No. 19-454

In the Supreme Court of the United States

DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS

v.

COMMONWEALTH OF PENNSYLVANIA, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE PETITIONERS

NOEL J. FRANCISCO
Solicitor General
Counsel of Record
JOSEPH H. HUNT
Assistant Attorney General
JEFFREY B. WALL
Deputy Solicitor General
HASHIM M. MOOPPAN
Deputy Assistant Attorney General
CHRISTOPHER G. MICHEL
BENJAMIN W. SNYDER
Assistants to the Solicitor General
SHARON SWINGLE
LOWELL V. STURGILL JR.
KAREN SCHOEN
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTIONS PRESENTED

The Patient Protection and Affordable Care Act (ACA), 42 U.S.C. 18001 *et seq.*, requires many group health plans and health-insurance issuers that offer group or individual health coverage to provide coverage for preventive services, including women's preventive care, without cost-sharing. See 42 U.S.C. 300gg-13(a). Guidelines and regulations implementing that requirement promulgated in 2011 by federal agencies mandated that such entities cover contraceptives approved by the Food and Drug Administration. The mandate exempted churches, and subsequent rulemaking established an accommodation for certain other entities with religious objections to providing contraceptive coverage. In October 2017, the agencies promulgated interim final rules expanding the exemption to a broader range of entities with sincere religious or moral objections to providing contraceptive coverage. In November 2018, after considering comments solicited on the interim rules, the agencies promulgated final rules expanding the exemption. The questions presented are as follows:

1. Whether the agencies had authority under the ACA and the Religious Freedom Restoration Act of 1993, 42 U.S.C. 2000bb *et seq.*, to expand the conscience exemption to the contraceptive-coverage mandate.

2. Whether the agencies' promulgation of the interim rules without notice and an opportunity for public comment rendered procedurally invalid the final rules that the agencies later issued after notice and an opportunity for public comment.

3. Whether the court of appeals erred in affirming a nationwide preliminary injunction barring implementation of the final rules.

TABLE OF CONTENTS

Table of Contents—Continued: Page

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Cases—Continued: Page

Constitution, statutes, regulations, and rule:

Constitution, statutes, regulations, and rule—Continued: Page

Statutes, regulations, and rule—Continued: Page

Miscellaneous: Page

Miscellaneous—Continued: Page

In the Supreme Court of the United States

No. 19-454

DONALD J. TRUMP, PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS

v.

COMMONWEALTH OF PENNSYLVANIA, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The amended opinion of the court of appeals (Pet. App. 1a-46a) is reported at 930 F.3d 543. The opinion of the district court granting a preliminary injunction (Pet. App. 104a-184a) is reported at 351 F. Supp. 3d 791. An earlier opinion of the district court granting a preliminary injunction (Pet. App. 47a-100a) is reported at 281 F. Supp. 3d 553.

JURISDICTION

The judgment of the court of appeals was entered on July 12, 2019. The petition for a writ of certiorari was filed on October 3, 2019, and was granted on January 17, 2020. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are reproduced in the appendix to this brief. App., *infra*, 1a-22a.

STATEMENT

A. Statutory And Regulatory Background

1. The preventive-services provision of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. 18001 *et seq.*, requires many group health plans and health-insurance issuers to provide coverage for certain preventive services without "cost sharing." 42 U.S.C. 300gg-13(a).[1] Specifically, the provision mandates coverage in four enumerated areas. The first three are defined by guidelines or recommendations that existed at the time of the ACA's enactment: certain "evidence-based items or services * * * in the current recommendations of the United States Preventive Services Task Force," 42 U.S.C. 300gg-13(a)(1); "immunizations that ha[d] in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention," 42 U.S.C. 300gg-13(a)(2); and, "with respect to infants, children, and adolescents, evidence-informed preventive care and screenings pro-

[1] The preventive-services provision is part of the Public Health Service Act (PHSA), 42 U.S.C. 201 *et seq.*, and is also incorporated into the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1001 *et seq.*; see 29 U.S.C. 1185d, and the Internal Revenue Code, see 26 U.S.C. 9815(a)(1). The Departments of Health and Human Services (HHS), Labor, and the Treasury enforce and have authority to promulgate regulations implementing the relevant portions of those statutes. *E.g.*, 42 U.S.C. 300gg-92; 29 U.S.C. 1191c; 26 U.S.C. 9833.

vided for" in already-existing "comprehensive guidelines supported by the" Health Resources and Services Administration (HRSA), a component of HHS, 42 U.S.C. 300gg-13(a)(3).

The fourth area of mandatory coverage, which is centrally relevant here, directs health plans to "provide coverage for[,] * * * with respect to women, such additional preventive care and screenings * * * as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph." 42 U.S.C. 300gg-13(a)(4). Unlike the recommendations and guidelines referenced in Section 300gg-13(a)(1)-(3), the HRSA guidelines referenced in Section 300gg-13(a)(4) did not exist at the ACA's passage. Instead, HRSA was authorized to develop such guidelines for the purpose of implementing the ACA.

2. HRSA released its first guidelines for implementing Section 300gg-13(a)(4) in August 2011. See 77 Fed. Reg. 8725, 8725 (Feb. 15, 2012). Those guidelines generally required that health plans provide coverage of (among other things) all contraceptive methods approved by the Food and Drug Administration (FDA). *Ibid.* HRSA specified, however, that under its guidelines health plans associated with churches and church "auxiliaries" would not be required to cover contraception. *Id.* at 8726. This so-called "church exemption" was consistent with rules adopted contemporaneously by the agencies that administer the ACA (see p. 2 n.1, *supra*) explaining that, under Section 300gg-13(a)(4)'s direction that HRSA develop guidelines for the mandatory coverage of women's preventive services, "it is appropriate that HRSA * * * takes into account the effect on the religious beliefs" of providers of group health plans. 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

HRSA's authority to create the church exemption was not challenged. Some regulated parties, however, asked that HRSA's guidelines be amended to exempt other organizations with conscientious objections to providing contraceptive coverage. See 78 Fed. Reg. 8456, 8459-8460 (Feb. 6, 2013). The agencies responded by creating an "accommodation," under which religious not-for-profit organizations (such as colleges or charities) could inform their insurer—or, in the case of self-insured plans, the plan's third-party administrator—that they objected on religious grounds to providing contraceptive coverage. 78 Fed. Reg. 39,870, 39,874-39,882 (July 2, 2013). The insurers or administrators would then be required to arrange contraceptive coverage for plan participants. *Id.* at 39,874-39,880.

For most eligible entities, the accommodation meant that plan participants would still receive contraceptive coverage through the objecting organization's health plan. In the case of some self-insured organizations, however, the agencies acknowledged that the accommodation would make such coverage effectively voluntary. See 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014). That is because a third-party administrator's obligation to provide contraceptive coverage under an objecting employer's plan arises solely from ERISA, which does not apply to so-called "church plan[s]" that are established or maintained in particular circumstances by not-for-profit organizations associated with churches or conventions of churches (such as religious hospitals or universities). 29 U.S.C. 1003(b)(2); see 29 U.S.C. 1002(33)(C)(i); *Advocate Health Care Network* v. *Stapleton*, 137 S. Ct. 1652, 1656 (2017). Thus, in addition to exempting churches and their integrated auxiliaries, the agencies also effectively exempted the self-insured

plans of many church-affiliated not-for-profit organizations.

B. Prior Litigation

The agencies' decision to apply the contraceptive-coverage mandate to employers with conscientious objections gave rise to extensive litigation. Objectors primarily contended that imposition of the mandate violated the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. 2000bb *et seq.*, which provides in relevant part that the "[g]overnment shall not substantially burden a person's exercise of religion," unless "application of the burden to the person * * * is the least restrictive means of furthering [a] compelling governmental interest." 42 U.S.C. 2000bb-1(a)-(b). That litigation produced two separate circuit conflicts that prompted this Court's review.

1. A circuit conflict first developed over application of the mandate to for-profit employers that were not eligible for either the church exemption or the accommodation. This Court resolved that conflict in *Burwell* v. *Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). The Court held that RFRA prohibited applying the mandate to closely held for-profit corporations with religious objections to providing contraceptive coverage. *Id.* at 705-736. The Court first determined that the mandate "imposes a substantial burden on the exercise of religion" for such employers. *Id.* at 726. The Court then concluded that, even assuming a compelling governmental interest in "guaranteeing cost-free access" to contraception, the mandate is not the least-restrictive means of furthering that interest. *Id.* at 728. The Court observed that the agencies had already established an accommodation available to not-for-profit employers and that, at a minimum, that less-restrictive alternative could

be extended to closely held for-profit corporations with religious objections to the mandate but not to the accommodation. See *id.* at 730-731. The Court "d[id] not decide * * * whether an approach of this type complies with RFRA for purposes of *all* religious claims." *Id.* at 731 (emphasis added).

2. Following *Hobby Lobby*, the agencies extended the accommodation to closely held for-profit entities. 80 Fed. Reg. 41,318, 41,323-41,328 (July 14, 2015). Numerous entities, however, continued to challenge the mandate, principally asserting that using the accommodation to comply with the mandate would itself make them complicit in providing contraceptive coverage "because it utilized the plans the [entities] themselves sponsored." 82 Fed. Reg. 47,792, 47,798 (Oct. 13, 2017). Another circuit split developed, and this Court granted writs of certiorari in several of the cases. *Ibid.*

After briefing and argument, the Court vacated the judgments and remanded the cases without resolving the underlying merits. *Zubik* v. *Burwell*, 136 S. Ct. 1557, 1560 (2016) (per curiam). Instead, the Court directed that, on remand, the parties be given an opportunity to resolve the dispute. See *ibid.*

3. In response to *Zubik*, the agencies sought public comment on whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while ensuring seamless contraceptive coverage for their employees. 81 Fed. Reg. 47,741 (July 22, 2016). The agencies received over 54,000 comments, but could not identify a way to amend the accommodation that would satisfy objecting organizations and ensure that women covered by those organizations' plans receive seamless contraceptive coverage. 82 Fed. Reg. at 47,798-47,799, 47,814. As a result, as of

January 2017, the pending litigation concerning the mandate and accommodation—dozens of cases, brought by more than 100 separate plaintiffs—remained unresolved. In addition, some nonreligious organizations with moral objections to providing contraceptive coverage filed suits challenging the mandate, which produced conflicting decisions. *Id.* at 47,843.

C. Proceedings Below

1. In an effort "to resolve the pending litigation and prevent future litigation," the agencies "reexamine[d]" the contraceptive-coverage mandate's "exemption and accommodation scheme." 82 Fed. Reg. at 47,799. In October 2017, the agencies jointly issued two rules under which HRSA would expand the exemption to cover not only churches and their integrated auxiliaries, but also other not-for-profit, educational, and for-profit entities that have sincere religious or moral objections to providing contraceptive coverage. See *id.* at 47,835 (religious exemption); *id.* at 47,861-47,862 (moral exemption).[2]

Like prior rules implementing the preventive-services provision, the expanded exemptions were initially authorized through interim final rules—*i.e.*, rules that took effect immediately but simultaneously invited public comment. 82 Fed. Reg. at 47,792, 47,838; see 75 Fed. Reg. 41,726, 41,729-41,730 (July 19, 2010); 76 Fed. Reg. at 46,624; 79 Fed. Reg. at 51,095-51,096. As in those earlier rulemakings, the agencies invoked their statutory authority to issue "interim final rules," 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92,

---

[2] For simplicity, this brief refers primarily to objecting employers, though the rules also apply to other eligible providers of insurance coverage.

without the notice-and-comment procedures ordinarily required by the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.*; see 82 Fed. Reg. at 47,813-47,815, 47,854-47,856; see also 75 Fed. Reg. at 41,755-41,756; 76 Fed. Reg. at 46,625; 79 Fed. Reg. at 51,097-51,098. The agencies additionally concluded that the "good cause" exception to the APA's notice-and-comment requirement, 5 U.S.C. 553(b)(B), permitted them to issue interim rules to protect freedom of conscience and resolve the litigation that had beset the prior rules. 82 Fed. Reg. at 47,813-47,815, 47,854-47,856.

2. Shortly after the agencies issued the interim rules, Pennsylvania filed this suit. It alleged that the interim rules were procedurally invalid because they failed to comply with the APA's notice-and-comment requirement, and were substantively invalid because they violated the ACA and were not justified by RFRA. C.A. App. 193-196. The district court agreed and granted a nationwide preliminary injunction barring implementation of the interim rules. Pet. App. 47a-103a. The government appealed, and its appeal was consolidated with an appeal by the Little Sisters of the Poor Saints Peter and Paul Home (Little Sisters), which had intervened to defend the interim rules. See *id.* at 9a-10a & n.6.

3. In November 2018, while the appeal was pending, the agencies promulgated final rules that incorporated responses to public comments and superseded the interim rules. See 83 Fed. Reg. 57,536 (Nov. 15, 2018) (religious exemption); *id.* at 57,592 (moral exemption).

Like the interim rules, the final rules expand the existing religious exemption to cover not-for-profit, educational, and for-profit organizations that had previously been ineligible. See 83 Fed. Reg. at 57,558-57,566,

57,590 (45 C.F.R. 147.132(a)). The agencies also finalized the exemption for similar entities (except for publicly traded companies) with sincere moral objections to such coverage. See *id.* at 57,614-57,621, 57,630-57,631 (45 C.F.R. 147.133(a)).

As with the original church exemption adopted in 2011, the agencies concluded that Congress had granted HRSA discretion to consider employers' potential conscientious objections to contraceptive coverage in determining what guidelines HRSA would support for purposes of the mandate. 83 Fed. Reg. at 57,540-57,542. The agencies further concluded that, "[b]ecause of the importance of the religious liberty values" and "moral convictions being accommodated," and "the limited impact of these rules," the expanded exemptions "are good policy." *Id.* at 57,552, 57,608.

The agencies also determined that the religious exemption was independently authorized by RFRA. 83 Fed. Reg. at 57,544-57,548. They concluded that RFRA required the religious exemption, *id.* at 57,546-57,548, and that "even if RFRA does not compel" the exemption, "an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*," *id.* at 57,544-57,545.

4. Following issuance of the final rules, New Jersey joined Pennsylvania's suit, and the two States sought an injunction against implementation of the final rules. Pet. App. 11a. The district court again granted a nationwide preliminary injunction. *Id.* at 104a-187a.

The district court concluded that the final rules likely complied with the APA's notice-and-comment requirements, but that the States were likely to succeed on their claim that the final rules were "fatally tainted"

by the procedural flaws identified by the court in the interim rules. Pet. App. 144a; see *id.* at 133a-145a. The court further held that the final rules are unlawful because neither the ACA nor RFRA authorizes the expanded exemption. *Id.* at 146a-168a. The court enjoined the agencies from "enforcing" the final rules "across the Nation." *Id.* at 186a.

5. The government appealed, the court of appeals consolidated that appeal with the earlier appeal, and the court affirmed. Pet. App. 1a-46a.

The court of appeals held that the States are likely to prevail on their claim that the agencies lacked statutory authority to promulgate the final rules. Pet. App. 32a-36a. The court concluded that Section 300gg-13(a) does not confer authority to establish exemptions to the contraceptive-coverage mandate. *Ibid.* It also held that RFRA did not require or permit the agencies to provide the religious exemption, because the existing accommodation already satisfies RFRA. *Id.* at 36a-41a.

The court of appeals further concluded that the final rules are likely procedurally invalid. Pet. App. 23a-32a. The court held that the agencies lacked authority to adopt the interim rules without notice and comment. *Id.* at 23a-28a. The court then concluded that the "deficits in the promulgation of the [interim rules] compromised the procedural integrity of the" final rules, because "[t]he notice and comment exercise surrounding the [f]inal [r]ules d[id] not reflect any real open-mindedness." *Id.* at 30a-32a.

Finally, the court of appeals upheld the injunction's "nationwide" scope. Pet. App. 43a. The court stated that "[a]n injunction geographically limited to the [plaintiff] States alone will not protect them from financial harm, as some share of their residents" are covered by plans

of out-of-state employers and may turn to state-funded services if their plans invoke the exemption. *Id.* at 45a.

SUMMARY OF ARGUMENT

The agencies had statutory authority to adopt the final rules, and they did so consistent with the APA's procedural requirements. The court of appeals' contrary holdings are erroneous and should be reversed. At a minimum, the court's affirmance of the preliminary injunction's nationwide scope was improper.

I. The court of appeals erred in holding that the agencies lacked statutory authority to expand the conscience exemption to the contraceptive-coverage mandate.

A. The plain text of 42 U.S.C. 300gg-13(a)(4) calls for the coverage of additional preventive services for women "as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph." That text allows HRSA ample authority to develop guidelines that account for sincere conscience-based objections to contraceptive coverage. HRSA has exercised that authority to maintain religious exemptions since it first implemented Section 300gg-13(a)(4) in 2011, including by creating the church exemption, which the court of appeals acknowledged is "facially at odds" with its understanding. Pet. App. 33a n.26. The statute's text and context thus refute the court's insistence that HRSA must make all-or-nothing choices about whether to mandate coverage of services like contraception. At a minimum, the agencies' reasonable contrary interpretation is entitled to deference.

B. RFRA also independently required, or at the very least authorized, the religious exemption.

In *Burwell* v. *Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), this Court held that the contraceptive-coverage

mandate, standing alone, substantially burdens the religious exercise of employers that sincerely object to providing such coverage, and that applying the mandate to those employers is not the least restrictive means of furthering any compelling governmental interest.

In adopting the religious exemption at issue here, the agencies acknowledged that, in some cases, a RFRA violation cannot be avoided merely by providing the accommodation as an alternative to direct provision of contraceptive coverage. Many employers sincerely believe, on religious grounds, that the government's use of their health plans to provide contraceptive coverage makes them complicit in providing such coverage. For such employers, requiring compliance with the accommodation would impose the same significant pressure to violate their beliefs—in the form of large monetary penalties for failure to comply—that this Court held to be a "substantial burden" in *Hobby Lobby*. The court of appeals avoided that conclusion only by holding that religious objectors are wrong to believe that using the accommodation would make them complicit in providing contraceptive coverage. But this Court has held that second-guessing the reasonableness of sincere religious beliefs in that manner is not appropriate under RFRA. Nor is application of the accommodation to employers with religious objections the least restrictive means of furthering a compelling governmental interest, as demonstrated by both the numerous other exceptions to the contraceptive-coverage mandate and the alternative avenues available to providing such coverage.

At a minimum, RFRA gives the agencies *discretion* to determine how best to alleviate the substantial burden the mandate creates. RFRA imposes a duty on agencies to avoid implementing federal law in a manner

that imposes substantial burdens on religious exercise unnecessarily. In carrying out that duty, agencies are not obligated to adopt the narrowest accommodation that would be lawful; they can choose to be more protective of religious rights than might be strictly required. Here, the agencies reasonably determined that "the most appropriate administrative response to the substantial burden identified by th[is Court] in *Hobby Lobby*" was to adopt the expanded religious exemption. 83 Fed. Reg. at 57,545.

II. The court of appeals further erred in holding that the final rules are invalid because of perceived procedural defects in the interim rules. The final rules, which are the only agency actions now at issue, fully complied with the required notice-and-comment procedures. Nothing in the APA suggests that procedural defects in the *interim* rules invalidate the *final* rules. In any event, the interim rules were procedurally valid because they were expressly authorized by statute and supported by good cause.

III. At the very least, this Court should vacate the nationwide preliminary injunction and limit any relief to the injuries of the plaintiff States. The sweeping nonparty relief ordered here contravenes bedrock principles of Article III and equity, and illustrates the problems with nationwide injunctions' increasing disruption of the federal-court system. If the Court does not uphold both rules on the merits, it should take this opportunity to resolve the status of nationwide injunctions, reiterating that judicial relief may be no broader than necessary to resolve the injuries of the plaintiffs to a particular case or controversy.

ARGUMENT

In *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016) (per curiam), this Court declined to decide whether the contraceptive-coverage mandate violated RFRA notwithstanding the accommodation that the agencies had offered to objecting organizations. Instead, the Court chose to allow the agencies and other parties to explore potential ways to resolve their disagreements. See *id.* at 1560-1561. The rules at issue here are the result of those efforts. After extensive but ultimately unsuccessful attempts to identify a modification of the accommodation that would satisfy all parties, the agencies determined that the best course was to leave the mandate in place but exempt those with sincere religious or moral objections to providing contraceptive coverage. The ACA grants the agencies authority to address conscience-based objections in that fashion, as evidenced by the church exemption that HRSA included when it first issued guidelines in 2011. Congress had no reason to create an all-or-nothing choice, in which the only way to avoid burdening the sincere religious or moral beliefs of *some* employers was to eliminate the coverage requirement for *all* employers. That conclusion is strongly reinforced by RFRA, which requires—or at least authorizes—the agencies to avoid the substantial burden the prior regime placed on the ability of objecting organizations to operate in accordance with their religious beliefs. The court of appeals erred in enjoining the agencies' effort to bring this long-running controversy to an end, and especially in doing so on a nationwide scale disconnected from the interests of the parties to this case. The decision below should be reversed.

I. THE AGENCIES HAD STATUTORY AUTHORITY TO ADOPT THE EXPANDED EXEMPTIONS

The ACA gives HRSA discretion to include religious and moral exemptions in the guidelines it develops and supports for purposes of the women's preventive-services mandate. 42 U.S.C. 300gg-13(a)(4). And RFRA independently requires—or at least authorizes—the expanded religious exemption.

A. The ACA Authorizes Both Expanded Exemptions

1. Under 42 U.S.C. 300gg-13(a)(4), a non-grandfathered group health plan "shall * * * provide coverage" without cost sharing for, "with respect to women, such additional preventive care and screenings * * * as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph."

The expanded religious and moral exemptions fall comfortably within this statutory text. The sweeping authorization for HRSA to "provide[] for" and "support[]" guidelines "for purposes of" the women's preventive-services mandate clearly grants HRSA the power not just to specify what services should be covered, but also to provide appropriate exemptions. 42 U.S.C. 300gg-13(a)(4). Under the guidelines HRSA promulgated pursuant to the final rules, a health plan must provide coverage of each form of FDA-approved contraception for women if—but only if—the organization that established or maintained the health plan does not have religious or moral objections to such coverage. See HRSA, *Women's Preventive Services Guidelines*, at n.**; see also 45 C.F.R. 147.132-147.133. A health plan therefore complies with the statutory requirement to provide coverage "for * * * such additional preventive care and screenings * * * as provided for in [HRSA's] comprehensive guidelines," 42 U.S.C. 300gg-13(a)(4), so

long as the plan covers all forms of contraception to which no such conscientious objections exist. Where such conscientious objections do exist, the "comprehensive guidelines supported by [HRSA]" do not include a coverage requirement, and the statute thus does not impose one. *Ibid.*

The context in which Section 300gg-13(a)(4) appears strongly supports that reading. In the three preceding paragraphs, Congress required health plans to provide coverage for preventive services identified in specific, preexisting guidelines and regulations that had been developed for purposes unrelated to the ACA. See 42 U.S.C. 300gg-13(a)(1)-(3). Those paragraphs all lack the "as provided for" and "for purposes of this paragraph" language that Congress included in 42 U.S.C. 300gg-13(a)(4). That textual difference confirms that in the distinct area of preventive services for women, which could potentially include the sensitive subject of contraception, Congress conferred on HRSA authority to develop new guidelines designed with a specific "purpose[]" in mind—setting the conditions under which coverage would be required by law, rather than (as with the preexisting guidelines) simply providing recommendations to medical professionals about best practices. *Ibid.*

Consistent with that understanding, Congress omitted in Section 300gg-13(a)(4) a requirement that HRSA's guidelines with respect to preventive services for women be "evidence-based" or "evidence-informed." 42 U.S.C. 300gg-13(a)(1) and (3). Read in contrast with the nearby provisions that contain such requirements, see *ibid.*, that omission confirms HRSA's authority to consider a more comprehensive set of factors in deciding the circumstances in which it would "support[]" a coverage

mandate for a particular service, including taking account of potential conscientious objections. 42 U.S.C. 300gg-13(a)(4); see *Russello* v. *United States*, 464 U.S. 16, 23 (1983).

The agencies have understood Section 300gg-13(a)(4) this way from the outset. In 2011, the agencies explained that the preexisting guidelines referenced in Sections 300gg-13(a)(1)-(3) "were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients," whereas the new HRSA guidelines referenced in Section 300gg-13(a)(4) "exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women." 76 Fed. Reg. at 46,623. Given Congress's choice to give "HRSA the authority to develop comprehensive guidelines * * * 'for purposes of this paragraph,'" the agencies concluded in 2011 that "it is appropriate that HRSA, in issuing these Guidelines, takes into account the effect on the religious beliefs of certain religious employers if coverage of contraceptive services were required in the group health plans in which employees in certain religious positions participate." *Ibid.* (citation omitted). To be sure, the specific lines the agencies drew in 2011 were different from the ones drawn in the final rules under review here—but the recognition of authority to draw those lines, and to take account of conscientious objections in doing so, is exactly the same.

This reading of Section 300gg-13(a)(4) is also consistent with Congress's purposes. As this Court has recognized, Congress chose "not [to] specify what types of preventive care must be covered" under that provision, but "[i]nstead * * * authorized [HRSA] to make

that important and sensitive decision." *Burwell* v. *Hobby Lobby Stores, Inc.*, 573 U.S. 682, 697 (2014). Having decided to give HRSA authority to make this "important and sensitive decision" in its best judgment, *ibid.*, Congress had no reason to create a system in which the only way HRSA could account for the conscientious objections of some employers—which the States do not dispute HRSA can do—is to create no coverage requirement for *any* employer. Instead, as the plain text of Section 300gg-13(a)(4) makes clear, HRSA may "support[]" guidelines that "provide[] for" contraceptive coverage "for purposes of" that provision only by employers that do not have sincere religious or moral objections. 42 U.S.C. 300gg-13(a)(4).

At the very least, the foregoing shows that the agencies' consistent interpretation of Section 300gg-13(a)(4) is reasonable in light of the statutory text and context, and thus entitled to deference. See *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984). The court of appeals' decision could be reversed on that basis alone.

2. In concluding that the final rules exceeded the agencies' authority under the ACA, the court of appeals emphasized that Section 300gg-13(a) uses the word "'shall,'" which "denotes a requirement." Pet. App. 33a (citation omitted). In the court's view, that use of "'shall'" means that "[t]he authority to issue 'comprehensive guidelines' concerns the type of services that are to be provided," but "does not provide authority to undermine Congress's directive concerning who must provide coverage for these services." *Ibid.*

That approach misreads the statute. Section 300gg-13(a)(4) directs that a non-grandfathered health plan "shall" offer coverage, without cost sharing, "as

provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. 300gg-13(a)(4). That obligation to comply with the guidelines is unquestionably mandatory, as the court of appeals noted. But the fact that a plan has a mandatory obligation to offer coverage "as provided for" in guidelines supported by HRSA has no bearing on what sort of coverage requirement HRSA may determine to "support[]" for that plan. *Ibid.* On the contrary, Section 300gg-13(a)(4) expressly contemplates that HRSA will decide what it will or will not "provide[] for" and "support[]" in the guidelines it issues "for purposes of" that provision. *Ibid.*

The church exemption adopted in 2011 illustrates the proper understanding of the statute. There, HRSA supported guidelines under which the health plans of churches and their integrated auxiliaries were not required to cover contraception, even though contraceptive methods were listed in the guidelines for purposes of requiring coverage by *other* employers. See 76 Fed. Reg. at 46,623. Churches' health plans were not thereby excused from the statutory obligation to provide coverage "as provided for" in HRSA's guidelines. 42 U.S.C. 300gg-13(a)(4). Rather, the guidelines were drafted in such a way as to provide different requirements for churches and their integrated auxiliaries than for other employers. Nothing in the statute prevented HRSA from drafting its guidelines in that way then, and nothing does today.

The court of appeals' interpretation of Section 300gg-13(a)(4), by contrast, would foreclose the longstanding church exemption. Indeed, the court itself acknowledged as much. See Pet. App. 33a n.26. To be sure, the court attempted to explain that inconsistency away on the ground that the church exemption might be

required by the First Amendment's Free Exercise Clause, pointing to this Court's precedents affirming "ministerial exception[s]" to other statutes. *Id.* at 34a n.26. But the church exemption is not tailored to the ministerial exception or any other cognizable First Amendment concern. The church exemption applies to *all* employees of a church or integrated auxiliary, regardless of whether they have religious functions that would qualify for the ministerial exception. See *Hosanna-Tabor Evangelical Lutheran Church & Sch.* v. *EEOC*, 565 U.S. 171, 192-193 (2012). The church exemption also applies to *all* churches and integrated auxiliaries, regardless of whether they have religious objections to contraception. See 45 C.F.R. 147.131(a) (2016). Contrary to the court of appeals' attempted reconceptualization, the church exemption was justified by the statutory authority the agencies cited when it was adopted in 2011: Section 300gg-13(a)(4). And once it is accepted that HRSA had statutory authority under that provision to create an exemption for churches, nothing in the statute or elsewhere supports the court of appeals' position that HRSA could not expand that exemption to other, non-church entities with conscientious objections to the mandate.

B. RFRA Requires Or At Least Authorizes The Expanded Religious Exemption

1. RFRA requires the expanded religious exemption

The religious exemption is independently required by RFRA, which prohibits the government from "substantially burden[ing] a person's exercise of religion" unless the government "demonstrates that" application of the burden to that person is "the least restrictive

means" of furthering a "compelling governmental interest." 42 U.S.C. 2000bb-1(b).

a. In *Hobby Lobby*, this Court addressed whether application of the contraceptive-coverage mandate to employers that "object on religious grounds to providing health insurance that covers" certain methods of contraception is consistent with RFRA. 573 U.S. at 720. The Court held that it is not. See *id.* at 719-732.

Addressing the threshold "substantial burden" question, the Court explained that if objecting employers "do not yield to th[e mandate's] demand" that they provide coverage to which they object on religious grounds, "the economic consequences will be severe." *Hobby Lobby*, 573 U.S. at 720-721. Given those consequences, the Court had "little trouble concluding" that the mandate imposes a substantial burden on the employers' exercise of religion: "Because the contraceptive mandate forces [objecting employers] to pay an enormous sum of money * * * if they insist on providing insurance coverage in accordance with their religious beliefs, the mandate clearly imposes a substantial burden on those beliefs." *Id.* at 719, 726. The Court rejected the argument that "the connection between what the objecting parties must do" and "the end that they find to be morally wrong * * * is simply too attenuated." *Id.* at 723. So long as the asserted religious belief is sincere, the Court explained, "federal courts have no business addressing * * * whether the religious belief asserted in a RFRA case is reasonable." *Id.* at 724.

The Court then held that the mandate is not the least restrictive means of furthering a compelling governmental interest. *Hobby Lobby*, 573 U.S. at 726-732. Even "assum[ing] that the interest in guaranteeing cost-free access" to contraception is compelling, the

Court concluded that the mandate does not comply with RFRA's "exceptionally demanding" "least-restrictive-means standard." *Id.* at 728. The "most straightforward" way for the government to provide its desired contraceptive access, the Court explained, "would be for the Government to assume the cost of providing the [objected-to] contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." *Ibid.* Ultimately, though, the Court concluded that it did not need to "rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive-means test." *Id.* at 730. That was because the accommodation the agencies had previously created for certain not-for-profit religious organizations that were ineligible for the church exemption, see pp. 4-5, *supra*, "demonstrated that [the government] has at its disposal an approach that is less restrictive" than the mandate. 573 U.S. at 730. For that reason, RFRA prohibited application of the mandate to Hobby Lobby and the other objecting plaintiffs. *Ibid.* The Court emphasized, however, that because the accommodation was sufficient to address "the religious beliefs asserted" by the specific parties before the Court, it did not need to decide—and therefore did not decide—whether the accommodation was enough to "compl[y] with RFRA for purposes of *all* religious claims." *Id.* at 731 & n.40 (emphasis added).

b. Considering the issue that the Court specifically reserved in *Hobby Lobby*, the agencies have now concluded that the accommodation is not sufficient to comply with RFRA for all religious claims. 83 Fed. Reg. at 57,545-57,548. Accordingly, a broader religious exemption is required. See *ibid.*

i. The accommodation does not eliminate the substantial burden that the contraceptive-coverage mandate imposes on certain employers with conscientious objections. As became clear in litigation following *Hobby Lobby*, some employers hold the sincere religious belief that participating in a process by which their employees receive contraceptive coverage "makes them complicit in providing [that] coverage," even if the coverage is actually paid for by other parties. *Priests for Life* v. *United States Dep't of Health & Human Servs.*, 808 F.3d 1, 15 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from the denial of rehearing en banc). Those employers believe that the accommodation is such a process because it commandeers their own health plans to provide coverage, and requires them to facilitate notification to the health plan issuer or third-party administrator that will, upon receiving such notification, provide contraceptive coverage in connection with their plans. See *id.* at 25 n.11; see also *Sharpe Holdings, Inc.* v. *United States Dep't of Health & Human Servs.*, 801 F.3d 927, 939-943 (8th Cir. 2015), vacated and remanded, 136 S. Ct. 2006 (2016); 83 Fed. Reg. at 57,546. Offering the accommodation as an alternative means of compliance with the mandate thus leaves in place the same "substantial burden on the ability of the objecting parties to conduct business in accordance with their religious beliefs" that this Court identified in *Hobby Lobby*. 573 U.S. at 724 (emphasis omitted). If the objecting employers "d[id] not yield to th[e] demand" to violate their beliefs, the "economic consequences" would be every bit as "severe." *Id.* at 720. Indeed, the very same $100-per-day-per-employee tax, or $2000-per-year-per-employee penalty, would apply. See *ibid.*; see also 26 U.S.C. 4980D, 4980H; *Priests for Life*, 808 F.3d

at 19 (Kavanaugh, J., dissenting) (concluding that the accommodation imposes a substantial burden on RFRA plaintiffs "under *Hobby Lobby*").

The court of appeals did not dispute the severe economic consequences that such employers would face if they followed their religious beliefs and refused to comply. Nor did it dispute the sincerity of those religious beliefs. Instead, the court held that the employers' objections are misplaced because, in the court's view, "the submission of the self-certification form does *not* make the employers 'complicit' in the provision of contraceptive coverage." Pet. App. 39a (emphasis added; brackets and citation omitted). The court reasoned that "[f]ederal law, rather than any involvement by the employers in filling out or submitting the self-certification form, creates the obligation of the insurance issuers and third-party administrators to provide coverage for contraceptive services." *Ibid.* (brackets and citation omitted).

That approach to assessing the existence of a substantial burden cannot be reconciled with this Court's decision in *Hobby Lobby*, which the court of appeals largely ignored. See Pet. App. 36a-41a. *Hobby Lobby* squarely held that the courts could not reject the RFRA claim concerning contraceptive coverage on the ground that "the connection between what the objecting parties must do" and "the end that they find to be morally wrong" is "too attenuated." 573 U.S. at 723. So long as a claimant's asserted belief "reflects 'an honest conviction'" about the answer to that question, "it is not for [courts] to say" that those "religious beliefs are mistaken." *Id.* at 725 (citation omitted). *Hobby Lobby* thus "adamantly rejected the basic premise of the" argument embraced by the decision below. *Priests for Life*, 808 F.3d

at 18 (Kavanaugh, J., dissenting); see *id.* at 19 ("Judicially second-guessing the correctness * * * of plaintiffs' religious beliefs is exactly what the Supreme Court in *Hobby Lobby* told [lower courts] not to do."); cf. *Thomas* v. *Review Bd. of the Ind. Emp't Sec. Div.*, 450 U.S. 707, 714-716 (1981); *Hobby Lobby Stores, Inc.* v. *Sebelius*, 723 F.3d 1114, 1152 (10th Cir. 2013) (en banc) (Gorsuch, J., concurring), aff'd, 573 U.S. 682 (2014).

ii. Because requiring religious objectors to comply with the mandate through the accommodation would impose a "substantial[] burden" on their religious exercise, the agencies could demand such compliance only if they "demonstrate[] that application of the" accommodation "is the least restrictive means of furthering [a] compelling governmental interest." 42 U.S.C. 2000bb-1(b). The agencies have now recognized that they cannot make that showing. See 83 Fed. Reg. at 57,546-57,548. Under RFRA, therefore, the agencies were required to provide an exemption for religious objectors.

In assessing whether an asserted governmental interest is compelling, this Court has explained that "a law cannot be regarded as protecting an interest of the highest order . . . when it leaves appreciable damage to that supposedly vital interest unprohibited." *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah*, 508 U.S. 520, 547 (1993) (citation and internal quotation marks omitted); see *Gonzales* v. *O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 433 (2006) (applying same principle under RFRA). Applying that principle here compels the agencies' conclusion. Neither the contraceptive-coverage mandate itself nor the accommodation has ever been applied to the tens of thousands of employers that qualify as "churches, their integrated auxiliaries, and conventions or associations

of churches," 26 U.S.C. 6033(a)(3)(A)(i); see 76 Fed. Reg. at 46,623; 83 Fed. Reg. at 57,580. And since 2013, the accommodation has provided an effective exemption for self-insured "[c]hurch plans" of certain church-affiliated organizations, because their third-party administrators are not subject to regulation under ERISA. 79 Fed. Reg. at 51,095 n.8. That is particularly significant because this effective exemption applies to some large religious universities and hospitals, based solely on their classification under ERISA. See pp. 4-5, *supra*. Given those existing exceptions, the agencies correctly determined that applying the mandate or accommodation to other religious objectors was not necessary to satisfy a compelling governmental interest. See 83 Fed. Reg. at 57,546-57,548.

This Court's decision in *O Centro Espirita* is directly analogous. There, the Court held that the existence of an exemption from requirements of the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, for some religious adherents (those who use peyote for religious purposes) "fatally undermine[d]" the position that denying a similar exemption to other religious adherents (those who use hoasca) was necessary to advance a compelling governmental interest. 546 U.S. at 434; see *id.* at 433-435. Similarly here, the agencies' experience with the existing exemptions has shown that while mandating contraceptive coverage may make such coverage more "seamless" for plan beneficiaries, no "compelling government interest" will be "undermined" by allowing additional religious objectors to opt out. 83 Fed. Reg. at 57,548.

This is particularly so given the alternative avenues available for obtaining contraceptive coverage. For example, many women could obtain such coverage through the health plans of other family members. See 83 Fed.

Reg. at 57,551. In addition, existing federal, state, and local programs provide free or subsidized contraceptives to low-income women. See *ibid.*; see also *Hobby Lobby*, 573 U.S. at 728-730 (noting potential less-restrictive alternative is for the government "to assume the cost" of providing coverage to the employees of objecting employers).

In light of the foregoing, the agencies correctly concluded that RFRA prohibited them from imposing on religious objectors the substantial burden that compliance with the mandate (whether through the accommodation or otherwise) would entail.

2. RFRA authorizes the expanded religious exemption

a. At the very least, RFRA authorizes the agencies to adopt the expanded religious exemption. In RFRA, Congress instructed agencies to avoid imposing substantial burdens on religious exercise that they determine are unnecessary to any compelling governmental interest. Congress did so by making RFRA applicable to "the implementation" of "all Federal law," 42 U.S.C. 2000bb-3(a), and by directing the statute's central command to the "[g]overnment," 42 U.S.C. 2000bb-1(a)-(b); see *ibid.* ("[The g]overnment shall not substantially burden a person's exercise of religion" unless the "[g]overnment * * * demonstrates" that doing so is "the least restrictive means of furthering [a] compelling governmental interest."). Accordingly, where an agency determines that its mode of implementing federal law would substantially and unnecessarily burden a person's exercise of religion, the Executive Branch has the authority—consistent with the responsibility to "take [c]are that the [l]aws be faithfully executed," U.S. Const. Art. II, § 3—to modify its implementation to avoid a violation of RFRA.

Critically, RFRA does not dictate the *means* by which the agencies must satisfy that duty here. As the agencies explained, "[a]lthough RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest," RFRA does not "prescribe[] the remedy by which the government must eliminate that burden." 83 Fed. Reg. at 57,545 (emphasis omitted). Likewise, this Court in *Hobby Lobby* held that the contraceptive-coverage mandate impermissibly "imposes a substantial burden" on objecting employers, 573 U.S. at 726, but it did not determine how the government may or must eliminate that burden, noting only that the existing accommodation would be a suitable less-restrictive alternative for the particular employers in that case. See *id.* at 731.

Accordingly, the agencies, after years of consultation and litigation, eventually determined that "the most appropriate administrative response to the substantial burden identified * * * in *Hobby Lobby*" was to expand the religious exemption. 83 Fed. Reg. at 57,545. They explained that while "[t]he prior administration *chose*" to attempt to comply with RFRA "through the complex accommodation," RFRA did not "compel[] that novel choice or prohibit[] the current administration from employing the more straightforward choice of an exemption." *Ibid.* The agencies further observed that if they had "simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead." *Ibid.* It would therefore make little sense to conclude that, having opted to try to resolve religious

objections through use of the accommodation, the agencies were forever committed to that complicated and controversial approach by mere "path dependence." *Ibid.*

The agencies' discretion to explore alternative means of addressing the substantial burden imposed by the mandate was especially clear here because of the "continued litigation" and "legal uncertainty" over whether the existing accommodation was sufficient. 83 Fed. Reg. at 57,545; see *Ricci* v. *DeStefano*, 557 U.S. 557, 585 (2009). In *Ricci*, this Court recognized that an entity faced with potentially conflicting statutory obligations should be afforded some leeway in resolving that conflict. 557 U.S. at 585. "[T]o resolve any conflict between the disparate-treatment and disparate-impact provisions of" Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.*, the Court held that an employer need only have a strong basis to believe that an employment practice violates the disparate-impact ban in order to take certain remedial actions that would otherwise violate its disparate-treatment ban. *Ricci*, 557 U.S. at 584; see *id.* at 583-585. Similarly here, the agencies reasonably responded to the considerable doubt about the sufficiency of the accommodation by adopting the religious exemption. Cf. *Walz* v. *Tax Comm'n*, 397 U.S. 664, 669 (1970) (recognizing "room for play in the joints" when accommodating exercise of religion).

b. The court of appeals never directly addressed the agencies' determination that, "even if RFRA does not compel" the exemption, RFRA at least permits them to adopt it. 83 Fed. Reg. at 57,544; see Pet. App. 36a-41a. The closest the court came was its statement that "[b]ecause Congress has deemed the courts the adjudicator of private rights of actions under RFRA, * * * we

owe the Agencies no deference when reviewing determinations based upon RFRA." Pet. App. 37a (citation omitted).

To the extent that statement suggests agencies lack authority to modify existing regulations in order to avoid what they reasonably perceive to be a RFRA violation, it is incorrect. As the court of appeals itself recognized, courts are the "adjudicator[s] of private *rights of actions* under RFRA." Pet. App. 37a (emphasis added). When a party brings suit alleging that the government has violated RFRA, therefore, a court must resolve those legal claims for itself. It does not follow, however, that the government lacks any discretion about how to avoid violations in the first place. As noted (see p. 27, *supra*), Congress addressed RFRA's operative command to the "[g]overnment," not simply to courts. 42 U.S.C. 2000bb-1(a)-(b). The judiciary can of course provide relief when the government has *exceeded* RFRA's bounds. 42 U.S.C. 2000bb-1(c). But nothing in the statute requires the government to press right up against what a court might find those outer bounds to be.

c. Finally, the court of appeals separately reasoned that the religious exemption was impermissible under RFRA because it would "impose an undue burden on nonbeneficiaries—the female employees who will lose coverage for contraceptive care." Pet. App. 41a. As the Court in *Hobby Lobby* recognized, however, a RFRA remedy is not invalid merely because it allows a religious objector to withhold a benefit from third parties. 573 U.S. at 729 n.37. Such a remedy simply leaves the third parties in the same place they would have been in if the government had not regulated the religious objector in the first place.

This Court's decisions in the analogous context of the First Amendment confirm that principle. In *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos*, 483 U.S. 327 (1987), for example, the Court rejected an Establishment Clause challenge to Title VII's religious exemption to the bar on religious discrimination in employment, even though that result required affirming the employer's right to terminate the plaintiff's employment. *Id.* at 329-330. While the plaintiff was "[u]ndoubtedly" adversely affected, the Court observed, "it was the Church[,] * * * not the Government, who put him to the choice of changing his religious practices or losing his job." *Id.* at 337 n.15. And the Church's employees had no right to insist that the government extend Title VII's general prohibition to reach the Church. See *ibid.*

The same reasoning applies here. Congress has not created a statutory right to contraceptive coverage. The contraceptive-coverage mandate comes only from HRSA's regulatory decision, and all agree that HRSA could choose to reverse that decision and exclude contraceptive coverage from the preventive-services mandate entirely. That HRSA has taken the lesser step of supporting exemptions—first the church exemption in 2011, then the effective exemption for self-insured church plans in 2013, and now the expanded exemption—does not burden plan beneficiaries in any sense relevant here, because they are no worse off than before HRSA chose to act in the first place.

II. THE FINAL RULES ARE PROCEDURALLY VALID

The final rules are procedurally valid, regardless of whether the interim rules were properly adopted. In any event, the interim rules were procedurally valid too.

A. The Final Rules Comply With The APA's Procedural Requirements Regardless Of Whether The Interim Rules Did

The APA generally requires federal agencies to provide notice and an opportunity for public comment before issuing binding rules. 5 U.S.C. 553(b)-(c). That is precisely what the agencies did in issuing the final rules here. The final rules are accordingly valid. Contrary to the court of appeals' mistaken view, any perceived procedural "deficits in the promulgation of the" now-superseded *interim* rules did not somehow "compromise[] the procedural integrity of the" *final* rules. Pet. App. 31a.

1. The final rules comply with the APA's procedural requirements

a. When a federal agency issues substantive rules, it typically must comply with Section 4 of the APA, 5 U.S.C. 553, which "prescribes a three-step procedure for so-called 'notice-and-comment rulemaking,'" *Perez* v. *Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015). First, the agency must publish a "notice of proposed rule making" or otherwise provide "actual notice" of specified information about the rule. 5 U.S.C. 553(b). Second, the agency must "give interested persons an opportunity to participate in the rule making through submission of" comments. 5 U.S.C. 553(c). Finally, the "agency must consider and respond to significant comments," *Perez*, 575 U.S. at 96, and "incorporate in the" rule "a concise general statement of [its] basis and purpose," 5 U.S.C. 553(c).

The APA creates several exceptions to those requirements. Of relevance here, an agency can issue an immediately effective rule if it finds "good cause" that notice-and-comment procedures would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C.

553(b)(B). In addition, subsequent statutes can "supersede or modify" the APA's notice-and-comment requirements if they "do[] so expressly." 5 U.S.C. 559.

In some cases, agencies that adopt rules under exceptions to the notice-and-comment requirement nevertheless voluntarily solicit public input. They often do so through an "interim final rule," which takes effect immediately but is later superseded by a final rule incorporating the agency's response to comments. 1 Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 5.10, at 647 (6th ed. 2019). Interim final rules thus provide "a practical compromise between the need for temporal urgency and the desirability of public participation," and they have been broadly encouraged and adopted. *Ibid.*; see Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 Admin. L. Rev. 703, 704-727 (1999) (Asimow); 60 Fed. Reg. 43,108, 43,110-43,113 (Aug. 18, 1995).

b. The agencies at issue here created the religious and moral exemptions through interim rules, 82 Fed. Reg. at 47,792, 47,838, which were later superseded by the final rules, 83 Fed. Reg. at 57,536, 57,592. It is undisputed that the interim rules no longer have any binding effect. See *ibid.* The States' only live challenge is thus to the *final* rules. See Pet. App. 13a-14a, 133a.

The final rules complied with the relevant procedural requirements under a "straightforward reading of the APA." *Perez*, 575 U.S. at 101. The agencies provided "notice" and invited comments from "interested" members of the public, 5 U.S.C. 553(b)-(c), when they issued the interim rules, 82 Fed. Reg. at 47,792, 47,838. The agencies then issued the final rules "with changes [to the interim rules] based on comments." 83 Fed. Reg. at

57,540, 57,596. The agencies also provided detailed "respon[ses] to significant comments," *Perez*, 575 U.S. at 96, along with thorough explanations for their decisions, see 83 Fed. Reg. at 57,540-57,573, 57,596-57,625.

The "States do not argue" that "the notice provided [through the interim rules] was inadequate." Pet. App. 137a n.17. And while the States contended in the district court that the agencies had not adequately responded to comments, the court rejected that claim, *id.* at 135a-137a, and the States did not press it in the court of appeals, see *id.* at 30a n.24. The States thus effectively concede that the agencies' procedures for adopting the final rules "followed the statutory mandate of the" APA. *Vermont Yankee Nuclear Power Corp.* v. *Natural Res. Def. Council, Inc.*, 435 U.S. 519, 547 (1978). The APA requires no more. *Id.* at 548. The final rules are accordingly procedurally valid.

2. Any procedural defects in the interim rules do not undermine the procedural validity of the final rules

a. The court of appeals held that the final rules were procedurally invalid not because they failed to comply with the APA's notice-and-comment requirements, but because they did "not reflect any real open-mindedness toward the position set forth in the" *interim rules*. Pet. App. 30a. That conclusion has no foundation in the APA and provides no basis for enjoining the final rules.

i. The APA requires "reasoned decisionmaking." *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 520 (2009). As noted above, it also requires agencies to consider and respond to significant comments. *Perez*, 575 U.S. at 96. Those statutory obligations could be paraphrased as requiring that agencies "remain 'open-minded' about the issues raised and engage with the substantive responses submitted." *Prometheus Radio*

Project v. *FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (citation omitted). But the court of appeals here did not conclude that the agencies lacked open-mindedness in that sense. Cf. Pet. App. 30a n.24. The court instead adopted a distinct and more stringent requirement of what it termed "real open-mindedness," applicable only when a final rule follows an allegedly invalid interim rule. *Id.* at 30a.

The APA contains no such additional requirement. The court of appeals' imposition of a novel, heightened standard for notice-and-comment rulemaking therefore conflicts with the "longstanding principle[]" that the APA "'sets forth the *full extent* of judicial authority to review executive agency action for procedural correctness.'" *Perez*, 575 U.S. at 101-102 (emphasis added; citation omitted); see *Vermont Yankee*, 435 U.S. at 525 ("cautioning reviewing courts against engrafting their own notions of proper procedures upon agencies"). This Court has reversed lower courts for transgressing that principle. See *Perez*, 575 U.S. at 102-103; *Vermont Yankee*, 435 U.S. at 548. It should do the same here. "So long as the agency meets normal APA standards by giving consideration to material public comments, it should not matter that the request for comments accompanied an invalidly-adopted interim rule." Asimow 726.

ii. Even if some additional demonstration of open-mindedness were required when an agency finalizes interim rules, the agencies readily satisfied that requirement here. The agencies carefully revisited and explained their reasons for adopting the final rules in light of the comments, some of which they incorporated and some of which they did not. See, *e.g.*, 83 Fed. Reg. at 57,557-57,558, 57,568-57,571, 57,616-57,619, 57,622-57,623.

The court of appeals held that the agencies failed to display "real open-mindedness" principally because the

final rules included only "minor changes" from the interim rules. Pet. App. 30a; see *ibid.* (stating that the final rules "simply echoed" the reasoning supporting the interim rules). The court's position is untenable. The APA does not require a final rule to include major changes from a proposed rule. Nor does it require an agency to provide different reasons for a final rule than were offered for a proposed rule. On the contrary, the APA requires a proposed rule to provide "fair notice" of the final rule's content, and a final rule that departs too far from the proposal may violate Section 553. *Long Island Care at Home, Ltd.* v. *Coke*, 551 U.S. 158, 174 (2007). Nothing suggests that a different principle should apply when an agency adopts a final rule that had its genesis in an interim rule—especially one that solicited public comment.

Indeed, if the comments opposing an interim rule are ill considered, it would be the opposite of "reasoned decisionmaking," *Fox*, 556 U.S. at 520, for an agency to nevertheless make changes to the interim rule simply to demonstrate an "open mind," Pet. App. 30a (citation omitted). Moreover, under the court of appeals' view, it is unclear how an agency could ever purge the purported "taint" from a procedurally defective but substantively reasonable interim rule. Such a proposition cannot be squared with the APA's recognition that harmless errors do not require invalidating agency action. 5 U.S.C. 706; see *Shinseki* v. *Sanders*, 556 U.S. 396, 407 (2009).

In sum, while "changes or revisions" in response to comments may be "indicative of an open mind," an "agency's failure to make any does not mean its mind is closed." *Advocates for Highway & Auto Safety* v. *Federal Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir.

1994). Where, as here, an agency considers and explains its response to comments in a final rule, the final rule is procedurally valid even if the interim rule was not. See, *e.g.*, *ibid.*; *Levesque* v. *Block*, 723 F.2d 175, 185, 188-189 (1st Cir. 1983).

b. The court of appeals alternatively held that the interim rules "impaired the rulemaking process by altering the [a]gencies' starting point in considering the" final rules, thereby "chang[ing] the question presented concerning the [f]inal [r]ules from whether they should create the exemptions to whether they should depart from them." Pet. App. 30a-31a. That reasoning is equally misguided.

As a factual matter, the interim rules did not pose the "question * * * whether the[agencies] should depart from" the interim rules. Pet. App. 31a. The agencies did not, for example, suggest that the interim rules would be afforded any reliance interests or presumption of correctness. The agencies instead "request[ed] and encourage[d] public comments on all matters addressed in the[] interim final rules," 82 Fed. Reg. at 47,813, 47,854, thus serving as a notice of proposed rulemaking with respect to final rules. Any suggestion that status quo bias motivated the agencies to finalize the interim rules is especially inapposite here because the interim rules had been enjoined for virtually their entire existence. See Pet. App. 101a-103a. The interim rules thus did not represent even the temporary status quo ante when the agencies adopted the final rules.

The court of appeals suggested that allowing the final rules to remain in effect would give agencies an incentive "to circumvent" the APA. Pet. App. 31a (citation omitted). That assertion is misplaced. To begin, it

disregards the presumption of regularity owed to agencies. See, *e.g.*, *Citizens to Pres. Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 415 (1971). Moreover, it is both speculative and puzzling. The States offer no evidence that agencies commonly concoct false claims of good cause to allow their rules to take effect without notice and comment, only to simultaneously and voluntarily solicit public comment. That is likely because rational agencies have no incentive to make bad-faith claims of good cause. By issuing an unjustified interim rule likely to be invalidated, an agency would subject itself to burdensome litigation fated to result in the loss of any benefits that came from the interim rule, and also likely to complicate its defense of the final rule. Whatever the hypothetical incentives for gamesmanship, agencies do not take such risks in reality. Cf. *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2421 (2019) (plurality opinion).

B. The Interim Rules Were Procedurally Valid

In any event, the interim rules were procedurally valid, and thus provide no basis for enjoining the final rules. Under the APA, an agency may issue rules without prior notice and comment if Congress has "expressly" authorized it to do so in other statutes, 5 U.S.C. 559, or if the agency establishes "good cause," 5 U.S.C. 553(b)(B). The agencies properly invoked both grounds here.

1. The interim rules were expressly authorized by statutes other than the APA

Identical provisions of the PHSA, ERISA, and the Internal Revenue Code authorize the agencies to "promulgate such regulations as may be necessary or appropriate to carry out the [specified statutes]," and

also to "promulgate any interim final rules as the Secretary determines are appropriate." 42 U.S.C. 300gg-92; 29 U.S.C. 1191c; 26 U.S.C. 9833. That "express[]" conferral of authority "supersede[s]" the APA's default notice-and-comment requirements and justifies the interim rules at issue here. 5 U.S.C. 559.

That conclusion follows from the statutory text. Congress authorized the agencies to issue "any interim final rules as the Secretary determines are appropriate" in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, Tit. I, Subtit. A, §§ 101, 102, Tit. IV, Subtit. A, § 401(a), 110 Stat. 1951, 1976, 2082. At that time, the term "interim final rules" was widely understood to describe rules issued without the APA's default notice-and-comment procedures. *Ibid.* In 1995, for example, the Administrative Conference of the United States published recommendations explaining that agencies "commonly" use the term "'interim final rulemaking' to describe the issuance of a final rule *without prior notice and comment*, but with a post-promulgation opportunity for comment." 60 Fed. Reg. at 43,111 (emphasis added); see, *e.g.*, *Bowen* v. *American Hosp. Ass'n*, 476 U.S. 610, 618-619 (1986) (plurality opinion) (contrasting an "Interim Final Rule" on which HHS did not "solicit public comment" before promulgation with "Proposed Rules" on which "it invited comment"). Congress naturally incorporated that settled understanding into its authorization for the agencies to issue "any interim final rules as the Secretary determines are appropriate." 42 U.S.C. 300gg-92; 29 U.S.C. 1191c; 26 U.S.C. 9833; see, *e.g.*, *Food Mktg. Inst.* v. *Argus Leader Media*, 139 S. Ct. 2356, 2362 (2019).

Other statutory language reinforces that conclusion. The respective Secretaries would not be free to issue "interim final rules" as *they* "determine[] * * * appropriate," 42 U.S.C. 300gg-92; 29 U.S.C. 1191c; 26 U.S.C. 9833, if they were required to follow the default rulemaking procedures prescribed in the APA. Indeed, if the statutes simply authorized the agencies to issue interim rules that the APA already authorized them to issue, the provisions would be meaningless. See *Duncan* v. *Walker*, 533 U.S. 167, 174 (2001) (reaffirming the "cardinal principle of statutory construction" that language should not be rendered "superfluous, void, or insignificant") (citations omitted).

The agencies' reading of the statutes also has deep roots. Starting immediately after the provisions' enactment in 1996, agencies have invoked them to issue interim rules without notice-and-comment procedures. See, *e.g.*, 62 Fed. Reg. 16,979 (Apr. 8, 1997); 62 Fed. Reg. 66,932 (Dec. 22, 1997); 63 Fed. Reg. 57,546 (Oct. 27, 1998). That consistent practice includes multiple interim rules implementing the preventive-services provision. See pp. 7-8, *supra* (citing interim rules adopted in 2010, 2011, and 2014). The interim rules adopted by the agencies here are justified by that same longstanding construction of the plain statutory text. See 83 Fed. Reg. at 57,586, 57,629-57,630.

The court of appeals observed that some statutes authorizing departures from the APA's procedural requirements do so through mandatory commands to promulgate interim rules by a specific deadline. See Pet. App. 24a. But nothing in Section 559's text or this Court's construction of it suggests that Congress may authorize departures from the APA only in that one particular way. See, *e.g.*, *Marcello* v. *Bonds*, 349 U.S. 302,

310 (1955) (explaining that Congress need not "employ magical passwords" to authorize departures from the APA's procedural requirements).

The court of appeals also suggested a narrow reading of the statutory provisions that relies on the sentence *prior* to the one expressly authorizing the agencies to issue "interim final rules." 42 U.S.C. 300gg-92; 29 U.S.C. 1191c; 26 U.S.C. 9833. That sentence confers *separate* authority for the agencies to make rules "consistent with section 104 of" HIPAA. *Ibid.* The relevant HIPAA provision in turn instructs the agencies to "ensure" that regulations "relating to the same matter over which two or more" agencies have statutory responsibility "are administered so as to have the same effect at all times." 42 U.S.C. 300gg-92 note. The court read those interlocking provisions—neither of which the agencies rely on here—to mean that the agencies could "proceed by [interim final rules]" only "where a Secretary need[s] to regulate within his or her own domain temporarily while sorting out . . . inter-agency conflict." Pet. App. 25a (citation and internal quotation marks omitted; second set of brackets in original). That convoluted reading has no connection to the text the agencies actually invoke, which squarely authorizes them to issue "interim final rules as * * * appropriate" to enforce the relevant statutes. 42 U.S.C. 300gg-92; 29 U.S.C. 1191c; 26 U.S.C. 9833. No reason exists to "favor [the court's] most unlikely reading over th[e agencies'] obvious one." *Azar* v. *Allina Health Servs.*, 139 S. Ct. 1804, 1813 (2019).

2. The interim rules were justified by the APA's good-cause exception

The agencies also had "good cause" under 5 U.S.C. 553(b)(B) to issue the interim rules without prior notice

and comment. As the agencies thoroughly explained, the uncertainty created by conflicting lower-court decisions and ongoing litigation—as well as the need to protect employers with sincere religious and moral objections from potentially devastating penalties—made a lengthy notice-and-comment period "impracticable" and "contrary to the public interest." 82 Fed. Reg. at 47,813, 47,815; see *id.* at 47,813-47,815, 47,854-47,856.

The court of appeals rejected the agencies' finding of good cause on the ground that "[a]ll regulations are directed toward reducing harm in some manner," and "[u]ncertainty precedes every regulation." Pet. App. 27a-28a. Those general observations overlook the agencies' specific need to issue the interim rules without prior notice and comment in these distinctive circumstances. The agencies did not rely on "urgency alone," *id.* at 75a, or the need to eliminate any possible uncertainty regarding existing law. Rather, they acted to end protracted litigation involving dozens of cases and plaintiffs that had resulted in multiple prior trips to this Court. See pp. 5-7, *supra*. The agencies, moreover, sought to protect the liberty of employers threatened with devastating civil penalties for following their religious and moral precepts. Those interests provide good cause.

III. AT A MINIMUM, THIS COURT SHOULD VACATE THE NATIONWIDE INJUNCTION

In all events, the scope of the preliminary injunction, which bars application of the rules to any person anywhere in the Nation, exceeded the district court's authority. Members of this Court have highlighted the serious "equitable and constitutional questions raised by the rise of nationwide injunctions"—orders that "direct how the defendant must act toward persons who are not

parties to the case." *Department of Homeland Sec.* v. *New York*, 140 S. Ct. 599, 600-601 (2020) (Gorsuch, J., concurring in the grant of stay); see *Trump* v. *Hawaii*, 138 S. Ct. 2392, 2428-2429 (2018) (Thomas, J., concurring). The expansive nonparty relief in this case starkly illustrates the legal and practical defects in nationwide injunctions. Indeed, the district court admitted that the relief it granted "may prove overbroad." Pet. App. 183a. And the Ninth Circuit not only vacated a parallel nationwide injunction, *California* v. *Azar*, 911 F.3d 558, 584 (2018) (*California I*), cert. denied, 139 S. Ct. 2716 (2019), but predicted that this Court "very well may vacate the nationwide scope of the injunction" in this case, *California* v. *U.S. Dep't of Health & Human Servs.*, 941 F.3d 410, 423 (2019), petitions for cert. pending, Nos. 19-1038, 19-1040, and 19-1053 (filed Feb. 19, 2020). If the Court reaches the question, it should do just that.

A. Nationwide Injunctions Exceed Courts' Constitutional And Equitable Powers

1. "Article III of the Constitution limits the exercise of the judicial power to 'Cases' and 'Controversies.'" *Town of Chester* v. *Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (citation omitted). That limitation "confines the federal courts to a properly judicial role." *Ibid.* (citation omitted). Of particular relevance here, a federal court may entertain a suit only by a plaintiff who has suffered a concrete "injury in fact," and the court may grant relief only to remedy "the inadequacy that produced [the plaintiff's] injury." *Gill* v. *Whitford*, 138 S. Ct. 1916, 1929-1930 (2018) (citations omitted). In short, neither standing nor remedies are "dispensed in gross." *Lewis* v. *Casey*, 518 U.S. 343, 358 n.6 (1996). This Court has accordingly narrowed injunctions that extended relief beyond the harms to "any plaintiff in th[e] lawsuit,"

id. at 358, and refused to adjudicate claims by plaintiffs whose harms "ha[ve already] been remedied," *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 494 (2009).

Principles of equity reinforce those limitations. A court's equitable authority to award relief is generally confined to relief "traditionally accorded by courts of equity" in 1789. *Grupo Mexicano de Desarrollo, S. A.* v. *Alliance Bond Fund, Inc.*, 527 U.S. 308, 319 (1999). And it is a longstanding principle that injunctive relief may "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" in that case. *Califano* v. *Yamasaki*, 442 U.S. 682, 702 (1979); see *Hawaii*, 138 S. Ct. at 2427 (Thomas, J., concurring) (explaining that English and early American "courts of equity" typically "did not provide relief beyond the parties to the case"). In some cases, such as properly certified class actions, relief may extend to a broad range of plaintiffs. *Califano*, 442 U.S. at 702 (nationwide class action). And some plaintiffs' injuries can be remedied only in ways that incidentally benefit nonparties. See, *e.g.*, *Dayton Bd. of Educ.* v. *Brinkman*, 433 U.S. 406, 414 (1977) (school-desegregation remedy). But even in those cases, courts are adjudicating only the rights of the parties before them, not passing on laws or issues as a general matter.

2. Nationwide injunctions are irreconcilable with those constitutional and equitable limitations. By definition, a nationwide injunction extends relief to parties that were not "plaintiff[s] in th[e] lawsuit, and hence were not the proper object of th[e court's] remediation." *Lewis*, 518 U.S. at 358. And when a court awards relief to nonparties, it transgresses the boundaries of relief "traditionally accorded by courts of equity" in 1789. *Grupo Mexicano*, 527 U.S. at 319; see Samuel L. Bray,

Multiple Chancellors: Reforming the National Injunction, 131 Harv. L. Rev. 417, 424-445 (2017) (Bray) (detailing historical practice).[3]

Nationwide injunctions create other legal and practical problems. They circumvent the procedural rules governing class actions, which permit relief to absent parties only if rigorous safeguards are satisfied. Fed. R. Civ. P. 23. They enable forum shopping, and empower a single district judge to effectively nullify the decisions of all other lower courts by barring application of a challenged policy in any district nationwide. See *New York*, 140 S. Ct. at 601 (Gorsuch, J., concurring). And they operate asymmetrically. A nationwide injunction anywhere freezes the challenged action everywhere. So the government must prevail in every suit to keep its policy in force, while plaintiffs can derail a federal statute or regulation nationwide with a single district-court victory. See *ibid.* (describing a recent example). That dynamic defies both class-action requirements and the usual rule that nonparties may not bar the government from relitigating issues in subsequent cases in different forums. See *United States* v. *Mendoza*, 464 U.S. 154, 158-163 (1984).

Moreover, the prospect that a single district-court decision can enjoin a government policy nationwide for years while the ordinary appellate process unfolds often leaves the Executive Branch with little choice but to seek emergency relief. See *New York*, 140 S. Ct. at 600-

---

[3] Scholars have debated whether the first nationwide injunction was issued in the 1960s, see Bray 437, or at some point earlier in twentieth century, see Mila Sohoni, *The Lost History of the "Universal" Injunction*, 133 Harv. L. Rev. 920, 924-925 (2020). Whatever the better view on that question, the debate underscores that nationwide injunctions were not a traditional part of equity in 1789.

601 (Gorsuch, J., concurring). That in turn deprives the judicial system, including this Court, of the benefits that accrue when numerous courts grapple with complex legal questions in a common-law-like fashion. *Ibid.*

In short, nationwide injunctions "take a toll on the federal court system." *Hawaii*, 138 S. Ct. at 2425 (Thomas, J., concurring). And that toll is growing. According to the Department of Justice's best estimates, federal district courts have issued more than 50 nationwide injunctions in the past three years, nearly as many as were issued in the entire history of the United States before that time. The Department has opposed nationwide injunctions across different presidential administrations. See, *e.g.*, Gov't C.A. Br. at 54-56, *Texas* v. *United States*, 809 F.3d 134 (5th Cir. 2015) (No. 15-40238), aff'd by an equally divided Court, 136 S. Ct. 2771 (2016); Gov't Br. at 40-47, *Earth Island*, *supra* (No. 07-463). As courts' issuance of such disruptive injunctions grows "increasingly widespread," the need for correction by this Court has become acute. *New York*, 140 S. Ct. at 600 (Gorsuch, J., concurring).

B. Any Relief In This Case Should Be Narrowed To The Plaintiff States

The nonparty relief awarded in this case illustrates the problems with nationwide injunctions. If this Court does not reverse on the merits, the injunction should "be narrowed to redress only the injury shown as to the plaintiff states." *California I*, 911 F.3d at 584.

1. This suit was brought by two States, Pennsylvania and New Jersey. The States do not contend that they are directly affected by the rules. They instead claim they will be injured through a complex chain reaction: women who work for employers or attend

schools that previously provided contraceptive coverage, but that claim an exemption under the final rules, may not be able to obtain contraception elsewhere (*e.g.*, through a spouse's or parent's plan or by paying out of pocket), and may instead use state-funded services for contraception or unintended pregnancy. Pet. App. 15a-21a. Even if that theory of injury were enough to support standing, it cannot support an injunction against application of the rules to *all employers*, *everywhere*.

The overbreadth of the district court's relief is largely uncontested. As the court itself acknowledged, the States produced no evidence that applying the expanded exemptions to an employer in New Mexico, for example, would have any effect on the States' own fiscs. Pet. App. 182a. The same could be said of countless other applications of the final rules. That alone is enough to foreclose a nationwide injunction. An Article III court's remedy must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established." *Whitford*, 138 S. Ct. at 1931 (citation omitted). The remedy awarded here plainly is not.

2. The court of appeals nevertheless concluded that "a nationwide injunction is necessary to provide the States complete relief." Pet. App. 44a. The court observed that some of the States' residents work out of state and some of their students come from out of state, and that such individuals might (through an even more elaborate version of the chain reaction described above) turn to services funded by Pennsylvania or New Jersey if their out-of-state plans invoke the expanded exemptions. *Id.* at 44a-45a. But even if such speculative and contingent cross-border considerations were proper, the court did not find—and no evidence suggests—that Pennsylvania and New Jersey would be harmed by

every application of the rules to *anyone in the Nation*. The injunction accordingly violates the principle that relief must "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano*, 442 U.S. at 702.

Moreover, any hypothetical injuries arising from cross-border scenarios would be insubstantial at best. Many New Jersey residents who work out of state do so in Pennsylvania, and vice versa. See Gov't C.A. Br. 82 (citing census data). Limiting the injunction to those two States would therefore fully redress any harm to the States with respect to those individuals. And although some residents may work in other adjoining States, all but one of those States (Ohio) require health-insurance plans (aside from self-insured plans) to provide contraceptive coverage. *Id.* at 82-83. Many residents who work in other States may also be unaffected because their out-of-state employer is ineligible for the expanded exemptions or legally or effectively exempt from the mandate for other reasons. *Id.* at 83-84. Any actual harm to Pennsylvania and New Jersey from the application of the rules to out-of-state entities is thus so speculative and attenuated that it is outweighed by the government's interest in protecting rights of conscience. Cf. *Winter* v. *Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24-26 (2008) (emphasizing the importance of balancing the equities in considering injunctive relief).

3. In affirming the nationwide injunction, the court of appeals also stated that "Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations." Pet. App. 44a. The court based that

assertion on 5 U.S.C. 706(2), which provides that a "reviewing court shall * * * hold unlawful and set aside agency action" taken unlawfully.

The court of appeals' reliance on the APA to support the nationwide injunction is misplaced. This case does not involve a final decision under Section 706(2), see Pet. App. 44a, but rather a preliminary injunction. And Section 705 of the APA itself adopts the general rule that preliminary injunctive relief should be limited as "necessary to prevent irreparable injury"—*i.e.*, the injury to the parties who brought the suit. 5 U.S.C. 705.

More generally, Section 706(2)'s directive to "set aside" unlawful "agency action" does not mandate that "agency action" shall be set aside globally, rather than as applied to the plaintiffs who brought the suit. 5 U.S.C. 706(2). The statutory context strongly supports the party-specific understanding, which is consistent with ordinary remedial limitations. See pp. 43-45, *supra*. Congress enacted the APA against a background rule that statutory remedies should be construed in accordance with "traditions of equity practice." *Hecht Co.* v. *Bowles*, 321 U.S. 321, 329 (1944). While Congress "may intervene and guide or control the exercise of the courts' discretion," this Court will "not lightly assume that Congress has intended to depart from established [equity] principles." *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 313 (1982).

Nothing in the APA's text or history—or this Court's cases construing it—suggests that Congress took the dramatic step of *sub silentio* authorizing nationwide relief. Instead, Section 703 of the APA provides that review may be sought in cases like this through any of the traditionally available forms of relief, such as "actions

for declaratory judgments" or "writs of * * * injunction." 5 U.S.C. 703. And Section 702(1) provides that nothing in the APA's authorization of judicial review "affects * * * the power or duty of the court to * * * deny relief on any other * * * equitable ground." 5 U.S.C. 702(1); see *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 155 (1967). Particularly given that backdrop, the court of appeals erred in holding that the APA authorizes this nationwide injunction.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

NOEL J. FRANCISCO
Solicitor General
JOSEPH H. HUNT
Assistant Attorney General
JEFFREY B. WALL
Deputy Solicitor General
HASHIM M. MOOPPAN
Deputy Assistant Attorney General
CHRISTOPHER G. MICHEL
BENJAMIN W. SNYDER
Assistants to the Solicitor General
SHARON SWINGLE
LOWELL V. STURGILL JR.
KAREN SCHOEN
Attorneys

MARCH 2020

APPENDIX

1. 5 U.S.C. 553(b) and (c) provide:

Rule making

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity

for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

2. 5 U.S.C. 559 provides:

Effect on other laws; effect of subsequent statute

This subchapter, chapter 7, and sections 1305, 3105, 3344, 4301(2)(E), 5372, and 7521 of this title, and the provisions of section 5335(a)(B) of this title that relate to administrative law judges, do not limit, or repeal additional requirements imposed by statute or otherwise recognized by law. Except as otherwise required by law, requirements or privileges relating to evidence or procedure apply equally to agencies and persons. Each agency is granted the authority necessary to comply with the requirements of this subchapter through the issuance of rules or otherwise. Subsequent statute may not be held to supersede or modify this subchapter, chapter 7, sections 1305, 3105, 3344, 4301(2)(E), 5372, or 7521 of this title, or the provisions of section 5335(a)(B) of this title that relate to administrative law judges, except to the extent that it does so expressly.

3. 5 U.S.C. 706 provides:

Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

4. 42 U.S.C. 300gg-13(a) provides:

Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

(1) 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;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and[1]

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.[2]

---

[1] So in original. The word "and" probably should not appear.

[2] So in original. The period probably should be a semicolon.

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.[2]

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

5. 42 U.S.C. 300gg-92 provides:

Regulations

The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this subchapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter.

6. 26 U.S.C. 9833 provides:

Regulations

The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this chapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this chapter.

7. 29 U.S.C. 1191c provides:

Regulations

The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this part.

8. 42 U.S.C. 2000bb-1 provides:

Free exercise of religion protected

(a) In general

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person—

(1) is in furtherance of a compelling governmental interest; and

(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

9. 42 U.S.C. 2000bb-2 provides:

Definitions

As used in this chapter—

(1) the term "government" includes a branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States, or of a covered entity;

(2) the term "covered entity" means the District of Columbia, the Commonwealth of Puerto Rico, and each territory and possession of the United States;

(3) the term "demonstrates" means meets the burdens of going forward with the evidence and of persuasion; and

(4) the term "exercise of religion" means religious exercise, as defined in section 2000cc-5 of this title.

10. 42 U.S.C. 2000bb-3 provides:

Applicability

(a) In general

This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.

(b) Rule of construction

Federal statutory law adopted after November 16, 1993, is subject to this chapter unless such law explicitly excludes such application by reference to this chapter.

(c) Religious belief unaffected

Nothing in this chapter shall be construed to authorize any government to burden any religious belief.

11. 45 C.F.R. 147.131(a) (2016) provides:

Exemption and accommodations in connection with coverage of preventive health services.

(a) *Religious employers.* In issuing guidelines under § 147.130(a)(1)(iv), the Health Resources and Services Administration may establish an exemption from such guidelines with respect to a group health plan established or maintained by a religious employer (and

health insurance coverage provided in connection with a group health plan established or maintained by a religious employer) with respect to any requirement to cover contraceptive services under such guidelines. For purposes of this paragraph (a), a "religious employer" is an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

12. 45 C.F.R. 147.131 provides:

Accommodations in connection with coverage of certain preventive health services.

(a)-(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii), or 45 CFR 147.133(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a) or § 147.133, the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph

(d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule.* If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule.* In plan years that begin after January 14, 2019, if contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that

provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 or § 147.133 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 or § 147.133 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health

insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Deparement of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 or § 147.133 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion

thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health

coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) "Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer]."

(f) *Reliance.* (1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if

the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(g) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(h) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

13. 45 C.F.R. 147.132 provides:

Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained

by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then

the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

14. 45 C.F.R. 147.133 provides:

Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified be-

low. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or

maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not

all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.