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1 **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

2 **45 C.F.R. Part ____**

3 **RIN____**

4 **[Title]**

5 **AGENCY: Office of the Secretary**

6 **ACTION: Proposed Rule**

7

8 **SUMMARY:** The Department of Health and Human Services proposes to promulgate

9 regulations to ensure that, in accordance with the Church Amendments (42 U.S.C. § 300a-7),

10 Public Health Service (PHS) Act §245 (42 U.S.C. § 238n), and the Weldon Amendment

11 (Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209),

12 Department funds do not support morally coercive or discriminatory practices or policies in

13 violation of federal law. This notice of proposed rulemaking proposes to define key terms, and to

14 ensure that recipients of Department funds know about their legal obligations under these

15 nondiscrimination provisions, the Department proposes to require written certification by

16 recipients that they will comply with all three statutes.

17

18 **DATES:** Submit written or electronic comment on the regulations proposed by this document

19 by [OFR—insert (x) days from date of display].

20 **ADDRESSES:**

21 **FOR FURTHER INFORMATION CONTACT:**

22 **SUPPLEMENTARY INFORMATION:**

23 **I. Background**

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1 Religious liberty and freedom of conscience have long been protected in the Constitution
2 and laws of the United States. The U.S. Congress and State legislatures have enacted, and
3 Presidents and State governors have signed, laws making it illegal for institutions to discriminate
4 against individuals on the basis of religion in hiring, promotion, and benefit practices; requiring
5 employers to provide reasonable accommodation for employees’ religious beliefs in the
6 workplace; protecting conscientious objectors in time of war, regardless of whether they objected
7 on religious or philosophical grounds; protecting objecting individuals from participating in
8 executions; protecting individuals’ consciences in health service programs and research activities
9 funded by the federal government; and protecting the rights of all health care entities, individual
10 or institutional, from being forced to participate in certain activities.

11 Workers in all sectors of the economy enjoy legal protection of their consciences and
12 religious liberties. In the health care industry, there are several statutory provisions that
13 specifically address individuals’ religious and conscience rights. These federal statutes prohibit
14 recipients of certain federal funds from coercing individuals into participating in actions they
15 find religiously or morally objectionable. These same provisions also prohibit discrimination on
16 the basis of one’s objection to or participation in specific procedures, including abortion or
17 sterilization, or one’s participation in or refusal to participate in abortion or sterilization
18 procedures. More recently, statutory provisions and appropriations riders have been enacted that
19 prohibit federal programs and State and local governments from discriminating against
20 individuals and institutions that refuse to, among other things, provide, refer for, pay for, or
21 cover, abortion.

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23 **Conscience Clauses/Church Amendments [42 U.S.C. § 300a-7]**

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1 The conscience provisions contained in 42 U.S.C. § 300a-7 (collectively known as the
2 “Church Amendments”) were enacted at various times during the 1970s in response to debates
3 over whether receipt of federal funds required the recipients of such funds to provide abortions
4 or sterilizations. The first conscience provision in the Church Amendments, 42 U.S.C. § 300a-
5 7(b), provides that “[t]he receipt of any grant, contract, loan, or loan guarantee under [certain
6 statutes implemented by the Department of Health and Human Services] . . . by any individual or
7 entity does not authorize any court or any public official or other public authority to require”: (1)
8 the individual to perform or assist in a sterilization procedure or an abortion if it would be
9 contrary to his/her religious beliefs or moral convictions; (2) the entity to make its facilities
10 available for sterilization procedures or abortions, if the performance of sterilization procedures
11 or abortions in the facilities is prohibited by the entity on the basis of religious beliefs or moral
12 convictions; or (3) the entity to provide personnel for the performance of sterilization procedures
13 or abortions if it would be contrary to the religious beliefs or moral convictions of such
14 personnel.

15 The second conscience provision in the Church Amendments, 42 U.S.C. § 300a-7(c)(1),
16 prohibits any entity which receives a grant, contract, loan, or loan guarantee under certain
17 Department-implemented statutes from discriminating against any physician or other health care
18 personnel in employment, promotion, termination of employment, or the extension of staff or
19 other privileges because the individual either “performed or assisted in the performance of a
20 lawful sterilization procedure or abortion,” or “because he refused to perform or assist in the
21 performance of such a procedure or abortion on the grounds that his performance or assistance in
22 the performance of the procedure or abortion would be contrary to his religious beliefs or moral

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1 convictions, or because of his religious beliefs or moral convictions respecting sterilization
2 procedures or abortions.”

3 The third conscience provision, contained in 42 U.S.C. § 300a-7(c)(2), prohibits any
4 entity which receives a grant or contract for biomedical or behavioral research under any
5 program administered by the Department from discriminating against any physician or other
6 health care personnel in employment, promotion, termination of employment, or extension of
7 staff or other privileges “because he performed or assisted in the performance of any lawful
8 health service or research activity,” or “because he refused to perform or assist in the
9 performance of any such service or activity on the grounds that his performance of such service
10 or activity would be contrary to his religious beliefs or moral convictions, or because of his
11 religious beliefs or moral convictions respecting any such service or activity.”

12 The fourth conscience provision, 42 U.S.C. § 300a-7(d), provides that “[n]o individual
13 shall be required to perform or assist in the performance of any part of a health service program
14 or research activity funded in whole or in part under a program administered by [the Department]
15 if his performance or assistance in the performance of such part of such program or activity
16 would be contrary to his religious beliefs or moral convictions.”

17 The final conscience provision contained in the Church Amendments, 42 U.S.C. § 300a-
18 7(e), prohibits any entity that receives a grant, contract, loan, or loan guarantee under certain
19 Departmentally implemented statutes from denying admission to, or otherwise discriminating
20 against, “any applicant (including for internships and residencies) for training or study because
21 of the applicant’s reluctance, or willingness, to counsel, suggest, recommend, assist, or in any
22 way participate in the performance of abortions or sterilizations contrary to or consistent with the
23 applicant’s religious beliefs or moral convictions.”

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Public Health Service Act § 245 [42 U.S.C. § 238n]

Enacted in 1996, section 245 of the Public Health Service Act (PHS Act) prohibits the Federal government and any State or local government receiving federal financial assistance from discriminating against any health care entity on the basis that the entity refuses to: (1) receive training in abortion; (2) provide abortion training; (3) perform abortions; (4) provide referral for such abortions; or (5) provide referrals for abortion training. In addition, PHS Act section 245 requires that, in determining whether to grant legal status to a health care entity (including a State’s determination of whether to issue a license or certificate such as a medical license), the Federal government and any State or local government receiving federal financial assistance deem accredited any post-graduate physician training program that otherwise would be accredited but for the reliance on an accrediting standard that requires an entity: (1) to perform induced abortions; or (2) to require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training.

Weldon Amendment [Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209]

The Weldon Amendment, originally adopted as section 508(d) of the Labor-HHS Division (Division F) of the 2005 Consolidated Appropriations Act, Pub. L. 108-447 (Dec. 8, 2004), has been readopted (or incorporated by reference) in each subsequent HHS appropriations act. [Title V of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006, Pub. L. 109-149, § 508(d), 119 Stat. 2833, 2879-80; Revised Continuing Appropriations Resolution of 2007, P.L 110-5 §2, 121 stat 8, 9

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1 ;Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209]
2 The Weldon Amendment provides that “[n]one of the funds made available under this Act
3 [making appropriations for the Departments of Labor, Health and Human Services, and
4 Education] may be made available to a Federal Agency or program, or to a State or local
5 government, if such agency, program, or government subjects any institutional or individual
6 health care entity to discrimination on the basis that the health care entity does not provide, pay
7 for, provide coverage of, or refer for abortions.” It also defines “health care entity” to include
8 “an individual physician or other health care professional, a hospital, a provider-sponsored
9 organization, a health maintenance organization, a health insurance plan, or any other kind of
10 health care facility, organization, or plan.”

11

12 **The Laws in the Courts**

13 The federal courts have recognized the breadth and importance of statutory and other
14 conscience protections for health care professionals and workers. Shortly after its passage, a
15 federal appellate court decision characterized the importance of conscience protections contained
16 in the Church Amendments. Faced with the question of a denominational hospital’s right to
17 refuse to perform sterilization procedures, the Ninth Circuit affirmed a lower court decision
18 protecting the hospital’s right to refuse to perform sterilizations and abortions on religious or
19 moral grounds: “If [a] hospital’s refusal to perform sterilization [or, by implication, abortion]
20 infringes upon any constitutionally cognizable right to privacy, such infringement is outweighed
21 by the need to protect the freedom of religion of denominational hospitals ‘with religious or
22 moral scruples against sterilizations and abortions.’” *Taylor v. St. Vincent’s Hospital*, 523 F.2d
23 75, 77 (9th Cir. 1975) (citations omitted).

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The Problem

Despite the fact that several conscience statutes protecting health care entities from discrimination have been in existence for decades, recent events suggest the public and people in the health care industry are largely uninformed of the protections afforded to individuals and institutions under these provisions. This lack of knowledge in the health professions can be detrimental to conscience and other rights, particularly for individuals and entities with moral objections to abortion and other medical procedures.

A recent *New England Journal of Medicine* (NEJM) study surveyed doctors’ attitudes toward treatments like euthanasia, abortion, and the issuance of contraception to minors without parental consent. They found that, although many physicians oppose the procedures (52% objected to abortion for failed contraception, for example), 86% felt they were obligated to present all options regardless of their own objections and 71% believed physicians were obligated to assist objectionable procedures by referring the patient to another clinician.¹

A *New York Times* editorial commenting on the *NEJM* study criticized physicians who refuse to present treatment options they deem immoral:² “Any doctors who cannot talk to patients about legally permitted care because it conflicts with their values should give up the practice of medicine.”³ Several letters to the editor concurred in *The New York Times’s* conclusion.⁴

¹ Farr A. Curlin, M.D., Ryan E. Lawrence, M.Div., Marshall H. Chin, M.D., M.P.H., and John D. Lantos, M.D. *Religion, Conscience, and Controversial Clinical Practices*, *New England Journal of Medicine*. Volume 356:593-600, Number 6 (February 8, 2007).

² *Doctors Who Fail Their Patients*, N.Y. TIMES, February 13, 2007, at <http://www.nytimes.com/2007/02/13/opinion/13tue3.html?ex=1329022800&en=e19265912d278899&ei=5124&partner=permalink&exprod=permalink>. See appendix for full article.

³ *Id.*

⁴ *Doctors’ Beliefs and Good Medicine (6 Letters)*, N.Y. TIMES, February 18, 2007, at <http://www.nytimes.com/2007/02/18/opinion/18docs.html?ex=1173502800&en=bf0fc6b8ee1085b8&ei=5070> [“It

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1 Recently both New York and California have passed laws requiring employers offering
2 employee prescription drug benefits to pay for contraception.⁵ Both statutes have narrow
3 religious exceptions, yet they do not protect faith-based charities, hospitals, or other faith-based
4 organizations.

5 Under a bill recently considered in the Colorado legislature, the attorney general of
6 Colorado would be allowed to consider “reductions in the availability and accessibility of health
7 care services in the communities served by the hospital,” in determining whether he or she will
8 allow such a transaction to continue as the parties originally planned.⁶ Some have interpreted
9 the provisions of this bill to empower the State attorney general: (1) to prevent hospitals with
10 policies against providing abortions from acquiring hospitals that do provide abortions; or (2) to
11 require those hospitals that do not provide abortions to provide abortions, if the acquisition of the
12 other hospital will result in the loss of abortion services in the hospital being purchased.⁷

13 In 2005, Illinois Governor Rod Blagojevich issued executive orders requiring “a retail
14 pharmacy serving the general public [... to] dispense the contraceptive, or a suitable alternative
15 permitted by the prescriber, to the patient or the patient's agent without delay,” over the objection
16 of pharmacist groups.⁸

is the height of hypocrisy for a doctor to engage in immoral acts like withholding accurate information (or deliberately misinforming a patient by exaggerating risks) in the name of ‘morality.’ Fundamentalist religious beliefs may be an explanation for why these doctors feel the way they do, but religious beliefs should not be an excuse for unethical behavior.”].

⁵ NY CLS Ins § 3221 (2007); Cal Health & Saf Code § 1367.25 (2006); Cal Ins Code § 10123.196 (2006).

⁶ Colo. Gen. Assemb. 66- 08-1203, 2nd Sess., (Colo. 2008).

⁷ Michael Baggot, *Colorado Bills Could See Catholic Hospitals Forced to Provide Abortions or Close Down*, LIFESITENEWS.NET, March 17, 2008 at <http://www.lifesitenews.com/ldn/2008/mar/08031704.html>.

⁸ See 68 Ill. Adm. Code 1330.91 (j) (2008). See also *Pharmacist Resists Illinois Rule on Contraceptives*, FOXNEWS.COM, August 22, 2005, at <http://www.foxnews.com/story/0,2933,166426,00.html>, Letter to the Honorable Rod R. Blagojevich, Governor, State of Illinois, from Michael Patton, Executive Director of Illinois Pharmacists Association, John A Gans, Executive Vice President, American Pharmacists Association, and Henri Manasse, Executive Vice President and Chief Operating Officer, American Society of Health-System Pharmacists (April 5, 2005) (on file in appendix, available at <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=3201&TEMPLATE=/CM/ContentDispl>

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1 In May 2007, Connecticut passed a law requiring all hospitals to distribute Plan B to rape
2 victims, despite religious organizations’ objections to the abortifacient nature of the drug.⁹

3 A New Jersey law requires pharmacies to fill prescriptions “despite any conflicts of
4 employees to filling a prescription and dispensing a particular prescription drug or device due to
5 sincerely held moral, philosophical or religious beliefs.”¹⁰

6 Massachusetts¹¹ and New Mexico¹² have passed laws similar to the laws and executive
7 orders in Connecticut, Illinois, and New Jersey.

8 In May 2005, the Catholic Medical Association, an organization of Catholic physicians in
9 the United States and Canada, reported “receiv[ing] numerous reports of pressure and persuasion
10 being exerted on medical students, clerkships, and residents in public and private hospitals to
11 conform to institutional policies and ‘accept their share’ of duties requiring performance of
12 participation in activities contrary to Catholic ideology.”¹³

13 Lawsuits, editorials, and media reports have appeared throughout the United States
14 detailing efforts to require individuals and institutions to provide controversial medicine or

[ay.cfm](#)) (“[T]he order requires pharmacists and pharmacy operations to comply with one specific set of beliefs. Our profession is composed of individuals, not automatons.”).

⁹ “(b) The standard of care for each licensed health care facility that provides emergency treatment to a victim of sexual assault shall include promptly[...]

(3) Providing emergency contraception to such victim of sexual assault at the facility upon the request of such victim, except that a licensed health care facility shall not be required to provide emergency contraception to a victim of sexual assault who has been determined to be pregnant through the administration of a pregnancy test approved by the United States Food and Drug Administration.” Conn. Gen. Stat. § 19a-112e (2007).

¹⁰ N.J. Stat. § 45:14-67.1 (2008).

¹¹ “Facilities that provide emergency care shall promptly offer emergency contraception at the facility to each female rape victim of childbearing age, and shall initiate emergency contraception upon her request.” ALM GL ch. 111, § 70E (i)(4) (2008).

¹² “A hospital that provides emergency care for sexual assault survivors shall [...] provide emergency contraception at the hospital to each sexual assault survivor who requests it.” N.M. Stat. Ann. § 24-10D-3 (A)(3) (2008).

¹³ *Report of the Task Force on Issues of Conscience*, The Linacre Quarterly, May 2005, at 134. Available at <http://www.cathmed.org/publications/Conscience.pdf>.

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1 services in violation of their conscience and describing instances of discrimination against those
2 who act according to their conscience.¹⁴

3 The foregoing examples appear to indicate an increasingly pervasive attitude toward the
4 health care professions—namely, that health care personnel and institutions should be required to
5 violate their consciences by providing or assisting in the provision of controversial medicine or
6 procedures, or else face being blacklisted, excluded from practice, terminated from their jobs, or
7 otherwise subjected to discrimination.

8

9 **The Department's Response**

10 In general, the Department is concerned that the development of an environment in the
11 health care industry that is intolerant of certain religious beliefs, ethnic and cultural traditions,
12 and moral convictions may discourage individuals from underrepresented and diverse
13 backgrounds from entering health care professions. Additionally, religious and faith-based
14 organizations have a long tradition of providing medical care in the United States, and continue
15 to do so today. A trend that isolates and excludes some among various religious, cultural, and

¹⁴ See, e.g., *Moralists at the Pharmacy*, N.Y. TIMES, April 3, 2005 (“Any pharmacist who cannot dispense medicines lawfully prescribed by a doctor should find another line of work.”), and response: Letter from The Academy of Managed Care Pharmacy, The American College of Clinical Pharmacy, The American Pharmacists Association, The American Society of Health-System Pharmacists, The New York State Council of Health-System Pharmacists, The Pharmacists Society of the State of New York to the N.Y. Times (April, 2005) (available at <http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=3462&TEMPLATE=/CM/ContentDisplay.cfm>) (“[T]he editorial seeks to transform pharmacists from thinking health care professionals into robots or automatons forbidden from having personal beliefs, and from exercising their considerable professional judgment gained during years of education and practice.”). See also, Li Fellers, *Ambulance Firm Faces Bias Suit; Worker Fired After Refusing to go to Abortion Clinic*, CHICAGO TRIBUNE, May 9, 2004 at C3 (“An ambulance worker who was fired after she refused to transport a woman to an abortion clinic filed a religious-discrimination lawsuit against her employer Friday... ‘I just felt really strongly it was something that I couldn't do,’ said Adamson, a devout Christian who is adamantly anti-abortion. ‘It would be against everything that I believe in and everything that I support.’”); Steven Ertelt, *Appeals Court Rules Wal-Mart Can Ignore Pharmacist's Conscience Plea*, LIFESITENEWS.NET, May 5, 2007, at <http://www.lifenews.com/state2269.html>, Stabile, Susan, *State attempts to define religion: the ramifications of applying mandatory prescription contraceptive coverage statutes to religious employers*, 28 Harv. Journ. Law & Pub. Policy. 741 (Jun. 2005); NY CLS Ins § 3221 (2007); Cal Health & Saf Code § 1367.25 (2006); Cal Ins Code § 10123.196 (2006).

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1 ethnic groups from participating in the health care industry is especially troublesome when
2 considering current and anticipated shortages of health care professionals in many medical
3 disciplines facing the country.

4 More importantly, the various branches of the federal government have considered these
5 issues and have repeatedly reached the same resolution. This is true in the executive agencies,¹⁵
6 the federal courts, and in Congress, as described above. Individuals and entities are free to hold
7 and express an attitude that is intolerant of others' beliefs that they should refrain from certain
8 practices based on their religious beliefs or moral convictions. A violation of federal law occurs,
9 however, when individuals and entities, while at the same time receiving certain federal funds,
10 express this attitude in actions that discriminate against others. The examples above and others
11 demonstrate the need for the Department to educate the public and the health care industry on
12 long-standing federal conscience and other protections and to take steps to better ensure the
13 enforcement of these protections.

14 The Department also notes that, while many recipients of Department funds currently
15 must certify compliance with federal nondiscrimination laws, federal conscience protections are
16 not mentioned in existing forms. For example, Form PHS-5161-1, required as part of Public
17 Health Service grant applications, requires applicants to certify compliance with all federal
18 nondiscrimination laws, including laws prohibiting discrimination on the basis of race, color,
19 national origin, religion, sex, handicap, age, drug abuse, alcohol abuse or alcoholism, and other
20 federal nondiscrimination laws. The Department seeks to raise awareness of federal conscience,

¹⁵ The [...] suggestion that the requirement to provide options counseling [including abortion counseling] should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds, is likewise rejected[...] [S]uch a requirement is not necessary: under 42 U.S.C. 300a-7(d), grantees may not require individual employees who have such objections to provide such counseling. 65 FR 41270 at 41274 (2000).

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1 laws by specifically including reference to the nondiscrimination provisions contained in the
2 Church Amendments, PHS Act §245, and the Weldon Amendment in certifications currently
3 required of most existing and potential recipients of Department funds.

4 Toward these ends, the Department has concluded that regulations and related efforts are
5 necessary, in order to (1) educate the public and the health care industry on the obligations
6 imposed and protections afforded by federal law; (2) work with State and local governments and
7 other recipients of funds from the Department to ensure compliance with the nondiscrimination
8 requirements embodied in the Church Amendments, PHS Act § 245, and the Weldon
9 Amendment; (3) when such compliance efforts prove unsuccessful, to enforce these
10 nondiscrimination laws through the various Department mechanisms to ensure that Department
11 funds do not support morally coercive or discriminatory practices or policies in violation of
12 federal law; and (4) to otherwise take an active role in promoting open communication within the
13 healthcare industry, and between providers and patients, fostering a more inclusive, tolerant
14 environment in the health care industry than may currently exist.

15 These proposed actions are consistent with the Administration's current efforts to ensure
16 that community and faith-based organizations are able to participate in federal programs on a
17 level playing field with other organizations. More importantly, they are intended to promote
18 compliance with federal conscience and other protections for health care personnel and entities
19 and to ensure that recipients of federal funds are not discriminating in violation of federal law.

20

21 II. Summary of the Proposed Rule

22 This proposed rule sets out, and provides further definition of, the rights and
23 responsibilities created by the federal nondiscrimination provisions. This proposed rule would

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1 also require recipients of Department funds to certify compliance with these requirements as a
2 prerequisite to the receipt of funds. This proposed rule, in order to ensure proper enforcement,
3 would define certain terms for the purposes of this proposed regulation.

4 The Department of Health and Human Services Office for Civil Rights has been
5 designated to receive complaints of discrimination based on the nondiscrimination provisions
6 and this proposed regulation. It will coordinate handling of complaints with the staff of the
7 Departmental programs from which the entity receives funding. Enforcement of the
8 requirements proposed in this proposed regulation will be conducted through the usual and
9 ordinary program mechanisms, in addition to False Claims Act enforcement mechanism
10 available to the public. At this point, the Department does not intend to conduct compliance
11 reviews on the specific issue of compliance with the nondiscrimination provisions and this
12 proposed regulation when finalized. However, compliance with the requirements proposed
13 herein would be examined as part of any broader compliance reviews conducted by Department
14 staff. If the Department becomes aware that a State or local government or an entity may be in
15 violation of the requirements or prohibitions proposed herein, the Department would work with
16 such government, or entity to assist such government, or entity to come into compliance with
17 such requirements or prohibitions. If, despite the Department's assistance, compliance is not
18 achieved, the Department will consider all legal options, including termination of funding and
19 retrieval of previous funding under 45 C.F.R. 74, claims under the Program Fraud Civil
20 Remedies Act, and other measures.

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22 III. Statutory Authorities

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1 On the basis of the following statutory authority, the Secretary proposes to promulgate
2 these regulations, requiring certification of compliance with anti-discrimination statutes as a
3 precondition to receipt of Department funds.

4 5 U.S.C. § 301 empowers the head of an Executive department to prescribe regulations
5 “for the government of his department, the conduct of its employees, the distribution and
6 performance of its business, and the custody, use, and preservation of its records, papers, and
7 property.”

8 The Church Amendments, 42 U.S.C. § 300a-7 (2000), prohibit recipients of Department
9 funding under the PHS Act and several other statutes from discriminating against employees and
10 others who participate in health service programs or research activities funded in whole or part
11 by the Department who refuse to perform certain medical services, including sterilization,
12 abortion, or research activities because of religious or moral beliefs. Specifically, section 300a-
13 7(c)(1)(A) and (B) provides that recipients may not discriminate in the employment of or the
14 extension of staff privileges to any health care professional because he refused, because of his
15 religious beliefs or moral convictions, to perform or assist in the performance of any sterilization
16 or abortion procedures. Section 300a-7(d) provides that no individual shall be required to
17 perform or assist in the performance of *any* health service program or research activity funded in
18 whole or part by the Department contrary to his religious beliefs or moral convictions.¹⁶

¹⁶Section 300a-7(c)(1) provides that “[n]o entity which receives a grant, contract, loan, or loan guarantee under the [Act] . . . may (A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or (B) . . . in the extension of staff or other privileges to any physician or other health care personnel . . . because he refused to perform or assist in the performance of . . . [an] abortion” on the grounds that doing so “would be contrary to his religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(c)(1). Section 300a-7(c)(2) provides that “[n]o entity which receives . . . a grant or contract for biomedical or behavioral research under any program administered by [HHS]” may discriminate in the employment of or the extension of staff privileges to any health care professional “because he refused to perform or assist in the performance of” “any lawful health service” based on religious belief or moral conviction. 42 U.S.C. § 300a-7(c)(2). Section 300a-7(d) provides that “[n]o individual [may] be required to perform or assist in the performance of any part of a health service program . . . funded in whole or in part under a program administered by the Secretary of Health and Human

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1 Public Health Service (PHS) Act § 245, 42 U.S.C. § 238n (1996), prohibits the Federal
2 government and any State or local government that receives federal financial assistance from
3 discriminating against any health care entity (including both individual and institutional
4 providers) on the basis that the entity refuses to (1) receive training in abortion; (2) provide
5 abortion training; (3) perform abortions; (4) provide referral for such abortions; and (5) provide
6 referrals for abortion training. 42 U.S.C. §238n(a).

7 The Weldon Amendment, Consolidated Appropriations Act, 2008, Pub. L. No. 110-161,
8 § 508(d), 121 Stat. 1844, 2209 (2008), prohibits a federal agency or program, or any State, or
9 local government from receiving Department funds if such agency, program, or government
10 subjects any institutional or individual health care entity to discrimination on the basis that the
11 health care entity does not provide, pay for, provide coverage of, or refer for abortions.

12 These statutory provisions require that recipients of Department funds refrain from
13 discriminating against institutional and individual health care entities for their participation or
14 refusal to participate in certain medical services or research activities funded by the federal
15 government. They empower the Department to promulgate regulations to enforce these
16 prohibitions. Finally, the Department also has the legal authority to require that such recipients
17 certify their compliance with these proposed requirements and to require their subrecipients to
18 likewise certify their compliance with these proposed requirements.

Services” if doing so “would be contrary to his religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(d). Section 300a-7(e) prohibits any entity that receives funding under the PHS Act from denying admission to, or otherwise discriminating against, “any applicant (including for internships and residencies) for training or study because of the applicant’s reluctance . . . to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions . . . contrary to or consistent with the applicant’s religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(e). In addition, section 300a-7(b) provides in part that “[t]he receipt of any grant, contract, loan, or loan guarantee under the [PHS Act] . . . by any individual or entity does not authorize any court or any public official or other public authority to require” (1) the individual to perform or assist in an abortion if it would be contrary to his/her religious beliefs or moral convictions; or (2) the entity to make its facilities available for abortions, if the performance of abortions in the facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or provide personnel for the performance of abortions if it would be contrary to the religious beliefs or moral convictions of such personnel. 42 U.S.C. § 300a-7(b).

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III. Provisions of the Proposed Rules

§ 45 CFR x.1 Definitions

Abortion: An abortion is the termination of a pregnancy. There are two commonly held views on the question of when a pregnancy begins. Some consider a pregnancy to begin at conception (that is, the fertilization of the egg by the sperm), while others consider it to begin with implantation (when the embryo implants in the lining of the uterus).¹⁷ A 2001 Zogby International *American Values* poll revealed that 49% of Americans believe that human life begins at conception.¹⁸ Presumably many who hold this belief think that any action that destroys human life after conception is the termination of a pregnancy, and so would be included in their definition of the term “abortion.”¹⁹ Those who believe pregnancy begins at implantation believe the term “abortion” only includes the destruction of a human being after it has implanted in the lining of the uterus.

Both definitions of pregnancy inform medical practice. Some medical authorities, like the American Medical Association and the British Medical Association, have defined the term “established pregnancy” as occurring after implantation.²⁰ Other medical authorities present different definitions. *Stedman’s Medical Dictionary*, for example, defines pregnancy as “[t]he

¹⁷ *Merriam-Webster’s Dictionary* defines pregnancy as “the condition of being pregnant,” and defines “pregnant” as “containing a developing embryo, fetus, or unborn offspring within the body.” MERRIAM-WEBSTER’S DICTIONARY at <http://www.merriam-webster.com/dictionary/pregnancy>.

¹⁸ ZOGBY INTERNATIONAL, *AMERICAN VALUES VOLUME V*, 15 (January 16, 2001).

¹⁹ Medical dictionaries support this view. For example, *Stedman’s Medical Dictionary* Defines “abortion” as the “[e]xpulsion from the uterus of an embryo or fetus before viability[...].” *STEDMAN’S MEDICAL DICTIONARY* 4 (28th ed. 2006).

²⁰ See e.g., *FDA Rejection of Over-The-Counter Status for Emergency Contraception Pills*, AMA House of Delegates Resolution 443, (2004), at http://www.ama-assn.org/ama1/pub/upload/mm/15/res_hod443_a04.doc (The Plan B pill is a post-coital contraception method which [...] induce(s) minor changes to the endometrium to inhibit ovum implantation; therefore, it cannot terminate an established pregnancy...”); BRITISH MEDICAL ASSOCIATION, *ABORTION TIME LIMITS: A BRIEFING PAPER FROM THE BMA 1* (2005) (“The term “abortion” is used [...] to refer to the induced termination of an established pregnancy [i.e. after implantation].”) at [http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFAbortionTimeLimits/\\$FILE/Abortiontimelimits.pdf](http://www.bma.org.uk/ap.nsf/AttachmentsByTitle/PDFAbortionTimeLimits/$FILE/Abortiontimelimits.pdf).

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1 state of a female after conception and until the termination of the gestation.”²¹ *Dorland’s*
2 *Medical Dictionary* defines pregnancy, in relevant part, as “the condition of having a developing
3 embryo or fetus in the body, after union of an oocyte and spermatozoon.”²²

4 Because the statutes that would be enforced through this regulation seek, in part, to
5 protect individuals and institutions from suffering discrimination on the basis of conscience, the
6 conscience of the individual or institution should be paramount in determining what constitutes
7 abortion, within the bounds of reason. As discussed above, both definitions of pregnancy are
8 reasonable and used within the scientific and medical community. The Department proposes,
9 then, to allow individuals and institutions to adhere to their own views and adopt a definition of
10 abortion that encompasses both views of abortion. Therefore, for the purpose of these proposed
11 regulations, and implementing and enforcing the Church Amendment, Public Health Service Act
12 §245, and the Weldon Amendment, the Department proposes to define abortion as “any of the
13 various procedures—including the prescription and administration of any drug or the
14 performance of any procedure or any other action—that results in the termination of the life of a
15 human being in utero between conception and natural birth, whether before or after
16 implantation.”

17 *Assist in the Performance:* The Department, in considering how to interpret the term
18 “assist in the performance,” seeks to provide broad protection for individuals’ consciences. The
19 Department seeks to avoid judging whether a particular action is genuinely offensive to an
20 individual. At the same time, the Department wishes to guard against potential abuses of these
21 protections, limiting the definition of “assist in performance” only to those actors who have a

²¹ STEDMAN’S MEDICAL DICTIONARY 1553 (28th ed. 2006).

²²DORLAND’S MEDICAL DICTIONARY at

http://www.mercksource.com/pp/us/cns/cns_hl_dorlands_split.jsp?pg=/ppdocs/us/common/dorlands/dorland/seven/000086088.htm

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1 logical connection to the procedure, health service or health service program, or research activity
2 to which they object.

3 Therefore, the Department proposes to interpret this term broadly, as encompassing
4 individuals who are members of the workforce of the Department-funded entity performing the
5 objectionable procedure. When applying the term “assist in the performance” to members of an
6 entity’s workforce, the Department proposes to include participation in any activity with a
7 logical connection to the objectionable procedure, including referrals, training, and other
8 arrangements for offending procedures. For example, an operating room nurse would assist in
9 the performance of surgical procedures, and an employee whose task it is to clean the
10 instruments used in a particular procedure, would be considered to assist in the performance of
11 the particular procedure.

12 *Health Care Entity / Entity:* While both PHS Act § 245 and the Weldon Amendment
13 provide exemplary lists of specific types of protected individuals and health care organizations,
14 neither statute provides an exhaustive list of such health care entities. PHS Act §245 defines
15 “health care entity” as “includ[ing] an individual physician, a postgraduate physician training
16 program, and a participant in a program of training in the health professions.” As the
17 Department has previously indicated, the definition of “health care entity” in PHS Act § 245
18 encompasses institutional entities, such as hospitals and other entities.²³ The Weldon
19 Amendment defines the term “health care entity” as “includ[ing] an individual physician or other
20 health care professional, a hospital, a provider-sponsored organization, a health maintenance
21 organization, a health insurance plan, or any other kind of health care facility, organization, or
22 plan.” The Church Amendment does not define the term “entity,” and does not use the term
23 “health care entity.”

²³ See Letter from Secretary Tommy G. Thompson to Hon. W.F. Tauzin, September 24, 2002.

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1 In keeping with the definitions in PHS Act §245 and the Weldon Amendment, the
2 Department proposes to define “health care entity” to include the specifically mentioned
3 organizations from the two statutes. It is important to note that the Department does not intend
4 for this to be a comprehensive list of relevant organizations for purposes of the regulation, but
5 merely an exemplary list.

6 *Health Service / Health Service Program:* One of the provisions in the Church
7 Amendments uses the term “health service,” another uses the term, “health service program.”
8 Neither define the terms, nor does the PHS Act define “health service program.” In developing
9 an appropriate definition for “health service program,” we have looked at the Social Security
10 Act. Section 1128B(f)(1) of the Social Security Act, 42 U.S.C. §1320a-7b(f)(1) defines the
11 similar term “federal health care program” as “any plan or program that provides health benefits,
12 whether directly, through insurance, or otherwise, which is funded directly, in whole or in part,
13 by the United States Government.”

14 Accordingly, the term “health service program” should be understood to include an
15 activity related in any way to providing medicine, health care, or any other service related to
16 health or wellness, including: programs where the Department provides care directly (e.g., Indian
17 Health Service); programs where grants pay for the provision of health services (e.g., HRSA
18 programs such as community health centers); programs where the Department reimburses
19 another entity that provides care (e.g., Medicare); and health insurance programs where federal
20 funds are used to provide access to health coverage (e.g., SCHIP, Medicaid, and Medicare
21 Advantage). Similarly, we propose that the term “health service” means any service so provided.

22 *Individual:* For the purposes of this part, the Department proposes to define “individual”
23 to mean a member of the workforce (see definition of “workforce” below) of an entity or health

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1 care entity. One conscience clause of the Church Amendments, 42 U.S.C. §300a-7(d), provides
2 that “[n]o *individual* shall be required to perform or assist in the performance of any part of a
3 health service program or research activity funded in whole or in part under a program
4 administered by the Secretary of Health, Education and Welfare [Secretary of Health and Human
5 Services] if his performance or assistance in the performance of such part of such program or
6 activity would be contrary to his religious beliefs or moral convictions (emphasis added).”

7 *Instrument:* We propose to use “instrument” to mean the variety of means by which the
8 Department conveys funding and resources to organizations, including: grants, cooperative
9 agreements, contracts, grants under a contract, and memoranda of understanding. The definition
10 of “instrument” is intended to include all means by which the Department conveys funding and
11 resources.

12 Later in the document, rather than repeating a specific list of examples whenever the
13 regulation mentions a source of funding or resources, the drafters have included the word
14 “instrument” in brackets.

15 *Recipients:* This term is used to encompass any entity that receives Department funds
16 directly.

17 *Sub-recipients:* This term is used to encompass any entity that receives Department funds
18 indirectly.

19 *Workforce:* We propose to define “workforce” as including employees, volunteers,
20 trainees, and other persons whose conduct, in the performance of work for an entity, is under the
21 control or authority of such entity, whether or not they are paid by the Department-funded entity.
22 The definition is drawn from the “Administrative Data Standards and Related Requirements”

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1 rules implementing Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts
2 160, 162, and 164 (2006) at 45 C.F.R. 160.103.

3 In defining both “individual” and “workforce,” the Department proposes definitions that
4 provide a reasonable scope for the natural persons protected by 42 U.S.C. § 300a-7(d) and the
5 corresponding provisions of these regulations. By limiting the scope of persons protected by
6 these regulations to those who are under the control or authority of an entity that implements a
7 health services program or research activity funded in whole or in part under a program
8 administered by the Department, we provide the bright line necessary for Department-funded
9 entities subject to the Church Amendment provisions to set policies or otherwise take steps to
10 secure conscience protections within the workplace and, thus, to comply with the Church
11 Amendment and these regulations.

12

13 x.2 Applicability

14 The proposed “Applicability” section of the regulation outlines the certifications various
15 entities must provide in order to receive Department funds. This section would direct entities to
16 the appropriate sections that contain the relevant requirements from the three statutes that form
17 the basis of this regulation.

18

19 x.3 Requirements and Prohibitions

20 The “Requirements and Prohibitions” section explains the obligations that the Church
21 Amendments,²⁴ PHS Act §245, and the Weldon Amendment impose on entities which receive

²⁴ In researching and drafting the current proposed rule, the Department became aware that the Church Amendments reference in two places the Developmental Disabilities Services and Facilities Construction Act, which was repealed on October 30, 2000, and on the same day replaced with the Developmental Disabilities Assistance and Bill of Rights Act of 2000. While section (e) of the Church Amendments was changed to reflect this replacement, sections

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1 funding from the Department. These provisions are taken from the relevant statutory language
2 and make up the elements of the certification provided by the entities. We intend for the
3 proposed requirements and prohibitions to be interpreted using the definitions proposed in
4 section x.1.

5
6 x.4 Written Certification of Compliance

7 In the “Written Certification of Compliance” section of the regulation, the Department
8 seeks to require recipients and sub-recipients of Department funds to certify compliance with the
9 Church Amendments, PHS Act § 245, and the Weldon Amendment, as applicable.

10 We have noted above the reported attitudes of many commentators and others within the
11 health care industry toward health care personnel who desire to avoid performing or assisting in
12 the performance of certain services. We are concerned that these reported attitudes may indicate
13 a lack of knowledge on the part of States, local governments, and the health care industry of the
14 rights of health care entities created by, and the corresponding obligations imposed upon the
15 recipients of certain federal funding by, the non-discrimination provisions.

16 The proposed regulation requires that entities certify in writing that, as a material
17 prerequisite to the receipt of certain federal funds, entities will operate in compliance with the
18 Church Amendment, PHS Act §245, and the Weldon Amendment. Certification provides a
19 demonstrable way of ensuring that the recipients of such funding know of, and attest that they
20 will comply with, the applicable nondiscrimination provisions. Sub-recipients of federal funds—

(b) and (c)(1) were left unchanged. It seems unlikely that Congress would knowingly continue to cite to a repealed statute; accordingly, the Department has tentatively concluded that this discrepancy was likely a result of a drafting error. The proposed rule assumes that Congress intended to substitute the Developmental Disabilities Assistance and Bill of Rights Act of 2000 in instances where the Developmental Disabilities Services and Facilities Construction Act is mentioned.

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1 entities that will receive federal funds indirectly through another entity—are required to provide
2 certification as set out in the “Certification of Compliance” section. This certification by sub-
3 recipients is a certification made directly to the Department, and is a material prerequisite to the
4 payment of funds by the Department to the principal recipient of funds.

5 If a recipient or a sub-recipient of federal financial assistance violates the
6 antidiscrimination protections, the fact that it has certified that it would not so discriminate may
7 provide additional remedies for the Department, as well as the affected entity or entities,
8 including actions brought under the False Claims Act and the Program Fraud Civil Remedies Act
9 of 1986.

10 The False Claims Act allows anyone with knowledge of a fraud against the federal
11 Government to bring a claim against the defrauding individual or organization on behalf of the
12 Government. Successful litigants are eligible to receive up to 30% of the collected damages,
13 which includes fines of up to \$10,000 and three times the actual damages suffered by the
14 government.²⁵

15 The Program Fraud Civil Remedies Act of 1986 (PFCRA) enables agencies to bypass
16 courts and create administrative procedures to combat fraud. Under the PFCRA, the Department
17 created a regulatory scheme to handle fraudulent claims. 45 C.F.R. Part 79 sets up guidelines
18 and procedures before an Administrative Law Judge in the case of fraud arising when an entity
19 applies for any contract, grant, loan, or benefit from the Department.

20 Note: *When providing certification, recipients and applicants should substitute the*
21 *appropriate means of funding or resources where the bracketed word “instrument” appears.*
22

23 **IV. Request for Comment**

²⁵ See 31 U.S.C. 3729 (a) (2007).

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1 The Department, in order to craft its final rule to best reflect the environment within the
2 health care industry, seeks comment on several matters related to this Proposed Rule. In
3 particular, the Department seeks the following:

- 4 • Comment on all issues raised by the proposed regulation.
- 5 • Information with regard to general knowledge or lack thereof of the protections
6 established by these nondiscrimination provisions, including any facts, surveys, audits,
7 reports, or any other evidence of knowledge or lack of knowledge on these matters in the
8 general public, as well as within the healthcare industry and educational institutions.
- 9 • In the years following *Roe v. Wade*, there was some confusion about whether the receipt
10 of federal funds permitted public officials to require entities to provide abortions or
11 perform sterilizations. The debate was resolved, and statutory provisions like Section (b)
12 of the Church Amendments were promulgated to protect entities from public authorities
13 who would claim that the receipt of federal funds creates a legal obligation for the entity
14 to provide abortions. The Department seeks information, including any facts, surveys,
15 audits, or reports on whether this remains an issue, that is, do public authorities continue
16 to claim that the receipt of federal funds is sufficient basis for entities to be required to
17 provide abortions or perform sterilizations. If so, how, if at all, should the Department
18 address this problem?
- 19 • As noted above, it is unclear to what extent there is knowledge of the protections afforded
20 by the nondiscrimination provisions, and the Department is specifically seeking comment
21 on the issue. The Department also seeks comment on what are the most effective
22 methods of educating recipients of Department funds, their employees, and participants
23 of the protections against discrimination found in the Church Amendments, (PHS) Act

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1 §245, and the Weldon Amendment. What is the best method for communicating to the
2 public the protections afforded by these statutes, and any regulation implementing them?

- 3 ○ One option is to require the physical posting of notices of nondiscrimination
4 protections in conspicuous places within the buildings of recipients of funds, and
5 on applications to educational programs that are recipients of funds. Have notices
6 been effective educational tools with respect to individuals' rights under federal
7 law?
- 8 ○ Another option is to require inclusion of nondiscrimination protections in
9 applications for training, residency, and educational programs.
- 10 ○ Another option is requiring notice of nondiscrimination protections on websites
11 and in employee / volunteer handbooks of recipients.

12 The Department seeks further comment on this matter—both on the merit of the options
13 mentioned, and on new ideas for educating the public.

14 15 *Executive Order 13132—Federalism*

16 Executive Order 13132 establishes certain requirements that an agency must meet when it
17 promulgates a proposed rule (and subsequent final rule) that imposes substantial direct
18 requirement costs on state and local governments, preempts State law, or otherwise has
19 Federalism implications.

20 All three acts enforced in this proposed regulation— the Church Amendments, PHS Act
21 §245, and the Weldon Amendment—impose restrictions on states, local governments, and public
22 entities receiving funds under certain Department-implemented statutes. Insofar as these
23 regulations impact state and local governments, they do so only to the extent that States, local

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1 governments, and public entities are out of compliance with existing federal conscience statutes.
2 Since we expect the recipients of Department funds to comply with existing federal law, we
3 anticipates the impact on States and local governments to be negligible.

4 On the other hand, the proposed regulation may suggest interpretations of statutory terms
5 that are broader than the interpretations many states or local governments may have followed to
6 date. In particular, the terms “abortion” and “assist in the performance” have been defined by
7 this proposed regulation to provide broad conscience protections for health care entities. While
8 the proposed regulatory action does not preempt any state laws, it seeks to enforce federal law
9 restricting the expenditure of funds among all current recipients of Department funds, including
10 States, to entities that comply with federal law.

11 The Government can, without violating the Constitution, selectively fund a
12 program to encourage certain activities it believes to be in the public interest,
13 without at the same time funding an alternative program which seeks to deal with
14 the problem in another way. In so doing, the Government has not discriminated
15 on the basis of viewpoint; it has merely chosen to fund one activity to the
16 exclusion of the other[...] There is a basic difference between direct state
17 interference with a protected activity and state encouragement of an alternative
18 activity consonant with legislative policy. *Rust v. Sullivan*, 500 U.S. 173,193
19 (1991) (citations omitted).
20

21 In this instance, the Department is proposing to fund programs in a way that ensures
22 compliance with federal conscience protections for health care entities. At the same time, the
23 Department seeks to avoid funding programs that engage in illegal discrimination. The proposed
24 regulation does so without infringing on any state or local statutes, and will have an impact on
25 state and programs only insofar as they engage in illegal discrimination according to the
26 definitions set out in the statutes. The Department will consult with States and local
27 governments to seek ways to minimize any burden imposed on the States and local governments
28 by these proposed regulations, consistent with meeting the Department’s objectives of ensuring:

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1 (1) knowledge of the obligations imposed, and the rights and protections afforded, by these
2 federal nondiscrimination provisions; and (2) compliance with the nondiscrimination provisions.

3

4 ANALYSIS OF IMPACTS

5 *Executive Order 12866—Regulatory Planning and Review*

6 HHS has examined the economic implications of this proposed rule as required by
7 Executive Order 12866 (as amended September 30, 1993). Executive Order 12866 directs
8 agencies to assess all costs and benefits of available regulatory alternatives and, when regulation
9 is necessary, to select regulatory approaches that maximize net benefits (including potential
10 economic, environmental, public health and safety, and other advantages; distributive impacts;
11 and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a
12 number of specified conditions, including: having an annual effect on the economy of \$100
13 million, adversely affecting a sector of the economy in a material way, adversely affecting
14 competition, or adversely affecting jobs. A regulation is also considered a significant regulatory
15 action if it raises novel legal or policy issues. HHS has determined that this proposed rule is not
16 a significant regulatory action as defined by Executive Order 12866.

17 An underlying assumption of this regulation is that the health care industry, including
18 entities receiving Department funds, will benefit from more diverse and inclusive workforces by
19 informing health care workers of their rights and fostering an environment in which individuals
20 from many different faiths and philosophical backgrounds are encouraged to participate. As a
21 result, we cannot accurately account for all of the regulation's future benefits, but the
22 Department is confident that the future benefits will exceed the costs of complying with the
23 regulation.

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1 We estimate that each of the 503,904 funding recipients will spend 15 minutes reviewing
2 the certification language and reviewing files before signing. According to BLS wage data, the
3 mean hourly wage for a Medical and Health Services Manager is \$40.86. We estimate the
4 loaded rate to be \$61.29. Thus, the cost associated with the act of certification is \$7.7 million
5 (503,904 x .25 x \$61.29).

6 Indirect costs associated with the certification requirement might include costs for such
7 actions as staffing/scheduling changes and internal reviews to assess compliance. Potential
8 liability costs for certifiers include the defense costs, paying settlements or judgments, and
9 paying fines resulting from actions brought by individuals claiming discrimination. There is
10 insufficient data to estimate the number of funding recipients not currently compliant with the
11 Church Amendments, PHSA § 245, or the Weldon Amendment, as applicable. However,
12 because together these three federal statutes have been in effect for many years, we expect
13 indirect certification costs and potential liability costs for Department funding recipients to be
14 minimal.

15 The total quantifiable costs of the proposed regulation, if finalized, are estimated to be
16 \$7.9 million in the first year. We anticipate the costs to be lower in subsequent years; we believe
17 that very few new entities will be required to implement the requirements of this regulation.

18

19 *Regulatory Flexibility Act*

20 HHS has examined the economic implications of this proposed rule as required by the
21 Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a
22 substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze
23 regulatory options that would lessen the economic effect of the rule on small entities. This

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1 proposal, if finalized, will not impose significant costs on small entities. Therefore, the Secretary
2 certifies that this rule will not result in a significant impact on a substantial number of small
3 entities.

4

5 *Unfunded Mandates Reform Act of 1995*

6 Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-
7 benefit and other analyses before any rulemaking if the rule would include a “Federal mandate
8 that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by
9 the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The
10 current inflation-adjusted statutory threshold is about \$115 million. HHS has determined that
11 this proposed rule would not constitute a significant rule under the Unfunded Mandates Reform
12 Act.

13

14 **LIST OF REFERENCES**

15 **LIST OF SUBJECTS IN 45 C.F.R. Part X**

16 **[add list of subjects per F.R. conventions]**

17 Therefore, under the Church Amendment, 42 U.S.C. § 300a-7, Public Health Service Act § 245,
18 42 U.S.C. § 300a-7, 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated
19 Appropriations Act, 2008, Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209, the Department
20 of Health and Human Services proposes to adopt part x as follows:

21

22 PART X—[Title of Regulation]

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1 1. The authority citation for 45 C.F.R. part x is adopted to read as follows: Authority: 42
2 U.S.C. § 300a-7, 42 U.S.C. §238n, 109 P.L. 119; 119 Stat. 2883 § 508 (d), 31 U.S.C.
3 6306, 41 U.S.C. 253, and 40 U.S.C. § 471.

4 2. Section x.1 is adopted to read as follows:

5

6 § x.1 Definitions

7 For the purposes of this part:

8 “*Abortion*” means any of the various procedures—including the prescription, dispensing,
9 and administration of any drug or the performance of any procedure or any other action—that
10 results in the termination of the life of a human being in utero between conception and natural
11 birth, whether before or after implantation.

12 “*Assist in the Performance*,” means to participate in any activity with a logical
13 connection to a procedure, health service or health service program, or research activity, so long
14 as the individual involved is a part of the workforce of a [Department-funded] entity. This
15 includes referral, training, and other arrangements for the procedure, health service, or research
16 activity.

17 “*Health Care Entity*” includes an individual physician or other health care professional, a
18 participant in a program of training in the health professions, a post graduate physician training
19 program, a hospital, a provider-sponsored organization, a health maintenance organization, a
20 health insurance plan, laboratory or any other kind of health care organization or facility.

21 “*Entity*” includes an individual physician or other health care professional, a participant
22 in a program of training in the health professions, a post graduate physician training program, a
23 hospital, a provider-sponsored organization, a health maintenance organization, a health

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1 insurance plan, laboratory or any other kind of health care organization or facility. It may also
2 include components of State or local governments.

3 “*Health Service / Health Service Program*” includes any plan or program that provides
4 health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or
5 in part, by the Department. It may also include components of State or local governments.

6 “*Individual*” means a member of the workforce of an entity / health care entity.

7 “*Instrument*” is the means by which federal funds are conveyed to the recipient, and
8 includes grants, cooperative agreements, contracts, grants under a contract, memoranda of
9 understanding, and any other funding or employment instrument or contract.

10 “*Recipient*” means an organization receiving financial assistance directly from the
11 Department awarding agency to carry out a project or program. The term includes public and
12 private institutions of higher education, public and private hospitals, commercial organizations,
13 and other quasi-public and private nonprofit organizations such as, but not limited to, community
14 action agencies, research institutes, educational associations, and health centers. The term may
15 include foreign or international organizations (such as agencies of the United Nations) which are
16 recipients, subrecipients, or contractors or subcontractors of recipients or subrecipients at the
17 discretion of the Department awarding agency.

18 “*Sub-recipient*” means an organization receiving financial assistance indirectly from the
19 Department awarding agency to carry out a project or program. The term includes public and
20 private institutions of higher education, public and private hospitals, commercial organizations,
21 and other quasi-public and private nonprofit organizations such as, but not limited to, community
22 action agencies, research institutes, educational associations, and health centers. The term may
23 include foreign or international organizations (such as agencies of the United Nations) which are

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1 recipients, subrecipients, or contractors or subcontractors of recipients or subrecipients at the
2 discretion of the Department awarding agency.

3 “*Workforce*” includes employees, volunteers, trainees, and other persons whose
4 conduct, in the performance of work for a Department-funded entity, is under the control or
5 authority of such entity, whether or not they are paid by the Department-funded entity.

6

7 3. Section x.2 is adopted to read as follows:

8

9 x.2 Applicability

10 (a) Any State or local government that receives federal funds through the Department of Health
11 and Human Services is required to comply with subsections x.3(a), x.4, and x.5(a) below.

12 (b) Any State or local government, any part of any State or local government, or any other
13 public entity that receives Department funds must comply with subsection x.3(e) below.

14 (c) Any entity that receives federal funds from the Department of Health and Human Services to
15 implement any part of any federal program is required to comply with subsections x.3(a) and x.4
16 below.

17 (d)(1) Any entity, including a State or local government, that receives a grant, contract, loan, or
18 loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act,
19 or the Developmental Disabilities Assistance and Bill of Rights Act of 2000, must comply with
20 subsections x.3(c)(1) and x.4.

21 (2) In addition to complying with the provisions set forth in (c)(1), any such entity that is an
22 educational institution, teaching hospital, program for the training of health care professionals or
23 health care workers shall comply with subsections x.3(a)(2) and x.4 below.

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1 (e)(1) Any entity, including a State or local government, that carries out any part of any health
2 service program or research activity funded in whole or in part under a program administered by
3 the Secretary of Health and Human Services must comply with subsections x.3(d)(1) and x.4
4 below.

5 (2) In addition to complying with the provisions set forth in (d)(1), any such entity that
6 receives grants or contracts for biomedical or behavioral research under any program
7 administered by the Secretary of Health and Human Services is required to comply with
8 subsection x.3(d)(2) below.

9

10 x.3 Requirements and Prohibitions

11 (a) Entities to whom this subsection x.3 (a) applies shall not:

12 (1) subject any institutional or individual health care entity to discrimination for refusing: (A) to
13 undergo training in the performance of induced abortions, or to require, provide, refer for, or
14 make arrangements for training in the performance of induced abortions; (B) to perform, refer
15 for, or make other arrangements for, induced abortions; and / or (C) to refer for abortions;

16 (2) subject any institutional or individual health care entity to discrimination for attending or
17 having attended a post-graduate physician training program, or any other program of training in
18 the health professions, that does not or did not require attendees to perform induced abortions or
19 require, provide, or refer for training in the performance of induced abortions, or make
20 arrangements for the provision of such training;

21 (3) For the purposes of granting a legal status to a health care entity (including a license or
22 certificate), providing such entity with financial assistance, services or benefits, fail to deem
23 accredited any postgraduate physician training program that would be accredited but for the

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1 accrediting agency's reliance upon an accreditation standard or standards that require an entity to
2 perform an induced abortion or require, provide, or refer for training in the performance of
3 induced abortions, or make arrangements for such training, regardless of whether such standard
4 provides exceptions or exemptions;

5 (b) Entities to whom this subsection x.3 (b) applies shall not:

6 (1) require any individual to perform or assist in the performance of any sterilization procedure
7 or abortion if performing or assisting in the performance of such activity would be contrary to his
8 religious beliefs or moral convictions; or

9 (2) require an entity to make its facilities available for the performance of, or provide personnel
10 for the performance or assistance in the performance of sterilization procedure or abortion
11 procedures if such actions are prohibited by the entity based on religious beliefs or moral
12 convictions, or if the performance or assistance in performance with the procedure would be
13 contrary to the religious beliefs or moral convictions of the personnel;

14

15 (c) Entities to whom this subsection x.3(c) applies shall not:

16 (1) discriminate against any member of the workforce in the employment, promotion,
17 termination, or extension of staff or other privileges because he performed or assisted in the
18 performance, or refused to perform or assist in the performance of a lawful sterilization
19 procedure or abortion on the grounds that doing so would be contrary to his religious beliefs or
20 moral convictions, or because of his religious beliefs or moral convictions concerning abortions
21 or sterilization procedures themselves;

22 (2) discriminate against or deny admission to any applicant for training or study because of
23 reluctance or willingness to counsel, suggest, recommend, assist, or in any way participate in the

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1 performance of abortions or sterilizations contrary to or consistent with the applicant's religious
2 beliefs or moral convictions.

3

4 (d) The entities to whom this subsection x.3(d) applies shall not:

5 (1) require any individual to perform or assist in the performance of any part of a health
6 service program or research activity if such service or activity would be contrary to his religious
7 beliefs or moral convictions.

8 (2) The entities to whom this part applies shall not discriminate in the employment, promotion,
9 termination, or the extension of staff or other privileges to any physician or other health care
10 personnel because he performed, assisted in the performance, refused to perform, or refused to
11 assist in the performance of any lawful health service or research activity on the grounds that his
12 performance or assistance in performance of such service or activity would be contrary to his
13 religious beliefs or moral convictions, or because of the religious beliefs or moral convictions
14 concerning such activity themselves.

15

16 (e) The entities to whom this subsection (e) applies shall not, on the basis that the individual or
17 entity has received a grant, contract, loan, or loan guarantee under the Public Health Service Act,
18 the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and
19 Bill of Rights Act of 2000, require (A) such individual to perform or assist in the performance of
20 any sterilization procedure or abortion if his performance or assistance in the performance of
21 such procedure or abortion would be contrary to his religious beliefs or moral convictions, or (B)
22 such entity to (i) make its facilities available for the performance of any sterilization procedure
23 or abortion if the performance of such procedure or abortion in such facilities is prohibited by the

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1 entity on the basis of religious beliefs or moral convictions, or (ii) provide any personnel for the
2 performance or assistance in the performance of any sterilization procedure or abortion if the
3 performance or assistance in the performance of such procedure or abortion by such personnel
4 would be contrary to the religious beliefs or moral convictions of such personnel.

5

6 x.4 Written Certification of Compliance:

7 (a) **Certification Requirement.** As a material prerequisite to payment of Department funds
8 administered as part of any Department activity, program, or research activity (including
9 biomedical or behavioral research), recipients shall include the following written certifications
10 and any certifications by sub-recipients in the application for the grant, cooperative agreement,
11 contract, grant under a contract, memorandum of understanding or other funding or employment
12 instrument or contract, as applicable. Certifications shall be made by an officer or other
13 individual authorized to bind the recipient or sub-recipient. No organizations or entities shall
14 receive Department funds directly or indirectly without providing the Certification of
15 Compliance as set out in this regulation.

16

17 (b) **Notification of Certification Requirement.** The Department shall notify recipients of
18 funding of the certification requirement at the time of award through the Request for Proposal,
19 Request for Agreement, or other public announcement of the availability of the funding.
20 Recipients shall not construe anything in this paragraph to mean that an entity or organization is
21 in any way exempt from providing the certification in the event the Department should fail to
22 provide notification.

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1 (c) **Certification by Sub-recipients.** Organizations or entities that are sub-recipients of the
2 organization or entity providing the initial Certification of Compliance must provide the
3 Certification of Compliance as set out in Section x.4 (e)(2) of this regulation, submitted as part of
4 the recipient’s application for the [grant, cooperative agreement, contract, grant under a contract,
5 memorandum of understanding or other funding] or in a separate writing signed by the sub-
6 recipients’ officer or other person authorized to bind the sub-recipient. Certification of
7 compliance by sub-recipients is a material prerequisite to the payment of funds by the
8 Department to recipients.

9
10 (d) **Renewal of Certification.** Recipients and sub-recipients of funds must file a renewed
11 certification upon any renewal, extension, amendment, or modification of the grant, cooperative
12 agreement, contract, grant under a contract, memorandum of understanding or other funding or
13 employment instrument or contract that extends the term of such instrument or adds additional
14 funds to it. Recipients that are already recipients and sub-recipients as of the effective date of
15 this regulation must file a certification upon any extension, amendment, or modification of the
16 grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or
17 other funding instrument that extends the term of such instrument or adds additional funds to it.

18
19 (e) **Certification.**

20 (1) **For Recipients.** All recipients of Department funds shall provide the following
21 certification:

22 “As the duly authorized representative of the recipient I certify that the recipient of funds made
23 available through this [instrument] will not discriminate on the basis of an entity’s past

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1 involvement in, or refusal to assist in the performance of, the practices of abortion or
2 sterilization, and will not require involvement in procedures that violate an individual’s
3 conscience as part of any part of any health service program, in accord with all applicable
4 sections of 45 C.F.R. ____.

5
6 I further certify that the recipient acknowledges that these certifications are a material
7 prerequisite to payment of U.S. Government funds in connection with this [instrument], and that
8 any violation of these certifications shall be grounds for termination by the Department of any
9 grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or
10 other funding or employment instrument or contract prior to the end of its term and recovery of
11 appropriated funds expended prior to termination. I further certify that the recipient will include
12 this identical certification requirement in any [instrument] to a sub-recipient of funds made
13 available under this [instrument], and will require such sub-recipient to provide the same
14 certification that the organization or entity provided, and that these certifications by sub-
15 recipients are material prerequisites to receipt of Department funds by the recipient.”

16 **(2) For sub-recipients.** All sub-recipients of Department funds shall provide the following
17 certification, as a material prerequisite of receipt of Department funds by the recipient:

18 “As the duly authorized representative of the recipient I certify that the recipient of funds made
19 available through this [instrument] will not discriminate on an entity’s past involvement in, or
20 refusal to assist in the performance of, the practices of abortion or sterilization, and will not
21 require involvement in procedures that violate an individual’s conscience as part of any part of
22 any health service program, in accord with all applicable sections of 45 C.F.R. ____.

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1 I further certify that the recipient acknowledges that these certifications by the sub-recipient of
2 funds are certifications made directly to the Department, as a material prerequisite to payment of
3 U.S. Government funds to the primary recipient in connection with this [instrument], and that
4 any violation of these certifications shall be grounds for termination by the Department of the
5 recipient's grant, cooperative agreement, contract, grant under a contract, memorandum of
6 understanding or other funding or employment instrument or contract prior to the end of its term
7 and recovery of appropriated funds expended prior to termination”

8

9

10