



Supplemental Comments of the Center for Reproductive Rights

Interim Final Rules on Preventive Services
CMS-9992-IFC2

Submitted December 1, 2011

The Center for Reproductive Rights respectfully submits the following supplemental comments on the interim final rule on preventive services (“the rule”). Since 1992, the Center for Reproductive Rights has worked towards a time when the promise of reproductive freedom is enshrined in law in the United States and throughout the world. We envision a world in which every woman is free to decide whether and when to have children; every woman has access to a full range of the best reproductive healthcare available; and every woman can make choices without fear, coercion or discrimination. More simply, we envision a world where every woman participates with full dignity as an equal member of society.

Since the Department published the rule on August 3, 2011, and the docket for public comments closed on September 30, 2011, the rule has continued to receive considerable attention in the media, among advocates and in Congress. The Center submits these supplemental comments to address issues that continue to be publicly debated regarding the contraceptive coverage requirement, including issues raised at the Subcommittee on Health of the House Committee on Energy and Commerce’s “Do New Health Law Mandates Threaten Conscience Rights and Access to Care?” hearing on November 2, 2011 (“the hearing”). Specifically, the comments address the following issues:

1. The importance of sterilization as a form of contraception for many women;
2. The need for the rule to require coverage without cost sharing for the full range of contraceptive options;
3. Why expanding the proposed religious exemption would violate the Establishment Clause;
4. The inapplicability of the legal authority cited by proponents of a broad religious exemption;
5. The hollowness of threats being made by Catholic charitable organizations to halt services for low-income individuals; and
6. Why the Employee Retirement Income Security Act (ERISA) church plan exemption cannot be a legal basis for a broadened exemption.
7. Harassment and discrimination experienced by abortion providers;

8. The process through which the coverage requirement was developed was open and transparent; and
9. Data show that family planning incurs substantial cost savings.

I. Sterilization Is an Important Reproductive Health Service for Women

In a recent congressional hearing, some criticized the rule's contraceptive services coverage requirement because it differs from most state contraceptive equity laws in that it includes sterilization. Inclusion of sterilization in the coverage requirement is appropriate and necessary, however, because it is a critically important method of contraception for many women.

Most state contraceptive coverage requirements use a parity approach -- requiring coverage of prescription contraception if a health insurance plan covers other forms of prescription drugs. As such, sterilization does not fall within the ambit of these coverage requirements. The Department's rule, however, is not similarly limited, nor should it be.

The facts on sterilization clearly demonstrate the need for such coverage on a no-copay basis. American women rely increasingly on sterilization as a form of contraception as they age. In 2002, 50% of women 40 and older relied on this method.¹ Sterilization is more commonly used by women with higher numbers of children, and those with lower education and income.² One-half of women who choose sterilization have the procedure performed on an inpatient basis following childbirth. The other half have what is referred to as outpatient "interval" sterilizations, which take place six weeks or more postpartum, typically in an outpatient surgery center or physician office.³

Tubal sterilization following a cesarean section ("c-section") has the significant benefits of combining two surgical procedures into one, thereby lowering the woman's risk of complications, as well as shortening her recovery time, when compared with a c-section followed by an interval tubal sterilization. Post-partum sterilization is often recommended for women who have had three or more c-sections because these women face increased risk of significant pregnancy complications with a subsequent c-section delivery.

Despite the clinical importance of sterilization for many women – for some it can literally be life-saving – religious doctrine often impedes women's ability to obtain the procedure. Research by Dr. Lori Freedman reveals that the primary disadvantage of working in a Catholic hospital that was cited by physicians was an inability to perform sterilizations, particularly following a c-section delivery.⁴

This physician sentiment was borne out by fact-finding research conducted by the Center for Reproductive Rights in three communities in which previously secular hospitals came under Catholic control. In all three places, the explicit prohibition on tubal sterilization was overwhelmingly identified by physicians as the most significant change in women's access to reproductive healthcare services after the hospitals adopted the Religious and Ethical Directives for Catholic Healthcare. Because many women living in these predominantly low-income

¹ Chan and Westoff, "Tubal sterilization trends in the United States," FERTILITY AND STERILITY (June 2010).

² Id.

³ Id.

⁴ Presentation at American Public Health Association annual meeting, November 1, 2011.

communities face significant barriers to leaving the community for care due to transportation and cost concerns, they cannot easily access services at other hospitals, even when it is available.

Our research revealed that many physicians were outraged by the blanket denial of sterilization following Catholic control of the hospital; a family physician who served on the Board of Directors of one hospital resigned in protest. Another physician described in vivid detail the impact of the denial of sterilization services required by strict adherence to Catholic doctrine:

There are only so many c-sections a woman should have. With every one the next pregnancy is markedly compromised. [T]here's a higher risk the placenta can implant on the uterine scar ... you can't get the placenta out, there's morbid hemorrhage [she demonstrates by turning on the faucet until the water runs vigorously]. ...It's absolutely unconscionable ... The Pope, the Cardinal, the Board is not going to be there, not going to be here when she is hemorrhaging, bloody, you can't see, it's horrible, the uterus is cut, she needs a massive transfusion. Six months later she still looks awful, like death warmed over; she can't take care of the little ones she has.⁵

Some providers retired from the practice of obstetrics or moved their practices to other communities because they felt that practicing under the Catholic healthcare directives required them to practice sub-standard medicine. Others risked disciplinary action (and the potential for loss of staff privileges and associated malpractice coverage) by doing tubal sterilizations after the prohibition went into effect, when their medical and ethical duties – and their consciences – would not allow them to follow hospital policy prohibiting performance of tubal sterilization.

The documented impact on patients was even more harsh, and sometimes even tragic. Some had to go to hospitals in other communities to deliver their babies so that they could have post-partum sterilizations, while others who lacked the ability to do this had to simply forego the procedure, even when future pregnancies were medically contraindicated. The physicians interviewed by the Center all told stories of women who were unable to obtain sterilizations who subsequently became pregnant when they did not want to; one with six children died in childbirth. On top of the clinical problems presented by denying women access to sterilization, the women affected also reported feelings of anger and disrespect at having their wishes overridden by a rigid and out-of-touch hospital policy. For women with difficulty accessing reversible contraceptive methods, or who lack control over their reproductive lives, sterilization is often the only viable option; making it unavailable can literally be fatal for some women.

These stories vividly illustrate how severely one-sided the discussion over so-called “conscience” protections has been in the context of women’s reproductive healthcare. The primary concern has been over the consciences of a handful of religious institutions. Absent from the discourse is concern for the consciences of healthcare providers who seek to provide medically necessary care to their patients and who are prevented from doing so by religious – not medical – guidelines, and of the consciences of the individual women who need access to contraception to control their reproductive lives and manage their health. The consciences of those would refuse to provide legal, necessary healthcare should not be elevated over the consciences of doctors, nurses and others who seek to provide access to necessary services, or

⁵ Interview with Dr. Gwen Patterson, Sierra Vista Regional Health Center in Sierra Vista, Arizona, November 17, 2010.

the consciences of the patients who rely on these providers for care and have a right to health and self-determination.

II. Women Must Have Access to the Full Range of Contraceptive Options Without Cost Sharing

On July 19, 2010, the Department issued an interim final rule to implement the preventive services coverage requirement in Section 2713 of the ACA. See 75 FR 41726 (July 19, 2010). While the specific women's preventive services had not yet been determined at the time this earlier rule was promulgated, this 2010 rule applies to all categories of required preventive services. The agency's preamble to the rule specifically states that:

If a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived.

75 FR 41728-9. The proposed regulations themselves state: "Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline." See 26 CFR § 54.9815-2713T(a)(4); 29 CFR § 2590.715-2713(a)(4); 45 CFR § 147.130(a)(4). A likely interpretation of this language is that insurers would be permitted to use mechanisms such as formularies to specify which forms and brands of contraception it will cover without cost sharing.

The Center is concerned that the value of the Department's new contraceptive coverage benefit could be undermined by an overly restrictive interpretation of the allowed medical management techniques. In order to ensure that this core benefit for women not be rendered hollow by insurer limitations, we encourage the Department to ensure that certain safeguards are put in place.

Due to the unique nature of contraception, it is important that a wide range of brands and formulations be available to women, as not all methods work equally well for all women. In addition, some women are limited to particular methods or medications due to other health conditions. And for some, the side effects mean they cannot tolerate certain methods or medications. The American College of Obstetricians and Gynecologists (ACOG) has stated:

Due to the side-effect profile of some medications and devices, the difference in permanence and reversibility of contraceptives, and women's personal preferences, health plans must ensure a complete range of choices for women and their clinicians. Because contraceptive methods vary in effectiveness and because not all contraceptives will be clinically appropriate for all women, providing access to all forms of contraception best enables women to meet their individual medical needs and reproductive goals. For example, oral contraceptives are not all

the same. They differ in regimen (e.g. 21/7 day, 24/4 day, or continuous) and in components (e.g. different progestins, some add iron or folic acid).⁶

Factors that may affect which type of contraceptive to utilize include:⁷

- Age older than 35 years
 - Tobacco smoking
 - Hypertension
 - Lipid disorders
 - Diabetes
 - Migraine headaches
 - Fibrocystic breast changes, fibroadenoma, or family history of breast cancer
BRCA1 or BRCA2
 - Uterine leiomyomata
 - Breastfeeding postpartum
 - Concomitant medications
 - Scheduled for surgery
 - History of venous thromboembolism
 - Hypercoagulable conditions
 - Anticoagulation therapy
 - Obesity
 - Systemic lupus erythematosus
 - Sickle cell disease
 - Depression
- Human immunodeficiency virus (HIV) (acquisition, transmission, and progression).

Research also indicates that women and couples are more likely to use contraception successfully if given their contraceptive method of choice, thus coverage of a full range of contraceptive options is needed.⁸

In sum, hormonal contraceptives vary in their effectiveness in highly personal and medically important ways. It is essential that all methods be made available without cost sharing as the rule requires, as inconsistent use of contraception leads to numerous unintended pregnancies, the core problem that the requirement is designed to combat.

But within methods, the question as to the extent of coverage without cost sharing also arises. The Center encourages the Department to treat contraceptives in the same manner that HIV and certain other drugs are treated by the Medicare Part D program. Under Medicare Part D, prescription drug plans must cover all drugs in the antiretroviral drug class, along with five other drug classes, and they may not apply utilization management techniques (such as prior authorization) to such drugs. These "classes of clinical concern" are afforded such treatment because of the importance of matching patients to therapies that work best.

⁶ American College of Obstetricians and Gynecologists. *Practice Bulletin No. 110: Noncontraceptive Uses of Hormonal Contraceptives*, *Obstetrics and Gynecology* 2010;115:206–18.

⁷ American College of Obstetricians and Gynecologists. *ACOG Practice Bulletin No. 73: Use of hormonal contraception in women with coexisting medical conditions*, *Obstetrics and Gynecology* 2006;107:1453–72.

⁸ Noone J. *Finding the Best Fit: A Grounded Theory of Contraceptive Decision Making in Women*, *Nursing Forum* Oct-Dec 2004; 39(4); Henshaw SK. *Unintended pregnancy in the United States*. *Family Planning Perspectives*, 1998; 30:24-29.

Given the fundamental importance of preventing unintended pregnancy, it is similarly critical that women have the ability to obtain the optimal method of birth control for their particular needs without cost sharing. Allowing insurers to cover only one or two formulations of oral contraceptives could render the benefit virtually meaningless to women who, for various reasons, cannot use those particular types of pills. It is essential that individual women and their physicians be able to determine the contraceptive method that is most suited for them to ensure maximum efficacy, and not have that choice artificially constrained by a restrictive formulary.

If, however, the Department concludes that it must permit health insurers to apply *some* limitations to the contraception requirement,⁹ it must include strong protections for consumers in the rule. The Center urges the Department to ensure that if health insurers are permitted to establish formularies for the FDA-approved contraceptive methods that must be covered without cost sharing, such formularies include a sufficient number of brand-name or generic products in each category of hormonal contraceptives and contraceptive devices (for example, monophasic, biphasic, triphasic and other forms of oral contraception). As is true in the Medicare Part D program, any contraception formularies should include within each therapeutic category and class at least two drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs.

In addition, insurers should be required to cover a medically necessary non-formulary product without cost sharing if prior authorization is obtained. These protections are similar to the requirements under federal law for Medicaid coverage of outpatient drugs. *See* 42 USC § 1396r-8(d)(4) (states offering coverage for outpatient drugs in their Medicaid programs may establish formularies if they permit coverage of an excluded drug pursuant to a prior authorization program that provides a response within 24 hours of an authorization request). The Medicare Part D program also requires access to non-formulary drugs when medically necessary through an exception process, and private insurance plans also typically include a similar process. Such an approach is consistent with the guidelines of medical professionals: "The American College of Obstetricians and Gynecologists supports patient or clinician requests for branded OCs or continuation of the same generic or branded OC if the request is based on clinical experience or concerns regarding packaging or compliance, or if the branded product is considered a better choice for that individual patient."¹⁰

It is also important that if restrictive formularies are permitted, the insurer pharmacy and therapeutics committee making the decisions on which contraceptive products to include on the formulary should contain members who possess clinical expertise in contraception. With dozens of brands and generics available on the market, it will be important to ensure that a sufficient number of different oral contraceptives be placed on a formulary to allow for the widest possible choice within the constraints of the formulary. The process for selecting products for inclusion must be guided by medical experts with current knowledge of the state of the art in contraceptive options.

⁹ The regulations governing implementation of the preventive services rule, including the contraception requirement, are currently an interim final rule, and thus subject to modification. The Department is therefore able to adjust the "reasonable medical management" provision in the rule with respect to its applicability to contraception.

¹⁰ "Brand versus generic oral contraceptives." ACOG Committee Opinion No. 375. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007; 110:447-8.

Finally, insurers should not be allowed to adopt “step therapy” as a medical management technique. This mechanism, also known as “fail first,” requires patients to try less expensive therapies before more expensive ones will be covered. Only if the less expensive therapy proves ineffective will coverage for more costly alternatives be approved. In the case of contraception, even one act of sexual intercourse with no contraception or an ineffective method can result in a pregnancy. Restricting women to methods that they are unable to tolerate or use effectively, and requiring “failure” before granting access to more suitable methods, would be potentially disastrous and dramatically undercut the underlying goal of the rule – preventing unintended pregnancy.

III. Expanding the Religious Exemption Would Violate the Establishment Clause

Opponents of the contraceptive coverage requirement have mentioned the possibility of litigation unless they are granted a broader religious exemption than the one currently proposed. In fact, however, were the Administration to broaden the exemption, it would also open itself to legal challenge.

Indeed, neither the Constitution nor the Religious Freedom Restoration Act requires any religious exemption to the contraceptive coverage rule. The highest state courts of California and New York, confronting a religious exemption virtually identical to the one proposed by the Department, both concluded that a broader exemption was not legally compelled.¹¹

A broader exemption to the Department’s rule is **not** required. In fact, broadening the exemption beyond that proposed by the Department would raise serious constitutional concerns and invite litigation challenging the expanded rule under the Establishment Clause of the First Amendment for two reasons: first, because the Establishment Clause prohibits the government from subjecting a public benefit to religious restrictions; and second, because the Establishment Clause forbids religious exemptions that impose costs on third parties.

A. The Establishment Clause Prohibits the Government from Subjecting a Public Benefit to Religious Restrictions

One of the primary evils the Establishment Clause is designed to combat is the “active involvement of the sovereign in religious activity.”¹² That is precisely what is at issue here, where the government is seeking to delegate its authority to religious institutions. The government, through a transparent, scientifically rigorous process, has determined that it has a compelling interest in ensuring that women have access to FDA-approved contraceptives without affordability barriers. An expanded exemption would allow religiously affiliated employers to interpose themselves between this benefit and the intended recipients – their employees. But the Supreme Court has made clear that the government may not delegate to a religious organization the decision of whether or not to extend a benefit.

¹¹ *Catholic Charities of the Diocese of Albany v. Serio*, 859 N.E.2d 459, 465 (N.Y. 2006) (“The existence of a limited exemption for ministers from antidiscrimination laws does not translate into an absolute right for a religiously affiliated employer to structure all aspects of its relationship with its employees in conformity with church teachings.”); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 93 (Cal. 2004).

¹² *Comm. For Public Educ. and Religious Liberty v. Nyquist*, 413 U.S. 756, 772 (1973).

For example, in *Larkin v. Grendel's Den, Inc.*,¹³ the Supreme Court overturned a statute that allowed religious institutions to veto liquor licenses within a 500-foot radius from the house of worship. In so holding, the Court held that the liquor law unconstitutionally delegated state power to a religious institution.¹⁴ In particular, the *Larkin* court noted that the statute in question “delegate[ed] important...governmental powers to religious bodies,” thus “impermissibly entangling government and religion.”¹⁵

More recently, in *Board of Education of Kiryas Joel Village School District v. Grumet*,¹⁶ the Supreme Court invalidated a statute creating a special school district for a religious community. At issue, the Court’s plurality opinion explained, was the fact that the statute “deleg[ated] the State’s discretionary authority...to a group defined by its character as a religious community.”¹⁷

The greater the extent of the exemption, the greater is the scope of impermissible delegation of authority. Indeed, vesting a religious entity with secular authority – ceding implementation of the preventive-services mandate to religious institutions – strikes at the very core OF the anti-establishment principle dating back to Jefferson’s original *Memorial and Remonstrance Against Religious Assessments*: “The core of that principle...is that ‘no man shall be compelled to frequent or support any religious worship, place, or ministry whatsoever...’”¹⁸ The exemption, by forcing employees to live out the religious beliefs of their employers – notwithstanding a national government requirement to provide no-copay contraception – violates the Establishment Clause.

B. The Establishment Clause Prohibits Religious Exemptions that Impose a “Substantial Burden” or “Monetary Cost” on Third Parties

The economic impact of an expanded religious exemption would be to impose a *de facto* tax in the amount of the cost of contraception on those working for religiously affiliated employers. This is because *only* employees at religiously affiliated entities would pay for their contraception out-of-pocket – a cost that the Institute of Medicine recommendation demonstrated is sometimes prohibitive. And, conversely, all religious employers would receive a *de facto* tax benefit – the savings from not having to pay for contraceptive coverage.

Courts have struck down religious exemptions that exact a toll on third parties as this one does. This was precisely the Supreme Court’s holding in *Texas Monthly v. Bullock*.¹⁹ In *Texas Monthly*, the Court struck down a Texas sales tax exemption for religious periodicals. In so doing, the Court rejected the state’s argument that a tax exemption was constitutionally required to avoid a Free Exercise violation. In a critical footnote, the Court explained that the Constitution does not, *per se*, prohibit religious exemptions to generally applicable laws, and listed several examples of permissible exemptions, such as an exemption to the military-dress requirement allowing religious adherents to wear certain headgear or other attire. However, the Court emphasized that the common thread in these permissible exemptions was that they “did not, or would not, impose substantial burdens on non-beneficiaries while allowing others to act

¹³ 459 U.S. 116 (1982).

¹⁴ *Id.* at 122.

¹⁵ *Id.* at 126.

¹⁶ 512 U.S. 687 (1994).

¹⁷ *Id.* at 696.

¹⁸ Thomas Jefferson, *Memorial and Remonstrance Against Religious Assessments*, quoted in *Comm. For Public Educ. and Religious Liberty v. Nyquist*, 413 U.S. 756, 770 n.28 (1973).

¹⁹ 489 U.S. 1 (1989).

according to their religious beliefs...nor [would they] impose monetary costs on [those] who opposed...the religious instruction...²⁰

Whereas there is no cost – economic or otherwise – of allowing, for example, Jewish soldiers to wear a yarmulke, there is a significant cost associated with allowing a broad exemption for religiously affiliated institutions – one that these institutions will pass on to their employees. Indeed, the broad religious exemption sought by religious charities and hospitals would impose both “substantial burdens” *and* “monetary costs” on nonbelievers by stripping them of a critically important health benefit, and forcing them to pay for contraception out of pocket.

Not only does allowing an institutional employer’s “conscience” to trump employees’ conscience right violate the Establishment Clause, it is also fundamentally unfair. The proposed rule would not require any employer to purchase contraception – it only requires that employers offer coverage for those services – allowing each employee’s conscience to determine whether she wishes to avail herself of the benefit or not. It is particularly unfair, given that affordability remains a significant barrier to contraceptive access, to have a corporate employer’s “conscience” trump the consciences of individual workers, and at the same time, jeopardize their health.

IV. The Cases Cited by Proponents of a Broadened Religious Exemption Are Not On-Point

A number of religiously affiliated organizations²¹ submitted comments to the Department in favor of a broader religious exemption. These comments, which are nearly identical in substance, commonly cite a handful of cases to bolster their argument that the Free Exercise Clause of the First Amendment to the U.S. Constitution requires a broader exemption. All of these cases, however, are inapposite to the question, as demonstrated below. (This material is also being submitted separately in chart form for ease of reference.)

Case: *Larson v. Valente*, 456 U.S. 228 (1982)

Holding: Under the First Amendment, a law granting a denominational preference – preferring one religion to another – is subject to strict scrutiny and can only be justified by a compelling governmental interest. *Larson*, 456 U.S. at 246-47.

Proposition for Which Case is Cited: “The government may not pick and choose among difference religious organizations when it imposes some burden.” **Note:** The Council for Christian Colleges and Universities, Wheaton College, and the University of Sioux Falls all claim to be quoting *Larson*. In fact, no such sentence appears in *Larson* or in any other case.

Why the Case is Distinguishable: The statute in *Larson* targeted religious groups that solicited more than 50 percent of their funds from nonmembers. The Supreme Court found that this statute made “explicit and deliberate distinctions between different religious organizations.”

²⁰ *Id.* at 18 n.8. The lower courts have similarly looked at whether a religious exemption imposes a cost on third parties in determining whether it violates the Establishment Clause. *See, e.g., Children’s Healthcare is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000); *Charles v. Verhagen*, 220 F. Supp. 2d 955 (W.D. Wis. 2002).

²¹ The religiously affiliated groups that have submitted nearly identical comments include the Council for Christian Colleges and Universities, Wheaton College, and the University of Sioux Falls.

Larson, 456 U.S. at 247. This violated the Constitution’s prohibition on laws favoring one religious denomination over another.

In contrast, the no-copay-contraception requirement is a neutral, generally applicable law that mandates a baseline benefit for members of the public. The law is not based on anti-religious animus or a denominational preference.

Case: *NLRB v. Catholic Bishop of Chicago*, 440 U.S. 490 (1979)

Holding: The National Labor Relations Board does not have jurisdiction over teachers at church-operated schools, whether those schools are “completely religious” or “religiously associated.”

Proposition for Which Case is Cited: “It is not only the conclusions that may be reached by the [government] which may impinge on rights guaranteed by the Religion Clauses, but also the very process of inquiry leading to findings and conclusions.” *NLRB*, 440 U.S. at 502.

The comments of the religiously affiliated institutions argue that *NLRB* stands for the proposition that the government may not determine which institutions qualify or do not qualify for a religious exemption.

Why the Case is Distinguishable: In *NLRB*, the NLRB differentiated between “religiously affiliated schools” and “completely religious schools,” and claimed jurisdiction only over “religiously affiliated schools.”

The case is not applicable with respect to the no-copay-contraception requirement, because the proposed religious exemption distinguishes between houses of worship and religiously affiliated entities. In order to be analogous to *NLRB*, the exemption would have to distinguish between “completely religious” versus “religiously associated” houses of worship.

In addition, NLRB explicitly underscored the appropriateness of the NLRB’s exercise of jurisdiction over non-teacher employees at religious schools, including rectors, procurators, clerical employees, cafeteria workers, etc.

Case: *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327 (1987)

Holding: A religious exemption to Title VII’s prohibition on religious discrimination in employment does not violate the Establishment Clause, even where a religious employer is hiring for a nonreligious position.

Proposition for Which Case is Cited: “The line [between secular and religious activities] is hardly a bright one, and an organization might understandably be concerned that a judge would not understand its religious tenets and sense of mission.” *Latter-Day Saints*, 483 U.S. at 336.

The comments claim the case stands for the proposition that the government may not distinguish between an organization's religious and secular activities.

Why the Case is Distinguishable: The comments quote a non-controversial statement of dictum – that line-drawing can be difficult in the context of determining which activities of a religious institution are religious and which are secular – and use that statement to suggest that the government may not engage in any such line-drawing. This analysis fails because it reads a singular sentence in a particular case in a complete vacuum, ignoring the fact that the Supreme Court and the lower courts have repeatedly upheld such line drawing – and that the highest courts of California and New York both rejected claims that the U.S. Constitution prohibits distinguishing between houses of worship on the one hand and religiously affiliated organizations on the others. *See Catholic Charities of the Diocese of Albany v. Serio*, 859 N.E.2d 459, 465 (N.Y. 2006); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 93-94 (Cal. 2004).

Case: *Mitchell v. Helms* 530 U.S. 793 (2000)

Holding: A plurality of the Court held that a program to aid school programs, including parochial-school programs, does not violate the Establishment Clause.

Proposition for Which Case is Cited: “It is well established, in numerous other contexts, that courts should refrain from trolling through a person’s or institutions religious beliefs.” *Mitchell*, 530 U.S. at 828

The comments cite *Mitchell* for the proposition that the Department of Health and Human Services, by proposing the no-copay-contraception requirement, is “trolling” through organizations’ religious belief.

Why the Case is Distinguishable: This case is completely inapposite, because in no sense does the no-copay-contraception requirement have anything to do with an organization’s particular religious beliefs. Instead, it is a neutral, generally applicable law.

Indeed, the plurality opinion in *Mitchell* cited in the comments actually supports the constitutionality of the no-copay-contraception requirement, because according to the Court, the religious nature of an organization that may be affected by a law is irrelevant; the relevant inquiry is whether there is a “secular purpose.” *Mitchell*, 530 U.S. at 827. Here, the no-copay-contraception requirement is based on sound medical and public health findings and the recommendation of the expert panel convened by the Institute of Medicine.

Case: *New York v. Cathedral Academy*, 434 U.S. 125 (1977)

Holding: A statute allowing reimbursement to private schools – including parochial schools – for the costs of testing services required by state law violates the Establishment Clause.

Proposition for Which Case is Cited: “The prospect of church and state litigating in court about what does or does not have religious meaning touches the very core of the constitutional guarantee against religious establishment.” *Cathedral Academy*, 434 U.S. at 133.

The comments cite this case for the proposition that the government cannot distinguish a “religious employer” from a “non-religious employer.”

Why the Case is Distinguishable: The quotation is taken out of context. The subject of the sentence is the Court’s concern that in a broad program of reimbursement to parochial schools, the government cannot know whether the funds are being used to reimburse secular or religious expenses.

The case is wholly inapplicable to the no-copay-contraception requirement, because nothing in the interim final rule requires the government to determine whether particular expenses by religious employers are religious or secular.

Case: *Keller v. State Bar of California*, 496 U.S. 1 (1990)

Holding: State bar association may not use compulsory dues to pay for political activities not reasonably related to the regulation of the legal profession.

Proposition for Which Case is Cited: The comments cite *Keller* for the proposition that the Department of Health and Human Services may not require a religious institution to adopt a practice to which it objects.

Why the Case is Distinguishable: The use of compulsory dues to fund purely ideological activities is completely different than requiring all employers – including religiously affiliated employers – to include certain services in their health-insurance coverage. Whereas the acts in *Keller* were purely ideological, here the no-copay-contraception requirement is based on sound medical science.

Moreover, the majority in *Keller* distinguished a state bar association and its “very specialized characteristics” from government, which is obligated to “espouse the views of a majority.” *Keller*, 496 U.S. at 12.

Case: *Boy Scouts of America v. Dale*, 530 U.S. 640 (2000)

Holding: A state public-accommodation law may not be invoked to require the reinstatement of group member expelled for identifying as homosexual.

Proposition for Which Case is Cited: The comments invoke *Dale* for the proposition that “compelling an organization to do something that they [sic] had a conscientious objection to would violate their [sic] freedom of expressive association.”

Why the Case is Distinguishable: This case is not relevant, because it deals exclusively with organizations’ rights to exclude individuals. The no-copay-contraception requirement in no way forces any organization to accept (or exclude) any individual as a member. Nothing in *Dale* suggests that a neutral, generally applicable law cannot be enforced against both secular and religious employers.

V. Threats by Religious Organizations to Stop Providing Insurance or Services Should Be Disregarded

A. Threats from Religiously-Affiliated Groups to Discontinue Services If A Special Exemption Is Not Created Are a Strategy also Employed (and Discredited) in Other Contexts

In seeking a broadened religious exemption, religiously affiliated groups make two arguments. First, they argue that a broader religious exemption is required by the Constitution and the Religious Freedom Restoration Act. For the reasons set forth in our initial comments and above, this argument does not withstand legal scrutiny.

Second, religiously affiliated groups, at times, threaten to cut off services for employees and members of the public they serve. Indeed, in other contexts, the Archdiocese of Washington has threatened to cut off services to the needy if demands for a broadened religious exemption were not met. For example, in the face of a proposed Washington, D.C. law to permit same-sex marriages, Chancellor Belford of the Archdiocese threatened that unless the District of Columbia Council broadened the religious exemption, services to the poor and homeless would “be adversely impacted,”²² referring to the Church’s services to 68,000 needy individuals, including one-third of Washington’s homeless population who go to city-owned shelters managed by the Catholic Church. The Council refused to give in to these demands; Council Member Phil Mendelson trenchantly noted that a few decades ago, churches also sought religious exemptions based on their beliefs that “separation of the races was ordained by God,” a belief that they have long since abandoned.

B. Allowing Additional Exemptions Would Undermine Public Services

²² Tim Craig and Michelle Boorstein, *Catholic Church Gives D.C. Ultimatum*, Wash. Post, Nov. 12, 2009, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/11/11/AR200911116943.html>. Catholic Charities in Illinois – which received \$30 million in taxpayer funding for its adoption program – similarly threatened to displace 350 foster children and lay off 58 workers unless it received a broad religious exemption. See Manya A. Brachear, *Catholic Charities of Rockford Ends Foster Care, Adoption Services*, Chicago Tribune, May 26, 2011, available at http://articles.chicagotribune.com/2011-05-26/news/ct-met-rockford-catholic-charities-st20110526_1_catholic-charities-adoption-services-care-and-adoption.

Neither Congress nor the Department of Health and Human Services should accede to demands for a broadened religious exemption based on concerns that religiously affiliated groups will cut services for employees or members of the public they serve. As a preliminary matter, at least some of the previously lodged threats to discontinue services have never been acted upon, and are unlikely to be. Catholic Charities in both New York and California argued at the time that those state contraceptive equity laws were being debated that a contraceptive-coverage requirement nearly identical to the one at issue here would jeopardize their charitable work – yet both still exist and continue to provide services to the needy.

There are, of course, other examples in which religiously affiliated organizations have carried through on threats to eliminate services. For example, earlier this year, after a civil-union law went into effect, the Catholic Church announced that it would stop providing adoption services through Catholic Charities – displacing 350 foster children and putting 58 employees out of work.

While such closures are regrettable, the solution is not to capitulate to religiously affiliated organizations' demands for ever-broader exemptions. If such organizations are not willing or able to provide charitable services that are consistent with a shared set of social values in a pluralistic society, others will step in to perform these services.

In addition, an ever-expanding patchwork of opt-outs jeopardizes the provision of public services in America. Many of the religiously affiliated institutions that are seeking special opt-outs are charities that serve the poor and needy; hospitals that serve the sick; and schools and universities that serve children and young adults. Virtually all of these organizations serve individuals without regard to their religious background. Already, these institutions serve millions of people; Catholic hospitals, for example, see about 17% of all hospital patients nationwide.

Offering broader exemptions to these institutions will only result in a patchwork of providers of public services – soup kitchens, shelters, hospitals, schools, and universities – that are permitted to play by a different set of rules: allowed to discriminate on the basis of sex or sexual orientation; allowed to provide sub-standard medical care by “opting out” of comprehensive reproductive care – perhaps even in emergencies -- and allowed to deprive employees of the basic minimum benefits to which virtually all other employees nationwide are entitled.

VI. HHS Should Not Look to the Existing Church Plan Exemption to Expand the Religious Exemption to the Contraceptive Coverage Rule

The United States Conference of Catholic Bishops and other religious organizations have suggested that the exemption for "church plans" found within the federal Employee Retirement Income Security Act (ERISA) would be a useful model for a broadened religious exemption to the contraceptive coverage requirement. The Department should reject this suggestion.

A. Importing the ERISA Church Plan Exemption Into the Rule is Outside the Scope of the Authority Delegated to the Department by Congress

A church plan is defined in ERISA as follows:

The term “church plan” means a plan established and maintained (to the extent required in clause (ii) of subparagraph (B)) for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under section 501 of title 26.

29 U.S.C. §1002(33)(A). The church plan exemption means participants in these plans lack protections that participants in other plans have that are found in Titles I and IV of ERISA (and any Department of Labor regulations thereunder), which include regulations of benefit plans, such as reporting, disclosure, fiduciary, and claims and appeals requirements.

As past legislation amply shows, Congress exempts church plans from certain federal health benefit requirements and not others; it knows how to effectuate such an exemption when it wishes to do so. Instances in which Congress has chosen to exempt church plans include the Consolidated Omnibus Budget and Reconciliation Act of 1986 (COBRA) and the Women’s Health and Cancer Rights Act of 1998 (requiring coverage for reconstructive surgery after mastectomy). The clear trend since 1996, however, has been for federal health care requirements not to exempt church plans, and the Affordable Care Act is consistent with this trend. Examples of federal health care requirements that do not exempt church plans include:

- Health Insurance Portability and Accountability Act of 1996 (HIPAA);
- Newborns’ and Mothers’ Health Protection Act of 1996 (mandatory hospital length of stay following delivery);
- Michelle’s Law of 2008 (coverage for certain dependent children);
- Children’s Health Insurance Program Reauthorization Act of 2009(CHIPRA) (requiring notice of certain state CHIP programs);
- Mental Health Parity and Addiction Equity Act of 2008; and
- Patient Protection and Affordable Care Act (PPACA) Coverage of Preventive Health Services.

Congress did not include a church plan exemption in the Affordable Care Act. Therefore, adding a religious exemption to one provision in the Act is beyond the scope of the agency’s authority. Had Congress wanted to make church plans exempt, it would have done so.

B. Expanding the Proposed Exemption to Match the ERISA Church Plan Definition Would Create Substantial Uncertainty Regarding Who is Covered by the Preventive Services Mandate

Trying to use the ERISA church plan definition would introduce a substantial amount of uncertainty into the rule, as entities and their employees seek to determine whether they fall within the exemption. It is not uncommon for litigation to arise around whether a particular employer plan qualifies as a church plan, as meeting this definition has significant implications for the scope of duties that apply to plan administrators. *See, e.g., Chronister v. Baptist Health*, 442 F.3d 648 (8th Cir. 2006); *Lown v. Continental Casualty Co.*, 238 F.3d 543 (4th Cir. 2001); *Hall v. USAble Life*, 774 F.Supp.2d 953 (E.D. Ark. 2011); *Thorkelson v. Publishing House of the Evangelical Lutheran Church in America*, 764 F.Supp.2d 1119 (D. Minn. 2011).

Moreover, the Bishops, the Catholic Health Association (CHA) and others do not want to adopt the ERISA church plan definition as is – they want to use it merely as a model or starting point. For example, in its comments on the rule, the CHA stated:

We strongly believe that the concepts contained in Section 414(e) [the codification of the church plan exemption in the Internal Revenue Code] are instructive for developing an appropriate religious employer exemption to the contraceptive mandate to be applied to employer health plans. To be clear, we are not suggesting that the exemption be applied only to plans that are “church plans” under Section 414(e), nor are we intending to impact the interpretation of Section 414(e) in the “church plan” context. Instead, we are suggesting that the principles that Congress developed in 1980 [when Congress made permanent a prior temporary extension of the church plan exemption to church-related employers] to define organizations that are “associated with a church” serve as an appropriate model for the religious employer exemption applicable to the contraceptive mandate.

Similarly the United States Conference of Catholic Bishops in its comments also referenced the existing church plan exemption, but stated “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.”

Any attempt to craft a new variant of the church plan definition would be an invitation for still more uncertainty, as its precise contours would not be immediately known and their practical implications would be obscure. The church plan definition from 1974 is still litigated today. Development of a different, yet similar, exemption would inevitably engender more such battles, risking uncertainty, litigation and deprivation of needed health care by employers without a basis in law.