



Office of the General Counsel

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August 31, 2011

Submitted Electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-9992-IFC2
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Interim Final Rules on Preventive Services File Code CMS-9992-IFC2

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops, we respectfully submit the following comments on the interim final rule on preventive services. 76 Fed. Reg. 46621 (Aug. 3, 2011). Our comments fall into two broad categories.

First, we comment on the mandate that all health plans cover prescription contraceptives, sterilization, and related patient education and counseling (“HHS mandate” or “the mandate”). This mandate, we submit, should be rescinded in its entirety. These are not “health” services, and they do not “prevent” illness or disease. Instead, they disrupt the healthy functioning of the reproductive system, introducing health risks in the process; and they are designed to prevent pregnancy, which is not a disease.¹

The HHS mandate is also unprecedented in federal law and more radical than any state contraceptive mandate enacted to date. Insofar as it requires coverage of drugs that can operate to cause an abortion, the mandate violates the Weldon amendment, certain provisions of the Patient Protection and Affordable Care Act (“PPACA” or “the Act”) dealing with abortion and non-preemption, and

¹ As the FDA’s own medical advisers explained long ago: “The oral contraceptives present society with problems unique in the history of human therapeutics. Never will so many people have taken such potent drugs voluntarily over such a protracted period for an objective other than for control of disease.” U.S. Food and Drug Administration, Advisory Committee on Obstetrics and Gynecology, Report on the Oral Contraceptives 1 (1966).

the Administration’s own public assurances, both pre- and post-enactment, that the Act does not require coverage of abortion.

Finally, as applied to individuals and organizations with a religious objection to contraceptives, sterilization, and related counseling and education, the HHS mandate violates various protections under the Religion Clauses and Free Speech Clause of the First Amendment, as well as the Religious Freedom Restoration Act (“RFRA”) and the Administrative Procedure Act (“APA”).

Second, we comment on the regulation’s religious exemption (“HHS exemption” or “the exemption”). The exemption provides no protection at all for *individuals* or *insurers* with a moral or religious objection to contraceptives or sterilization, who will experience burdens to conscience under this new mandate. Instead, it provides protection only to *employers* with similar objections, and even then to a very small subset of religious employers.

The exemption is narrower than any conscience clause ever enacted in federal law, and narrower than the vast majority of religious exemptions from state contraceptive mandates. The exemption also fails to make clear whether it covers sterilization and education and counseling about sterilization. By failing to protect insurers, individuals, most employers, or any other stakeholders with a religious objection to such items and procedures, the HHS exemption, like the mandate itself, violates the First Amendment and the APA.

In sum, we urge HHS to rescind the mandate in its entirety.² Only rescission will eliminate all of the serious moral problems the mandate creates; only rescission will correct HHS’s legally flawed interpretation of the term “preventive services.” If HHS nonetheless persists in mandating coverage of contraceptives, sterilization, and related education and counseling, it must address the especially grave legal and constitutional problems it creates (1) by including in the mandate those drugs that can cause an abortion, and (2) by failing to protect all stakeholders with a religious or moral objection to the mandate. HHS is legally forbidden from mandating coverage of any drug that can cause an abortion, and from forcing individuals or institutions to provide coverage for contraception, sterilization, or related education and counseling over their religious or moral objections.

² By “the mandate,” we are referring, of course, only to the requirement that health plans cover contraceptives, sterilization, and related education and counseling. We are not referring to the entire list of preventive services for women. Moreover, our references to the HHS mandate and the HHS exemption should be taken as applying to all three departments that issued the interim final rule. Any relief requested here from HHS is sought from all three departments.

Indeed, such nationwide government coercion of religious people and groups to sell, broker, or purchase “services” to which they have a moral or religious objection represents an unprecedented attack on religious liberty.

Our more detailed comments follow.

I. The HHS Mandate

Although HHS has not requested comments on this topic, we urge HHS, in the strongest possible terms, to reconsider its decision to include contraceptives (including abortifacients) and sterilization among the “preventive services” that insurers will be forced to cover. That critical change is appropriate for the following reasons.

A. Our prior comments urging HHS to limit the “preventive services” mandate to services that promote health and prevent disease should be revisited and have been reinforced by subsequent scientific studies.

In our comments last year, we explained why HHS should not include contraceptives in any list of mandated “preventive services.” We attach those earlier comments, marked as Addendum A, and incorporate them by reference into the present set of comments so they may be considered anew.³

Many of our previous observations about contraceptives are equally applicable to sterilization. Subjecting a person to drugs and procedures that render a healthy bodily system dysfunctional—in this case, making a woman temporarily or permanently infertile—is not properly seen as basic health care, much less as an appropriate candidate for mandatory health coverage. Indeed, many contraceptive drugs, far from preventing disease and injury, are associated with adverse health outcomes. Just as these drugs are not “health” services, they are not “preventive” services; they prevent (or abort) pregnancy, and pregnancy is not a disease. Our earlier comments addressed this at some length.

In the brief time since those comments, additional studies have been published which suggest that newer hormonal contraceptives may increase women’s risk of blood clots to a greater extent than earlier drugs,⁴ and that taking

³ These earlier comments are also available online at <http://old.usccb.org/ogc/preventive.pdf>.

⁴ U.S. Food and Drug Administration, “FDA Drug Safety Communication: Safety Review of possible increased risk of blood clots with birth control pills containing drospirenone” (May 31, 2011) (available at <http://www.fda.gov/Drugs/DrugSafety/ucm257164.htm>).

hormonal contraceptives is associated with an increased risk that women will both contract and transmit HIV.⁵ Yet screening and counseling to *prevent* HIV infection is a widely accepted element in HHS’s list of “preventive services” for women. Mandating coverage for drugs that can increase this risk places the interim final rule at war with itself.

B. The HHS mandate is unprecedented at the federal level and the most radical among the States.

At the federal level, the HHS mandate is an utter novelty. Until now, no federal law of any kind, or at any time, has required private health plans to cover contraceptives or sterilization. Efforts to pass such a law in Congress have consistently failed.⁶

When compared with the laws of the 50 states, the HHS contraceptive mandate is the most radical in the Nation. A substantial number of states (at least 22) have no contraceptive mandate whatsoever. Of the 28 states with some type of contraceptive mandate,⁷ none is as sweeping as the one adopted by HHS:

- *First*, no state requires coverage of contraceptives in *all* plans. State contraceptive mandates generally exclude self-insured and ERISA plans.
- *Second*, no state (except California and Georgia) mandates contraceptive coverage in plans that have no prescription drug coverage.
- *Third*, no state (except Vermont) requires coverage of sterilization.

⁵ R. Heffron, *et al.*, “Hormonal contraceptive use and risk of HIV-1 transmission: a prospective cohort analysis,” Abstract, 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, International AIDS Society (July 17-20, 2011) (available at <http://pag.ias2011.org/abstracts.aspx?aid=1715>). As long ago as 1999, an NIH-funded analysis of 28 prior studies found “a significant association between oral contraceptive use and HIV-1 seroprevalence or seroincidence.” C. Wang, *et al.*, “Risk of HIV Infection in Oral Contraceptive Pill Users: A Meta-analysis,” 21 *Journal of Acquired Immune Deficiency Syndromes* (1999), 51-58 at 51 (available at <http://www.jaids.org/pt/re/jaids/fulltext.00126334-199905010-00007.htm>).

⁶ Since 1997, at least 21 bills have been introduced in Congress to mandate prescription contraceptive coverage in private health plans (generally to apply to plans that have other prescription drug coverage), under the titles “Equity in Prescription Insurance and Contraceptive Coverage Act” or “Prevention First Act.” A Senate committee hearing was held on two of these bills—in 1998 and then in 2001. No committee or subcommittee of Congress has ever reported out any of these 21 bills.

⁷ The state contraceptive mandates and exemptions are listed in Addendum B.

Thus, the requirement that *all* plans cover contraceptives (including “emergency contraceptives”) *and* sterilization is not only unprecedented in federal law, but far more sweeping than any state law. The fact that a mandate of such scope has not commanded the support of any legislature in this country is a telling commentary on how radical the HHS mandate is, and how far removed it is from legislatively-enacted public policy throughout the Nation.⁸

C. By requiring coverage of drugs that can cause abortion, the HHS mandate violates the Weldon amendment, PPACA’s own abortion and non-preemption provisions, and the Administration’s own assurances that PPACA would not be construed to require coverage of abortion.

The HHS mandate requires coverage of “all FDA-approved contraceptives.” HHS claims in a fact sheet that the mandate does “not include abortifacient drugs.”⁹ However, the regulation itself, which obviously takes precedence over any governmental “fact sheet,” contains no such exclusion. Moreover, studies show that at least one drug approved by the FDA for “contraceptive use,” a close analogue to the abortion drug RU-486 (mifepristone), can cause an abortion when taken to avoid pregnancy.¹⁰ And the prospect remains that other drugs, approved now or in the future by the FDA for contraceptive use, will be shown to have a similar effect.

1. Violation of the Weldon Amendment. Insofar as the HHS mandate requires coverage of any drug that operates to cause an abortion, it violates the Weldon amendment, which has been included in every Labor/HHS appropriations law since 2004.¹¹ The amendment states that “None of the funds made available in

⁸ Here we address the HHS *mandate*. Equally radical is the undue narrowness of the HHS *exemption*, addressed below. Each problem, of course, exacerbates the other.

⁹ See <http://www.healthcare.gov/news/factsheets/womensprevention08012011a.html>.

¹⁰ The drug in question is ulipristal (HRP 2000, or Ella). See A. Tarantal, *et al.*, “Effects of Two Antiprogestins on Early Pregnancy in the Long-Tailed Macaque (*Macaca fascicularis*),” 54 *Contraception* 107-115 (1996), at 114 (“studies with mifepristone and HRP 2000 have shown both antiprogestins to have roughly comparable activity in terminating pregnancy when administered during the early stages of gestation”); G. Bernagiano & H. von Hertzen, “Towards more effective emergency contraception?,” 375 *The Lancet* 527-28 (Feb. 13, 2010), at 527 (“Ulipristal has similar biological effects to mifepristone, the antiprogestin used in medical abortion”).

¹¹ For the most recent enactment of the Weldon amendment, see Consolidated Appropriations Act, 2010, Pub. L. 111-117, Div. D, § 508(d) (Dec. 16, 2009). The amendment remains in legal effect through a series of Continuing Resolutions.

this Act [*i.e.*, the Labor/HHS appropriations bill from which HHS derives its funding] may be made available to a Federal agency or program ... if such agency ... [or] program ... subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not ... pay for ... [or] *provide coverage of ... abortions*” (emphasis added). The term “health care entity” is defined by the Weldon amendment to include “a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.”

By operation of the Weldon amendment, no Labor/HHS funds may be made available to HHS if it subjects any health care plan to discrimination on the basis that the plan does not provide coverage of abortions. Obviously, to *require* that all plans cover any form of abortion is the most direct form of abortion-based discrimination one could imagine against plans that would exclude abortion coverage. Thus, insofar as the HHS contraceptive mandate requires coverage of any drug that can cause an abortion, it violates the Weldon amendment.¹²

2. Violation of PPACA § 1303(b)(1)(A). Insofar as it requires coverage of abortifacient drugs, HHS’s contraceptive mandate also violates the abortion and non-preemption provisions of the Patient Protection and Affordable Care Act (“PPACA” or “Act”). Section 1303(b)(1)(A) of PPACA states that “nothing in this title”—*i.e.*, title I of the Act, which includes the provision dealing with “preventive services”—“shall be construed to require a qualified health plan to provide coverage of [abortion] services ... as part of its essential health benefits for any plan year.” As Section 1303 goes on to state, it is “the issuer” of a plan that “shall determine whether or not the plan provides coverage” of abortion services. Thus, under PPACA, it is not HHS that has the authority to decide whether a plan covers abortion, but the plan issuer.

There is no indication in the text or legislative history of PPACA that Congress intended, on the one hand, to bar the mandatory coverage of *surgical* abortion, but to permit the mandatory coverage of so-called *medical* (*i.e.*, drug-induced) abortion. Indeed, Congress itself drew no distinction between surgical and medical abortion when, in PPACA, it decided to give plans the discretion

¹² A plan claiming the protection of the Weldon amendment is not required to assert a religious or moral objection to abortion or abortion referral. This is clear from the statutory text; the amendment says nothing about religious or moral objections. The government simply may not create a mandate for involvement in abortion services that would discriminate against plans that decline such involvement for any reason.

whether or not to cover abortion. If HHS were to impute this senseless distinction to Congress, it would construe the law unreasonably.

3. Violation of PPACA § 1303(c)(1). Insofar as the HHS mandate requires coverage of any such drug, it also conflicts with State laws in at least 11 states that restrict abortion coverage in all plans or in all exchange-participating plans.¹³ Section 1303(c)(1) of PPACA states that nothing in the Act preempts, or has any effect on, any State law regarding abortion coverage. Accordingly, the HHS mandate, as applied to any drug that can cause abortion, is invalid where it conflicts with any state law restricting abortion coverage.

4. Violation of Public Assurances Against Mandatory Coverage of Abortion. Finally, the mandate violates the Administration's public assurances, both before and after enactment of PPACA, that the Act would not be construed to require coverage of abortion. Such assurances played a major role in securing final passage of the bill, and were formalized in an Executive Order issued by the President. *See* Executive Order 13535, "Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act," 75 Fed. Reg. 15599 (Mar. 24, 2010). Any federal mandate to require such coverage now in regulations implementing PPACA would run afoul of the Administration's previously-stated position on this issue.

Thus, if HHS were to decline to rescind the mandate entirely, then it would violate the Weldon amendment, PPACA, and the Administration's own stated policy, unless it excluded from the mandate any drug that can cause an abortion.

D. The HHS mandate violates the Religion and Free Speech Clauses of the United States Constitution.

The HHS mandate violates several distinct protections under the Religion and Free Speech Clauses of the First Amendment: (1) Free Exercise and Establishment Clause protections against laws that discriminate based on religion; (2) Free Exercise and Establishment Clause protections against laws that interfere with internal governance of religious institutions; (3) Free Exercise protections against laws that impose "substantial burdens" on religious exercise (a) pursuant to

¹³ Those states are Arizona, Idaho, Kentucky, Louisiana, Mississippi, Missouri, North Dakota, Oklahoma, Rhode Island, Tennessee, and Virginia. *See* Ariz. Rev. Stat. § 20-121; Idaho Code §§ 41-1848, 41-2142, 41-2210A, 41-3439; Ky. Rev. Stat. Ann. § 304.5-160; La. Stat. Ann. tit. 22 § 1014; Miss. Code §§ 41-41-95 to 41-41-99; Mo. Ann. Stat. § 376.805; N.D. Cent. Code § 14-02.3-03; Okla. Stat. Ann. tit. 63, § 1-741.3; R.I. Stat. § 27-18-28; Tenn. Code Ann. § 56-26-134; Va. Acts 2011, c. 823.

a system of “individualized exemptions,” or (b) in conjunction with other fundamental rights (so-called “hybrid rights”); (4) Free Speech protections against compelled speech; and (5) Free Speech protections of expressive association.¹⁴

1. Religious Discrimination. The contraceptive mandate is a “religious gerrymander” that targets Catholicism for special disfavor *sub silentio* and therefore violates both the Free Exercise and Establishment Clauses of the First Amendment. Though neutral on its face, “the effect of [the mandate] in its real operation is strong evidence of its object.” *Church of the Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 535 (1993). Before the mandate, *insurers* were free to issue plans covering contraception and sterilization (or not); *employers* were free to sponsor, and usually subsidize, plans with this coverage (or not); and *employees* were free to choose this coverage and pay for it through their premiums (or not). As a result of this freedom, not only was religious conviction accommodated among all these stakeholders, but coverage for contraception and sterilization was very widespread.¹⁵

HHS would nonetheless force those few who would object to selling, buying, or brokering the coverage to do so.¹⁶ In other words, the class that suffers under the mandate is defined precisely by their beliefs in objecting to these “services.” Moral opposition to all artificial contraception and sterilization is a minority and unpopular belief, and its virtually exclusive association with the Catholic Church is no secret. Thus, although the mandate does not expressly target Catholicism, it does so implicitly by imposing burdens on conscience that are well known to fall almost entirely on observant Catholics—whether employees, employers, or insurers. Such religious discrimination is forbidden by both the Free Exercise and Establishment Clauses of the First Amendment. *See, e.g., Lukumi*,

¹⁴ In this section, we address only the legal defects in the HHS mandate. In a later section of these comments, we address similar defects in the HHS exemption.

¹⁵ *See* Guttmacher Institute, “In Brief: Fact Sheet: Facts on Contraceptive Use in the United States” (June 2010) (available at www.guttmacher.org/pubs/fb_contr_use.html) (“Nine in 10 employer-based insurance plans cover a full range of prescription contraceptives” in the United States).

¹⁶ Indeed, some have defended the mandate precisely on the grounds that the great majority of secular employers already purchase contraceptive coverage, indicating that a central goal of the mandate is to force those with moral or religious objections to do the same.

508 U.S. at 532 (Free Exercise Clause); *Larson v. Valente*, 456 U.S. 228, 244-45 (1982) (Establishment Clause).¹⁷

2. Interference with Church Governance. In a well-established line of cases under both Religion Clauses, the Supreme Court has acknowledged the “power [of churches] to decide for themselves, free from state interference, matters of church government as well as those of faith and doctrine.” *Kedroff v. St. Nicholas Cathedral*, 344 U.S. 94, 116 (1952).¹⁸ It is difficult to imagine a more intrusive form of state interference in church governance than laws forcing churches as employers (save those few excepted) to purchase for, and then provide without charge to, their employees services that violate the religion’s own moral rules. It is no less problematic when church insurers—mutual aid societies that come into existence precisely to protect a religious community and its members—are forced to sell coverage that violates the community’s own rules. If the state forces church institutions to violate their own moral rules, then their governance structure is damaged not only by the immediate compulsion, but also by severely compromising that church’s ability to enforce those same rules internally in the future. HHS should avoid this unprecedented—and unconstitutional—interference with the ability of the Church to govern itself and its institutions.

3. “Substantial Burdens” That Trigger Strict Scrutiny. In *Sherbert v. Verner*, 374 U.S. 398 (1963), the Supreme Court construed the Free Exercise Clause generally to forbid “substantial burdens” on religious exercise, unless they satisfy strict scrutiny. *Id.* at 403. But in *Employment Division v. Smith*, 494 U.S. 872 (1990), the Supreme Court distinguished *Sherbert*, narrowing the application of the “substantial burdens” test to two, more limited circumstances: (a) where the

¹⁷ The fact that the mandate’s coercion is targeted is further obscured by those who, without a hint of irony, would describe the mandated abortion, contraception, and sterilization as “free.” See, e.g., Jenny Gold, “Free Birth Control For Many, Courtesy of HHS,” *Kaiser Health News* (Aug. 1, 2011) (available at <http://capsules.kaiserhealthnews.org/index.php/2011/08/free-birth-control-for-many-courtesy-of-hhs/>); Althea Fung, “HHS Regulations Require Free Preventive Services for Women,” *National Journal* (Aug. 2, 2011) (available at <http://www.nationaljournal.com/healthcare/hhs-regulations-require-free-preventive-services-for-women-20110801>). But these “services” never have been, and never will be, free—someone will always have to pay for them. The only difference after the mandate is that those who pay for the “services” will now include people and groups who object to them in conscience. Calling the coverage “free” leaves the impression that there is no longer any bill to pay at all; in reality, the same bill is being newly foisted on those with moral and religious objections to paying it.

¹⁸ This line of cases was left intact by *Employment Division v. Smith*, 494 U.S. 872 (1990), which otherwise significantly narrowed the range of claims triggering strict scrutiny under the Free Exercise Clause. *Id.* at 877. See *infra* Section I.D.3.

burdens are applied pursuant to an “individualized governmental assessment of the reasons for the relevant conduct,” *id.* at 884; and (b) where the burden involves a “hybrid situation” implicating other constitutional protections, such as the freedoms of speech or association, *id.* at 881-82.

Both circumstances are present here, creating two independently sufficient violations of the Free Exercise Clause. The HHS mandate imposes “substantial burdens” on the religious exercise of Catholic employers, employees and insurers with moral and religious objections to contraception and sterilization; those burdens trigger strict scrutiny because they are imposed both pursuant to a system of “individualized exemptions,” and in a manner that involves “hybrid rights”; and those burdens are not justified by a “compelling state interest.”

A “substantial burden” is imposed, at a minimum, where the law forces a person or group “to choose between following the precepts of [their] religion and forfeiting benefits, on the one hand, and abandoning one of the precepts of [their] religion in order to accept [government benefits], on the other hand.” *Sherbert*, 374 U.S. at 404. This threshold is far exceeded here, because church employees, employers, and insurers must choose between religious observance and the violation of a regulatory mandate—not the mere loss of a government benefit.

HHS has imposed that burden pursuant to a “mechanism for individualized exemptions,” *Smith*, 494 U.S. at 884. Indeed, the burdens would not be imposed at all, if not for a series of discretionary decisions by HHS—first to construe “preventive services” to include contraception and sterilization, and so to impose a burden almost exclusively on Catholics; then to establish the narrow, four-part exemption for a subset of religious employers, drafted by the ACLU for the California legislature; and then to apply that exemption on a case-by-case basis to exclude an employer. This stands in stark contrast to the kind of across-the-board rules that the Court in *Smith* was so concerned to insulate from constitutional challenge in cases where they happen to burden religious exercise.

The mandate also burdens religious exercise in a manner that implicates other fundamental rights, creating a “hybrid situation” that also triggers strict scrutiny under *Smith*. As discussed further below, the mandate compels expression by, and interferes with the expressive association of, religious insurers and employers, who are forced to offer for sale and to sponsor services that they exist in part to oppose.

Finally, the burdens are not “narrowly tailored” to serve any “compelling state interest.” The particular “preventive services” at issue are not life-saving, and

do not even prevent disease; they are designed to prevent the healthy state of pregnancy, and can actually introduce health risks. Moreover, “a law cannot be regarded as protecting an interest ‘of the highest order’ ... when it leaves appreciable damage to that supposedly vital interest unprohibited.” *Lukumi*, 508 U.S. at 546. The law at issue here, at a minimum, admits of a construction that allows no advancement *at all* of the interest of maximizing coverage for contraception and sterilization, as HHS is entirely free not to declare them “preventive services.” In other words, if Congress did not even see fit to make explicit that these “services” should be included within the mandate, HHS’s decision to include them cannot fairly be said to serve a “compelling state interest.”

And even if the interest were somehow “compelling,” the law is not “narrowly tailored” to serve that interest. If the mandate remains in place, it seems entirely probable that many individuals and organizations, instead of purchasing and sponsoring plans, will feel obliged in conscience to do precisely the opposite by dropping coverage altogether, rather than compromising their religious and moral beliefs. Thus, the mandate is not well tailored to the goal of *expanding* access to coverage, because it encourages individuals and organizations to *drop* coverage.¹⁹

4. Compelled Speech. The HHS mandate also interferes with the right of free speech. It does so by coercing many conscientious objectors, including but not limited to religious organizations, to subsidize—and thereby endorse—conduct that they teach or otherwise state is wrong. *See, e.g., Keller v. State Bar of California*, 496 U.S. 1 (1990) (holding that state bar members could not be compelled to finance political and ideological activities with which they disagree); *Aboud v. Detroit Board of Education*, 431 U.S. 209 (1977) (holding that state employees could not be required, consistent with the First Amendment, to provide

¹⁹ While some may defend the mandate by citing a government interest in reducing unintended pregnancies and abortions, there is ample evidence that programs advancing ready access to contraceptives fail to serve that interest. *See* USCCB Secretariat of Pro-Life Activities, “Fact Sheet: Greater Access to Contraception Does Not Reduce Abortions” (Mar. 17, 2011) (available at <http://old.usccb.org/prolife/issues/contraception/contraception-fact-sheet-3-17-11.pdf>), and “Fact Sheet: Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion” (Apr. 6, 2011) (available at <http://old.usccb.org/prolife/issues/contraception/contrafactsheet.pdf>). In an analysis of 23 published studies from 10 countries, not one study showed easier access to “emergency contraception” achieving *any* statistically significant reduction in rates of unintended pregnancy or abortion. E. Raymond *et al.*, “Population Effect of Increased Access to Emergency Contraceptive Pills,” *Obstetrics & Gynecology* 109 (2007): 181-8.

financial support for ideological union activities unrelated to collective bargaining).

When a religious organization in particular pays for private conduct, the inescapable message is that it does not disapprove of that conduct. As noted above, a religious organization cannot communicate an effective message that conduct is morally wrong at the same time that it subsidizes that conduct. In particular, Catholic organizations cannot effectively and persuasively communicate the Church's teaching that contraception and sterilization are immoral if they simultaneously pay for contraceptives for their employees or (in the case of colleges and universities) for their students.

In short, the First Amendment protects the right of these church entities "to hold a point of view different from the majority and to refuse to foster ... an idea they find morally objectionable." *Wooley v. Maynard*, 430 U.S. 705, 715 (1977). The HHS mandate violates this bedrock principle.

5. Expressive Association. In *Boy Scouts of America v. Dale*, 530 U.S. 640 (2000), the Court held that the Scouts' "freedom of expressive association" under the Free Speech Clause prevented the government from enforcing its public accommodations law to require the inclusion of a gay assistant scoutmaster. *Id.* at 648. The Court held that compelling the Scouts to admit Dale into a leadership position would "force the organization to send a message, both to the youth members and the world, that the [organization] accepts homosexual conduct as a legitimate form of behavior." *Id.* at 653.

Similarly, in *Hurley v. Irish-American Gay, Lesbian & Bisexual Group*, 515 U.S. 557 (1995), a unanimous Court held that the organizers of a St. Patrick's Day parade had a First Amendment right to exclude a gay and lesbian group whose presence was thought to communicate a message about homosexual conduct to which the organizers objected. The parade organizers had that right even though they had no particular message on the subject that they wished to convey—only a preference "not to propound a particular point of view." *Id.* at 575. Again, the "principle of speaker's autonomy" prevailed. *Id.* at 580.

Church organizations have an even stronger right than the parade organizers and Boy Scouts to join together in an organization that reflects a particular set of beliefs; they have the additional protection of the Religion Clauses. And if non-religious organizations have a constitutional right to exclude individuals whose mere *presence* was thought by those groups to send a message that they did not

like, then how much clearer the right of a church organization not to subsidize *conduct* that contradicts its teaching.

The compelled subsidization in this case strikes at the heart of the Church’s ability to communicate its unambiguous commitment to basic moral teachings and to form associations that maintain their adherence to those teachings. The Free Speech Clause forbids such compulsion, and so HHS should avoid it.

E. The HHS mandate violates the Religious Freedom Restoration Act.

The Religious Freedom Restoration Act (“RFRA”) requires that strict scrutiny be applied to any action of the federal government that substantially burdens the exercise of religion. 42 U.S.C. 2000bb-1(c). For the reasons noted above, *see supra* Section I.D.3., the mandate triggers and fails strict scrutiny and therefore violates RFRA.

F. The HHS mandate violates the Administrative Procedure Act.

Because the HHS mandate violates the Constitution and RFRA, it is not in accordance with law. It therefore violates the Administrative Procedure Act. 5 U.S.C. § 706 (authorizing a court to “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”).²⁰

Having addressed the legal flaws in the HHS mandate, we turn next to the legal defects in the exemption.

II. The HHS Exemption

A. The HHS exemption is narrower than the exemptions in the vast majority of states with contraceptive mandates.

HHS claims that its exemption is “based on existing definitions used by most States” that have a religious exemption from a contraceptive mandate. 76 Fed. Reg. at 46623 (emphasis added). The claim is demonstrably false. As noted

²⁰ The decision to issue the mandate as part of an interim final (rather than proposed) rule raises additional questions under the APA. Given the concerns express here, we obviously disagree with HHS’s assessment that it was in the “public interest” (76 Fed. Reg. at 46624) to have issued the mandate at all, let alone as an interim final rule. HHS gave the public no prior notice of the mandate, and the public interest was not served by waiving the usual notice and comment period.

below, the HHS exemption is in place in only *three* states,²¹ and most states with religious exemptions to a contraceptive mandate have *broader* exemptions.

Under the interim final rule, a “religious employer” is exempt from the HHS mandate if it is an organization that meets all of the following criteria: (a) its purpose is the inculcation of religious values, (b) it primarily hires persons who share the organization’s religious tenets, (c) it primarily serves person who share those tenets, and (d) it is a nonprofit as described in sections 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.²²

This language is virtually identical to the religious employer exemption in California’s contraceptive mandate, which was drafted by the ACLU.²³ Notably, the ACLU has taken the view that “[a]mong health care institutions, Christian Science sanatoria may exemplify those that should qualify for a religious exemption” from mandates like those at issue here, because they “are staffed by Christian Science healers, and they attend only to those seeking to be healed exclusively through prayer.” Catherine Weiss, et al., ACLU Reproductive Freedom Project, Religious Refusals and Reproductive Rights 10 (2002) (available at <http://www.aclu.org/FilesPDFs/ACF911.pdf>). Thus, the ACLU assures us, “[s]uch institutions generally conform to the definition set out in the ‘religious employer’ exemption to California’s contraceptive equity law.” *Id.* Far from being used in “most states,” this language is well outside the mainstream and is ill-suited to nationwide application.

It is important to note that almost half the states have no contraceptive mandate, and therefore leave people and institutions free to buy, sponsor, or sell health coverage without contraception and sterilization. Moreover, as HHS acknowledges (76 Fed. Reg. at 46623), most states with a contraceptive mandate

²¹It bears repeating that these state contraceptive mandates do not apply to all plans; thus, all of them are less sweeping than the HHS mandate. *See supra* Section I.B.

²² HHS should clarify why the fourth prong includes a reference to Section 6033(a)(1). That provision deals with all Form 990 filers. Subsections (a)(3)(A)(i) and (iii), however, collectively relate to churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order.

²³ ACLU Press Release, “ACLU Applauds CA Supreme Court Decision Promoting Women's Health and Ending Gender Discrimination in Insurance Coverage” (Mar. 1, 2004) (“The ACLU crafted the statutory exemption [at issue]...”)(available at <http://www.aclu.org/reproductive-freedom/aclu-applauds-ca-supreme-court-decision-promoting-womens-health-and-ending-gend>).

have some kind of religious exemption.²⁴ Nineteen states have an exemption from a state contraceptive mandate.²⁵ Of those 19 states:

- Only three have a religious exemption that is as narrow as the one set out in the interim final rule.²⁶
- Twelve states have a broader exemption.²⁷
- Twelve states do not require that the exempt organization's purpose be the inculcation of religious values.²⁸
- Twelve states do not require that the exempt organization primarily hire persons who share the organization's religious tenets.²⁹
- Thirteen states do not require that the exempt organization primarily serve persons who share those tenets.³⁰
- Sixteen states do not require that the exempt organization satisfy the tax code criteria set out in the fourth prong of the HHS exemption.³¹

²⁴ Citations are provided in Addendum B.

²⁵ Arizona, Arkansas, Connecticut, Delaware, Hawaii, Maine, Maryland, Massachusetts, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Rhode Island, West Virginia, Wisconsin, and Michigan. Our count includes only those states with conscience protection set out in the state contraceptive mandate itself. The number of states with a conscience exemption from a state contraceptive mandate may actually be higher than 19, if one takes into account freestanding state conscience provisions. For example, Illinois has a contraceptive mandate, but also has a law relieving health care payers of any liability for declining to pay for or arrange for the payment of any health care service that violates that payer's conscience. Ill. Comp. Stat. Ann. § 70/11.2.

²⁶ California, New York, and Oregon.

²⁷ Arizona, Arkansas, Connecticut, Delaware, Hawaii, Maryland, Missouri, New Mexico, North Carolina, Rhode Island, West Virginia, and Michigan. Five other states (Maine, Massachusetts, Nevada, New Jersey, and Rhode Island) have an exemption that is broader in some respects, narrower in others.

²⁸ Arizona, Connecticut, Delaware, Maine, Maryland, Massachusetts, Missouri, Nevada, New Jersey, New Mexico, Rhode Island, and West Virginia.

²⁹ Connecticut, Delaware, Hawaii, Maine, Maryland, Massachusetts, Missouri, Nevada, New Jersey, New Mexico, Rhode Island, and West Virginia.

³⁰ Arkansas, Connecticut, Delaware, Maine, Maryland, Massachusetts, Missouri, Nevada, New Jersey, New Mexico, North Carolina, Rhode Island, and West Virginia.

Thus, the exemption set out in the interim final rule is among the narrowest in the Nation. It is as if HHS asked: “Which state has the *narrowest* conscience exemption from a contraceptive mandate?”; and then proceeded to adopt that exemption as the one that will govern in all 50 states.

B. The HHS exemption is narrower than any other religious exemption in federal health care law.

Congress has consistently supported conscience protection with respect to health services. Family planning policy is just one illustration of this policy. For example, every year since 1986, Congress has prohibited discrimination against foreign aid grant applicants who offer only natural family planning on account of their religious or conscientious convictions.³² Every year since 1999, Congress has exempted religious health plans from a contraceptive coverage mandate in the federal employees’ health benefits program, and prohibited other health plans in this program from discriminating against individual health professionals in the plan who object to prescribing or providing contraceptives on moral or religious grounds.³³ Every year since 2000, Congress has affirmed its intent that a conscience clause protecting religious beliefs and moral convictions be a part of any contraceptive mandate in the District of Columbia.³⁴

Federal conscience protections are not limited to abortion and contraceptives. The Church amendment protects conscientious objection to

³¹ Arkansas, Connecticut, Delaware, Hawaii, Maine, Maryland, Massachusetts, Michigan, Missouri, Nevada, New Jersey, New Mexico, North Carolina, Rhode Island, and West Virginia.

³² For the most recent enactment, *see* Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, Div. F, tit. III (“Provided further, That in awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant’s religious or conscientious commitment to offer only natural family planning”).

³³ For the most recent enactment, *see id.*, Div. C, tit. VII, § 728 (“Nothing in this section shall apply to a contract with ... any existing or future plan, if the carrier for the plan objects to such coverage on the basis of religious beliefs... In implementing this section, any plan that enters into or renews a contract under this section may not subject any individual to discrimination on the basis that the individual refuses to prescribe or otherwise provide for contraceptives because such activities would be contrary to the individual’s religious beliefs or moral convictions”).

³⁴ For the most recent enactment, *see id.*, Div. C, tit. VIII, § 811 (“Nothing in this Act may be construed to prevent the Council or Mayor of the District of Columbia from addressing the issue of the provision of contraceptive coverage by health insurance plans, but it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions”).

sterilization (42 U.S.C. §§ 300a-7(b), 300a-7(c)(1), and 300a-7(e)) and, in programs funded or administered by HHS, to any health service to which there is a moral or religious objection (42 U.S.C. §§ 300a-7(c)(2) and 300a-7(d)). Congress has required that the Medicare and Medicaid statutes not be construed to require Medicare + Choice or Medicaid managed care plans to provide counseling and referral services to which they have a moral or religious objection. 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare); 42 U.S.C. § 1396u-2(b)(3) (Medicaid).

Similar protections have been adopted by regulation. *See, e.g.*, 48 C.F.R. § 1609.7001(c)(7) (stating that in the federal employees' health benefits program, "[p]roviders, health care workers, or health care plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course or practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs").³⁵ HHS itself recognizes that plans may not always provide particular services because of moral or religious objections. *See, e.g.*, 42 C.F.R. § 438.52 (contemplating circumstances in which a plan or provider "does not, because of moral or religious objections, provide the service the enrollee seeks").

Even if these and similar provisions are not directly applicable to the interim final rule, they underscore a consistent federal policy to protect the conscience rights of participants in the market for health services and health coverage. The interim final rule deviates from that policy by ignoring the conscience rights of stakeholders with religious or moral objections to contraceptives and sterilization.

C. It is unclear whether the HHS exemption even applies to sterilization and/or counseling and education about sterilization.

The interim final rule states that the Health Resources and Services Administration ("HRSA") "may establish exemptions from [its] guidelines ... with respect to any requirement to cover *contraceptive services* under such guidelines." 76 Fed. Reg. at 46626 (emphasis added). The preamble reiterates that HRSA has the discretion to exempt religious employer from the guidelines "where *contraceptive services* are concerned." *Id.* at 46623 (emphasis added).

It is unclear whether HHS considers sterilization to be a "contraceptive service." As a result, it is uncertain whether the exemption even applies to

³⁵ These are only examples. A fuller compendium of federal conscience laws and regulations is available at <http://old.usccb.org/prolife/issues/abortion/crmay08.pdf>.

sterilization or related counseling and education, as HRSA lists sterilization as a distinct service. This is a serious oversight, because sterilization ordinarily disables a woman's fertility permanently, therefore prompting especially important concerns from the viewpoint of medical ethics and government policy. Congress decided long ago that certain enumerated Acts of Congress should *not* be construed to require participation in sterilization. 42 U.S.C. § 300a-7.

The lack of clarity may have been a mere oversight but, left unaddressed, raises a question of unconstitutional vagueness. If HHS rejects our urgent plea to rescind the mandate, it should create an exemption that will adequately protect the right of all stakeholders not to offer or purchase coverage for contraceptives, sterilization, or related counseling and education. An exemption that applies only to some of these stakeholders, or some of these "services," is plainly inadequate.

D. The HHS exemption fails to encompass any individuals and most institutions with moral or religious objections to contraception or sterilization.

Until now, no federal law has prevented private insurers from accommodating purchasers and plan sponsors with moral or religious objections to certain services. Plans were free under federal law to accommodate those objections by allowing purchasers to choose not to buy coverage for gender change surgery, contraceptives, in vitro fertilization, or other procedures that the purchaser or sponsor found religiously or morally problematic. Likewise, federal law did not forbid any insurer, such as a religiously-affiliated insurer, to exclude from its plans any services to which the insurer itself had a moral or religious objection. Indeed, the freedom to exclude morally objectionable services has sometimes been stated affirmatively in federal law. For example, as noted above, the Federal Employees Health Benefits Program expressly allows health plans which exclude contraceptive coverage to be offered to federal employees if the carrier has a religious objection to such coverage.

Under the interim final rule, this will no longer be true. For the first time under federal law, HHS will require all plans (except grandfathered plans, for as long as they retain their grandfathered status) to include coverage for contraceptives and sterilization. *Individuals* with a moral or religious objection to these items and procedures will now be affirmatively barred by the HHS mandate from purchasing a plan that excludes those items. *Religiously-affiliated insurers* with a moral or religious objection likewise will be affirmatively barred from offering a plan that excludes them to the public, even to members of their own religion. *Secular organizations* (insurers, employers, and other plan sponsors) with

a moral or religious objection to coverage of contraceptives or sterilization will be ineligible for the exemption. And any *religious organization* that does not meet HHS's exceedingly crabbed definition of "religious employer" will also be affirmatively barred from purchasing such a plan even for its own employees.

This last point requires some elaboration. The HHS exemption, applicable nationwide, forces all church institutions with an outreach-oriented mission to provide health coverage for items that the institutions themselves hold and teach to be immoral, in violation of their institutional identity and sincerely held beliefs. The HHS exemption would penalize church organizations that engage in public ministry or service, by forbidding them to practice what they preach. This represents an unprecedented intrusion by the federal government into the precincts of religion that, if unchecked here, will support ever more expansive and corrosive intrusions in the future.

Just as alarming as the *fact* of HHS's intrusion into the precincts of religious organizations is the *manner* in which HHS has accomplished the intrusion, namely, by defining certain religious organizations as, in effect, "not religious enough"—and therefore not entitled to any exemption from the mandate—based on who they serve, how they constitute their workforce, and whether "inculcation of religious values" is "the purpose" of the agency. HHS has concluded, for example, that a church is *not* a religious employer if it (a) serves those who are not already members of the church, (b) fails to hire based on religion, *or* (c) does not restrict its charitable and missionary purposes to the inculcation of religious values. Under such inexplicably narrow criteria—criteria bearing no reasonable relation to any legitimate (let alone compelling) government purpose—even the ministry of Jesus and the early Christian Church would not qualify as "religious," because they did not confine their ministry to their co-religionists or engage only in a preaching ministry. In effect, the exemption is directly at odds with the parable of the Good Samaritan, in which Jesus teaches concern and assistance for those in need, regardless of faith differences. While the federal government can distinguish between a church and a secular entity for purposes of accommodating religion, the government has no business engaging in religious gerrymanders, whereby some churches are "in" and others are "out" for regulatory purposes based on who their teaching calls them to serve, how they constitute their workforce, or whether they engage in "hard-nosed proselytizing." *University of Great Falls v. NLRB*, 278 F.3d 1335, 1346 (D.C. Cir. 2002). *See also Colorado Christian Univ. v. Weaver*, 534 F.3d 1245, 1257-60 (10th Cir. 2008).

By taking a view of religion that is stingier than any ever placed into federal law, HHS would pressure a large number of religiously-affiliated organizations

with conscientious objections to contraceptives and sterilization—including religiously-affiliated social service agencies, hospitals, colleges and universities—either to provide coverage for these, or to drop health coverage altogether. This would include the freestanding plans that religiously-affiliated colleges and universities offer their own students.³⁶

E. The HHS exemption violates the Religion Clauses of the First Amendment.

As discussed in the preceding section, the HHS exemption does not apply to individuals, insurers, and many other stakeholders with a religious or moral objection to contraception or sterilization. As to those stakeholders, the mandate continues to suffer from the same constitutional and statutory defects that we described previously.³⁷

In addition, each prong of the four-pronged exemption is constitutionally problematic, and the exemption itself, like the mandate, violates the Religion Clauses of the First Amendment.

First, the government constitutionally may not “troll through a person’s or institution’s religious beliefs” to determine whether its purpose is to inculcate “religious values.” *Univ. of Great Falls*, 278 F.3d at 1341-42; *see also Colo. Christian Univ.*, 534 F.3d at 1261-66. Nor may the government constitutionally limit an exemption solely to religious institutions that engage in “hard-nosed proselytizing.” *Univ. of Great Falls*, 278 F.3d at 1346. Many religious organizations are not engaged in proselytizing when they deliver social, medical, psychological, and educational services, but they provide these services precisely for religious and moral reasons.

Second, the government may not decide that organizations are sufficiently “religious” only if they primarily serve and employ their co-religionists. In effect, HHS is purporting to distinguish between religious denominations and organizations that are, so to speak, insular in their workplace and ministry, and those that have a missionary outlook. This is blatantly unconstitutional.³⁸ Church

³⁶ It will not be lost upon impressionable students that their religiously-affiliated school says one thing about the moral status of contraception and sterilization but practices quite another in providing coverage for those very items.

³⁷ *See supra* Section I.D.

³⁸ *Larson v. Valente*, 456 U.S. 228 (1982) (the government may not pick and choose among different religious organizations when it imposes some burden); *Church of Lukumi Babalu Aye v.*

agencies with the temerity (in the government’s view) to hire and serve persons other than their own members are penalized by the HHS exemption or, alternatively, forced to fire non-members and withdraw from or limit public service. Such a forced choice is offensive, discriminatory, and unconstitutional under the Religion Clauses. The second and third prongs are also problematic from a practical standpoint, because they require religious organizations to make potentially intrusive inquiries into the religiosity of all their job applicants and clients.

Finally, the last prong of the exemption, which tracks certain of the annual Form 990 exemptions available under section 6033 of the Internal Revenue Code, is constitutionally defective because it bears no rational relationship to the purpose of either the mandate or the exemption.

Some explanation is necessary. The Form 990 filing requirement—the requirement from which section 6033(a)(2)(A)(i) and (iii) carve out exemptions—serves a two-fold purpose: it provides IRS with information necessary to the administration of the tax laws, and it makes tax-exempt organizations financially accountable to the IRS and the general public. This federal exemption from filing the annual Form 990 reflects Congressional sensitivity to the church-state entanglement issues inherent in mandating financial reporting and accountability on the part of churches and religious organizations. The exemption is an attempt to strike a balance between the requirements of tax administration, on the one hand, and the desire to avoid unnecessary entanglement in the financial affairs of certain organizations closely affiliated with churches on the other. The filing exemption, however, has no relevance whatsoever to church welfare or benefit plans, having been devised, as noted above, to serve an entirely different purpose.

Ironically, in deciding to track certain of the Form 990 filing exemptions, HHS overlooked another exemption that was developed specifically to accommodate pension and welfare plans offered by churches, namely the “church plan” exemption found in section 414(e) of the Internal Revenue Code. 26 U.S.C.

Hialeah, 508 U.S. 520 (1993) (government may not target one religion for a particular burden); *Wilson v. NLRB*, 920 F.2d 1282 (6th Cir. 1990) (holding that section 19 of the National Labor Relations Act, which exempts from mandatory union membership any employee who “is a member of and adheres to established and traditional tenets or teachings of a bona fide religion, body, or sect which has historically held conscientious objections to joining or financially supporting labor organizations,” is unconstitutional because it discriminates among religions and would involve an impermissible government inquiry into religious tenets), *cert. denied*, 505 U.S. 1218 (1992).

§ 414(e). Congress exempted “church plans” from the Employee Retirement Income Security Act of 1974 (“ERISA”), *see* 29 U.S.C. § 1002(33), and in 1980 broadly defined “church plan” to include any pension or welfare plan that covers employees of a church or tax-exempt organization associated with a church. *See* Multiemployer Pension Plan Amendments Act of 1980, Pub. L. 96-364. The term “associated with a church” is defined expansively to include any organization that shares common religious bonds and convictions with a church. 26 U.S.C. § 414(e)(3)(D); 29 U.S.C. § 1002(33)(c)(4). Under this exemption, the employees of church agencies—including social welfare organizations, adoption agencies, hospitals, universities, and nursing homes, to name but a few—are covered under church health plans that are exempt from ERISA. Congress enacted the church plan exemption precisely to avoid the church-state entanglement that would likely result from a narrower or more grudging exemption. *Cf. Univ. of Great Falls*, 278 F.3d at 1343 (defining “religious” organization expansively). One of the many benefits of a broad exemption is that it avoids government entanglement in religious governance. HHS’s chosen exemption does precisely the opposite.³⁹

In short, the fourth prong of the exemption is lifted from an entirely different statutory context, one having no bearing whatsoever on health plans. Congress’s concern in enacting the Form 990 filing exemptions was financial accountability and tax administration—not health insurance. As the fourth prong of the exemption bears no rational relationship to any legitimate governmental interest that the mandate or the exemption purports to advance, it does not withstand constitutional scrutiny any more than the rest of the exemption does.

F. The HHS exemption violates the Administrative Procedure Act.

Because the exemption violates the U.S. Constitution, it is plainly not “in accordance with law,” and therefore violates the APA. 5 U.S.C. § 706.⁴⁰

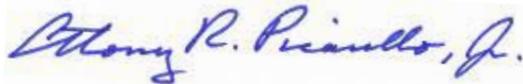
³⁹ Our discussion of the church plan exemption is not intended to suggest that such an exemption would be adequate. Indeed, such an exemption would be inadequate, because it would fail to protect many stakeholders with a moral or religious objection to contraceptives or sterilization, including individuals, insurers, and even many religiously-affiliated organizations.

⁴⁰ As was true of the HHS mandate, the failure to allow the usual notice and comment as to the HHS exemption raises additional questions under the APA.

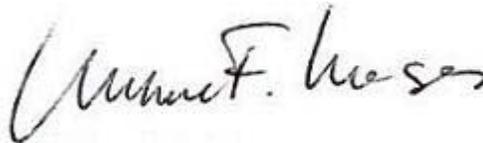
III. Conclusion

The HHS mandate should be rescinded in its entirety. If HHS refuses to do that, then it must address the most grievous and intolerable aspects of this misguided mandate by (a) excluding from the mandate those drugs that can cause an abortion, and (b) exempting all stakeholders with a religious or moral objection to contraceptives, sterilization, and related education and counseling.

Respectfully submitted,



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ADDENDUM A

USCCB COMMENTS FILED SEPT. 17, 2010



Office of the General Counsel

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By Hand

September 17, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: Interim Final Rules Relating to Coverage of Preventive Services,
File Code OCIIO-9992-IFC**

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (“the USCCB” or “Conference”), I offer the following comments on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, published at *75 Fed. Reg.* 41726 (July 19, 2010) (“Interim Final Rules”).

Interest of the United States Conference of Catholic Bishops

The Conference is a nonprofit corporation organized under the laws of the District of Columbia. All active Catholic bishops in the United States are members of the Conference. The Catholic Church, the largest religious denomination in the United States, has over 68 million adherents in over 18,000 parishes throughout the country. The Conference advocates and promotes the pastoral teaching of the bishops in such diverse areas as education, family life, health care, social welfare, immigration, civil rights, and the economy. The Conference participates in rulemaking proceedings of importance to the Catholic Church and its people in the United States.

The Conference has a particular concern that contraceptives and sterilization not be mandated as “preventive” services under the Patient Protection and Affordable Care Act (“PPACA”). To prevent pregnancy is not to prevent a disease -- indeed, contraception and sterilization pose their own unique and serious health risks to the patient. In addition, contraceptives and sterilization are morally problematic for many stakeholders, including religiously-affiliated health care providers and insurers. We believe that the Administration rightly does not include

contraceptives or sterilization as preventive services in the Interim Final Rules, and that future rulemaking or other guidance should also refrain from doing so.

Specifically, the Interim Final Rules defer a decision on “preventive care and screening” services specifically for women, stating that the Department of Health and Human Services expects to issue guidelines on these by August 1, 2011. *Id.* at 41728. Even this brief reference to preventive services for women, however, has prompted an announcement by Planned Parenthood that it will lobby public officials to insist on mandating “family planning” services under this rubric -- including mandatory coverage, without co-pays or out-of-pocket expenses, of “all forms of FDA-approved prescription contraception.”¹ These comments are prompted in part by that public announcement and campaign.

General Comments

In our view, prescription contraception as well as chemical and surgical sterilization are particularly inappropriate candidates for inclusion under mandated “preventive services” for all health plans. This is true for several reasons.

1. The meaning and purpose of “preventive services”

The justification for mandating coverage for preventive services, at no cost or low cost to enrollees, is obvious from the examples of recommended preventive services cited throughout the Interim Final Rules: blood pressure and cholesterol screening; diabetes screening for hypertensive patients; various cancer and sexually transmitted infection screenings; counseling related to aspirin use, tobacco cessation, and obesity; routine immunizations. *Id.* at 41731. These services are emphasized because they can prevent serious illnesses or life-threatening conditions that, once they do occur, will demand treatment to cure or reverse them – or at the very least, can provide an early warning so these conditions can be treated more quickly and with a greater likelihood of success.

This rationale simply does not apply to contraception and sterilization. Most drugs and devices in this area have a significant “failure” rate; but when they do succeed, what they most often “prevent” is a healthy pregnancy in a healthy woman of childbearing age. At various times women may have serious personal reasons for wanting to avoid or delay a pregnancy. However, these personal reasons do not transform a temporary or permanent condition of infertility into a prerequisite for health, or turn a healthy pregnancy into a disease condition.

Indeed, if contraception and sterilization were comparable to the preventive services recommended in the Interim Final Rules, the federal government would be mandating these services in order to obviate the need for providing the “cure” or treatment later (or to ensure that such cure or treatment is provided early, to enhance the likelihood of success). But the condition

¹ See “Planned Parenthood Supports Initial White House Regulations on Preventive Care: Highlights Need for New Guidelines on Women’s Preventive Health to Include Family Planning,” July 14, 2010, at www.plannedparenthood.org/about-us/newsroom/press-releases/planned-parenthood-supports-initial-white-house-regulations-preventive-care-highlights-need-new-33140.htm.

prevented by contraception and sterilization is pregnancy, which has its own natural course ending in live birth if not interrupted by medical intervention. The “cure” or “treatment” to eliminate this condition would have to be an abortion. But as a matter of clear statutory policy, PPACA *prohibits* any federal mandate to cover abortion as an essential health benefit in *all* circumstances. PPACA, §1303(b)(1)(A). Indeed, the Act not only leaves health plans free to exclude abortion, but explicitly allows each state to forbid coverage of abortion throughout its exchange. *Id.*, §1303(a)(1). Finally, with regard to the multi-state qualified health plans established under PPACA, at least one of these plans must exclude most abortions. *Id.*, §1334(a)(6). PPACA does not take this policy with regard to any other procedure.

In these provisions, the Act treats pregnancy as a healthy condition, and does not treat the existence of an unborn human life as an illness or condition requiring the “treatment” of abortion. It would be inconsistent to *require* all health plans to commit themselves to preventing this same condition.

Some may claim that contraception and sterilization are “preventive services” in the sense that they “prevent” abortion. But this is implausible for several reasons. First, abortion is not itself a disease condition, but a separate procedure that is performed only by agreement between a woman and a health professional. Second, most pregnancies, including unintended pregnancies, end in live birth rather than abortion, so it would be arbitrary to claim that preventing such pregnancies primarily prevents abortion rather than live birth. Third, studies have shown that the percentage of unintended pregnancies that are ended by abortion is *higher* if the pregnancy occurred during use of a contraceptive.² Finally, numerous studies have shown that contraceptive programs do not reliably or consistently reduce abortion rates.³ For example, one review summarizing 23 separate studies found that not one of the studies could show a reduction in abortion rates from programs expanding access to so-called “emergency contraception.”⁴ An evidence-based approach to health care does not permit the claim that mandating contraceptive coverage will reduce abortions.

One particular drug recently approved by the Food and Drug Administration (“FDA”) for “emergency contraception” poses an especially obvious problem in this regard. Ulipristal (trade name “Ella”) is a close analogue to the abortion drug RU-486, with the same biological effect – that is, it can disrupt an established pregnancy weeks after conception has taken place.⁵ Therefore it is contraindicated for women who are or may be pregnant. Yet its proposed use is targeted precisely at women who may already have conceived, as it would be administered up to

² While 40% of unintended pregnancies end in abortion, this percentage rises to 54% for women who used a contraceptive during the month they became pregnant. Guttmacher Institute, “Facts on Induced Abortion in the United States,” May 2010, at www.guttmacher.org/pubs/fb_induced_abortion.html.

³ See fact sheets by the USCCB Secretariat of Pro-Life Activities, “Greater Access to Contraception Does Not Reduce Abortions,” July 17, 2009, at www.usccb.org/prolife/issues/contraception/contrafactsheet.pdf, and “Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion,” February 16, 2007, at www.usccb.org/prolife/issues/abortion/factsheetec21607.shtml.

⁴ E. Raymond et al., “Population Effect of Increased Access to Emergency Contraceptive Pills,” *Obstetrics & Gynecology* 109 (2007): 181-8.

⁵ Documentation on this and other medical aspects of the drug is cited in testimony submitted to the FDA by the American Association of Pro-Life Obstetricians and Gynecologists, available at www.aaplog.org/?page_id=808.

five days *after* “unprotected” sex or contraceptive failure. Plans to market this drug simply as a “contraceptive” are misleading at best, and deprive women of the opportunity for genuine informed consent.

The policy advanced by Planned Parenthood – mandating coverage for “all forms of FDA-approved prescription contraception” as a preventive service – would therefore be in direct tension with the statutory prohibition on mandating any abortion service, as at least one of the drugs covered by that policy is an abortifacient drug.

2. Medical realities of contraceptive drugs and devices

The preventive services recommended under the Interim Final Rules share a basic medical profile: they pose little or no medical risk themselves, and they help prevent or ameliorate identifiable conditions that would pose known risks to life and health in the future.

Contraception presents the opposite profile. It is almost always prescribed for personal or lifestyle reasons, not for any specific medical justification; and it poses its own serious risks and side-effects, some of which can be life-threatening. Use of prescription contraception actually *increases* a woman’s risk of developing some of the very conditions that the “preventive services” listed in the Interim Final Rules are designed to *prevent*. Therefore a policy mandating contraceptive services as “preventive services” would be in contradiction with itself.

Women who use oral contraceptives may have an increased risk of heart-related side effects such as stroke, heart attacks and blood clots, especially if they also smoke cigarettes. The publishers of the *Physicians’ Desk Reference* warn women of these “[s]erious, and possibly life-threatening, side effects,” and add: “Seek medical attention immediately if you have any of the following: chest pain, coughing up blood, or shortness of breath (indicating a possible blood clot in the lung); pain in the calf (indicating a possible blood clot in the leg); crushing chest pain or heaviness (indicating a possible heart attack); sudden, severe headache or vomiting, dizziness, fainting, vision or speech problems, weakness, or numbness in an arm or leg (indicating a possible stroke); sudden partial or complete loss of vision (indicating a possible blood clot in the eye); breast lumps (indicating possible breast cancer or fibrocystic breast disease); severe pain or tenderness in the stomach (indicating a possible liver tumor); difficulty sleeping, lack of energy, fatigue, change in mood (possibly indicating depression); yellowing of the skin or whites of the eyes (jaundice), sometimes accompanied by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements (indicating possible liver problems).”⁶ According to other sources, various contraceptives have been associated with increased risk of myocardial infarction, stroke, venous thromboembolism, and hypertension, as well as sexually transmitted diseases such as Chlamydia and HIV.⁷

It needs to be recalled in this context that so many contraceptive drugs and devices are available only by prescription not primarily because they are medically indicated for any particular illness, but because they pose sufficient risks that it would be irresponsible to distribute them without medical supervision.

⁶ PDR Network, “Oral contraceptives,” at *PDRhealth* (2009), www.pdrhealth.com/drugs/rx/rx-mono.aspx?contentFileName=ora1310.html&contentName=Oral+contraceptives&contentId=554.

⁷ R.A. Hatcher et al., *Contraceptive Technology*, 18th rev. ed. (New York: Ardent Media, 2004), at 404-410, 445.

3. A threat to rights of conscience

Because any mandate for contraception and sterilization coverage under the rubric of “preventive services” would apply to a wide array of group health plans and health insurance issuers, it would pose an unprecedented threat to rights of conscience for religious employers and others who have moral or religious objections to these procedures. In this regard, the Administration’s promise that Americans who like their current coverage will be able to keep it under health care reform would be a hollow pledge. Currently, such employers, as well as insurance issuers with moral and religious convictions on these matters, are completely free under federal law to purchase and offer health coverage that excludes these procedures. They would lose this freedom of conscience under a mandate for all plans to offer contraception and sterilization coverage.

Such a mandate would also contradict longstanding federal precedents on respect for conscientious objection to such procedures and such coverage. For example:

- The Church amendment, a provision of federal law since 1973, protects conscientious objection to abortion *and sterilization* in various contests where federal funds are involved.⁸

- In foreign assistance programs for family planning, a statutory requirement renewed every year since 1986 has stated that “no applicant shall be discriminated against because of such applicant’s religious or conscientious commitment to offer only natural family planning” as opposed to contraceptive drugs or devices.⁹

- Every year since 2000, Congress has stipulated regarding any effort to mandate contraceptive coverage in the District of Columbia that “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”¹⁰

- In the United States’ international program for preventing and treating HIV/AIDS, organizations (specifically including faith-based organizations) are guaranteed the right to participate fully in the program without being required “to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.”¹¹

⁸ 42 U.S.C. §300a-7(b), (c)(1) and (e). The Church amendment also protects conscientious objection to any health service or research activity that is contrary to the religious beliefs or moral convictions of individuals participating in programs administered or funded by HHS. *Id.*, § 300a-7(c)(2) and (d).

⁹ Title III of Division F (Department of State, Foreign Operations, and Related Programs Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

¹⁰ Sec. 811 of Title VIII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

¹¹ United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, at 22 U.S.C. §7631 (d).

- Every year since 1999, in the only federal program to require health plans to cover contraception for a subset of the U.S. population, Congress has stated that this mandate in the Federal Employees Health Benefits Program will not apply to “any existing or future plan, if the carrier for the plan objects to such coverage on the basis of religious beliefs.” Moreover, any plan that enters into or renews a contract under this section may not subject any individual to discrimination on the basis that the individual refuses to prescribe or otherwise provide for contraceptives because such activities would be contrary to the individual’s religious beliefs or moral convictions.”¹²

These precedents reflect a longstanding commitment on the part of our federal government to respect the rights of conscience of all citizens, and to allow health care institutions and religious employers to participate fully in health programs (including programs for providing health coverage) without violating their moral or religious convictions. No federal law has yet been construed to require private health plans to provide coverage of contraception and sterilization. Instead, federal law has thus far left insurance issuers, employers and enrollees to negotiate such coverage in accord with their personal preferences and their moral and religious commitments. The federal government has no reason now to take away this freedom.

Conclusion

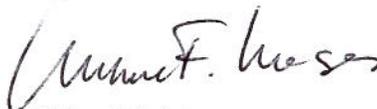
For the reasons stated above, the Department of Health and Human Services should not require coverage of contraception or sterilization in group or individual health plans as part of “preventive services.” These drugs, devices and procedures prevent not a disease condition, but the healthy condition known as fertility; they pose significant risks of their own to women’s life and health; and a federal program to mandate their inclusion would pose an unprecedented threat to rights of conscience. We hope these considerations will be taken into account as the Department continues deliberations on a final list of required preventive services for women.

Thank you for the opportunity to comment.

Sincerely,



Anthony R. Picarello, Jr.
General Counsel



Michael F. Moses
Associate General Counsel

¹² See Sec. 728 of Title VII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

ADDENDUM B

STATE CONTRACEPTIVE MANDATES AND EXEMPTIONS

Arizona

- Ariz. Rev. Stat. Ann § 20-826(Y) (corporation)
Exemption § 20-826(Z), AA(3)
- Ariz. Rev. Stat. Ann. § 20-1057.08(A) (health care services organizations)
Exemption § 20-1057.08(B) to (G)
- Ariz. Rev. Stat. Ann. § 20-1402(L) (group disability)
Exemption §20-1402(M), (N)(3)
- Ariz. Rev. Stat. Ann. §20-1404(U) (blanket disability)
Exemption §20-1404(V), (W)(3)
- Ariz. Rev. Stat. Ann. §20-2329(A) (accountable health plan)
Exemption §20-2329(B) to (F)

Arkansas

- Ark. Code. Ann. § 23-79-1101 to 1104
Exemption §§ 23-79-1104(b)(3); 23-79-1102(3)

California

- Cal. Ins. Code § 10123.196
Exemption § 10123.196(d)

Colorado

- Colo. Rev. Stat. Ann. § 10-16-104(3)

Connecticut

- Conn. Gen. Stat. Ann. § 38A-503e (individual and group)
Exemption § 38A-503e(b) to (f)
- Conn. Gen. Stat. Ann. § 38A-530e (group)
Exemption § 38A-530e(b) to (f)

Delaware

- Del. Code. Ann. 18 § 3559
Exemption § 3559(d)

Georgia

- Ga. Code Ann. § 33-24-59.6

Hawaii

- Haw. Rev. Stat. Ann. § 431:10A-116.6
- Haw. Rev. Stat. Ann. § 432:1-604.5
Exemption § 431:10A-116.7

Illinois

- 215 Ill. Comp. Stat. Ann. 5/356z.4

Iowa

Iowa Code Ann. § 514C.19

Maine

Me. Rev. Stat. Ann. tit. 24 § 2332-J (individual, group nonprofit)

Exemption § 2332-J(2)

Me. Rev. Stat. Ann. tit. 24-A § 2756 (individual health policies and contracts)

Exemption § 2756(2)

Me. Rev. Stat. Ann. tit. 24-A § 2847-G (group)

Exemption § 2847-G(2)

Me. Rev. Stat. Ann. tit. 24-A § 4247 (HMO individual and group)

Exemption § 4247(2)

Maryland

Md. Code Ann. Ins. § 15-826

Exemption § 15-826(c)

Massachusetts

Mass. Gen. Laws Ann. 175 § 47W (accident and sickness)

Exemption § 47W(c)

Mass. Gen. Laws Ann. 176A § 8W (hospital service)

Exemption § 8W(c)

Mass. Gen. Laws Ann. 176B § 4W (medical service agreement)

Exemption § 4W(c)

Mass. Gen. Laws Ann. 176G § 4O (HMO)

Exemption § 4O(c)

Missouri

Mo. Rev. Stat. § 376.1199(1)(4)

Exemption § 376.1199(4) to (7)

Nevada

Nev. Rev. Stat. Ann. §§ 689A.0415, .0417 (individual)

Exemption §§ 689A.0415(5), .0417(5)

Nev. Rev. Stat. Ann. §§ 689B.0376, .0377 (group)

Exemption §§ 689B.0376(5), .0377(5)

New Hampshire

N.H. Rev. Stat. Ann. § 415:18-i (insurer)

N.H. Rev. Stat. Ann. § 420-A:17-c (health service corp.)

N.H. Rev. Stat. Ann. § 420-B:8-gg (HMO)

New Jersey

N.J. Stat. Ann. § 17:48-6ee
Exemption § 17:48-6ee

New Mexico

N.M. Stat. Ann. § 59A-22-42 (health insurance policy, plan, certificate)
Exemption § 59A-22-42(D)
N.M. Stat. Ann. § 59A-46-44 (HMO)
Exemption § 59A-46-44(C)

New York

N.Y. Ins. § 3221(l)(16)
Exemption § 3221(l)(16)(A) to (C)

North Carolina

N.C. Gen. Stat. Ann. § 58-3-178
Exemption § 58-3-178(e)

Oregon

Or. Rev. Stat. § 743A.066
Exemption § 743A.066(4)

Rhode Island

R.I. Gen. Laws § 27-19-48 (hospital service corp.)
Exemption § 27-19-48(b) to (d)
R.I. Gen. Laws § 27-18-57 (accident and sickness)
Exemption § 27-18-57(b) to (e)
R.I. Gen. Laws § 27-20-43 (medical service corp.)
Exemption § 27-20-43(b) to (d)
R.I. Gen. Laws § 27-41-59 (HMO)
Exemption § 27-41-59(b) to (d) (HMO)

Vermont

Vt. Stat. Ann. tit. 8 § 4099c

West Virginia

W. Va. Code Ann. § 33-16E-2
Exemption § 33-16E-2(5)

Wisconsin

Wis. Stat. Ann. § 632.895(17)

ADMINISTRATIVE RULINGS/REGULATIONS

Michigan Civil Rights Commission, “Declaratory Ruling on Contraceptive
Equity” (Aug. 21, 2006)
Wash. Admin. Code § 284-43-822