by Practical Law Employee Benefits & Executive Compensation

District Court Vacates First Trump Administration's Exemptions to ACA's Contraceptives Mandate

In longstanding litigation, a Pennsylvania district court has vacated final regulations that were issued in November 2018 under the first Trump administration to further implement the <u>Affordable Care</u>

Act's (ACA's) contraceptives mandate (<u>Pennsylvania v. Trump</u>, (E.D. Pa. Aug. 13, 2025); see <u>Practice Note</u>, <u>Contraceptives Coverage Under the ACA</u> and <u>Reproductive Health Care for Group Health Plans Toolkit</u>). The 2018 final regulations, which were jointly issued by the <u>Departments of Labor</u> (DOL), <u>Health and Human Services</u> (HHS), and <u>Treasury</u> (collectively, Departments), significantly expanded the range of entities that could claim an exemption from the contraceptives mandate, as implemented (see <u>Practice Note</u>, <u>Contraceptives Coverage Under the ACA: Accommodations and Other Issues</u>).

Trump Administration Regulations Challenged in the Third and Ninth Circuits

As background, the ACA requires **group health plans** and health insurers to cover preventive care and screenings without cost-sharing for women "as provided for in comprehensive guidelines supported by [the **Health Resources and Services Administration** (HRSA)]" (a division of HHS). (The contraceptives mandate is part of the ACA's preventive health services requirements; see <u>Practice Note, Preventive Health Services Under the ACA, Other Than Contraceptives.</u>) In early guidance implementing the ACA, this provision was interpreted to include coverage of contraceptive methods and sterilization procedures approved by the **Food and Drug Administration** (FDA), but subject to an exemption for religious employers and an accommodation process for other entities (see <u>Practice Note, Contraceptives Coverage Under the ACA: Accommodation for Nonprofit and Certain For-Profit Entities</u>).

The Departments' 2018 final regulations:

- Expanded the existing religious beliefs exemption under the contraceptives mandate to make it
 available to additional employers, insurers, and other entities and individuals that object to
 contraceptives coverage based on sincerely held religious beliefs.
- Added a moral convictions exemption for certain entities and individuals with sincerely held moral objections to contraceptives coverage.

In January 2019, federal district courts in California and Pennsylvania issued **preliminary injunctions** (in separate cases) prohibiting implementation of the final regulations (see <u>Legal Update, Two District Courts Block Trump Administration's Final ACA Contraceptives Rules</u>). In the latter case, Pennsylvania and New Jersey challenged the final regulations on:

- Substantive grounds (arguing that the Departments lacked statutory authority under the ACA or the <u>Religious Freedom Restoration Act</u> (RFRA) to create the exemptions).
- Procedural grounds (because the 2018 regulations were not implemented consistent with noticeand-comment rulemaking procedures under the <u>Administrative Procedure Act</u> (APA)).

The federal government appealed this ruling, joined by the Little Sisters of the Poor, a religious nonprofit operated by a congregation of Roman Catholic women.

The Third Circuit affirmed the district court's injunction in July 2019, concluding that:

- The ACA authorized HRSA to decide which services were covered under the ACA's preventive services rules—but not to create exemptions from these requirements.
- RFRA did not require or permit the disputed religious beliefs exemption.

(For more information, see <u>Legal Update</u>, <u>Third Circuit Upholds Nationwide Injunction Blocking Trump Administration's ACA Contraceptives Final Rules</u>.)

As to the procedural challenge, the Third Circuit concluded that:

- The Departments should have conducted notice-and-comment rulemaking in initially issuing the regulations.
- The minimal changes between the initial and final versions of the regulations suggested a lack of open-mindedness in the Departments' rulemaking process.

In 2020, however, the Supreme Court reversed the Third Circuit (*Little Sisters of the Poor Saints Peter & Paul Home v. Penn.*, 591 U.S. 657 (2020); see <u>Legal Update</u>, <u>Supreme Court Upholds Trump Administration Exemptions to ACA's Contraceptives Mandate</u>). Regarding the notice-and-comment rulemaking argument, the Court concluded that the Departments had satisfied the required procedural requirements. The Court also held that the ACA statutorily authorized the Departments to establish religious and moral accommodations to the contraceptives mandate, as reflected in the 2018 regulations.

District Court: Departments' Rulemaking Was Arbitrary and Capricious

In its earlier rulings, the Pennsylvania district court did not reach the states' argument that the Departments' actions in issuing the 2018 regulations were arbitrary and capricious in violation of the APA (in other words, the states argued that the Departments did not engage in reasoned decisionmaking). The district court had stayed this matter while the Departments, under the Biden administration, were developing additional regulations to implement the ACA's contraceptives mandate. In December 2024, however, the Biden administration withdrew these regulations, following the election of President Trump to a second term (89 Fed. Reg. 106393Opens in a new window (Dec. 30, 2024); see Article, Post-Dobbs Proposals to Expand Access to ACA Contraceptives (Withdrawn: Dec. 2024)). As a result, with the 2018 regulations still in place, the remaining arbitrary and capricious claim could be resolved and the parties asked the court to rule on the matter without a trial (that is, by summary judgment).

Departments' Failure to Satisfactorily Explain Religious Beliefs Exemption Regulation. Addressing the religious beliefs exemption, the district court found that the Departments' actions were arbitrary and capricious because they failed to provide a satisfactory explanation for their rulemaking that contained a rational connection between:

- The problem meant to be solved by the regulations (that is, avoiding RFRA violations).
- The regulations' solution to that problem (exempting employers for whom complying with the regulations' accommodation did not pose a potential conflict in the first place).

The court observed that the Departments issued the religious beliefs exemptions (under the 2018 regulations) to address potential conflicts between the ACA contraceptives mandate and RFRA.

Some organizations, the court indicated, believed that invoking a regulatory accommodation that predated the 2018 regulations made them complicit in providing contraception (see <u>Practice Note</u>, <u>Contraceptives Coverage Under the ACA: Accommodations and Other Issues: Accommodations for</u>

<u>Eligible Organizations (Now Optional)</u>). However, the court concluded that the religious beliefs exemption under the 2018 regulations was not limited merely to these entities that maintained sincerely held, complicity-based objections to the accommodation. Rather, the 2018 regulations allowed even entities without such objections to exempt themselves. For example, the court noted, the 2018 regulations made the exemption available to publicly traded corporations, which are comprised of unrelated shareholders who would not likely:

- Hold a singular religious belief.
- Raise a unified religious exemption.

In addition, the court reasoned that the religious beliefs exemption contained "no backstop" regarding who could claim the exemption. For example, the court indicatd that the 2018 regulations allowed entities to exempt themselves from the contraceptives mandate without informing anyone of the objection, meaning that there was no method to assess:

- The sincerity of an objecting entity's religious beliefs.
- If complying with the contraceptives mandate would substantially burden the exercise of religion.

This, in the court's view, suggested a lack of rational connection to addressing potential conflicts between the ACA's contraceptives mandate and RFRA.

The district court also reasoned that the Third Circuit had specifically upheld the regulatory accommodation against a RFRA challenge, meaning that the Departments could not rely on RFRA as the reason why the 2018 regulations' religious beliefs exemption was necessary. (In doing so, the district court confirmed the ongoing validity of a core Third Circuit ruling—rejecting the Departments' assertion that the ruling was questionable legal authority.)

Moral Convictions Exemption. The district court also held that the 2018 regulations' moral convictions exemption was arbitrary and capricious. In doing so, the district court agreed with the states' argument that the Departments had relied on improper factors in establishing the moral convictions exemption. The court reasoned that the ACA did not authorize the Departments to factor moral exemptions in creating regulatory exemptions to the contraceptives mandate. In the district court's view, although the Departments were allowed to consider RFRA's potential impact regarding the religious beliefs exemption, RFRA did not apply to entities with moral objections.

However, the Court acknowledged that the Supreme Court (in its *Little Sisters* ruling from 2020) concluded that, under a plain reading of the statute, "the ACA gives HRSA broad discretion to define preventive care and screening and to create the religious and moral exemptions" (*Little Sisters*, 591 U.S. at 677). The district court largely dismissed this reference, though, reasoning that the Supreme Court in *Little Sisters* was not addressing whether the Departments had acted arbitrarily and capriciously in issuing the 2018 regulations (the question before the district court). Rather, at issue before the Supreme Court was whether the Departments were authorized under the ACA to establish exemptions at all.

The district court also rejected the federal government's argument that because Congress has permitted moral objections to regulatory frameworks in other areas (for example, in the abortion context), it also must have intended a moral objections exemption regarding the contraceptives mandate. Instead, the district court concluded that Congress's recognition of moral objections in other contexts (for example, abortion) must "be taken to mean that Congress did not intend for an entity's moral scruples to be considered in providing preventive services to women" (*Pennsylvania*, , at *20).

District Court: 2018 Regulations Were Inadequately Reasoned. The district court also found that the religious beliefs and moral convictions exemptions under the 2018 regulations must be vacated because the Departments failed to offer an adequate explanation for their rulemaking—including why they chose to change course from earlier iterations of implementing regulations under the ACA's contraceptives mandate. According to the district court, the Departments also failed to sufficiently address reasonable alternatives to the 2018 regulations.

The court agreed with the states that the Departments' changed positions concerning the safety, efficacy, and benefits of ACA contraceptives rendered the 2018 regulations arbitrary and capricious. For example, the Departments argued that they did offer studies raising empirical questions about the safety of contraceptives in issuing the 2018 regulations. However, the court noted that those studies were published in earlier years when the Departments still believed that contraceptives were safe and effective. As a result, the court concluded that the Departments failed to provide the more searching justifications that are required when an administrative agency reverses its position on factual matters underlying its regulations.

The court also agreed with the states' argument that the Departments' rulemaking was arbitrary and capricious because they did not address obvious alternatives in issuing the 2018 regulations (for example, an option offering individuals other channels to obtain contraceptives even if the individuals are participants in an exempt plan). Here, the court observed that proposed regulations issued by the Biden administration in 2023 (but withdrawn in 2024) would have provided individuals an independent pathway for obtaining contraceptives called an "individual contraceptive arrangement" (ICA) (see Article, ACA Contraceptives (Withdrawn: Dec. 2024): Individual Coverage Arrangements). The court concluded that the Departments' failed to consider such alternatives (or even to offer reasons for why they had rejected the alternatives).

In sum, the district court concluded that the Departments failed to:

- Show a sufficient justification for the religious beliefs and moral convictions exemptions under the 2018 regulations.
- Draw a rational connection between the problem the regulations sought to resolve (RFRA violations) and the regulations' solution for that problem (the expanded exemptions).
- Consider important alternatives.
- Demonstrate that the Departments' changed positions (relative to their prior findings and cited evidence) regarding the safety and effectiveness of contraceptives were justified.

Vacatur Was Authorized Under APA. Having found that the 2018 regulations' religious beliefs and moral convictions exemptions were arbitrary and capricious, the court concluded that the regulations must be vacated. Citing the APA, the court indicated that reviewing courts must hold unlawful and set aside agency actions that are found to be arbitrary and capricious (<u>5 U.S.C. § 706</u>). The court also referenced a concurring opinion in the Supreme Court's 2024 *Corner Post* ruling recognizing that the APA authorizes vacatur of regulations (*Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 829-830 (2024); see <u>Legal Update</u>, <u>Supreme Court Overrules Chevron Framework for Interpreting Laws Administered by Federal Agencies</u>). The court rejected the Departments' invitation to simply remand the 2018 regulations to the Departments without vacating them.

The court also concluded that the 2018 regulations did not lend themselves to being severed, reasoning that the regulations' provisions were not entirely independent of one another.

As a result, the district court vacated the 2018 regulations in their entirety.

Practical Impact

If the ACA's litigation history regarding contraceptives is a guide, it seems likely that the federal government will appeal the district court's latest ruling in this challenge to the Third Circuit. If such an appeal is unsuccessful, the second Trump administration could consider issuing still more implementing regulations addressing exemptions to the contraceptives mandate (and other issues).

For more information on the second Trump administration's regulatory priorities to-date, see <u>Article</u>, <u>2025 Trump Administration Executive Orders Affecting ERISA Health and Welfare Plans</u>.