

**IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT**

STATE OF NEBRASKA, ET AL.,

Plaintiffs-Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; KATHLEEN SEBELIUS, in her official capacity as the Secretary of United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF THE TREASURY; TIMOTHY F. GEITHNER, in his official capacity as the Secretary of the United States Department of the Treasury; UNITED STATES DEPARTMENT OF LABOR; SETH D. HARRIS, in his official capacity as Acting Secretary of the United States Department of Labor,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

BRIEF FOR APPELLEES

STUART F. DELERY
Principal Deputy Assistant Attorney General

DEBORAH R. GILG
United States Attorney

BETH C. BRINKMANN
Deputy Assistant Attorney General

MARK B. STERN
ALISA B. KLEIN
ADAM C. JED
(202) 514-8280
*Attorneys, Appellate Staff
Civil Division, Room 7240
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, D.C. 20530*

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SUMMARY OF THE CASE

The plaintiffs in this case challenge federal regulations that require certain group health plans to cover certain contraceptive services. The district court dismissed the claims on grounds of standing and ripeness.

The government stands ready to present oral argument if the Court believes that argument would aid its consideration of this appeal, and concurs in appellants' suggestion that fifteen minutes be allotted per side if the Court determines that argument is appropriate.

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OF THE TREASURY; TIMOTHY F. GEITHNER, in his official capacity as the
Secretary of the United States Department of the Treasury; UNITED STATES
DEPARTMENT OF LABOR; SETH D. HARRIS, in his official capacity as Acting
Secretary of the United States Department of Labor,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

BRIEF FOR APPELLEES

STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331,
1361. JA 4. The district court entered final judgment dismissing the suit on July 17,
2012. JA 76; see also JA 75 (opinion). Plaintiffs filed a notice of appeal on September
14, 2012. JA 77-81.

STATEMENT OF THE ISSUES

Plaintiffs are various employers, employees, and states that wish to challenge the regulatory requirement that certain group health plans cover FDA-approved contraception, as prescribed by a health care provider. The issues presented are:

1. Whether the district court correctly dismissed for lack of standing because plaintiffs failed to allege facts showing that they are subject to the regulations that they seek to challenge.

Most apposite authorities: *Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

2. Whether, even assuming that plaintiffs had demonstrated standing, their suit is unripe because the challenged regulations are being amended and plaintiffs are protected by an enforcement safe harbor during the rulemaking process.

Most apposite authorities: *Wheaton College v. Sebelius*, ___ F.3d ___, Nos. 12-5273, 12-5291, 2012 WL 6652505 (D.C. Cir. Dec. 18, 2012) (per curiam); *Am. Petroleum Inst. v. EPA*, 683 F.3d 382 (D.C. Cir. 2012).

STATEMENT OF THE CASE

The plaintiffs in this case challenge federal regulations that require certain group health plans to cover certain contraceptive services. The district court dismissed the claims on grounds of standing and ripeness.

The court held that plaintiffs' allegations failed to establish that the challenged rules apply to any plaintiff, and that they had therefore failed to establish the existence

of an actual case or controversy. The court noted that several plaintiffs admitted explicitly that the rules do not apply to them. Other plaintiffs asserted that they would fall outside the rules' exemptions, but they provided no factual allegations to support this legal conclusion. The court also held that plaintiffs could not establish standing based on the possibility that their group health plans might be covered by the regulations at some future point. The court noted that plaintiffs alleged no intention of changes that would bring their health plans within the rules' ambit.

The court held that, in any event, plaintiffs' claims are not ripe. The court explained that the Departments charged with enforcing the regulations (Health and Human Services ("HHS"), Labor, and the Treasury) are in the process of amending the regulations to accommodate religious concerns like the ones raised by plaintiffs, and that the Departments have established an enforcement safe harbor that protects plaintiffs' health plans during the rulemaking. Because challenges to the present rules may never need to be resolved, and plaintiffs are at no imminent risk of enforcement by the Departments, plaintiffs' claims are not justiciable.

STATEMENT OF FACTS

A. Statutory and Regulatory Background

1. The Patient Protection and Affordable Care Act and its implementing regulations establish minimum standards for certain group health plans. Many of the standards, including the one at issue here, do not apply to grandfathered health plans, which are plans that have continuously covered at least one individual since March 23,

2010 and have not, for example, eliminated substantially all benefits concerning a particular condition or made significant changes concerning cost sharing. See 42 U.S.C. § 18011(a)(2); see, *e.g.*, 45 C.F.R. § 147.140(a), (f), (g).

A non-grandfathered plan must cover certain preventive health services without cost-sharing. These preventive health services include immunizations recommended by the Advisory Committee on Immunizations Practices, see 42 U.S.C. § 300gg-13(a)(2); items or services that have an “A” or “B” rating from the U.S. Preventive Services Task Force, see *id.* § 300gg-13(a)(1); preventive care and screenings for infants, children, and adolescents as provided in guidelines of HHS’s Health Resources and Services Administration (“HSRA”), see *id.* § 300gg-13(a)(3); and certain preventive care and services for women as provided in HRSA guidelines, see *id.* § 300gg-13(a)(4). Collectively, these preventive health services coverage provisions require that non-grandfathered plans cover an array of services including immunizations, blood pressure screening, mammograms, cervical cancer screening, and cholesterol screening.¹

In addition, and as relevant here, these provisions require that non-grandfathered plans cover “[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling

¹ See, *e.g.*, U.S. Preventive Services Task Force “A” and “B” Recommendations, available at <http://www.uspreventiveservicestaskforce.org/uspstf/uspstabrecs.htm>.

for all women with reproductive capacity,’ as prescribed by a provider.” 77 Fed. Reg. 8725, 8725 (Feb. 15, 2012).

The regulations that implement this contraceptive-coverage requirement authorize the exemption of group health plans sponsored by “religious employers.” The regulations define a religious employer as an organization that has as its purpose the inculcation of religious values, that primarily hires and serves persons who share the religious tenets of the organization, and that is a non-profit organization as described in Internal Revenue Code provisions applicable to churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. See, *e.g.*, 45 C.F.R. § 147.130(a)(1)(iv)(B).

2. In issuing final regulations in February 2012, the Departments charged with enforcing the contraceptive-coverage requirement (HHS, Labor, and the Treasury), “announced [their] intention to ‘develop and propose changes to these final regulations that would meet two goals’ — providing contraceptive coverage without cost-sharing to covered individuals and accommodating the religious objections of non-profit organizations like appellants.” *Wheaton College v. Sebelius*, ___ F.3d ___, Nos. 12-5273, 12-5291, 2012 WL 6652505, at *1 (D.C. Cir. Dec. 18, 2012) (per curiam) (quoting 77 Fed. Reg. at 8727).

In announcing this rulemaking, the Departments also “created a safe harbor from enforcement of the contraceptive coverage requirement[.]” *Ibid.* (citing 77 Fed. Reg. at 8728); see also HHS, Guidance on the Temporary Enforcement Safe Harbor

(Feb. 10, 2012) (“HHS Guidance”).² The safe harbor applies to the group health plans of non-profit organizations that, consistent with applicable state law, have not provided some or all required contraceptive coverage since February 10, 2012, because of religious objections; that have given notice to plan participants that the plan will not provide such contraceptive coverage during the first plan year starting on or after August 1, 2012 when the contraceptive-coverage requirement becomes effective; and that have certified that they meet the safe-harbor criteria. See 77 Fed. Reg. at 8727-29; HHS Guidance 3. The safe harbor is available to any institution of higher education and the issuer of its student health insurance plan if the institution and its student health insurance plan satisfy these criteria. See, *e.g.*, 77 Fed. Reg. 16,453, 16,456-57 (Mar. 21, 2012). It also is available to entities that took some action to try to exclude or limit contraceptive coverage without success prior to February 10, 2012. See HHS, Guidance on the Temporary Enforcement Safe Harbor 3 (Aug. 15, 2012).³

The safe harbor will remain in effect until the first plan year that begins on or after August 1, 2013. See 77 Fed. Reg. 16,501, 16,503 (Mar. 21, 2012); HHS Guidance 3 (Feb. 10, 2012). For example, for entities with plan years that begin each January 1, the safe harbor will remain in effect until the plan year that begins January 1, 2014.

² Available at <http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf>.

³ Available at <http://cciio.cms.gov/resources/files/prev-services-guidance-08152012.pdf>.

In announcing the safe harbor, the Departments stated that “[b]efore the end of the temporary enforcement safe harbor,” they would “develop and propose” a way to accommodate religious objections to contraceptive coverage by certain non-exempt organizations. 77 Fed. Reg. at 8727, 8728. The Departments explained that they would “work with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing with respect to non-exempted, non-profit religious organizations with religious objections to such coverage.” *Id.* at 8728.

3. On March 21, 2012, the agencies issued an Advance Notice of Proposed Rulemaking (ANPRM), requesting comments “on the potential means of accommodating” the concerns of certain non-exempt religious organizations “while ensuring contraceptive coverage for plan participants and beneficiaries covered under their plans (or, in the case of student health insurance plans, student enrollees and their dependents) without cost sharing.” 77 Fed. Reg. 16,501, 16,501 (Mar. 21, 2012). The ANPRM stated: “The Departments intend to propose that, when offering insured coverage to a religious organization that self-certifies as qualifying for the accommodation, a health insurance issuer may not include contraceptive coverage in that organization’s insured coverage. This means that contraceptive coverage would not be included in the plan document, contract, or premium charged to the religious organization.” *Id.* at 16,505. (The ANPRM went on to state: “Instead, the issuer would be required to provide participants and beneficiaries covered under the plan separate coverage for contraceptive services * * * without cost sharing * * * .” *Ibid.*).

The ANPRM also suggested ideas and solicited comments on ways to accommodate religious objections to contraceptive coverage of religious organizations that sponsor self-insured group health plans for their employees. *Id.* at 16,506-07. The ANPRM reiterated that the Departments “intend to finalize these amendments to the final regulations such that they are effective by the end of the temporary enforcement safe harbor.” *Id.* at 16,503.

4. On December 14, 2012, the Departments informed the D.C. Circuit in the oral argument in *Wheaton College* that they will publish a Notice of Proposed Rulemaking (“NPRM”) in the first quarter of 2013 so as to be able to issue new final rules before the safe harbor expires in August 2013. See *Wheaton College*, 2012 WL 6652505, at *1 (describing this as “a binding commitment”).

B. Procedural History

1. The plaintiffs in this case include a group of States with objections to the regulation of private health plans (JA 5-6); three Catholic, non-profit organizations that provide group health coverage to employees (JA 8-12); and two individuals who are participants in group health plans sponsored by Catholic organizations (JA 6-8). Plaintiffs filed suit in February 2012, alleging that the requirement that certain group health plans cover certain contraceptive services violates the First Amendment and the Religious Freedom Restoration Act. JA 18-21.

2. The district court dismissed the claims of all the plaintiffs.

The court held that the State plaintiffs lack standing because they are not covered by the contraceptive-coverage requirement and any “theory of standing is based on layers of conjecture.” JA 60. The court held that in the alternative it would dismiss the State plaintiffs on prudential standing grounds, because the States do not fall within the zone of interests of the First Amendment or Religious Freedom Restoration Act., and would in any event dismiss their claims on the merits for similar reasons. JA 66-67 & n.14. The States have not appealed any of these rulings.

The court held that the private plaintiffs had failed to establish that they are subject to the contraceptive-coverage requirement and that they thus failed to show the existence of an actual case or controversy.

Of the three non-profit organizations, one “admit[ted] that its group health plan is grandfathered” and thus not required to cover contraception. JA 53. The court observed that the other two non-profit organizations “allege[d] that their group health plans are not grandfathered,” but explained that this “legal conclusion” was merely a “naked assertion” not supported by any facts in the complaint. JA 51-53 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007))).

The court found that “the individual plaintiffs have not shown that their current health plans will be required to cover contraception-related services under the Rule.” JA 57. One “admit[ted] that her health plan is grandfathered.” JA 56. And

another merely asserted the “legal conclusion” that her health plan is not grandfathered but “failed to allege facts” to support that conclusion. JA 55-56. The district court noted, moreover, that neither individual plaintiff had alleged facts showing whether her employer falls outside of the exemption for “religious employers.” JA 56-57.

The court rejected the attempt of one of the non-profit organizations to establish standing on the ground that it might at some point wish to change its health plan and would then lose grandfathered status. JA 53. The court noted that the plaintiff had not alleged that it “intends to make — or is even contemplating — specific changes to its plan that would end its grandfathered status.” *Ibid.* “Instead,” the court observed, “the plaintiffs merely speculate and/or assume” that this organization “will lose grandfathered status sometime in the future.” *Ibid.* The court similarly found unpersuasive one individual plaintiff’s argument that her group health plan will “become subject” to “the contraceptive coverage Rule’ when ‘her employer * * * substantially changes” its plan. JA 56. “[S]peculation” that her “plan may change ‘at some indefinite time,’” the court explained, “is insufficient to establish her standing to sue.” *Ibid.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 n.2 (1992)).

The court also held that “even if the plaintiffs were able to establish standing,” dismissal would be required because “their claims are not ripe.” JA 67. “The plaintiffs face no direct and immediate harm,” the court explained, “and one can only

speculate whether the plaintiffs will ever feel any effects from the Rule when the temporary enforcement safe harbor terminates.” JA 74. Thus, the court concluded, “[t]his case clearly involves ‘contingent future events that may not occur as anticipated, or indeed may not occur at all,’ and therefore it is not ripe for review.” JA 74 (quoting *Missouri Roundtable for Life v. Carnahan*, 676 F.3d 665, 674 (8th Cir. 2012) (quoting *281 Care Committee v. Arneson*, 638 F.3d 621, 631 (8th Cir. 2011))).

The court noted the “tentative nature of the Departments’ position on religious accommodations” and the fact that “the contraceptive coverage requirement will not be enforced until the Departments consider whether to adopt additional, broader religious accommodations.” JA 70. “[U]nder these circumstances,” the court concluded, adjudicating plaintiffs’ challenges to the present contraceptive coverage requirement “would deny the Departments a full opportunity to modify their positions and undermine the interests of judicial economy.” JA 70.

The court contrasted the present circumstances to those in *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), and other cases cited by plaintiffs, in which “there was a clear expectation of conformity with the challenged regulation” and enforcement was certain. JA 71. Here, by comparison, the “temporary enforcement safe harbor prevents the Rule from being enforced against the plaintiffs until August 1, 2013.” *Ibid.* And the rule now being challenged “will be amended during the safe harbor period to accommodate religious objections to the contraceptive coverage requirements.” *Ibid.* “Indeed,” the court noted, “the amendment process has already

begun.” *Ibid.* Accordingly, the court found that “the Rule’s impact upon the plaintiffs is not ‘sufficiently direct and immediate’ to warrant judicial intervention.” *Ibid.* (quoting *Abbott Labs.*, 387 U.S. at 152).

The court found unpersuasive plaintiffs’ assertions that in light of the possibility of future enforcement of these rules or similar rules, they must make present changes to their health coverage. JA 71-72. The court reasoned that any such hardship “is neither imminent nor inevitable” in light of the enforcement safe harbor and the rulemaking process intended to address religious objections like those raised in this case. JA 72. Similarly, the court rejected plaintiffs’ assertion that they “‘must start making plans’” now or risk harm to “employee retention and recruitment.” *Ibid.* The court explained that plaintiffs’ “complaint includes no allegations” supporting this theory. *Ibid.* In any event, “the plaintiffs’ desire to plan for future contingencies that may never arise” does not render justiciable their challenges to future and tentative regulations. *Ibid.*

The court also rejected plaintiffs’ contention that the ongoing regulatory amendment process constitutes “review-evading gamesmanship.” JA 73. The court observed that when the Departments published the final rules, they concurrently announced the temporary enforcement safe harbor and plan to amend the regulations before the end of the safe harbor, thus alleviating such concerns. *Ibid.*

The district court dismissed the case without prejudice. JA 75, 76.

SUMMARY OF ARGUMENT

I. Plaintiffs seek to raise religious objections to the regulatory requirement that certain group health plans cover certain contraceptive services. Plaintiffs have not properly alleged, however, that they are covered by the requirement they wish to challenge. Several plaintiffs admit that their group health plans do not meet the criteria for covered plans and instead are grandfathered. Several plaintiffs allege that their plans fall within the rules' ambit — that their plans are not grandfathered and that they are not covered by the “religious employer” exemption — but they allege no facts whatsoever to support that assertion.

The district court accordingly correctly dismissed the case for lack of standing. The question whether plaintiffs' group health plans even fall within the ambit of the rules they seek to challenge is a question of law that turns on the application of the statute and regulations to the facts of each group health plan. Plaintiffs had ample opportunity to amend their complaint to allege relevant facts but failed to do so. The district court was not required to accept as true plaintiffs' conclusory assertion that their plans are not grandfathered and not covered by the “religious employers” exemption, within the meaning of the rules.

II. The court also correctly held that plaintiffs' claims are not ripe. It is not controverted that the challenged requirement is in the process of being amended and that the individual and organizational plaintiffs' health plans are protected by an enforcement safe harbor. The district court correctly held that it would not offer an

advisory opinion with regard to regulations that have not been and likely never will be enforced against these plaintiffs. See *Wheaton College v. Sebelius*, ___ F.3d ___, Nos. 12-5273, 12-5291, 2012 WL 6652505, at *2 (D.C. Cir. Dec. 18, 2012) (per curiam) (same).

STANDARD OF REVIEW

The judgments of dismissal are subject to de novo review. See *Tony Alamo Christian Ministries v. Selig*, 664 F.3d 1245, 1248 (8th Cir. 2012).

ARGUMENT

THE DISTRICT COURT CORRECTLY HELD THAT PLAINTIFFS' CLAIMS ARE NOT JUSTICIABLE

I. The District Court Correctly Held That Plaintiffs Have Not Established Standing.

1. Plaintiffs have not challenged the dismissal of the State plaintiffs. They argue, however, that the district court was required to accept their allegation that the private plaintiffs' health plans are subject to the challenged regulations and that they were not required to allege facts to support that legal conclusion.

The Supreme Court has made clear that courts “are not bound to accept as true” a “legal conclusion couched as a factual allegation[.]” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (holding that it was not sufficient to assert that the defendants “engaged in parallel conduct” and had “entered into a contract, combination, or conspiracy to prevent competitive entry” in their respective markets. 550 U.S. at 550-51) (internal quotation marks omitted); see *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009) (holding that “naked assertion[s] devoid of further factual

enhancement” are insufficient to survive a motion to dismiss, and that courts therefore “are not bound to accept as true a legal conclusion couched as a factual allegation”) (internal quotation marks omitted); see also *United States v. Metro. St. Louis Sewer Dist.*, 569 F.3d 829, 834 (8th Cir. 2009) (“[A] plaintiff must clearly allege facts showing an injury in fact[.]”).⁴

Many of the minimum standards established by the statute and regulations, including the one at issue, do not apply to “grandfathered” health plans. See 42 U.S.C. § 18011(a)(2); see, e.g., 45 C.F.R. § 147.140(a), (f), (g). And the contraceptive-coverage requirement does not apply to plans sponsored by “religious employers.” See, e.g., 45 C.F.R. § 147.130(a)(1)(iv)(B) (defining “religious employer”). As the

⁴ Plaintiffs note that the bar on pleading “legal conclusion[s]” without “the requisite factual enhancement” most often arises when a legal conclusion is a “component of the plaintiff’s legal claim.” See Br. 18. Plaintiffs, however, do not dispute that this rule is equally applicable to legal conclusions that support jurisdiction. Rule 8(a)(1)’s requirement that pleadings establish the “grounds for the court’s jurisdiction” is as demanding as Rule 8(a)(2)’s requirement that pleadings establish “entitle[ment] to relief.” Both require a “short and plain statement” to those effects. Fed. R. Civ. P. 8(a)(1) & (2); see also *Metropolitan St. Louis Sewer Dist.*, 569 F.3d at 833-34 (“To demonstrate standing, a plaintiff must clearly allege facts showing an injury in fact * * * .”); *Palnik v. Westlake Entm’t, Inc.*, 344 Fed. App’x 249, 251-53 (6th Cir. 2009) (unpub.) (“complaint must have ‘established with reasonable particularity’ those specific facts that support jurisdiction”) (citing, among other authorities, *Twombly*). Indeed, the Supreme Court has made clear that a party “invoking federal jurisdiction” must support “each element” of standing “in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); see also *Warth v. Seldin*, 422 U.S. 490, 518 (1975) (“It is the responsibility of the complainant clearly to allege *facts* demonstrating that he is a proper party to invoke judicial resolution of the dispute and the exercise of the court’s remedial powers.”) (emphasis added).

district court noted, one organizational plaintiff has “admit[ted] that its group health plan is grandfathered” (JA 53), and one individual plaintiff has similarly “admit[ted] that her health plan is grandfathered” (JA 56). The remaining plaintiffs alleged no facts suggesting that they fall within the rules’ ambit, even after the case was dismissed without prejudice on those grounds, giving them an opportunity to replead. See generally *Semtek Int’l, Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 505 (2001) (“The primary meaning of ‘dismissal without prejudice,’ we think, is dismissal without barring the plaintiff from returning later, to the same court, with the same underlying claim.”).

Plaintiffs mistakenly liken their allegation that their group health plans fall within the challenged rules’ ambit to an allegation that a party “is a ‘corporation’ [or] ‘limited liability company.’” Br. 19. Labels like “corporation” are ordinarily shorthand for verifiable, factual claims, *e.g.*, that a party is incorporated or registered with a state as having certain corporate status. If, by contrast, a party were to allege that it would be eligible to register in a certain state as a limited liability company or that it is a resident of a certain state for purposes of diversity jurisdiction—applications of fact to law—a court would not be required to accept these allegations as true. Similarly, an allegation that someone is a “peace officer” (Br. 19) ordinarily communicates an objective and verifiable fact—that the person is in the employment of a police department. It is therefore not necessary to plead “training date” or “badge number.” *Ibid.* By contrast, if a party alleges that he is covered by a statute

that applies to certain police officers and not others, he must plead facts showing why he falls within one category and not the other.⁵

2. The district court also correctly rejected the contention of one of the organizational plaintiffs that it had established standing because it would be covered by the challenged regulations *if* it were to make substantial changes to its health plans. See JA 53-54. As the district court noted, that plaintiff did not allege that it “intends to make — or is even contemplating — specific changes to its plan that would end its grandfathered status” and “[i]nstead * * * merely speculate[s] and/or assume[s]” that it “will lose grandfathered status sometime in the future.” JA 53. It is of no matter that *some* employers with grandfathered plans may make substantial changes to their plans and become subject to the contraceptive coverage requirement. See Br. 24 (citing HHS estimates of how many employers will change their plans and lose grandfathered status). What is relevant here are the allegations of the plaintiffs in this suit.

⁵ Plaintiffs mistakenly suggest that in *Legatus v. Sebelius*, No. 12-cv-12061, 2012 WL 5359630 (E.D. Mich. Oct. 31, 2012), the plaintiffs proceeded without any factual allegations to support the contention that they were covered by the challenged rules. See Br. 21. In *Legatus*, however, the plaintiffs *did* allege facts showing that they fall within the rules’ ambit. See, *e.g.*, Complaint at 16 ¶ 93 (alleging that insurance provider notified the plaintiff that it must cover contraception); Exhibit 4 to Motion for Temporary Restraining Order, Declaration of Joseph Di Cresce at 3, ¶¶ 10-12 (alleging that the Weingartz health plan has changed since March 23, 2010, including a substantial increase in cost-sharing).

The same reasoning applies to the contentions of one individual plaintiff who admits that the rules do not cover her health plan but speculates that her plans might lose grandfathered status at some future point. See JA 56. As the court explained, “speculation” that a “plan may change ‘at some indefinite future time’ is insufficient” to establish standing. *Ibid.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 n.2 (1992)). Indeed, it is black letter law that neither “assumed future intent,” *County of Mille Lacs v. Benjamin*, 361 F.3d 460, 464 (8th Cir. 2004), nor “‘some day’ intentions—without any description of concrete plans,” *Lujan*, 504 U.S. at 564, can establish an injury in fact.

Plaintiffs’ argument that they are “forced into a corner” where “they” (or their employers) “must choose” between making certain changes to their group health plans and maintaining grandfathered status is merely a restatement of the same argument. See Br. 25-26. Plaintiffs have not alleged that they (or their employers) intend or even want to make changes to the group health plans at issue that would alter their grandfathered status. The possibility that if plaintiffs were to do something they do not allege they want to do, they would then be burdened, does not establish a present and concrete injury in fact.

II. The District Court Correctly Held That Plaintiffs’ Claims Are Not Ripe.

The district court correctly held that even if plaintiffs had established standing, their claims should be dismissed as unripe.

1. “The ripeness doctrine flows both from the Article III ‘cases’ and ‘controversies’ limitations and also from prudential considerations for refusing to exercise jurisdiction.” *Paraquad, Inc. v. St. Louis Hous. Auth.*, 259 F.3d 956, 958 (8th Cir. 2001). “[I]n order to establish that a claim is ripe for judicial review, a plaintiff must meet two requirements. First, it must demonstrate a sufficiently concrete case or controversy within the meaning of Article III of the Constitution. Second, prudential considerations must justify the present exercise of judicial power.” *United States v. McAllister*, 225 F.3d 982, 989 (8th Cir. 2000) (citations and internal quotation marks omitted).

To satisfy “the irreducible constitutional minimum of standing,” a plaintiff must demonstrate an injury that is “actual or imminent,” and also show that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Lujan*, 504 U.S. at 560 (internal quotation marks omitted). To meet this requirement, an injury must be “certainly impending.” *Paraquad, Inc.*, 259 F.3d at 959; see also *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012). “This court has repeatedly stated that a case is not ripe if the plaintiff makes no showing that the injury is direct, immediate, or certain to occur.” *Public Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 573 (8th Cir. 2003).

Even when the bedrock criteria of Article III are satisfied, “there may also be prudential reasons for refusing to exercise jurisdiction.” *Am. Petroleum*, 683 F.3d at

386 (quotation marks and citations omitted); see *McAllister*, 225 F.3d at 989. “In the context of agency decision making, letting the administrative process run its course before binding parties to a judicial decision prevents courts from ‘entangling themselves in abstract disagreements over administrative policies, and * * * protect[s] the agencies from judicial interference’ in an ongoing decision-making process.” *Am. Petroleum*, 683 F.3d at 386 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967)). “Postponing review” also “conserve[s] judicial resources” and “comports with [a court’s] theoretical role as the governmental branch of last resort.” *Id.* at 386-87 (citation and quotation marks omitted). “Put simply, the doctrine of prudential ripeness ensures that Article III courts make decisions only when they have to, and then, only once.” *Id.* at 387 (citations omitted).

“In assessing the prudential ripeness of a case,” the Court focuses “on two aspects: the ‘fitness of the issues for judicial decision’ and the extent to which withholding a decision will cause ‘hardship to the parties.’” *Ibid.* (quoting *Abbott Labs.*, 387 U.S. at 149). “The fitness requirement is primarily meant to protect the agency’s interest in crystallizing its policy before that policy is subjected to judicial review and the court’s interests in avoiding unnecessary adjudication and in deciding issues in a concrete setting.” *Ibid.* (quotation marks and citation omitted). “Courts decline to review tentative agency positions because doing so severely compromises the interests the ripeness doctrine protects.” *Ibid.* (quotation marks and citation omitted).

2. In publishing the rules at issue, the agencies announced an enforcement safe harbor for certain entities raising religious concerns of the type presented here, and it is not disputed that the individual and organizational plaintiffs' health plans are protected by the enforcement safe harbor. It is also not disputed that the current regulations are in the process of being amended to address the type of concerns raised by organizations that are currently subject to the safe harbor. It is thus clear that the government will not enforce the rules in their current form against these plaintiffs. Accordingly, the D.C. Circuit and eleven district courts, in addition to the court below, have held that similar claims premised on burdens on group health plans sponsored by non-profit organizations are not ripe. See *Wheaton College v. Sebelius*, ___ F.3d ___, Nos. 12-5273, 12-5291, 2012 WL 6652505, at *2 (D.C. Cir. Dec. 18, 2012) (per curiam) (“[T]he cases are not fit for review at this time because ‘[i]f we do not decide [the merits of appellants’ challenge to the current rules] now, we may never need to.’”) (third alteration in original) (quoting *Am. Petroleum*, 683 F.3d at 387).⁶

⁶ See also *Roman Catholic Archbishop of Washington v. Sebelius*, No. 12-cv-815 (D.C.C. Jan. 25, 2013); *Persico v. Sebelius*, No. 12-cv-123 (W.D. Pa. Jan. 22, 2013); *Colorado Christian Univ. v. Sebelius*, No. 11-cv-03350, 2013 WL 93188 (D. Colo. Jan. 7, 2013); *Catholic Diocese of Peoria v. Sebelius*, No. 12-cv-1276, 2013 WL 74240 (C.D. Ill. Jan. 3, 2013); *Univ. of Notre Dame v. Sebelius*, No. 12-cv-253, 2012 WL 6756332 (N.D. Ind. Dec. 31, 2012); *Catholic Diocese of Biloxi v. Sebelius*, No. 12-cv-00158, Mem. Op. and Order (S.D. Miss. Dec. 20, 2012); *Zubik v. Sebelius*, No. 12-cv-676, 2012 WL 5932977 (W.D. Pa. Nov. 27, 2012), appeal docketed, No. 13-1228 (3d Cir.); *Catholic Diocese of Nashville v. Sebelius*, No. 12-cv-934, 2012 WL 5879796 (M.D. Tenn. Nov. 21, 2012), appeal docketed, No. 12-6590 (6th Cir.); *Legatus v. Sebelius*, No. 12-cv-12061,

Plaintiffs are under no threat of imminent enforcement by the Departments and accordingly face no “‘immediate and significant’ hardship.” JA 69 (quoting *Am. Petroleum*, 683 F.3d at 386). They do not claim that their plans fall outside the scope of the enforcement safe harbor. Accordingly, as the district court explained, “[t]he plaintiffs face no direct and immediate harm * * * and one can only speculate whether the plaintiffs will ever feel any effects from the Rule when the temporary enforcement safe harbor terminates.” JA 74.

3. Plaintiffs mistakenly suggest that the very existence of published regulations renders their challenge ripe. See Br. 26-27. The point of the ripeness doctrine, however, is that in certain circumstances plaintiffs may *not* challenge a final published regulation. Thus, a challenge is “not ripe if the plaintiff makes no showing that the injury is direct, immediate, or certain to occur.” *Public Water Supply Dist. No. 10*, 345 F.3d at 573. And it is also not ripe if the rule is tentative, and there is no immediate and significant burden, such as “expected conformity” backed up by the imminent threat of prosecution and heavy sanctions for failure to comply. See *Am. Petroleum*, 683 F.3d at 389; see also *Abbott Labs*, 387 U.S. at 150-53.

2012 WL 5359630 (E.D. Mich. Oct. 31, 2012), appeals docketed, Nos. 13-1092, 13-1093 (6th Cir.); *Wheaton College v. Sebelius*, No. 12-cv-1169, 2012 WL 3637162 (D.D.C. Aug. 24, 2012); *Belmont Abbey College v. Sebelius*, No. 11-cv-1989, 2012 WL 2914417 (D.D.C. July 18, 2012); but see *Roman Catholic Archdiocese of New York v. Sebelius*, No. 12-cv-2542, 2012 WL 6042864 (E.D.N.Y. Dec. 4, 2012), motion for reconsideration or for certification under 28 U.S.C. § 1292(b) filed, Jan. 11, 2013, ECF No. 41.

Thus, even in *Abbott Labs.*, the case on which plaintiffs chiefly rely, the Court not only noted that there was a final rule but also inquired whether there was any “hint that th[e] regulation is * * * tentative” and whether “compliance was expected.” 387 U.S. at 151. In the companion case of *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158 (1967), the challenge to a final regulation was unripe because the challenged regulation “required” no action on the part of the challengers, and “no irremediable adverse consequences flow from requiring a later challenge.” *Id.* at 164-65; see also *Public Water Supply Dist. No. 10*, 345 F.3d at 573 (“This court has repeatedly stated that a case is not ripe if the plaintiff makes no showing that the injury is direct, immediate, or certain to occur.”); *McAllister*, 225 F.3d at 989-90 (case not ripe where legal rule that plaintiff challenges may never be applied against him); *Vorbeck v. Schnicker*, 660 F.2d 1260, 1266 (8th Cir. 1981) (disagreement “must have taken on fixed and final shape”) (quoting *Public Service Comm’n v. Wycoff Co.*, 344 U.S. 237, 243-44 (1952)). Indeed, the circumstances here are not materially distinguishable from those in *American Petroleum*, in which the D.C. Circuit dismissed a challenge to EPA regulations as unripe because “[a]fter the parties completed briefing, EPA issued a notice of proposed rulemaking that, if made final, would significantly amend” the challenged regulations. 683 F.3d at 384.

Plaintiffs correctly note that the safe harbor is “temporary.” Br. 27, 29. They fail to note, however, that the underlying rules are in the process of being amended and will be different when the safe harbor expires. Thus, “enforcement” of *these*

regulations is not “certain,” and no “injury” is “certainly impending.” Br. 27. The Departments have made clear that they will “never enforce” the regulations “in [their] current form against” religious organizations covered by the safe harbor. *Wheaton College*, 2012 WL 6652505, at *1 (emphasis omitted). “There will * * * be a different rule” that will be promulgated. *Ibid.*

As the district court explained, the facts of this case amply demonstrate that the government is not “engaged in review-evading gamesmanship.” JA 73. When the Departments announced the final rules, they also announced the temporary enforcement safe harbor and plan to amend the regulations before the end of the safe harbor. *Ibid.* “[T]he Rule is currently undergoing a process of amendment.” JA 74. And the “‘definite end date’ to the amendment process * * * ‘further alleviates any concern’” that the Departments are “‘using a new rulemaking to evade review.’” JA 73 (quoting *Am. Petroleum*, 683 F.3d at 389).

Plaintiffs concede that “had the temporary enforcement safe harbor been silent as to when it would expire * * * a conclusion of non-ripeness would be supportable.” Br. 28. It should be even more apparent that the announced rulemaking schedule renders their challenge unripe. As the district court noted, this “‘definite end date’ to the amendment process * * * further alleviates any concern” that the Departments are “‘using a new rulemaking to evade review.’” JA 73 (quoting *Am. Petroleum*, 683 F.3d at 389).

4. The district court also properly rejected plaintiffs' contentions that "they must take immediate account" of the present rule (Br. 28), and that they "must start making plans now as to which health care plans they will offer" when the safe harbor expires (Br. 29-30).

As the district court noted, "[t]he complaint includes no allegations stating that the plaintiffs must begin planning now." JA 72. And plaintiffs did not even argue to the district court, as they now argue here, that their claims are ripe because they must "provide plan participants a notice" that they do not cover contraceptive services in order to avail themselves of the safe harbor (Br. 29).

In any event, neither the alleged burden of sending a notice to plan participants nor of making unspecified plans can overcome the strong presumption against adjudicating challenges to a "tentative position." See *Am. Petroleum*, 683 F.3d at 389. Neither is the sort of substantial hardship, such as imminent threat of prosecution and heavy fines, that justifies review of a requirement in the process of being changed. See, e.g., *Abbott Labs*, 387 U.S. at 151-53. The district court thus correctly found that "the plaintiffs' desire to plan for future contingencies that may never arise does not constitute the sort of hardship that can establish the ripeness of their claims." JA 72 (citing *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 162 (7th Cir. 1976)); see also, e.g., *Colorado Christian Univ.*, 2013 WL 93188 at *8 ("present planning for future eventualities do[es] not demonstrate a 'direct and immediate' effect on plaintiff's 'day-to-day business' with 'serious penalties attached to noncompliance' as required to

establish hardship”) (quoting *Abbott Labs*, 387 U.S. at 152-53); *Catholic Diocese of Nashville*, 2012 WL 5879796, at *5 (“Plaintiffs’ desire to plan for future contingencies that may never arise does not constitute the sort of hardship that can establish the ripeness of their claims”).

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

STUART F. DELERY

Principal Deputy Assistant Attorney General

DEBORAH R. GILG

United States Attorney

BETH C. BRINKMANN

Deputy Assistant Attorney General

MARK B. STERN

ALISA B. KLEIN

ADAM C. JED /s/ *Adam Jed*

(202) 514-8280

Attorneys, Appellate Staff

Civil Division, Room 7240

U.S. Department of Justice

950 Pennsylvania Ave., N.W.

Washington, D.C. 20530

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/s/ Adam Jed

Adam C. Jed

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I hereby certify that on January 29, 2013, I electronically filed the foregoing brief with the Clerk of the Court by using the appellate CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Adam Jed

Adam C. Jed