

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

GENEVA COLLEGE,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary of the United
States Department of Health and Human Services;
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES; HILDA SOLIS,
Secretary of the United States Department of
Labor; UNITED STATES DEPARTMENT OF
LABOR; TIMOTHY GEITHNER, Secretary of
the United States Department of the Treasury, and
UNITED STATES DEPARTMENT OF THE
TREASURY,

Defendants.

Civil Action No.
2:12-CV-00207-JFC

DEFENDANTS' MOTION TO DISMISS

Pursuant to Federal Rule of Civil Procedure 12(b)(1), Defendants hereby move to dismiss this action. The grounds for this motion are set forth in the accompanying memorandum.

Respectfully submitted this 30th day of April, 2012,

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CERTIFICATE OF SERVICE

I hereby certify that on April 30, 2012, I caused a true and correct copy of this Motion to Dismiss and accompanying memorandum in support to be served on plaintiff's counsel by means of the Court's ECF system.

/s/ Eric R. Womack
ERIC R. WOMACK

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**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF
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INTRODUCTION

The Patient Protection and Affordable Care Act (“ACA”), Pub. L. No. 111-148, 124 Stat. 119 (2010),¹ and implementing regulations, require all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain recommended preventive services without cost-sharing (such as a copayment, coinsurance, or a deductible).² As relevant here, except as to group health plans of certain religious employers (and health insurance coverage sold in connection with those plans), the preventive services that must be covered include all Food and Drug Administration (“FDA”)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider. Plaintiff Geneva College filed suit seeking to have the Court declare the preventive services coverage regulations invalid and enjoin their implementation. Plaintiff alleges that its sincerely held religious beliefs prohibit it from providing the required coverage for certain services.

Over the past few months, defendants issued guidance on a temporary enforcement safe harbor and initiated a rulemaking to further amend the preventive services coverage regulations to address religious concerns such as those raised by plaintiff in this case. The enforcement safe harbor provides that defendants will not bring any enforcement action against non-profit organizations with religious objections to providing contraceptive coverage (and associated plans and issuers) if they meet certain criteria. The safe harbor protects such organizations until the first plan year that begins on or after August 1, 2013. Defendants also published an advance notice of proposed rulemaking (“ANPRM”) in the Federal Register that confirms defendants’ intent, before the expiration of the safe harbor period, to propose and finalize amendments to the preventive services coverage regulations to further accommodate non-exempt, non-grandfathered

¹ Amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

² A grandfathered plan is one that was in existence on March 23, 2010 and that has not undergone any of a defined set of changes. 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140.

religious organizations' religious objections to covering contraceptive services. The ANPRM suggests ideas and solicits public comment on potential accommodations, including, but not limited to, requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage and simultaneously to offer contraceptive coverage directly to such organizations' plan participants, at no charge.

In light of these actions, this Court lacks authority to adjudicate plaintiff's claims. As an initial matter, plaintiff's suit must be dismissed because plaintiff has not alleged any imminent injury from the operation of the regulations. Plaintiff sponsors a group health plan for its employees, and plaintiff has not made factual allegations that establish that the plan—which plaintiff's allegations suggest does not cover the contraceptive services to which plaintiff objects on religious grounds—is ineligible for grandfather status. It has merely offered a legal conclusion to that effect. Thus, even prior to defendants' most recent actions, plaintiff has not borne its burden to allege facts from which this Court could conclude that plaintiff is under any current obligation to offer coverage for contraceptive services. Moreover, even assuming that plaintiff's group health plan is not grandfathered, plaintiff has not alleged an imminent injury that would support standing in light of the enforcement safe harbor—which protects plaintiff (and the issuer(s) of plaintiff's employee and student health plans) until at least January 1, 2014—by which time defendants will, as they have announced publicly, have finalized amendments to the challenged regulations to accommodate the religious objections of organizations such as plaintiff.

The Court likewise lacks jurisdiction because this case is not ripe under the Third Circuit's three-factor framework articulated in *Step-Saver Data Systems, Inc. v. Wyse Technology*, 912 F.2d 643 (3d Cir. 1990). "Adversity of interest," "conclusivity," and "practical help, or utility," are all lacking because the temporary enforcement safe harbor will be in effect such that plaintiff, even if its group health plan is not eligible for grandfather status, will not suffer any hardship as a result of its failure to cover certain contraceptive services, and because

defendants have initiated a rulemaking to amend the challenged regulations to accommodate religious objections to providing contraceptive coverage, like plaintiff's.

BACKGROUND

I. STATUTORY BACKGROUND

Prior to the enactment of the ACA, many Americans did not receive the preventive health care they needed to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce health care costs. Due in large part to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) (“IOM REP.”). Section 1001 of the ACA—which includes the preventive services coverage provision that is relevant here—seeks to cure this problem by making recommended preventive care affordable and accessible for many more Americans.

The preventive services coverage provision requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing.³ 42 U.S.C. § 300gg-13. The preventive services that must be covered include, for women, such additional preventive care and screenings not separately recommended by the United States Preventive Services Task Force as provided in comprehensive guidelines supported by the Health Resources and Services Administration (“HRSA”), an agency within the Department of Health and Human Services (“HHS”). *Id.*

³ A group health plan includes a plan established or maintained by an employer that provides medical care to employees. 42 U.S.C. § 300gg-91(a)(1). The ACA does not require employers to provide health coverage for their employees, but, beginning in 2014, certain large employers may face assessable payments if they fail to do so under certain circumstances. 26 U.S.C. § 4980H.

Institutions of higher education are not required by federal law to provide, or to contract with health insurance issuers to provide, health insurance to their students. If students receive health insurance through a health insurance issuer, then the obligation to provide coverage for recommended preventive services rests on the issuer, not the institution of higher education. *See e.g.*, 45 C.F.R. § 147.130(a). If students receive health coverage directly through an institution of higher education, and not through a health insurance issuer, then there is no obligation to provide coverage for recommended preventive services under federal law. *See* 77 Fed. Reg. 16453, 16455 (Mar. 21, 2012).

Research shows that cost-sharing requirements can pose barriers to preventive care and result in reduced use of preventive services, particularly for women. IOM REP. at 109. Indeed, a 2010 survey showed that less than half of women are up to date with recommended preventive care screenings and services. *Id.* at 19. By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and utilization of recommended preventive services. 75 Fed. Reg. 41726, 41728 (July 19, 2010). Increased use of preventive services will benefit the health of individual Americans and society at large. 75 Fed. Reg. at 41733. Individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease; healthier workers will be more productive with fewer sick days; and increased utilization will result in savings due to lower health care costs. *Id.*; IOM REP. at 20.

Defendants issued interim final regulations on July 19, 2010 that provide, among other things, that a group health plan or health insurance issuer offering non-grandfathered health coverage must provide coverage for newly recommended preventive services, without cost-sharing, for plan years that begin on or after the date that is one year after the date on which the new recommendation is issued. 75 Fed. Reg. 41726. Because there were no existing HRSA guidelines relating to preventive care for women, HHS tasked the Institute of Medicine (“IOM”) with “reviewing what preventive services are necessary for women’s health and well-being” and developing recommendations for comprehensive guidelines. IOM REP. at 2. IOM conducted an extensive science-based review and, on July 19, 2011, published a report of its analysis and recommendations. *Id.* at 20-26. The report recommended that HRSA guidelines include, among other things, “the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” *Id.* at 10-12.

On August 1, 2011, HRSA adopted IOM’s recommendations in full, subject to an exemption relating to certain religious employers authorized by an amendment to the interim final regulations. *See* HRSA Guidelines, *available at* <http://www.hrsa.gov/womensguidelines/>. The amendment, issued on the same day, authorized HRSA to exempt group health plans

sponsored by certain religious employers (and associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46621 (Aug. 3, 2011). To qualify for the exemption, an employer must meet all the following criteria:

- (1) The inculcation of religious values is the purpose of the organization.
- (2) The organization primarily employs persons who share the religious tenets of the organization.
- (3) The organization serves primarily persons who share the religious tenets of the organization.
- (4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

45 C.F.R. § 147.130(a)(1)(iv)(B).⁴ Thus, as relevant here, the amended interim final regulations required non-grandfathered plans that do not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years beginning on or after August 1, 2012.

After considering the more than 200,000 comments they received on the amended interim final regulations, defendants decided to adopt in final regulations the definition of religious employer contained in the amended interim final regulations while also creating a temporary enforcement safe harbor for plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage that do not qualify for the religious employer exemption. 77 Fed. Reg. 8725-27 (Feb. 15, 2012).

Pursuant to the temporary enforcement safe harbor, defendants will not take any enforcement action against an employer, group health plan, or group health insurance issuer with respect to a non-exempt, non-grandfathered group health plan that fails to cover any recommended contraceptive service and that is sponsored by an organization that meets all of the following criteria:

⁴ Sections 6033(a)(1), (a)(3)(A)(i), and (a)(3)(A)(iii) of the Internal Revenue Code refer to "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," that are exempt from taxation under 26 U.S.C. § 501(a).

- (1) The organization is organized and operates as a non-profit entity.
- (2) From February 10, 2012 onward, contraceptive coverage has not been provided at any point by the group health plan sponsored by the organization, consistent with any applicable state law, because of the religious beliefs of the organization.
- (3) The group health plan sponsored by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third-party administrator) provides to plan participants a prescribed notice indicating that the plan will not provide contraceptive coverage for the first plan year beginning on or after August 1, 2012.
- (4) The organization self-certifies that it satisfies the three criteria above, and documents its self-certification in accordance with prescribed procedures.⁵

The safe harbor also applies to any institution of higher education and the issuer of its student health insurance plan if the institution and its student plan satisfy the criteria above. 77 Fed. Reg. at 16456-57. The safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. Guidance at 3. By that time, defendants expect significant amendments to the preventive services coverage regulations will have altered the landscape with respect to religious accommodations under the regulations by providing further relief to organizations like plaintiff.

Defendants began the process of amending the regulations on March 21, 2012 by publishing an ANPRM in the Federal Register. 77 Fed. Reg. 16501. The ANPRM “presents questions and ideas” on potential alternative means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations’ liberty interests. *Id.* at 16503. The purpose of the ANPRM is to provide “an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made” in the forthcoming amendments. *Id.* Among other options, the ANPRM suggests requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage on religious grounds and simultaneously to offer contraceptive coverage directly to the organization’s plan participants, at no charge. *Id.* at 16505. The ANPRM also suggests ideas and

⁵ HHS, Guidance on the Temporary Enforcement Safe Harbor (“Guidance”), at 3 (Feb. 10, 2012), available at <http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf>.

solicits comments on potential ways to accommodate religious organizations that sponsor self-insured group health plans for their employees and religious organizations that are non-profit institutions of higher education that arrange health insurance plans for their students. *Id.* at 16505-07. After receiving comments on the ANPRM, defendants will publish a notice of proposed rulemaking, which will be subject to further public comment before defendants issue amendments to the preventive services coverage regulations. *Id.* at 16501. Defendants intend to finalize the amendments such that they are effective by the end of the temporary enforcement safe harbor. *Id.* at 16503.

II. CURRENT PROCEEDINGS

Plaintiff brought this action to challenge the lawfulness of the preventive services coverage regulations to the extent that they require the health coverage it makes available to its employees and students to cover certain contraceptive services to which it objects. Plaintiff describes itself as a “Christ-centered institution of higher learning” with approximately 1,850 students and 350 employees. Compl. ¶¶ 10, 31, 32. Plaintiff’s allegations suggest that plaintiff currently makes available to its employees and students health plans that do not cover certain forms of contraception. *Id.* ¶¶ 45-46, 48. Plaintiff alleges that it believes emergency contraceptives prevent a fertilized egg from implanting in the wall of the uterus thereby causing what plaintiff believes is an abortion. Plaintiff further alleges that its “sincerely held religious beliefs prohibit it from providing coverage for abortion, abortifacients, embryo-harming pharmaceuticals, and related education and counseling, or providing a plan that causes access to the same through its insurance company.” *Id.* ¶ 102. Plaintiff also asserts that it does not qualify for the religious employer exemption because, among other things, the inculcation of religious values is only one of its purposes. *Id.* ¶ 66. Plaintiff claims the preventive services coverage regulations violate the First and Fifth Amendments to the United States Constitution, the Religious Freedom Restoration Act, and the Administrative Procedure Act.

STANDARD OF REVIEW

Defendants move to dismiss this case for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. The party invoking federal jurisdiction bears the burden of establishing its existence. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998). Where, as here, defendants challenge jurisdiction on the face of the complaint, the complaint must plead sufficient facts to establish that jurisdiction exists. This Court must determine whether it has subject matter jurisdiction before addressing the merits. *Id.* at 94-95.

ARGUMENT

I. THE COURT SHOULD DISMISS THIS CASE BECAUSE PLAINTIFF LACKS STANDING

Plaintiff lacks standing because it has not alleged a concrete and imminent injury resulting from the operation of the preventive services coverage regulations. To meet its burden to establish standing, a plaintiff must demonstrate that it has “suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Allegations of possible future injury do not suffice; rather, “[a] threatened injury must be certainly impending to constitute injury in fact.” *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). A plaintiff that “alleges only an injury at some indefinite future time” has not shown an injury in fact, particularly where “the acts necessary to make the injury happen are at least partly within the plaintiff’s own control.” *Lujan*, 504 U.S. at 564 n.2. In these situations, “the injury [must] proceed with a high degree of immediacy.” *Id.*

The preventive services coverage regulations do not apply to grandfathered plans. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140. A grandfathered plan is a health plan in which at least one individual was enrolled on March 23, 2010 and that has continuously covered at least one individual since that date. *Id.* A grandfathered plan may lose its grandfather status if, compared to its existence on March 23, 2010, it undergoes one or more changes provided in 45 C.F.R. § 147.140(g)(1).

Here, plaintiff alleges that it will sponsor a plan for its employees beginning January 1, 2013 that will not be eligible for grandfather status. Compl. ¶¶ 47, 89. But plaintiff alleges no facts whatsoever to support that bare legal conclusion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (observing that a court considering a motion to dismiss is “not bound to accept as true a legal conclusion couched as a factual allegation” or “naked assertion[s] devoid of further factual enhancement”). The regulations defining grandfathered health plan coverage make clear that merely entering into a new plan does not by itself cause a group health plan to lose grandfather status. 45 C.F.R. § 147.140(a)(1)(i) (“[A] group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer).”). Instead, the new plan must, when compared to the plan in existence on March 23, 2010, eliminate all or substantially all benefits to diagnose or treat a particular condition, increase a percentage cost-sharing requirement, significantly increase a fixed-amount cost-sharing requirement, significantly reduce the employer’s contribution, or impose or tighten an annual limit on the dollar value of any benefit. 26 C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1). Plaintiff does not allege that the plan beginning January 1, 2013 will have undergone any of these changes. Nor does plaintiff allege that it will alter its group health plan in the immediate future in any of these specified ways. And it is not to be expected that plaintiff would act to forego its grandfather status lightly. Accordingly, plaintiff’s allegations simply do not show that plaintiff will be required by the preventive services coverage regulations to provide coverage for the full range of FDA-approved contraceptive services—as opposed to continuing to offer the same grandfathered plan that purportedly does not, and presumably would not, cover the services to which plaintiff objects on religious grounds. Plaintiff therefore has not alleged any imminent injury as a result of the challenged regulations.

Furthermore, even if plaintiff had sufficiently alleged that its group health plan does not qualify for grandfather status, plaintiff still would not have alleged an injury in fact. Under the enforcement safe harbor, defendants will not take any enforcement action against an organization that qualifies for the safe harbor until the first plan year that begins on or after August 1, 2013. Guidance at 3. Plaintiff states that it “may not qualify” for the enforcement safe harbor “under its vague requirements.” Compl. ¶ 94. But even apart from plaintiff’s own implicit concession that it may qualify for the safe harbor, plaintiff alleges no facts to support any claim that it would not. *See Iqbal*, 129 S. Ct. at 1949-50; *RHJ Med. Ctr., Inc. v. City of DuBois*, 754 F. Supp. 2d 723, 732-33 (W.D. Pa. 2010).

Plaintiff alleges nothing to suggest it will be unable to meet the criteria for the enforcement safe harbor with respect to both its employee group health plan and its student health insurance plan. Because plaintiff alleges its plan year begins on January 1, Compl. ¶ 47, the earliest plaintiff could be subject to any enforcement action by defendants for failing to provide contraceptive coverage is January 1, 2014. With such a long time before the inception of any possible injury and the challenged regulations undergoing amendment, plaintiff cannot satisfy the imminence requirement for standing; the asserted injury is simply “too remote temporally.” *See McConnell v. FEC*, 540 U.S. 93, 226 (2003), *overruled in part on other grounds by Citizens United v. FEC*, 130 S. Ct. 876 (2010).

This defect in plaintiff’s suit does not implicate a mere technical issue of counting intermediate days; rather, it goes to the fundamental limitations on the role of federal courts. The “underlying purpose of the imminence requirement is to ensure that the court in which suit is brought does not render an advisory opinion in ‘a case in which no injury would have occurred at all.’” *Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 500 (D.C. Cir. 1994) (quoting *Lujan*, 504 U.S. at 564 n.2). The ANPRM published in the Federal Register confirms, and seeks comment on, defendants’ intention to propose amendments to the preventive services coverage regulations that will accommodate the concerns of religious organizations that object to providing contraceptive coverage for religious reasons, like plaintiff. 77 Fed. Reg. at 16501. The

ANPRM provides plaintiff, and any other interested party, with the opportunity to, among other things, comment on ideas suggested by defendants for accommodating religious organizations, offer new ideas to “enable religious organizations to avoid . . . objectionable cooperation when it comes to the funding of contraceptive coverage,” and identify considerations defendants should take into account when amending the regulations. *Id.* at 16503, 16507. Defendants, moreover, have indicated that they intend to finalize the amendments to the regulations before the rolling expiration of the temporary enforcement safe harbor starting on August 1, 2013. *Id.* at 16503. In light of the forthcoming amendments, and the opportunity the rulemaking process provides for plaintiff to shape those amendments, there is no reason to suspect that plaintiff will be required to sponsor a health plan or arrange health insurance that covers contraceptive services in contravention of its religious beliefs once the enforcement safe harbor expires. At the very least, given the anticipated changes to the preventive services coverage regulations, any claim of injury after the temporary enforcement safe harbor expires would differ substantially from plaintiff’s current claim. And, given the existing enforcement safe harbor, there is no basis for this Court to consider the merits of plaintiff’s claims. Accordingly, this case should be dismissed.

II. THE COURT SHOULD DISMISS THIS CASE BECAUSE IT IS NOT RIPE

“The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.” *Nat’l Park Hospitality Ass’n v. Dep’t of the Interior*, 538 U.S. 803, 808 (2003). It “prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies.” *Id.* at 807. It also “protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Id.* at 807-08. A case ripe for judicial review cannot be “nebulous or contingent but must have taken on fixed and final shape.” *Pub. Serv. Comm’n v. Wycoff Co.*, 344 U.S. 237, 244 (1952).

The Supreme Court, in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), laid out the two fundamental considerations for the determination of ripeness: (1) “the fitness of the issues

for judicial decision” and (2) “the hardship to the parties of withholding court consideration.” *Id.* at 149. In the context of declaratory judgments, the Third Circuit has refined those considerations into the three-pronged framework articulated in *Step-Saver Data Systems, Inc. v. Wyse Technology*, 912 F.2d 643 (3d Cir. 1990). Under the *Step-Saver* framework, courts look to the “adversity of interest” between the parties, the “conclusivity” that a declaratory judgment would have on the legal relationship between the parties, and the “practical help, or utility” of a declaratory judgment.” *Id.* at 647.⁶ None of these indicia of ripeness exists here.

Adversity of Interest: To satisfy the first prong of the *Step-Saver* framework, “the defendant must be so situated that the parties have adverse legal interests.” 912 F.2d at 648. “Although the party seeking review need not have suffered a completed harm to establish adversity of interest, it is necessary that there be a substantial threat of real harm and that the threat must remain real and immediate throughout the course of the litigation.” *Presbytery of N.J. v. Florio*, 40 F.3d 1454, 1463 (3d Cir. 1994). “[A] potential harm that is ‘contingent’ on a future event occurring will likely not satisfy this prong of the ripeness test.” *Pittsburgh Mack Sales & Serv. v. Int’l Union of Operating Eng’rs*, 580 F.3d 185, 190 (3d Cir. 2009).

Plaintiff seeks judicial review of the preventive services coverage regulations as applied to non-exempted, non-profit religious organizations that object to contraceptive coverage for religious reasons, like plaintiff. Defendants, however, have initiated a rulemaking to amend the preventive coverage regulations to accommodate the concerns expressed by plaintiff and similarly situated organizations and have made clear that the amendments will be finalized well before the earliest date on which the challenged regulations could be enforced by defendants

⁶ The Third Circuit has indicated that the three-step *Step-Saver* framework can be used somewhat interchangeably with the Supreme Court’s two-part framework set out in *Abbott Laboratories*. See *Phila. Fed’n of Teachers v. Ridge*, 150 F.3d 319, 323 n.4 (3d Cir. 1998). If the Court were to apply the *Abbott Laboratories* framework, this case would still be unripe. Given defendants’ ongoing administrative process, its public commitment to regulatory change, and the temporary enforcement safe harbor, the issues presented in this case are unfit for judicial review, and plaintiff will suffer no hardship from the Court’s withholding of consideration.

against plaintiff. 77 Fed. Reg. at 8728-29. Therefore, the alleged threatened injury is contingent upon the occurrence of uncertain future events, and cannot support a finding of adversity.

Moreover, the forthcoming amendments are intended to address the very issue that plaintiff raises here by establishing alternative means of providing contraceptive coverage without cost-sharing to women with reproductive capacity, as prescribed by a health care provider, while accommodating religious objections to covering contraceptive services by non-profit, religious organizations like plaintiff. And plaintiff will have several opportunities to participate in the rulemaking process and to provide comments and/or ideas regarding the proposed accommodations. There is, therefore, a significant chance that the amendments will alleviate altogether the need for judicial review, or at least narrow and refine the scope of any actual controversy to more manageable proportions. *See Texas v. United States*, 523 U.S. 296, 300 (1998) (“A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.”). Once the forthcoming amendments are finalized, if plaintiff’s concerns are not laid to rest, plaintiff “will have ample opportunity [] to bring its legal challenge at a time when harm is more imminent and more certain.” *Ohio Forestry Ass’n v. Sierra Club*, 523 U.S. 726, 734 (1998); *see also Tex. Indep. Producers and Royalty Owners Ass’n v. EPA*, 413 F.3d 479, 483-84 (5th Cir. 2005) (dismissing challenge to rule as unripe where agency deferred effective date of rule and announced its intent to consider issues raised by plaintiff in new rulemaking); *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999); *Lake Pilots Ass’n, Inc. v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160-62 (D.D.C. 2003) (holding challenge to rule was unripe where agency undertook a new rulemaking to address challenged issue).

Conclusivity: The second *Step-Saver* factor requires courts to determine whether there is a “real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.” 912 F.2d at 649. This requirement is based on the recognition that a declaratory judgment granted in the absence of a concrete set of facts “would itself be a ‘contingency,’ and

applying it to actual controversies which subsequently arise would be an ‘exercise in futility.’” *Armstrong World Indus., Inc. v. Adams*, 961 F.2d 405, 412 (3d Cir. 1992).

This case lacks conclusivity, as it is undoubtedly based on contingent facts. Although plaintiff raises largely legal claims, those claims are leveled at regulations that, as applied to plaintiff and similarly situated organizations, have not “taken on fixed and final shape.” *Pub. Serv. Comm’n*, 344 U.S. at 244. Once defendants complete the rulemaking outlined in the ANPRM, plaintiff’s challenge to the current regulations will be moot. *See The Toca Producers v. FERC*, 411 F.3d 262, 266 (D.C. Cir. 2005) (rejecting purely legal claim as unripe due to the possibility that it may not need to be judicially resolved). And judicial review of any future amendments to the regulations that result from the ongoing rulemaking would be too speculative to yield meaningful review, let alone constitute a challenge to a final rule as required by the APA. The ANPRM offers ideas and solicits input on potential, alternative means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations’ liberty interests. 77 Fed. Reg. at 16503. It does not preordain what amendments to the preventive services regulations defendants will ultimately promulgate; nor does it foreclose the possibility that defendants will adopt ideas not set out in the ANPRM. Thus, review of any of the suggested proposals contained in the ANPRM would only entangle the Court “in abstract disagreements over administrative policies.” *Abbott Labs.*, 387 U.S. at 148; *see also Tex. Indep. Producers*, 413 F.3d at 484; *Motor Vehicle Mfrs. Assoc. v. N.Y. Dep’t of Env’tl. Conservation*, 79 F.3d 1298, 1306 (2d Cir. 1996); *Lake Pilots Ass’n*, 257 F. Supp. 2d at 162. Judicial review at this time would inappropriately interfere with defendants’ ongoing rulemaking and may result in the Court deciding issues that may never arise.

Practical Help, or Utility: Finally, because “one of the primary purposes behind the Declaratory Judgment Act was to enable plaintiffs to preserve the status quo, a case should not be considered justiciable unless the court is convinced that [by its action] a useful purpose will be served.” *Armstrong*, 961 F.2d at 412 (quoting *Step-Saver*, 912 F.2d at 649). This prong of the

Step-Saver framework requires the Court to consider whether a declaratory judgment will affect the parties' plans of actions by alleviating legal uncertainty. 912 F.2d at 649 n.9.

Here, plaintiff alleges that, despite the temporary enforcement safe harbor and the upcoming amendments, it will have to take the preventive services regulations into account "as it plans expenditures, including employee compensation and benefits packages," which will have a "profound and adverse effect on the College." Compl. ¶¶ 92, 95. But "[m]ere economic uncertainty affecting plaintiff's planning is not sufficient to support premature review." *Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987). Plaintiff is not being compelled to make immediate and significant changes in its day-to-day operations under threat of serious civil and criminal penalties. *Compare Abbott Labs*, 387 U.S. at 153-54. As explained above, if the group health plan made available by plaintiff to its employees is eligible for grandfather status—and there are no factual allegations to indicate that it is not—then plaintiff can continue to sponsor this plan, which purportedly does not cover the contraceptive services to which plaintiff objects on religious grounds. Even if plaintiff sponsors a non-grandfathered group health plan, it can qualify for the temporary enforcement safe harbor, meaning defendants will not take any enforcement action against plaintiff (or the issuer(s) of plaintiff's employee and student health plans) for failure to cover contraceptive services until January 1, 2014, at the earliest. *See* Guidance at 3. And, by the time the enforcement safe harbor expires, defendants will have finalized amendments to accommodate religious objections to providing contraceptive coverage. *See* 77 Fed. Reg. at 8728-29. Therefore, this is not a case where plaintiff is faced with a "Hobson's choice" of foregoing lawful behavior or subjecting [itself] to prosecution under the challenged provision." *Armstrong*, 961 F.2d at 423-24 (relying on the lack of such a choice in concluding declaratory judgment would be of little practical help, or utility). The utility of resolving plaintiff's claims would be non-existent or, at most, minimal, and insufficient to make this case justiciable.

CONCLUSION

For all the foregoing reasons, this Court should grant defendants' motion to dismiss.

Respectfully submitted this 30th day of April, 2012,

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