencies will only consider medical management techniques to be reasonable if they have an exceptions process. Therefore, even if a plan or issuer covers all FDA-approved contraceptives without cost-sharing other than those that have a covered therapeutic equivalent, the Tri-Agencies would still expect these plans or issuers to make an exceptions process available to ensure access to medically necessary contraceptives.

GROOM INSIGHT: DOL has signaled in the context of its audit activity that communication of the exceptions process is an important aspect of ensuring that a plan or issuer meets the preventive services requirements with respect to zero-cost contraceptives. Accordingly, plans, issuers, and PBMs should ensure that plan documents and other communications with participants make clear that an exceptions process is available for instances where the treating provider deems the contraceptive at issue the most medically appropriate.

Although the FAQs state that plans and issuers may continue to satisfy the preventive services requirements of PHSA section 2713 using prior guidance, they clarify that, due to reports the Tri-Agencies have received of exceptions processes failing to comply with prior guidance, many plans and issuers may need to rethink their approach. Therefore, to ensure consumer access to contraceptive

GROOM LAW GROUP

benefits required under the ACA, the Tri-Agencies encourage plans and issuers to carefully review medical management techniques they apply to contraceptive products and services to ensure the techniques are reasonable and there is an exceptions process in place to ensure access to medically necessary contraceptive coverage.