No. 18-1514

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

COMMONWEALTH OF MASSACHUSETTS,

Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX MICHAEL AZAR II, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF THE TREASURY; STEVEN T. MNUCHIN, in his official capacity as Secretary of the Treasury; UNITED STATES DEPARTMENT OF LABOR; and R. ALEXANDER ACOSTA, in his official capacity as Secretary of Labor,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Massachusetts

BRIEF FOR THE APPELLEES

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INTRODUCTION

This action represents the latest chapter in years of litigation regarding the so-called contraceptive-coverage mandate. Since the adoption of the mandate pursuant to the Patient Protection and Affordable Care Act, numerous entities have challenged it, as well as a regulatory accommodation intended to address the religious objections of certain organizations not eligible for the regulatory exemption for churches. Dozens of lawsuits were left unresolved by the Supreme Court in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam). And despite numerous rounds of rulemaking and the solicitation of public comment, the administering agencies—the Departments of Health and Human Services (HHS), Labor, and the Treasury—were unable to find a way to amend the accommodation to both satisfy the organizations' conscience objections and ensure that women covered by those organizations' health plans receive contraceptive coverage.

In an effort to resolve the ongoing litigation and alleviate the burden on those with religious or moral objections to contraceptive coverage, the agencies issued interim final rules expanding the religious

exemption to the mandate and creating a new exemption for organizations with moral objections.

Massachusetts brought suit challenging the interim rules on both procedural and substantive grounds. The agencies have since issued final rules superseding the interim rules, but the gravamen of Massachusetts's substantive claims remains and thus the case is not moot. Massachusetts itself is not directly subject to the rules, which do not require States to take, or refrain from taking, any action. Instead, Massachusetts speculates (1) that Massachusetts employers are likely to exempt themselves from the mandate; (2) that, as a result, women will lose contraceptive coverage; and (3) that those women will seek and receive state-funded benefits, resulting in a loss of money to the Commonwealth. But Massachusetts has yet to identify a resident who will lose contraceptive coverage, let alone seek and receive state-funded services, and this chain of speculative assumptions is insufficient to demonstrate concrete injury for purposes of Article III standing. Nor can Massachusetts assert *parens patriae* standing to protect the well-being of its residents. Even apart from the speculative injury to Massachusetts's residents, it is well settled that "[a] State does not have

standing as *parens patriae* to bring an action against the Federal Government." *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982).

We do not argue here that no one has standing to challenge these rules. An individual who loses contraceptive coverage because of the rules may well have standing to challenge them. But having failed to identify even a single such individual, Massachusetts cannot submit its disagreement with federal policy for resolution by the courts. The district court correctly recognized that fundamental principle, and its decision should be affirmed.

STATEMENT OF JURISDICTION

Massachusetts invoked the jurisdiction of the district court under 28 U.S.C. § 1331. On March 12, 2018, the district court granted the government's motion for summary judgment on the ground that Massachusetts lacks Article III standing. *See* JA 1383. The district court entered final judgment on April 4, 2018. *See* JA 1423. Massachusetts filed a timely notice of appeal on May 29, 2018. *See* JA 1424. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether Massachusetts has demonstrated a sufficient likelihood of injury to establish Article III standing to bring this action given that the Commonwealth has provided no basis to conclude that Massachusetts residents will lose contraceptive coverage as a result of invocation of the challenged exemptions by Massachusetts employers, let alone that any such residents would seek and receive state-funded benefits or that Massachusetts may sue on their behalf.

STATEMENT OF THE CASE

A. The Affordable Care Act and the Contraceptive-Coverage Mandate

The Affordable Care Act requires most group health plans and health-insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without "any cost sharing requirements." 42 U.S.C. § 300gg-13(a). The Act does not specify the types of women's preventive care that must be covered. Instead, as relevant here, the Act requires coverage, "with respect to women," of such "additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [HRSA]," a component of HHS. *Id.* § 300gg-13(a)(4).

In August 2011, HRSA adopted the recommendation of the Institute of Medicine to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods. *See* 77 Fed. Reg. 8725, 8725 (Feb. 15, 2012). Coverage for such contraceptive methods was thus required for plan years beginning on or after August 1, 2012. *See* 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

At the same time, the agencies, invoking their authority under 42 U.S.C. § 300gg-13(a)(4), promulgated interim final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623. The rules were finalized in February 2012. *See* 77 Fed. Reg. at 8725. While various religious groups urged the agencies to expand the exemption to all organizations with religious or moral objections to providing contraceptive coverage, *see* 78 Fed. Reg. 8456, 8459-60 (Feb. 6, 2013), the agencies instead offered, in a later rulemaking, only what they termed an "accommodation" limited to religious not-for-profit organizations with religious objections to providing contraceptive coverage, *see* 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a group health plan established or maintained by an eligible objecting employer to opt out of any requirement to directly "contract, arrange, pay, or refer for contraceptive coverage." *Id.* at 39,874. The regulations then generally required the employer's health insurer or third-party administrator (in the case of self-insured plans) to provide or arrange contraceptive coverage for plan participants. *See id.* at 39,875-80.

In the case of self-insured church plans, however, coverage by the plan's third-party administrator under the accommodation was voluntary. Church plans are exempt from the Employee Retirement Income Security Act of 1974 (ERISA), and the authority to enforce a third-party administrator's obligation to provide separate contraceptive coverage derives solely from ERISA. The agencies thus could not require the third-party administrators of those plans to provide or arrange for such coverage, nor impose fines or penalties for failing to provide such coverage. *See* 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

Other employers were also exempt from the contraceptive-coverage mandate. The Affordable Care Act itself exempts from the preventive-services requirement, including the contraceptive-coverage mandate, so-called grandfathered health plans (generally, those plans that have not made specified changes since the Act's enactment), *see* 42 U.S.C. § 18011, which cover tens of millions of people, *see* 82 Fed. Reg. 47,792, 47,794 & n.5 (Oct. 13, 2017). And employers with fewer than fifty employees are not subject to the tax imposed on employers that fail to offer health coverage, *see* 26 U.S.C. § 4980H(c)(2), although

small employers that *do* provide nongrandfathered coverage must comply with the preventive-services requirement.

B. Challenges to the Contraceptive-Coverage Mandate and Accommodation

Many employers objected to the contraceptive-coverage mandate. In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court held that the Religious Freedom Restoration Act (RFRA) prohibited applying the mandate to closely held for-profit corporations with religious objections to providing contraceptive coverage. The Court held that the mandate "impose[d] a substantial burden on the exercise of religion" for employers with religious objections, *id.* at 2779, and that, even assuming a compelling governmental interest, application of the mandate to such employers was not the least restrictive means of furthering that interest, *id.* at 2780. The Court observed that the agencies had already established an accommodation for not-for-profit employers and that, at a minimum, this less-restrictive alternative could be extended to closely held for-profit corporations with religious objections. *Id.* at 2782. But although the Court held that such an option was a less restrictive means under

RFRA, the Court did not decide "whether an approach of this type complies with RFRA for purposes of *all* religious claims." *Id.* (emphasis added).

In response to *Hobby Lobby*, the agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. *See* 80 Fed. Reg. 41,318, 41,323-28 (July 14, 2015). Numerous entities, however, continued to challenge the mandate. They argued that the accommodation burdened their exercise of religion because they sincerely believed that the required notice and the provision of contraceptive coverage in connection with their health plans made them complicit in providing such coverage.

A split developed in the circuits, *see* 82 Fed. Reg. at 47,798, and the Supreme Court granted certiorari in several of the cases. The Court vacated the judgments and remanded the cases to the respective courts of appeals. *See Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam). The Court "d[id] not decide whether [the plaintiffs'] religious exercise ha[d] been substantially burdened, whether the Government ha[d] a compelling interest, or whether the current regulations [we]re the least

restrictive means of serving that interest." *Id.* at 1560. Instead, the Court directed that, on remand, the parties be given an opportunity to resolve the dispute. *See id.* In the meantime, the Court precluded the government from "impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice required under the accommodation]." *Id.* at 1561. Similar orders were entered in other pending cases.

In response to *Zubik*, the agencies sought public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for coverage for their employees. *See* 81 Fed. Reg. 47,741 (July 22, 2016). The agencies received over 54,000 comments, but could not find a way to amend the accommodation to both satisfy objecting organizations and provide coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).[1] The pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved.

[1] Available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

In addition, some nonreligious organizations with moral objections to providing contraceptive coverage had filed suits challenging the mandate. That litigation also led to conflicting decisions by the courts. *See* 82 Fed. Reg. 47,838, 47,843 (Oct. 13, 2017).

C. The Interim Final Rules

In an effort "to resolve the pending litigation and prevent future litigation from similar plaintiffs," the agencies reexamined the mandate's exemption and accommodation, and issued two interim final rules expanding the exemption while continuing to offer the existing accommodation as an optional alternative.

The first rule expanded the religious exemption to all nongovernmental plan sponsors, as well as institutions of higher education in their arrangement of student health plans, to the extent that those entities have sincere religious objections to providing contraceptive coverage. *See* 82 Fed. Reg. at 47,806. The agencies acknowledged that contraceptive coverage is "an important and highly sensitive issue, implicating many different views." *Id.* at 47,799. But "[a]fter reconsidering the interests served by the [m]andate," the "objections raised," and "the applicable Federal law," the agencies

"determined that an expanded exemption, rather than the existing accommodation, [wa]s the most appropriate administrative response to the religious objections raised by certain entities and organizations." *Id.* The agencies also explained that the new approach was necessary because "[d]espite multiple rounds of rulemaking," and even more litigation, they "ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations" or resolved the pending legal challenges that had divided the courts. *Id.*

The second rule created a similar exemption for entities with sincerely held moral objections to providing contraceptive coverage (but unlike the religious exemption did not apply to publicly traded companies). *See* 82 Fed. Reg. at 47,849-52. The rule was intended "to bring the [m]andate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues," *id.* at 47,844, as well as similar efforts by the States, *id.* at 47,847, and to resolve legal challenges by moral objectors that had given rise to conflicting court decisions, *id.* at 47,843.

The agencies concluded that their express statutory authority to issue "interim final rules," 26 U.S.C. § 9833; 29 U.S.C. § 1191c;

42 U.S.C. § 300gg-92, provided them with authority to issue the rules without prior notice and comment. The agencies also concluded that they had "good cause" to do so under the Administrative Procedure Act (APA), 5 U.S.C. § 553(b), in order to protect religious liberty and end the litigation that had beset the prior rules. *See* 82 Fed. Reg. at 47,813-15; 82 Fed. Reg. at 47,854-56.

The agencies solicited comments for 60 days post-promulgation in anticipation of final rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838. And, as discussed below (*see infra* subsection E), after reviewing all the comments received, the agencies issued final rules in November 2018.

D. Massachusetts's Challenge to the Interim Rules

Massachusetts brought suit challenging the interim rules. Massachusetts claimed that the rules (1) failed to comply with the APA's notice-and-comment requirements; (2) are not in accordance with law and exceed the agencies' authority; (3) violate the Establishment Clause; and (4) violate the Equal Protection Clause. *See* JA 31-35. Massachusetts requested that the district court declare the interim

rules unlawful and permanently enjoin their implementation nationwide.

The district court concluded that Massachusetts "lacks standing to prosecute this action" and granted the government's motion for summary judgment. JA 1383. The court explained that "the Commonwealth has failed to set forth specific facts establishing that it will likely suffer future injury from the [interim rules]." *Id.* In particular, the court explained, Massachusetts "has not established that it is likely that any Massachusetts employers will avail themselves of the [interim rules'] expanded exemptions," JA 1408, and has not "identif[ied] any particular woman who is likely to lose contraceptive coverage because of the [interim rules]," JA 1420.

The court found Massachusetts's reliance on the agencies' estimate of the number of women who could be affected by the interim rules and its "back-of-the-envelope reckoning" that the rules would affect a proportionate number of its residents to be "tenuous" and "unsupported by facts sufficient to satisfy its burden" to demonstrate Article III standing. JA 1403, 1405, 1406. The Commonwealth's "proportional estimate," the Court observed, "relies on conjecture and

speculation." JA 1420. Among other things, Massachusetts's own law requiring contraceptive coverage by insurance plans "renders suspect" the Commonwealth's assumption that the interim rules would affect a proportionate number of its residents as could be affected nationwide, the court explained. JA 1408. And "[t]he Commonwealth's affidavits with respect to whether women in the state will be affected," the court stated, "are conclusory and bereft of substance." JA 1420.[2]

E. The Final Rules

In November 2018, after reviewing and considering the public comments solicited in the interim rules (and after Massachusetts filed its opening brief in this appeal), the agencies promulgated final rules superseding the interim rules. *See* 83 Fed. Reg. 57,536 (Nov. 15, 2018) (religious exemption); 83 Fed. Reg. 57,592 (Nov. 15, 2018) (moral exemption). The final rules finalize the exemptions provided in the interim rules. While the agencies made certain changes in the final

[2] Two other groups of States separately challenged the interim rules: California and several other States obtained a nationwide preliminary injunction that was affirmed as to the merits but vacated as to scope. *See California v. Azar*, 911 F.3d 558 (9th Cir. 2018). Pennsylvania obtained a preliminary injunction that is currently on appeal. *See Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017), *appeal docketed*, No. 18-1253 (3d Cir. Feb. 15, 2018).

rules to clarify the intended scope of the exemptions, *see* 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593, the fundamental substance of the exemptions was finalized as set forth in the interim rules.[3] (Pursuant to this Court's order dated December 21, 2018, we address below whether the appeal is moot in light of the final rules.)

SUMMARY OF ARGUMENT

The district court's judgment should be affirmed.

I. Although the agencies have now issued final rules superseding the interim rules challenged by Massachusetts, Massachusetts's substantive challenge to the rules—and thus this case—is not moot. As an initial matter, Massachusetts's Article III standing to challenge the rules—the only issue on appeal—is a threshold issue that this Court can address without first considering whether the case has become moot. Such an approach is appropriate here because the final rules

[3] California, now joined by a larger group of States, challenged the final rules and obtained a preliminary injunction limited to the plaintiff States. *See California v. HHS*, No. 4:17-cv-5783, 2019 WL 178555 (N.D. Cal. Jan. 13, 2019), *appeal docketed*, No. 19-15118 (9th Cir. Jan. 24, 2019). Pennsylvania, joined by New Jersey, obtained a nationwide preliminary injunction. *See Pennsylvania v. Trump*, No. 2:17-cv-4540, 2019 WL 190324 (E.D. Pa. Jan. 14, 2019), *appeal docketed*, No. 19-1189 (3d Cir. Jan. 24, 2019).

finalize the challenged exemptions in the interim rules in substantially the same form and do not materially alter the question of Massachusetts's standing. Indeed, for much the same reasons that this Court should decide the standing question, the case is not moot. A case does not become moot when, as here, a challenged regulation is altered during the pendency of litigation but the changes are immaterial to the scope of the challenge.

II. The district court correctly held that Massachusetts has not demonstrated standing to challenge the interim final rules.

A. Massachusetts asserts that it will bear the costs of providing contraceptive (and other) services to eligible residents who lose contraceptive coverage under the challenged rules. But this claim of economic injury is too speculative to confer standing. Indeed, Massachusetts has not identified a single resident who will lose contraceptive coverage because of the challenged rules, much less a resident who will then be eligible for and request benefits from a state-funded program.

To start, Massachusetts has its own law requiring health-insurance plans to provide contraceptive coverage, which limits the

availability of the expanded exemption under the challenged rules to the subset of Massachusetts employers that are self-insured. While Massachusetts points to three self-insured employers that have expressed opposition to the contraceptive-coverage mandate, the Commonwealth provides no basis to conclude that any of them will use the expanded exemption rather than the accommodation, under which employees generally continue to receive no-cost contraceptive coverage through the employer's insurer or third-party administrator. And even if one or more of those employers decline to use the accommodation, Massachusetts merely speculates that women who lose coverage will not share their particular employer's religious or moral objections to contraception and would otherwise choose a contraceptive method to which the employer objects, and that such women will lack access to other private contraceptive coverage through a spouse's plan and be eligible for and seek state-funded services.

Massachusetts contends that the district court erred in requiring the Commonwealth to identify employers likely to use the expanded exemption and women likely to lose contraceptive coverage as a result. But as the district court correctly recognized, Massachusetts cannot

base its claim of economic injury on the agencies' estimate of the number of women who could be affected nationwide. The agencies' analysis alone does not show that, of the women who could lose contraceptive coverage nationwide, it is likely rather than inherently speculative that there is even a single particular woman who (1) resides in Massachusetts; (2) would wish to use the particular contraceptive method to which her employer objects; and (3) would seek and qualify for financial assistance from the Commonwealth.

Although the Ninth Circuit recently held that several other States had standing to challenge the rules, that court relied largely on the agencies' estimates of the number of women who could be affected nationwide and failed to consider all the contingencies that had to be met before the specific plaintiff States would suffer any injury.

B. Massachusetts's procedural challenge to the interim rules is moot. But even to the extent Massachusetts has a live claim, any such alleged procedural injury is not itself sufficient to establish standing. The mere existence of a procedural injury during the promulgation of a rule does not obviate the need to demonstrate a substantive injury caused by that rule.

C. Massachusetts's status as a sovereign State does not alter the standing analysis. The Commonwealth's attempt to assert *parens patriae* standing to protect the well-being of its residents is squarely foreclosed by Supreme Court precedent. And even if a State could challenge these rules in a *parens patriae* capacity, Massachusetts has not shown any injury to its residents traceable to the challenged rules. Nor can Massachusetts overcome these various obstacles to standing by invoking the "special solicitude" for States referred to in *Massachusetts v. EPA*, 549 U.S. 497, 520 (2007). Any such "special solicitude" does not alter the requirement to demonstrate an injury in fact. And in any event, the injury Massachusetts asserts here—whether the alleged economic injury asserted directly by Massachusetts or the alleged injury to its residents asserted by Massachusetts in its *parens patriae* capacity—is not the sort of unique sovereign interest that receives special solicitude under *Massachusetts*.

STANDARD OF REVIEW

Whether a plaintiff has standing is a legal question subject to de novo review. *See Katz v. Pershing, LLC*, 672 F.3d 64, 70 (1st Cir. 2012).

ARGUMENT

I. The Case Is Not Moot

Although the agencies have now issued final rules superseding the interim rules challenged by Massachusetts, Massachusetts's substantive challenge to the rules—and thus this case—is not moot.

1. The only issue decided below and raised by Massachusetts on appeal is whether the Commonwealth lacks standing to challenge the interim rules. Standing is a "core component" and an "essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Because standing is a threshold jurisdictional issue, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998), a court may conclude that a case should be dismissed for lack of standing without first addressing whether the case has become moot. As the Supreme Court has made clear, while a federal court generally may not rule on the merits without first determining that it has subject-matter jurisdiction, "there is no mandatory sequencing of jurisdictional issues." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007) (quotation marks omitted). Instead, a court "has leeway to choose among threshold

grounds for denying audience to a case on the merits." *Id.* (quotation marks omitted).

Courts of appeals have thus dismissed cases or appeals on the basis of standing without considering mootness. *See Nicklaw v. CitiMortgage, Inc.*, 839 F.3d 998, 1000 (11th Cir. 2016); *Staker v. Wells Fargo Bank, N.A. (In re Staker)*, 550 F. App'x 580, 582 (10th Cir. 2013); *Common Cause of Pa. v. Pennsylvania*, 558 F.3d 249, 256 n.2 (3d Cir. 2009); *National Comm. for the New River, Inc. v. FERC*, 433 F.3d 830, 832 n.1 (D.C. Cir. 2005); *Myers Investigative & Sec. Servs., Inc. v. United States*, 275 F.3d 1366, 1369 (Fed. Cir. 2002); *In re VMS Ltd. P'ship Sec. Litig.*, 976 F.2d 362, 366 n.7 (7th Cir. 1992).

Considerations of judicial economy counsel in favor of that approach here. Massachusetts's lawsuit challenges on various grounds the expanded exemptions in the interim rules. The final rules finalize those exemptions in substantially the same form. Accordingly, unless this Court reaches the arguments raised by Massachusetts on appeal and affirms the district court's ruling that Massachusetts lacks standing to challenge the rules, we anticipate that Massachusetts will seek to amend its complaint in district court (or file a new complaint) to

challenge the final rules. The likely outcome will again be dismissal for lack of standing, as the district court's reasoning in holding that Massachusetts lacks standing to challenge the interim rules applies with equal force to the final rules. And presumably in that event, Massachusetts will appeal again and the issue of standing will once again be presented to this Court.

We believe that the more prudent and efficient approach would be for the Court to decide the question of standing now. *Cf. Maryland Highways Contractors Ass'n v. Maryland*, 933 F.2d 1246, 1250 (4th Cir. 1991) (holding that case was moot in light of new statute, but in anticipation of a "new attack" on the statute, "elect[ing] to address the issue of standing in order to guide subsequent litigation"). To dismiss this appeal as moot without addressing standing would "prove more wasteful than frugal." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 192 (2000).

2. Indeed, for much the same reasons that this Court should decide the standing question, the case is not moot. A case does not become moot when, as here, a challenged regulation is altered in a manner that is "insignificant" to the scope of the challenge.

Northeastern Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, 508 U.S. 656, 661-62 & n.3 (1993) (holding that case was not moot where challenged ordinance was replaced by "sufficiently similar" ordinance after Court granted certiorari); *see also Conservation Law Found. v. Evans*, 360 F.3d 21, 25-27 (1st Cir. 2004) (holding that substantive challenge to framework was not moot where superseding framework was "largely an extension" of challenged framework). "[A] superseding statute or regulation moots a case only to the extent that it removes challenged features of the prior law." *Naturist Soc'y, Inc. v. Fillyaw*, 958 F.2d 1515, 1520 (11th Cir. 1992); *cf. Gulf of Maine Fishermen's All. v. Daley*, 292 F.3d 84, 88-90 (1st Cir. 2002) (holding that substantive challenge to framework was moot where similar provision in new framework was "based on new circumstances and data" and "d[id] not subject the [plaintiff] to the same action because [it] involve[d] an entirely new analysis").

As explained above, the final rules do not remove the "challenged features" of the interim rules, *Naturist Soc'y*, 958 F.2d at 1520, and presumably, Massachusetts will contend that the final rules harm the Commonwealth "in the same fundamental way" as the interim rules,

American Freedom Def. Initiative v. Washington Metro. Area Transit Auth., 901 F.3d 356, 362 (D.C. Cir. 2018) (holding that case was not moot where challenged moratorium was replaced by "fundamentally similar" guidelines); *see also Associated Gen. Contractors of Am. v. California Dep't of Transp.*, 713 F.3d 1187, 1193-94 (9th Cir. 2013); *Nextel West Corp. v. Unity Township*, 282 F.3d 257, 261-64 (3d Cir. 2002). Massachusetts's substantive challenges to the rules thus are not moot.

II. Massachusetts Has Not Demonstrated Standing to Challenge the Rules

To establish standing, a plaintiff bears the burden of demonstrating an injury that is "concrete[,] particularized," and "actual or imminent, not conjectural or hypothetical"; "fairly traceable to the challenged action"; and "redress[able] by a favorable decision." *Lujan*, 504 U.S. at 560-61 (quotation marks and alterations omitted). Because these requirements "are not mere pleading requirements but rather an indispensable part of the plaintiff's case," a plaintiff at the summary-judgment stage cannot rest on "mere allegations, but must set forth by affidavit or other evidence specific facts" demonstrating standing. *Id.* at

561 (quotation marks omitted). Here, Massachusetts fails to carry its burden for any of its three theories of standing: direct economic injury, procedural injury, and *parens patriae* interest in its residents' well-being.

We do not argue that no one has standing to challenge the rules. An individual who is denied coverage or faces an imminent denial of coverage because of the rules may well have standing to challenge them. But Massachusetts has yet to identify such a person. Nor has Massachusetts otherwise shown a sufficient likelihood of injury. And while Massachusetts undoubtedly disagrees with the policy of the federal government here, the federal courts were not established to adjudicate policy or political disputes, even if those disputes involve matters of public importance. Rather, a federal court may exercise Article III jurisdiction only where there is an actual case or controversy. *See Raines v. Byrd*, 521 U.S. 811, 818 (1997).

A. Massachusetts's Claims of Economic Injury Are Not Sufficient to Demonstrate Standing

Massachusetts contends that it will be injured, not because it is directly regulated by the rules, but because it will purportedly suffer

economic loss as a result of the rules, since it will have to either provide contraceptive coverage itself or fund medical treatment and other social services associated with unintended pregnancies. But where, as here, "the plaintiff is not himself the object of the government action or inaction he challenges," standing "is ordinarily substantially more difficult to establish" because it "depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Lujan*, 504 U.S. at 562 (quotation marks omitted). As this Court has recognized, "[o]utside the sphere of economic theory, predicting future injury and the behavior of third parties is usually suspect." *Sea Shore Corp. v. Sullivan*, 158 F.3d 51, 56 (1st Cir. 1998). And here, Massachusetts's claim of financial harm "depends upon several tenuous contingencies." *Id.*; *see also Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013) (concluding that plaintiffs lacked standing where claimed injury rested on a "speculative chain of possibilities").

Before Massachusetts will bear any costs as a result of the challenged rules, a number of events must occur:

1. A Massachusetts employer must use the expanded exemption and thereby deprive employees of contraceptive coverage they previously had. That means

    a. the employer must have previously provided contraceptive coverage (or used the accommodation, under which coverage is arranged by its insurer or third-party administrator); and

    b. the employer must invoke the expanded exemption and decline to use the accommodation.[4]

2. As a result of that decision, the employer's health plan must no longer cover the specific contraceptive methods that women participating in the plan would otherwise choose (since employers need not opt out of coverage of all contraceptive methods).

3. Women who lose coverage of their chosen contraceptive method must be eligible for, and seek, services from state-funded programs. That means

    a. such women must lack access to the desired coverage under a spouse's (or parent's) plan; and

    b. such women must be unable to pay out of pocket for contraceptive services.

Massachusetts's showing fails at each step.

[4] The rules also apply to institutions of higher education in their arrangement of student health plans, but for ease of reference we refer generally to "employers" unless the context requires otherwise.

1. Massachusetts Has Not Shown That Employers Will Deprive Residents of Contraceptive Coverage

Massachusetts has not provided specific facts sufficient to show, beyond speculation, that Massachusetts employers will use the expanded exemption under the challenged rules to deprive employees of contraceptive coverage they previously had.

At the outset, the challenged exemption is immaterial for all of the many employers in Massachusetts that rely on insurers to provide health coverage, because such employers are subject to the Commonwealth's own contraceptive-coverage law, which requires health-insurance plans to cover FDA-approved contraceptives without cost-sharing. *See* Mass. Br. 12-13. Because the Commonwealth's law does not apply to self-insured plans, which are generally governed exclusively by ERISA, the subset of self-insured employers are the only source of even potential injury to Massachusetts.

To be sure, the Commonwealth contends that "[m]ultiple Massachusetts employers with self-insured health plans have already expressed opposition to the contraceptive mandate either through litigation *or by using the [a]ccommodation*." Br. 18-19 (emphasis added).

But even if an employer is self-insured, the fact that it has been using the accommodation does not itself support Massachusetts's claimed injury. As explained (*supra* p. 6), the accommodation generally allows employees to continue to receive no-cost contraceptive coverage through the employer's insurer or third-party administrator. To the extent an employer continues to use the accommodation—which Massachusetts is not challenging and which was not materially altered by the interim or final rules—there will be no effect on employees. And Massachusetts provides no basis to conclude that any of the employers it has identified will use the expanded exemption under the challenged rules, rather than the accommodation.

Massachusetts points first (Br. 29) to Hobby Lobby Stores, Inc., and Autocam Medical Devices, LLC, both of which challenged the contraceptive-coverage mandate. But Massachusetts provides no reason to believe that either of those employers will decline to use the accommodation—which was made available to them and other closely held corporations as a result of Hobby Lobby's victory in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). Indeed, the fact that Hobby Lobby (and the other plaintiffs) did not contest that the

accommodation would be less restrictive of their religious exercise was the basis for the Supreme Court's conclusion that application of the contraceptive-coverage mandate to them did not satisfy RFRA. *See id.* at 2780-83. Massachusetts provides no evidence that Hobby Lobby or Autocam challenged the accommodation after the agencies made it available to them, and at the district court hearing, Massachusetts conceded that it was "unaware of whether [Hobby Lobby] intend[s] to make use of the expanded exemptions." JA 1431 (Tr.6:5-7).

Massachusetts relies solely on the agencies' inclusion of Hobby Lobby and Autocam in the spreadsheet of "litigating entities" (*i.e.*, entities that challenged the mandate or accommodation) that the agencies used to estimate the potential economic impact of the interim rules. But Massachusetts is mistaken in contending that the agencies "expect [that those two employers] will use the expanded exemptions." Br. 29. The agencies made no such determination. As the agencies explained, they "d[id] not have specific data" regarding "how many entities will use the voluntary accommodation moving forward" or "how many will use the expanded exemption." 82 Fed. Reg. 47,792, 47,818 (Oct. 13, 2017). And with respect to the "87 for-profit entities that filed

suit challenging the [m]andate in general," including Hobby Lobby and Autocam, the agencies stated that they "d[id] not know how many of those entities are using the accommodation, how many may be complying with the [m]andate fully, how many may be relying on court injunctions to do neither, or how many will use the expanded exemption moving forward." *Id.* Thus, for purposes of a required regulatory-impact analysis, the agencies conservatively assumed that virtually *all* of the employers that had previously challenged the mandate (except those already exempt under the prior rules or effectively exempt because they used self-insured church plans) would use the expanded exemption under the interim rules. *See id.* at 47,819. That assumption, however, does not provide a sufficient basis to conclude for purposes of Article III standing that Hobby Lobby and Autocam are in fact likely to use the exemption.[5]

Nor can Massachusetts rely (Br. 31) on the fact that another Massachusetts employer, Cummins-Allison Corporation, elected to use

[5] In the updated analysis in the final rules, the agencies also excluded from the revised estimate litigating entities that had received permanent injunctions precluding the government from enforcing the contraceptive-coverage mandate against them. *See* 83 Fed. Reg. 57,536, 57,575 (Nov. 15, 2018).

the accommodation under the prior rules. To our knowledge, Cummins-Allison did not challenge the accommodation, and Massachusetts provides no reason to believe that the company will stop using it and instead invoke the expanded exemption under the challenged rules. While the agencies assumed, for purposes of the regulatory-impact analysis, that some of the entities using the accommodation under the prior rules would use the expanded exemption instead, the agencies did not identify any specific entities that would switch from the accommodation to the expanded exemption. *See* 82 Fed. Reg. at 47,818. And nothing in the record suggests that Cummins-Allison would stop using the accommodation.[6]

While it is *possible* that these three employers could opt to use the expanded exemption, any such eventuality is too conjectural to demonstrate the requisite injury to Massachusetts. And, of course, the

[6] It is unclear whether Massachusetts is suggesting that Cummins-Allison is likely to use the exemption because it notified HHS of its "religious objections to providing contraceptive coverage." Br. 31 (citing JA 1355-80). In order to use the accommodation under the prior rules, an employer was required to provide notice (to its insurer, third-party administrator, or HHS) of its religious objections to providing contraceptive coverage. *See, e.g.*, 79 Fed. Reg. 51,092, 51,092-95 (Aug. 27, 2014). The fact that Cummins-Allison provided such notice does not mean that it objects to using the accommodation.

need to speculate about those employers' intentions is attributable to the Commonwealth's own litigation decisions, as Massachusetts could have sought to ascertain those employers' plans, through discovery or otherwise, but chose not to do so.

In district court, Massachusetts also identified the Little Sisters of the Poor as a litigating entity located in Massachusetts. *See* JA 1430 (Tr. 5:22-25). But the Little Sisters' use of the expanded exemption cannot support Massachusetts's standing to challenge the interim or final rules. Like many other entities that challenged the mandate and accommodation, the Little Sisters received a permanent injunction precluding the government from enforcing the contraceptive-coverage mandate against them. *See* Order at 2-3, *Little Sisters of the Poor Home for the Aged v. Sebelius*, No. 1:13-cv-2611 (D. Col. May 29, 2018).[7] And even apart from the injunction, the Little Sisters provide health coverage to their employees through a self-insured church plan (which even under the prior rules allowed employers, and effectively also their

[7] *See also* 83 Fed. Reg. at 57,575 & n.81 (noting that since the issuance of the interim rules, many litigating entities have received permanent injunctions precluding the government from enforcing the contraceptive-coverage mandate).

third-party administrators, to avoid any obligation to provide contraceptive coverage). *See Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1167, 1189 (10th Cir. 2015), *vacated and remanded*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam). Thus, the Little Sisters' employees already have not been receiving contraceptive coverage, and these rules will have no effect on them.[8]

2. Massachusetts Has Not Shown That Residents Will Lose Their Chosen Method of Employer-Sponsored Contraception

Even assuming that one of the employers identified by Massachusetts will use the expanded exemption and cease providing

[8] Amici Pennsylvania and other States assert that the administrative record identifies seven employers "located in Massachusetts and Amici States" that the agencies "expect will use the exemptions." Br. 10. But amici make no attempt to identify which of these entities are located in Massachusetts (the only State whose standing is at issue here). In any event, neither the cited record exhibits nor amici provide any basis to conclude that these employers will decline to use the accommodation. DAS Companies and J.E. Dunn Construction Group provided notice to HHS of their objection to providing contraceptive coverage, for purposes of using the accommodation. *See* JA 1359. To our knowledge, they have not challenged the accommodation. While the other five employers all brought litigation under the prior rules, none of them challenged the accommodation either. Indeed, Media Research Center sought a declaration that it was an "eligible organization" permitted to use the accommodation under the prior rules. *See* Compl. ¶¶ 4-7, *Media Research Ctr. v. Sebelius*, No. 1:14-cv-0379 (E.D. Va. Apr. 11, 2014).

coverage that it previously provided, Massachusetts does not identify any women who will be adversely affected by that employer's decision.

The exemptions created by the challenged rules apply only "to the extent" of an entity's sincerely held religious or moral objections. 82 Fed. Reg. at 47,809; *see also* 82 Fed. Reg. 47,838, 47,850 (Oct. 13, 2017); 83 Fed. Reg. at 57,558; 83 Fed. Reg. 57,592, 57,614 (Nov. 15, 2018). That means that an employer must still provide coverage for those contraceptives to which it does not object. *See* 83 Fed. Reg. at 57,558. Many of the employers that challenged the mandate (or accommodation) objected only to some contraceptives and covered many others—Hobby Lobby and the other plaintiffs in *Hobby Lobby*, for example, were willing to provide coverage for 14 of 18 FDA-approved contraceptive and sterilization methods. *See id.* at 57,575 & n.79. Likewise, Cummins-Allison objects only to certain contraceptives. *See* JA 1355.

Massachusetts merely speculates that an employer that uses the exemption will choose not to cover the contraceptive method that a particular employee would otherwise choose. Moreover, women covered by plans that cease providing coverage of all or some contraceptive

services may share the entity's religious or moral objections to such coverage. *See* 83 Fed. Reg. at 57,576 (noting that the agencies "do not have data" on "how many of [the litigating] entities would provide some contraception in their plans while only objecting to certain contraceptives" or on "how many of those women [participating in plans of the litigating entities] agree with their employers' or educational institutions' opposition to contraception").

It is telling that Massachusetts cannot point to a single woman who will lose coverage she would otherwise want. Massachusetts offers the declaration of a physician at Brigham & Women's Hospital, who states that she "anticipate[s] that some women in Massachusetts will lose coverage for contraceptive services as a result of their employer's exercise of one of the [interim rules'] exemptions." JA 697 ¶ 27. But as the district court observed (JA 1414-15), she offers no basis for her belief. She does not, for example, "state that her belief arises from patients informing her that they will lose contraceptive coverage due to their employers' exemption." JA 1415. Rather, her conclusion seems to be based entirely on her observation that "approximately 60% of Massachusetts' insured are covered through an employer-sponsored

health plan" and that "[m]any of these individuals have their coverage through self-funded plans, and therefore are not protected by Massachusetts state laws mandating contraceptive coverage." JA 697 ¶ 26. But a simple recitation of the percentage of individuals covered by self-insured plans is not sufficient to support a claim that any woman in Massachusetts will lose coverage for the specific contraceptive method she would otherwise choose.

3. Massachusetts Has Not Shown That Any Adversely Affected Residents Will Impose Financial Harm on the Commonwealth

Even assuming that some Massachusetts women will lose coverage of their chosen contraceptive method, Massachusetts fails to demonstrate economic injury as a result. A woman who loses coverage of her chosen contraceptive method through her employer may still have access to such coverage through a spouse's (or parent's) plan. Or she may otherwise be able to pay out of pocket for contraceptive services and thus may not seek, or be eligible for, services from a state-funded program. Because Massachusetts has not pointed to a particular woman who will lose coverage, it is wholly speculative that Massachusetts's alleged fiscal injury will ever materialize.

The speculative nature of Massachusetts's claims is reflected in its own declarations. For instance, the General Counsel of the Massachusetts Department of Public Health stated only that "[a]n increase in the prevalence of employer-sponsored insurance that does not provide coverage for comprehensive family planning services would likely result in an increase in the number of Massachusetts residents eligible for and receiving services funded by [state programs]." JA 43 ¶ 8. But she offered no basis for concluding that any Massachusetts employers would cease providing contraceptive coverage they had previously provided or that any women who lost such coverage would lack access by other means (such as a spouse's plan) and would in fact be eligible for and seek state-funded services.

Likewise, the President and CEO of Planned Parenthood League of Massachusetts, which receives state funding, declared that she "anticipate[s] that additional women who lose coverage for contraceptive services because of the [interim rules] . . . will seek care at our health centers." JA 50 ¶ 18. But she did not identify any women who are likely to lose coverage and offered no basis for her belief that any such women would seek care at her health center—beyond

asserting that such hypothetical women "will come from a wide range of social and economic backgrounds," JA 50 ¶ 20.

Massachusetts's estimate of the number of women with employer- or union-sponsored insurance who are financially eligible for state-funded programs is not sufficient to overcome the deficiencies in these declarations. Massachusetts estimates that roughly 365,000 women (approximately 25% of Massachusetts women of child-bearing age) have employer- or union-sponsored health coverage and are financially eligible for state-funded programs. *See* JA 55-57 ¶¶ 5-8; *see also* Br. 33. But that figure does not provide a sufficient basis to conclude that women who lost contraceptive coverage through their own employers as a result of the interim rules would turn to state-funded programs.

For instance, as the district court observed (JA 1416), Massachusetts's estimate may include employees of governmental entities (which are not eligible for the exemption under the interim rules) and employees covered by insured plans (which are subject to Massachusetts's own contraceptive-coverage law). The estimate may also include employees of entities that are already exempt from the contraceptive-coverage mandate under the prior rules (*i.e.*, under the

exemption for churches) or effectively exempt under the prior rules (*i.e.*, because they were using self-insured church plans) or protected by injunctions precluding the government from enforcing the mandate against them. It is unknown how Massachusetts's estimate would change if such women were excluded. Further, the estimate includes union-sponsored health coverage, although to our knowledge no union has ever expressed a religious or moral objection to providing contraceptive coverage.

Massachusetts states that it "already provides" secondary (or "wraparound coverage") for 150,000 residents to supplement their employer-sponsored insurance. Br. 36; *see also* JA 39 ¶ 4. Massachusetts does not say how many of these residents were included in its estimate of the number of women eligible for state-funded services. And Massachusetts does not say whether it is providing contraceptive coverage to any of these residents. But to the extent that Massachusetts is providing such coverage because, for example, these residents work for employers that are already exempt (or effectively exempt) from the contraceptive-coverage mandate under the prior rules or otherwise protected by injunctions precluding the government from

enforcing the mandate against them, the challenged rules will have no effect.

In any event, it is too speculative to assume that women who work for the *specific* employers that Massachusetts claims are likely to use the exemption would be eligible for and would in fact seek state-funded services. This is not a case in which one can simply rely on the "law of averages," *Berner v. Delahanty*, 129 F.3d 20, 24 (1st Cir. 1997), because the likelihood that a woman employed by a particular employer is financially eligible for state-funded services depends not just on the percentage of women across Massachusetts who are eligible for such services, but also on the particular employer—for example, on the types of jobs offered by the employer and the salaries the employer pays (compared with other Massachusetts employers). A court "cannot base a determination of standing upon a naked statistical assertion." *Nelsen v. King County*, 895 F.2d 1248, 1251 (9th Cir. 1990). Instead, the analysis "must be individualized and must consider all the contingencies that may arise in the individual case before the future harm will ensue." *Id.* Here, Massachusetts has provided no admissible evidence regarding the jobs held by employees of the three employers that it identified or the

wages they receive.[9] Moreover, Massachusetts's "naked statistic[]," *id.*, does not take into account whether an employee who lost coverage of her chosen contraceptive method through one of these three employers would have access to alternative coverage through, for example, a spouse's plan.

4. The Agencies' Regulatory-Impact Analysis Does Not Support Massachusetts's Standing

Unable to point to employers likely to use the expanded exemption under the challenged rules and women likely to lose coverage of their chosen contraceptive method as a result, Massachusetts argues (Br. 37-40) that the district court erred in requiring the Commonwealth to identify such employers and women.

a. Relying on the agencies' estimate (for purposes of a required regulatory-impact analysis) that the interim rules could affect 31,715 to 120,000 women, Massachusetts asserts that "Massachusetts employers, like employers in other States, are likely to use the [interim rules'] expanded exemptions, causing Massachusetts women to lose

[9] Massachusetts states only that Autocam has "a manufacturing facility in Plymouth," that Hobby Lobby has "four retail stores" in Massachusetts, and that Cummins-Allison has "an office located in Framingham." Br. 30, 31.

contraceptive coverage." Br. 27. But as the district court correctly recognized (JA 1403-08), Massachusetts cannot rely solely on the agencies' estimates.[10]

The agencies' analysis alone does not show that it is likely rather than speculative that, of the women who could lose contraceptive coverage because of the rules, there is even a single particular woman who (1) resides in Massachusetts; (2) would wish to use the particular contraceptive method to which her employer objects; and (3) would seek and qualify for financial assistance from the Commonwealth.

To begin, Massachusetts cannot simply assume (Br. 26-27) that the interim rules will affect a proportionate number of its residents as could be affected nationwide. The rules do not operate on individual women, but on employers. While it was appropriate for the agencies, in estimating the potential economic impact of the rules, to estimate the

[10] The agencies revised the regulatory-impact analysis in the final rules to take into account updated data and now estimate that 70,515 to 126,400 women could be affected. *See* 83 Fed. Reg. at 57,575-81; 83 Fed. Reg. at 57,625-27 (estimating that 15 women could be affected by the moral exemption). The increase in the lower end of the range is attributable to a revised estimate of the number of individuals covered by plans currently using the accommodation. *See* 83 Fed. Reg. at 57,576. The fundamental problem with Massachusetts's reliance on the agencies' estimates remains unchanged, however.

total number of women who could be affected by the rules, the relevant question here is whether a *Massachusetts employer* will use the exemption, a question the agencies' analysis does not address.

The lower end of the agencies' estimate is based in part on the number of women covered by health plans sponsored by litigating entities (*i.e.*, entities that challenged the mandate or accommodation). We do not know whether those employers—or their employees—are distributed proportionately across the States. Moreover, Massachusetts has already identified the two Massachusetts litigating entities included in the agencies' estimate (Hobby Lobby and Autocam), but as discussed (*supra* pp. 30-32), neither Massachusetts nor the administrative record provides any basis to conclude that those companies will decline to use the accommodation.[11]

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[11] Even to the extent other litigating entities are Massachusetts employers, those employers may not be required to comply with the mandate or accommodation even in the absence of the challenged rules. Many employers that challenged the mandate or accommodation under the prior rules are currently protected by injunctions precluding the government from enforcing the mandate against them. *See* 83 Fed. Reg. at 57,575 & n.81 (excluding from revised estimate in final rules litigating entities that had received permanent injunctions). It bears noting that the Catholic Benefits Association, one of the litigating entities that received such an injunction, represents more than 1,000

Continued on next page.

The agencies' lower estimate is also based on their assumption that some entities currently using the accommodation will switch to the exemption under the challenged rules. The agencies, however, had no "specific data" as to how many—or which—employers might switch from the accommodation to the exemption. 82 Fed. Reg. at 47,818; *see also* 83 Fed. Reg. at 57,577. The agencies did not even have a complete list of entities using the accommodation, as many entities elected to notify their insurers or third-party administrators directly, rather than notify HHS. *See* 82 Fed. Reg. at 47,817-18. The agencies thus made some educated assumptions about the number of women who might be covered by plans electing to switch from the accommodation to the exemption. These regulatory-impact assumptions, however, are too conjectural to support an Article III argument—and certainly do not provide "concrete evidence," Mass. Br. 42—that women in

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employers. *See* Catholic Benefits Ass'n, https://catholicbenefitsassociation.org/. Many of those employers did not themselves challenge the mandate but are protected by that injunction. *See* Order, *Catholic Benefits Ass'n v. Hargan*, No. 5:14-cv-0240 (W.D. Okla. Mar. 7, 2018); *see also* Order at 19-20, *Catholic Benefits Ass'n*, *supra* (June 4, 2014) (defining membership groups covered by the injunction).

Massachusetts will lose coverage of their chosen contraceptive methods.[12]

Moreover, Massachusetts has identified only one Massachusetts employer that was not a litigating entity and that used the accommodation under the prior rules (Cummins-Allison). And as discussed (*supra* pp. 32-33), neither the administrative record nor Massachusetts provides any basis for concluding that Cummins-Allison will stop using the accommodation. To be sure, since the spreadsheet that Massachusetts relies on includes only those accommodated employers that notified HHS (rather than, for example, their third-party administrator), there could be other Massachusetts employers that used the accommodation under the prior rules. But Massachusetts can only speculate that such an entity exists—let alone that it would switch from the accommodation to the exemption.

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[12] The agencies also explained that "[i]t is not clear the extent to which this number overlaps with the number estimated above of 6,400 women in plans of litigating entities that may be affected by these rules." 83 Fed. Reg. at 57,578. While the agencies conservatively assumed that there was no overlap "[i]n order to more broadly estimate the possible effects of these rules," *id.*, that only underscores the layers of conjecture in the analysis.

The agencies' upper estimate is intended to take into account the possibility that employers other than litigating and accommodated entities might use the expanded exemption. The estimate is based on a 2010 survey finding that approximately 6% of employer respondents did not offer contraceptive coverage before the implementation of the Affordable Care Act. *See* 82 Fed. Reg. at 47,822; 83 Fed. Reg. at 57,579. Although the agencies did not know "what motivated those employers to omit contraceptive coverage"—for example, "whether they did so for religious or other reasons"—the agencies used this data to provide another estimate of the number of women who could be affected by the expanded exemption. 83 Fed. Reg. at 57,579. The agencies made reasonable assumptions, and their analysis was a reasonable method of attempting to estimate an "upper bound" for the potential overall economic impact of the challenged rules. *Id.* But again, the agencies' regulatory-impact analysis is too conjectural to support Massachusetts's claimed Article III injury. As the Supreme Court has made clear, "[s]tanding is not an ingenious academic exercise in the conceivable," but "requires, at the summary judgment stage, a factual showing of perceptible harm." *Lujan*, 504 U.S. at 566 (quotation marks omitted). A

"factual showing" that *Massachusetts* employers will use the exemption under the interim rules is missing here.

The absence of that factual showing is particularly significant given that, as the district court explained, Massachusetts's own contraceptive-coverage law "renders suspect the Commonwealth's assumption that the [interim rules] would affect women proportionally throughout the country." JA 1408. Apparently attempting to address that concern, Massachusetts applies the percentage of employees in self-insured plans (which are not subject to the state contraceptive-coverage law) to its estimates of the number of women who could lose coverage. But as the district court recognized, there is still substantial "uncertainty" about the impact on Massachusetts employers. *See* JA 1407-08. For example, the agencies believe that publicly traded companies are unlikely to use the expanded exemption, and it is unclear whether and to what extent self-insured employers in Massachusetts are publicly traded or already exempt (or effectively exempt) from the contraceptive-coverage mandate under the prior rules or otherwise protected by injunctions precluding the government from enforcing the mandate against them. Without a more particularized showing,

Massachusetts's assumption that the rules will proportionately affect its residents is fatally speculative.

In any event, as discussed, even if one assumed that the rules will affect at least some Massachusetts residents, without knowledge of the circumstances surrounding both an employer that invokes the exemption and an employee faced with the loss of such employer-sponsored coverage, it is sheer speculation that Massachusetts will incur any costs. An employer that uses the exemption may still cover a particular woman's chosen contraceptive method. Unless Massachusetts identifies employers that will use the exemption and women covered by those employers' health plans, it is impossible to determine whether women in Massachusetts are likely to lose employer-sponsored coverage of their chosen contraceptive methods. Moreover, even if one could say with certainty that women in Massachusetts would lose such coverage under the challenged rules, the Commonwealth's alleged economic injury would still be too speculative to support Article III standing. The loss of contraceptive coverage will not translate into economic injury to Massachusetts if women have other access to private coverage, such as

through a spouse's plan, or are otherwise willing and able to pay out of pocket for contraception.

b. Relying on the agencies' regulatory-impact analysis, the Ninth Circuit recently held that several other States had standing to challenge the interim rules because they purportedly had "shown that the threat to their economic interest is reasonably probable." *California v. Azar*, 911 F.3d 558, 571-73 (9th Cir. 2018). But that court failed to address the many layers of speculation on which the States' claim of injury rested.

To begin, while the Ninth Circuit stated that the agencies "accounted for key factors likely to skew the estimate, including that some objecting employers will continue to use the accommodation instead of the new, expanded exemptions," *California*, 911 F.3d at 572, the court ignored the fact that the agencies had no "specific data" as to how many—or which—employers might "use the voluntary accommodation moving forward" or instead "use the expanded exemption," 82 Fed. Reg. at 47,818. The court observed that the record "includes names of specific employers identified by the [regulatory-impact analysis] as likely to use the expanded exemptions, including

those operating in the plaintiff states like Hobby Lobby Stores, Inc." *California*, 911 F.3d at 572. But as discussed (*supra* pp. 30-33), the administrative record provides no basis to conclude that Hobby Lobby (or the other identified employers) would decline to use the accommodation, and neither the plaintiff States nor the Ninth Circuit offered any such basis. Nor did the court address that the agencies' mere assumptions for purposes of a regulatory-impact analysis are not sufficient to satisfy plaintiffs' obligations to establish Article III standing.

Further, the Ninth Circuit ignored the fact that some employees may share their employers' objections to contraceptive coverage and that many employers that challenged the mandate objected only to some contraceptives and covered many others—facts that render speculative any contention that an employer that uses the exemption will choose not to cover the contraceptive method that a particular employee would otherwise choose.

Finally, the Ninth Circuit overlooked the lack of evidence that any residents of the plaintiff States who did lose contraceptive coverage would be eligible for, and seek, state-funded benefits. The court asserted

that the States' declarations demonstrated that "women losing coverage from their employers will turn to state-based programs or programs reimbursed by the state." *California*, 911 F.3d at 572. But the declarations themselves were speculative, offering no basis to conclude that any such women would in fact qualify for state-funded programs and lack access to other private contraceptive coverage through a spouse's plan.

c. Massachusetts contends that, "[i]n a comparable case, Texas was not required to identify the noncitizens who would apply for state-subsidized driver's licenses in order to establish fiscal injury likely to be caused by a federal policy that enabled those noncitizens to get licenses." Br. 39-40 (citing *Texas v. United States*, 809 F.3d 134 (5th Cir. 2015)). But the alleged injury in *Texas* did not rely on the same sort of contingencies as those relied on here, and Massachusetts thus can draw no support from that case (which, of course, is not controlling here in any event).

In *Texas*, the State claimed that it would incur significant costs in issuing driver's licenses to aliens accorded deferred action under the challenged policy. *See* 809 F.3d at 155. Under Texas law, otherwise

ineligible aliens would automatically become eligible for driver's licenses once they were granted deferred action, *see id.* at 149, and because Texas subsidized its licenses, it lost money on each license issued regardless of who it was issued to, *see id.* at 155. The court thus concluded that Texas had demonstrated economic injury: Texas would incur costs in issuing driver's licenses to aliens who received deferred action under the challenged policy, and it was undisputed that such aliens were present in Texas and would apply for licenses. *See id.* The economic injury did not depend on the particular individual granted deferred action or the particular circumstances surrounding his participation in the program. *Any* deferred-action recipient under the challenged policy would be eligible to apply for a state-subsidized license, and Texas would incur a financial loss.

The Commonwealth likewise can draw no support from *Massachusetts v. EPA*, 549 U.S. 497 (2007). The Commonwealth contends that, in that case, it "was not required to identify the parcels of state land that would be lost to sea level rise in order to establish injury." Br. 40. But in that case, the Commonwealth was *already* being injured—"rising seas ha[d] already begun to swallow Massachusetts'

coastal land." *Massachusetts*, 549 U.S. at 522. And its injury—the "loss of [its] sovereign territory" to rising seas, *id.* at 523 n.21—did not depend on which particular parcel of state land was lost.

By contrast, here, as discussed, given the particular chain of contingencies alleged, without knowledge of the circumstances surrounding both an employer that invokes the expanded exemption and an employee faced with the loss of such employer-sponsored coverage, it is sheer speculation that Massachusetts will incur any costs at all.

B. Massachusetts's Procedural Injury Is Not Sufficient to Establish Standing

As a threshold matter, Massachusetts's procedural challenge to the interim rules (unlike its substantive challenge) is moot in light of the final rules. *See Gulf of Maine*, 292 F.3d at 88-90; *see also Safari Aviation Inc. v. Garvey*, 300 F.3d 1144, 1150 (9th Cir. 2002) (Because "the life of the interim rule is over, no purpose is served by reviewing its rulemaking procedures."); *cf. Conservation Law Found.*, 360 F.3d at 23 n.2, 26-27 (holding that procedural challenge was not moot where statute contemplated periodic issuance of "framework adjustments,"

and where "alleged procedural deficiency" was likely to recur with subsequent frameworks, especially given that notice was provided in promulgating new framework only "in light of this appeal"). But even if Massachusetts continues, as it contends, to have a live procedural claim with respect to the final rules (*see* Mass. Resp. to Mot. to Govern at 3 n.1), the Commonwealth lacks standing to assert it.

1. As the district court held (JA 1421-22), because Massachusetts has not shown any injury traceable to the interim rules, the Commonwealth cannot rely on its alleged procedural injury to establish standing to challenge the rules. This Court and the Supreme Court have made clear that a party claiming procedural harm "is not relieved from compliance with the actual injury requirement for standing." *United States v. AVX Corp.*, 962 F.2d 108, 119 (1st Cir. 1992). "[T]he requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed" even when "the procedural right has been accorded by Congress." *Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009). Thus, "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." *Id.* at 496.

That means that Massachusetts "must show some concrete harm, apart from the denial of [its] right to participate [in the rulemaking], that constitutes 'injury in fact' for standing purposes." *Bensman v. U.S. Forest Serv.*, 408 F.3d 945, 955 (7th Cir. 2005). In other words, Massachusetts must show that the interim rules themselves will cause the Commonwealth some injury. *See AVX*, 962 F.2d at 119 (explaining that "the actual injury, if there is any, can only stem" from the underlying agency action, not "from an alleged impairment of the citizenry's right to comment"); *see also Arpaio v. Obama*, 797 F.3d 11, 21 (D.C. Cir. 2015) ("[T]he plaintiff in a procedural-injury case . . . must still show that the agency action was the cause of some redressable injury to the plaintiff." (quotation marks omitted)). As discussed above, however, Massachusetts has not demonstrated any such injury.

2. Massachusetts mistakenly suggests (Br. 50) that its showing is sufficient here because a plaintiff asserting a procedural injury need not "meet[] all the normal standards for redressability and immediacy," *Lujan*, 504 U.S. at 572 n.7. The point in *Lujan* was that a plaintiff need not show that compliance with the proper procedures would have changed the substantive *content* of the challenged agency action—here,

that the challenged rules would have been different if the agencies had followed the APA's normal notice-and-comment procedures. But a plaintiff must still demonstrate a substantive *injury* caused by the challenged agency action. That is made clear by the example the *Lujan* Court gave: "one living adjacent to the site for proposed construction of a federally licensed dam," the Court explained, "has standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered, and even though the dam will not be completed for many years." *Id.* But the Court left no doubt that such a plaintiff must still suffer a "distinctive concrete harm," *id.* at 577, that is not "conjectural or hypothetical," *id.* at 560 (quotation marks omitted). Indeed, in *Summers*, the Court concluded that plaintiffs lacked standing to assert a procedural injury because they had not demonstrated the sort of "actual or imminent injury" required to establish standing for their substantive claim. 555 U.S. at 496-97 (quoting *Lujan*, 504 U.S. at 564). Here, too, Massachusetts's claim of economic harm is too speculative to

demonstrate standing—for either its substantive claims or its procedural claim.

C. Massachusetts's Status as a Sovereign State Does Not Alter the Standing Analysis

1. Massachusetts Cannot Challenge the Rules as *Parens Patriae* on Behalf of Its Citizens

Massachusetts contends (Br. 50-53) that it also has *parens patriae* standing on the basis of its quasi-sovereign interest in protecting the well-being of its residents. The Supreme Court, however, has long held that "[a] State does not have standing as *parens patriae* to bring an action against the Federal Government." *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982). In other words, "a state may not attempt as parens patriae to enforce rights of its citizens 'in respect of their relations with the Federal Government.'" *Pennsylvania v. Porter*, 659 F.2d 306, 317 (3d Cir. 1981) (en banc) (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 486 (1923)). That is "no part of [a State's] duty or power," because the citizens of a State are also citizens of the United States, and "it is the United States, and not the state, which represents them as parens patriae, when such

representation becomes appropriate." *Mellon*, 262 U.S. at 485-86. When a State brings suit to protect its citizens from the government of the United States, "it usurps this sovereign prerogative of the federal government and threatens the general supremacy of federal law." *Virginia ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 269 (4th Cir. 2011) (quotation marks omitted); *see also Indiana v. EPA*, 796 F.3d 803, 809-10 (7th Cir. 2015); *Iowa ex rel. Miller v. Block*, 771 F.2d 347, 354-55 (8th Cir. 1985).

The Commonwealth misplaces its reliance on *Massachusetts*, 549 U.S. 497, in contending (Br. 53 n.22) that it may proceed as *parens patriae* here. In that case, the Supreme Court concluded that Massachusetts had standing to challenge the EPA's decision not to regulate greenhouse-gas emissions. But in finding standing, the Court did not invoke Massachusetts's *parens patriae* interests—*i.e.*, its interests in protecting its citizens' well-being. Rather, the Court relied on Massachusetts's own interests in protecting its sovereign territory. *Massachusetts*, 549 U.S. at 522; *see also Center for Biological Diversity v. U.S. Dep't of the Interior*, 563 F.3d 466, 476-77 (D.C. Cir. 2009) (observing that Massachusetts was suing in its individual interest).

In any event, even if a State could challenge the interim and final rules in its *parens patriae* capacity, Massachusetts has not demonstrated standing to do so here. As discussed, Massachusetts has not shown any injury to its residents traceable to the challenged rules: it has not identified any Massachusetts employers that will use the expanded exemption rather than the accommodation, let alone a woman who would be adversely affected by such an employer's decision.

2. Massachusetts Is Not Entitled to "Special Solicitude" Here

Massachusetts cannot overcome these obstacles to standing by invoking the "special solicitude" for States referred to in *Massachusetts*, 549 U.S. at 520. To begin, "special solicitude" would be of no help to Massachusetts here, as it does not alter the requirement to demonstrate a concrete injury. Indeed, in *Massachusetts*, there was no dispute that the Commonwealth was *already* being injured—"rising seas ha[d] already begun to swallow Massachusetts' coastal land." *Id.* at 522; *see also Delaware Dep't of Nat. Res. & Envtl. Control v. FERC*, 558 F.3d 575, 579 n.6 (D.C. Cir. 2009) ("This special solicitude does *not* eliminate the state petitioner's obligation to establish a concrete injury, as Justice

Stevens' opinion amply indicates."). As discussed, here Massachusetts has not demonstrated injury to its fisc or to the well-being of its residents, as the Commonwealth has not even identified a single woman who is likely to lose contraceptive coverage she wants.

In any event, Massachusetts has not asserted the sort of sovereign interest that warrants special solicitude. In *Massachusetts*, the Commonwealth asserted an injury akin to the injury that would occur if a contiguous State redrew its boundaries to assert dominion over part of Massachusetts's territory: Massachusetts alleged that rising seas would "lead to the loss of [its] sovereign territory." 549 U.S. at 523 n.21. Such a loss of territory would mean the loss of Massachusetts's ability to regulate conduct—either because Massachusetts has no jurisdiction over adjacent water or because that loss of territory would move inland the outer boundaries of Massachusetts's jurisdiction over adjacent water (*e.g.*, if Massachusetts's jurisdiction extends a certain distance from the coastline).

The special solicitude afforded Massachusetts in that case should not be extended to the type of injury that is asserted here—whether the alleged economic injury asserted directly by Massachusetts or the

alleged injury to the well-being of its residents asserted by Massachusetts in its *parens patriae* capacity. The standing doctrine is built on separation-of-powers principles and "concern about the proper—and properly limited—role of the courts in a democratic society." *Allen v. Wright*, 468 U.S. 737, 750, 752 (1984). These concerns apply with special force where, as here, the actions of one of the branches of the federal government are being challenged. *See Raines*, 521 U.S. at 819-20. Thus, in the absence of an overriding sovereign interest—such as the interest a State has in its own territorial boundaries—the Supreme Court's "standing inquiry has been especially rigorous." *Id.* at 819.

CONCLUSION

For the foregoing reasons, the district court's judgment should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Rule 32(a)(7)(B) because it contains 11,904 words, excluding the parts of the brief exempted under Rule 32(f), according to the count of Microsoft Word.

/s/ Karen Schoen
Karen Schoen

CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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