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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

3 Things To Know About Proposed OTC Contraception Regs

By Kellie Mejdrich

Law360 (October 23, 2024, 8:04 PM EDT) -- The Biden administration's proposal to require private health insurers to pick up the cost of over-the-counter contraception could increase access for an estimated 52 million women.

The U.S. Department of Labor, the U.S. Department of Health and Human Services and the U.S. Department of the Treasury jointly unveiled **proposed rules Monday** that would force private health insurers to cover the cost of OTC contraception items, including the no-prescription daily birth control pill, male condoms and the morning-after pill.

Sarah Raaii, a partner at McDermott Will & Emery LLP who advises on employee benefits and healthcare issues, called the proposal "the administration's latest move to expand access to reproductive care" after the U.S. Supreme Court's 2022 decision revoking women's national right to an abortion in [Dobbs v. Jackson Women's Health Organization](#).

The agencies had emphasized the need for the contraception **rules**, which the White House said would expand access to 52 million Americans of childbearing age, in the wake of that ruling.

Raaii said the proposal also served as "a reiteration that to some extent, no matter what state you're in, reproductive care is on the ballot."

Here are three things to know about the newly proposed regulations.

New Regs Driven by Opill Approval

Attorneys highlighted how they've been anticipating the proposed rules since the agencies **requested information** on OTC preventive care products in October 2023.

"We were expecting it," said Lisa Campbell, principal and co-chair of Groom Law Group's health services practice. Campbell pointed to the request for information, or RFI, on OTC products as a major signal that rules were coming.

The RFI came months after the U.S. Food and Drug Administration in July 2023 **approved Opill**, a daily birth control tablet, for over-the-counter nonprescription use, which the agencies said in the proposed rules was also a major driver behind the new OTC coverage requirements.

Already, plans have long complied with the Affordable Care Act's requirement for prescription birth control coverage without cost sharing. But the agencies said in the proposed rules that in response to the RFI, several commenters urged broader coverage of OTC contraceptives and argued that the current prescription requirement on birth control is based only on agency guidance and not on the Public Health Services Act or its implementing regulations.

The agencies said in the proposal that they are planning for additional proposed rules in the future that would address preventive services coverage requirements beyond contraception. But Campbell highlighted that the proposed rules limit the coverage expansion to just OTC contraception products for now.

"I do think at least they're recognizing that we're going to start slow," Campbell said.

Quantity Limits Can Limit Plan Costs

Campbell and other attorneys said another important takeaway from the proposal is that the agencies gave health plans and insurance issuers the green light to impose so-called medical management techniques to contain costs and potentially minimize abuses of a new expansion in insurance coverage for OTC products.

The agencies said in their proposal that they wanted to "strike a balance" between ensuring preventive services coverage guaranteed by federal law "and allowing plans and issuers to contain costs, promote efficient delivery of care, and minimize risks of fraud, waste, and abuse."

The proposed rules outline how health plans and insurance issuers can establish an exceptions process to whatever medical management plans and issuers might use to limit access to a given form of preventive care where coverage without cost sharing would otherwise be required under the PHS Act. The exceptions process established by the proposal would apply to medical management of preventive services coverage overall, not just expanded contraception coverage proposed by the rules. But the proposed rules also contain specific proposals affecting how medical management can limit contraception coverage.

The agencies also made clear that the exact contours of how this exceptions process language might work are still in development. The agencies requested comments in the proposal on what specific terminology to use in the exceptions process portion of the rules, as well as how plans might communicate information on accessing exceptions to health plan participants.

Campbell, at Groom Law, said she took heed of medical management language in the proposal.

"I think there's a lot of concern about fraud, waste and abuse," as well as the potential for individuals stockpiling and reselling OTC contraception items, Campbell said.

"I do think the departments at least recognize ... that's an issue," Campbell said. "They do say that there can be reasonable medical management on this."

Susan Nash, an employee benefits partner in Winston & Strawn LLP's Chicago office, said she was also interested in the medical management portion of the proposed rules. Nash further highlighted how the proposal builds on previous guidance from the agency on medical management in the context of preventive services from 2022 and January 2024.

"The medical management discussion was interesting because, anecdotally, a lot of women have had barriers to obtaining free contraceptives under their medical plans, whether it's through medical management techniques or prior authorization, et cetera," Nash said.

Nash said the agencies' previous guidance had cited this difficulty and encouraged plans and issuers to look at how medical management techniques were affecting coverage of cost-free contraceptives.

"I think that there's a tension there between plans and issuers wanting to make sure that drugs are safe and effective, and that there's no fraud and abuse going on, but also that patients can get access to these medications for free under the law as required," Nash added.

Legal Challenges Expected

In addition to watching for the rules' official publication in the Federal Register, attorneys said they're keeping an eye out for eventual legal challenges that might halt future implementation of the coverage expansion. The agencies said in a Federal Register posting online Wednesday that official publication of the proposal is scheduled for Monday.

Fueling the potential for legal challenges is that the Supreme Court did away with the so-called Chevron doctrine via decisions in [Loper Bright Enterprises v. Raimondo](#) and [Relentless Inc. v. Department of Commerce](#) in June. Under Chevron, the justices had held that if Congress hadn't directly "spoken to the precise question at issue," courts must defer to a federal agency's interpretation of the law.

There's also the possibility that additional religious objections to things like the morning-after pill might spark a challenge to the contraception policies, attorneys said.

Erin Sutton, an associate with Epstein Becker Green in the firm's healthcare and life sciences practice, said she thought the agencies' proposed rules were "careful" to point out that the proposed policy changes wouldn't modify conscience protections for employers, plans and issuers under other previously finalized rules that allow them to obtain exemptions from providing contraception.

"Nevertheless, I think this is a topic that ... we can always expect to be litigated," Sutton said. "It's certainly a contentious topic."

Raaii, with McDermott, agreed that attorneys can't rule out a legal challenge to these regulations in the future.

"Just especially in this environment after the Loper Bright decision, I think it's certainly a possibility to have these challenged," Raaii said.

--Editing by Abbie Sarfo.

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