

1 **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

2 **45 CFR Part 88**

3 **RIN 0991-AB48**

4 **Ensuring that Department of Health and Human Services Funds Do Not Support Coercive**
5 **or Discriminatory Policies or Practices In Violation of Federal Law**

6 **AGENCY: Office of the Secretary**

7 **ACTION: Proposed Rule**

8

9 **SUMMARY:** The Department of Health and Human Services proposes to promulgate
10 regulations to ensure that Department funds do not support morally coercive or discriminatory
11 practices or policies in violation of federal law, pursuant to the Church Amendments (42 U.S.C.
12 § 300a-7), Public Health Service (PHS) Act §245 (42 U.S.C. § 238n), and the Weldon
13 Amendment (Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, § 508(d), 121 Stat.
14 1844, 2209). This notice of proposed rulemaking proposes to define certain key terms.

15 Furthermore, in order to ensure that recipients of Department funds know about their legal
16 obligations under these nondiscrimination provisions, the Department proposes to require written
17 certification by certain recipients that they will comply with all three statutes, as applicable.

18

19 **DATES:** Submit written or electronic comment on the regulations proposed by this document
20 by [OFR—insert 30 days from date of display].

21 **ADDRESSES:** In commenting, please refer to “Provider Conscience Regulation”. Because of
22 staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

23 You may submit comments in one of four ways (no duplicates, please):

1 1. Electronically. You may submit electronic comments on this regulation to
2 <http://www.Regulations.gov> or via e-mail to consciencecomment@hhs.gov. To submit
3 electronic comments to www.Regulations.gov, go to the Web site and click on the link
4 “Comment or Submission” and enter the keywords “provider conscience”. (Attachments should
5 be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

6 2. By regular mail. You may mail written comments (one original and two copies) to the
7 following address only: Office of Public Health and Science, Department of Health and Human
8 Services, Attention: Brenda Destro, Hubert H. Humphrey Building, 200 Independence Avenue,
9 S.W., Room 728E, Washington, DC, 20201.

10 3. By express or overnight mail. You may send written comments (one original and two
11 copies) to the following address only: Office of Public Health and Science, Department of
12 Health and Human Services, Attention: Brenda Destro, Hubert H. Humphrey Building, 200
13 Independence Avenue, S.W., Room 728E, Washington, DC, 20201.

14 4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written
15 comments (one original and two copies) before the close of the comment period to the following
16 address: Room 728E, Hubert H. Humphrey Building, 200 Independence Avenue, S.W.,
17 Washington, D.C. 20201. (Because access to the interior of the Hubert H. Humphrey Building is
18 not readily available to persons without Federal Government Identification, commenters are
19 encouraged to leave their comments in the mail drop slots located in the main lobby of the
20 building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping
21 in and retaining an extra copy of the documents being filed.)

22 Comments mailed to the addresses indicated as appropriate for hand or courier delivery
23 may be delayed and received after the comment period.

1 Submitting Comments: We welcome comments from the public on all issues set forth in
2 this proposed rule to assist us in fully considering issues and developing policies. For all
3 comments submitted, you should specify the subject as “Provider Conscience Regulation”.

4 Inspection of Public Comments: All comments received before the close of the comment
5 period are available for viewing by the public, including any personally identifiable or
6 confidential business information that is included in a comment. We post all comments received
7 before the close of the comment period on the following Web site as soon as possible after they
8 have been received: <http://www.Regulations.gov>. Click on the link “Comment or Submission”
9 on that Web site to view public comments.

10 Comments received timely will also be available for public inspection as they are
11 received, generally beginning approximately 3 weeks after publication of a document, at the
12 headquarters of the Department of Health and Human Services, Hubert H. Humphrey Building,
13 200 Independence Avenue, S.W., Washington, D.C., 20201, Monday through Friday of each
14 week from 8:30 a.m. to 4 p.m.

15 **Electronic Access**

16 This Federal Register document is also available from the Federal Register online
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19 asynchronous dial-in. Internet users can access the database by using the World Wide Web (the
20 Superintendent of Documents’ home page address is <http://www.gpoaccess.gov/>), by using local
21 WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password
22 required). Dial-in users should used communications software and modem to call (202) 512-
23 1661; type swais, then login as guest (no password required).

1 **FOR FURTHER INFORMATION CONTACT:** Brenda Destro, (202) 401-2305, Office of
2 Public Health and Science, Department of Health and Human Services, Room 728E, Hubert H.
3 Humphrey Building, 200 Independence Avenue, SW, 20201.

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5 **SUPPLEMENTARY INFORMATION:**

6 **I. Background**

7 Religious liberty and freedom of conscience have long been protected in the Constitution
8 and laws of the United States. Workers in all sectors of the economy enjoy legal protection of
9 their consciences and religious liberties. In federal law, there are several provisions that prohibit
10 recipients of certain federal funds from coercing individuals in the health care field into
11 participating in actions they find religiously or morally objectionable. These same provisions
12 also prohibit discrimination on the basis of one's objection to, participation in, or refusal to
13 participate in, specific medical procedures, including abortion or sterilization. In addition, there
14 is a provision that prohibits the federal governments and state and local governments from
15 discriminating against individual and institutional providers who refuse, among other things, to
16 receive training in abortions, require or provide such training, perform abortions, or refer for or
17 make arrangements for abortions or training in abortions. More recently, an appropriations
18 provision has been enacted that prohibits certain federal agencies and programs and State and
19 local governments that receive certain federal funds from discriminating against individuals and
20 institutions that refuse to, among other things, provide, refer for, pay for, or cover, abortion.

21

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

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

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 (1) refuses to receive training in the performance of abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions; (2) refuses to make arrangements for such activities; or (3) attends or attended a post-graduate physician training program or any other training program in the health professions that does not (or did not) perform abortions or require, provide, or refer for training in the performance of abortions or make arrangements for the provision of such training. In addition, PHS Act § 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, Div. G, § 508(d), 121 Stat. 1844, 2209 (Dec. 26, 2007)]

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,

1 2004), has been readopted (or incorporated by reference) in each subsequent HHS appropriations
2 act. Title V of the Departments of Labor, Health and Human Services, and Education, and
3 Related Agencies Appropriations Act, 2006, Pub. L. 109-149, § 508(d), 119 Stat. 2833, 2879-80;
4 Revised Continuing Appropriations Resolution of 2007, P.L 110-5, §2, 121 Stat. 8, 9;
5 Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, Div. G, § 508(d), 121 Stat. 1844,
6 2209. The Weldon Amendment provides that “[n]one of the funds made available under this Act
7 [making appropriations for the Departments of Labor, Health and Human Services, and
8 Education] may be made available to a federal agency or program, or to a State or local
9 government, if such agency, program, or government subjects any institutional or individual
10 health care entity to discrimination on the basis that the health care entity does not provide, pay
11 for, provide coverage of, or refer for abortions.” It also defines “health care entity” to include
12 “an individual physician or other health care professional, a hospital, a provider-sponsored
13 organization, a health maintenance organization, a health insurance plan, or any other kind of
14 health care facility, organization, or plan.”

15

16 **The Laws in the Courts**

17 The federal courts have recognized the breadth and importance of statutory and other
18 conscience protections for health care professionals and workers. Shortly after its passage, a
19 federal appellate court decision characterized the importance of conscience protections contained
20 in the Church Amendments. Faced with the question of a denominational hospital’s right to
21 refuse to perform sterilization procedures, the Ninth Circuit affirmed a lower court decision
22 protecting the hospital’s right to refuse to perform sterilizations and abortions on religious or
23 moral grounds: “If [a] hospital’s refusal to perform sterilization [or, by implication, abortion]

1 infringes upon any constitutionally cognizable right to privacy, such infringement is outweighed
2 by the need to protect the freedom of religion of denominational hospitals ‘with religious or
3 moral scruples against sterilizations and abortions.’” *Taylor v. St. Vincent’s Hospital*, 523 F.2d
4 75, 77 (9th Cir. 1975) (citations omitted).

6 **The Problem**

7 There appears to be an attitude toward the health care professions that health care
8 professionals and institutions should be required to provide or assist in the provision of medicine
9 or procedures to which they object, or else risk being subjected to discrimination. Reflecting this
10 attitude, in some instances the standards of professional organizations have been used to define
11 the exercise of conscience to be unprofessional, forcing health care professionals to choose
12 between their capacity to practice in good standing and their right of conscience.¹

13 Despite the fact that several conscience statutes protecting health care entities from
14 discrimination have been in existence for decades, the Department is concerned that the public
15 and many health care providers are largely uninformed of the protections afforded to individuals
16 and institutions under these provisions. This lack of knowledge within the health professions can
17 be detrimental to conscience and other rights, particularly for individuals and entities with moral
18 objections to abortion and other medical procedures.

20 **The Department’s Response**

21 In general, the Department is concerned that the development of an environment in the
22 health care field that is intolerant of individual conscience, certain religious beliefs, ethnic and

¹ “HHS Secretary Calls on Certification Group to Protect Conscience Rights,” March 14, 2008. Available at <http://www.hhs.gov/news/press/2008pres/03/20080314a.html>.

1 cultural traditions, and moral convictions may discourage individuals from diverse backgrounds
2 from entering health care professions. Such developments also promote the mistaken beliefs that
3 rights of conscience and self-determination extend to all persons, except health care providers.
4 Additionally, religious and faith-based organizations have a long tradition of providing medical
5 care in the United States, and they continue to do so today – some of these are among the largest
6 providers of health care in this nation. A trend that isolates and excludes some among various
7 religious, cultural, and/or ethnic groups from participating in the delivery of health care is
8 especially troublesome when considering current and anticipated shortages of health care
9 professionals in many medical disciplines facing the country.

10 The Department also notes that, while many recipients of Department funds currently
11 must certify compliance with federal nondiscrimination laws, federal conscience protections are
12 not mentioned in existing forms. For example, Form PHS-5161-1, required as part of Public
13 Health Service grant applications, requires applicants to certify compliance with all federal
14 nondiscrimination laws, including laws prohibiting discrimination on the basis of race, color,
15 national origin, religion, sex, handicap, age, drug abuse, and alcohol abuse or alcoholism. The
16 Department seeks to raise awareness of federal conscience laws by specifically including
17 reference to the nondiscrimination provisions contained in the Church Amendments, PHS Act
18 §245, and the Weldon Amendment in certifications currently required of most existing and
19 potential recipients of Department funds.

20 Toward these ends, the Department has concluded that regulations and related efforts are
21 necessary, in order to (1) educate the public and health care providers on the obligations
22 imposed, and protections afforded, by federal law; (2) work with State and local governments
23 and other recipients of funds from the Department to ensure compliance with the

1 nondiscrimination requirements embodied in the Church Amendments, PHS Act § 245, and the
2 Weldon Amendment; (3) when such compliance efforts prove unsuccessful, enforce these
3 nondiscrimination laws through the various Department mechanisms, to ensure that Department
4 funds do not support morally coercive or discriminatory practices or policies in violation of
5 federal law; and (4) otherwise take an active role in promoting open communication within the
6 healthcare industry, and between providers and patients, fostering a more inclusive, tolerant
7 environment in the health care industry than may currently exist.

8 This regulation does not limit patient access to health care, but rather protects any
9 individual health care provider or institution from being compelled to participate in, or from
10 being punished for refusal to participate in, a service that, for example, violates their conscience.

11 These proposed actions are consistent with the Administration’s current efforts to ensure
12 that community and faith-based organizations are able to participate in federal programs on a
13 level playing field with other organizations.

14

15 **II. Summary of the Proposed Rule**

16 This proposed rule sets out, and provides further definition of, the rights and
17 responsibilities created by the federal nondiscrimination provisions. It clarifies the scope of
18 nondiscrimination protections to applicable members of the Department’s workforce, as well as
19 and health care entities and members of the workforces of entities receiving Department funds.

20 This proposed rule would also require certain recipients of Department funds to certify
21 compliance with these requirements. In order to ensure proper enforcement, this proposed rule
22 would define certain terms for the purposes of this proposed regulation.

1 The Office for Civil Rights of the Department of Health and Human Services has been
2 designated to receive complaints of discrimination based on the nondiscrimination statutes and
3 this proposed regulation. It will coordinate handling of complaints with the staff of the
4 Departmental programs from which the entity with respect to whom a complaint has been filed
5 receives funding. Enforcement of the requirements set forth in this proposed regulation will be
6 conducted through the usual and ordinary program mechanisms. Compliance with the
7 requirements proposed herein would likely be examined as part of any broader compliance
8 review conducted by Department staff. If the Department becomes aware that a State or local
9 government or an entity may be in violation of the requirements or prohibitions proposed herein,
10 the Department would work with such government or entity to assist such government or entity
11 to come into compliance with such requirements or prohibitions. If, despite the Department's
12 assistance, compliance is not achieved, the Department will consider all legal options, including
13 termination of funding, return of funds paid out in violation of nondiscrimination provisions
14 under 45 CFR 74, and other measures.

15

16 **III. Statutory Authority**

17 On the basis of the above-mentioned statutory authority, the Secretary proposes to
18 promulgate these regulations, requiring certification of compliance with the anti-discrimination
19 statutes.

20 The statutory provisions discussed above require that the Department and recipients of
21 Department funds (including State and local governments) refrain from discriminating against
22 institutional and individual health care entities for their participation or refusal to participate in
23 certain medical procedures or services, including certain health services, or research activities

1 funded in whole or in part by the federal government. The Department has authority to
2 promulgate regulations to enforce these prohibitions. Finally, the Department also has the legal
3 authority to require that recipients certify their compliance with these proposed requirements and
4 to require their sub-recipients to likewise certify their compliance with these proposed
5 requirements. In addition, 5 U.S.C. § 301 empowers the head of an Executive department to
6 prescribe regulations “for the government of his department, the conduct of its employees, the
7 distribution and performance of its business, and the custody, use, and preservation of its records,
8 papers, and property.”

9

10 **IV. Provisions of the Proposed Rule**

11 Section 88.1 Purpose

12 The “Purpose” section of the regulation sets forth the objective that the proposed
13 regulation would, when finalized, provide for the implementation and enforcement of federal
14 nondiscrimination statutes protecting the conscience rights of health care entities. It also states
15 that the statutory provisions and regulations contained in this Part are to be interpreted and
16 implemented broadly to effectuate these protections.

17

18 Section 88.2 Definitions

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

1 reasonable connection to the procedure, health service or health service program, or research
2 activity 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 reasonable 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; an employee whose task it is to clean the instruments
10 used in a particular procedure would be considered to assist in the performance of the particular
11 procedure.

12 *Health Care Entity / Entity:* While both PHS Act § 245 and the Weldon Amendment
13 provide examples of specific types of protected individuals and health care organizations, neither
14 statute provides an exhaustive list of such health care entities. PHS Act § 245 defines “health
15 care entity” as “includ[ing] an individual physician, a postgraduate physician training program,
16 and a participant in a program of training in the health professions.” As the Department has
17 previously indicated, the definition of “health care entity” in PHS Act § 245 also encompasses
18 institutional entities, such as hospitals and other entities.² The Weldon Amendment defines the
19 term “health care entity” as “includ[ing] an individual physician or other health care
20 professional, a hospital, a provider-sponsored organization, a health maintenance organization, a
21 health insurance plan, or any other kind of health care facility, organization, or plan.” The
22 Church Amendment does not define the term “entity,” and does not use the term “health care
23 entity.”

² See Letter from Secretary Tommy G. Thompson to Hon. W.F. Tauzin, September 24, 2002.

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, as well as other types of entities referenced in the Church
4 Amendments. It is important to note that the Department does not intend for this to be a
5 comprehensive list of relevant organizations for purposes of the regulation, but merely a list of
6 examples.

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

15 Building on this broad definition, we propose that the term “health service program”
16 should be understood to include an activity related in any way to providing medicine, health
17 care, or any other service related to health or wellness, including programs where the Department
18 provides care directly (e.g., Indian Health Service); programs where grants pay for the provision
19 of health services (e.g., Administration for Children and Families programs such as the
20 Unaccompanied Refugee Minor and the Division of Unaccompanied Children Services programs
21 and HRSA programs such as community health centers); programs where the Department
22 reimburses another entity that provides care (e.g., Medicare); and health insurance programs
23 where federal funds are used to provide access to health coverage (e.g., SCHIP, Medicaid, and

1 Medicare Advantage). Similarly, we propose that the term “health service” means any service so
2 provided.

3 *Individual:* For the purposes of this part, the Department proposes to define “individual”
4 to mean a member of the workforce (see definition of “workforce” below) of an entity or health
5 care entity. One conscience clause of the Church Amendments, 42 U.S.C. §300a-7(d), provides
6 that “[n]o *individual* shall be required to perform or assist in the performance of any part of a
7 health service program or research activity funded in whole or in part under a program
8 administered by the Secretary of Health, Education and Welfare [Secretary of Health and Human
9 Services] if his performance or assistance in the performance of such part of such program or
10 activity would be contrary to his religious beliefs or moral convictions (emphasis added).”

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

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

18 *Sub-recipient:* This term is used to encompass any entity that receives Department funds
19 indirectly through a recipient or sub-recipient.

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

1 rules implementing Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts
2 160, 162, and 164 (2006) at 45 CFR 160.103. In keeping with this definition, persons and
3 organizations under contract with an entity, if they are under the control or authority of the
4 entity, would be considered members of the entity’s workforce.

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

14

15 Section 88.3 Applicability

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

20

21 Section 88.4 Requirements and Prohibitions

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

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 88.2.

5
6 Section 88.5 Written Certification of Compliance

7 In the “Written Certification of Compliance” section of the regulation, the Department
8 seeks to require certain recipients and sub-recipients of Department funds to certify compliance
9 with the Church Amendments, PHS Act § 245, and the Weldon Amendment, as applicable, and
10 to provide for the affected recipients and sub-recipients requirements for collecting, maintaining,
11 and submitting written certifications.

12 We are concerned that there is a lack of knowledge on the part of States, local
13 governments, and the health care industry of the rights of health care entities created by, and the
14 corresponding obligations imposed on the recipients of certain federal funding by, the non-
15 discrimination provisions. Under this proposed rule, recipients of federal funds would be
16 required to submit their certifications directly to the Department as part of the instrument or in a
17 separate writing signed by the recipients’ officer or other person authorized to bind the recipient.
18 They would also be required to collect and maintain certifications by sub-recipients who receive
19 Department funds through them.

20 The proposed regulation requires that entities certify in writing that they will operate in
21 compliance with the Church Amendments, PHS Act §245, and the Weldon Amendment as
22 applicable. Certification provides a demonstrable way of ensuring that the recipients of such
23 funding know of, and attest that they will comply with, the applicable nondiscrimination

1 provisions. Sub-recipients of federal funds—entities that will receive federal funds indirectly
2 through another entity (a recipient or other sub-recipient)—are required to provide certification
3 as set out in the “Sub-recipient” subsection of the “Certification of Compliance” section, and
4 submit them to the recipients through which they receive Department funds for maintenance.
5 Although it is collected and maintained by the recipient, this certification by sub-recipients is a
6 certification addressed to the Department, not to the recipients collecting the certification.
7 Recipients are expected to comply with requirements for retention of and access to records set
8 forth in 45 CFR 74.53.

9 While all recipients and sub-recipients of Department funds are required to comply with
10 the Church Amendments, PHS Act § 245, and the Weldon Amendment, as applicable, section
11 88.5(e) contains three important exceptions from the requirement to provide the written
12 certification: (1) physicians, physician offices, and other health care practitioners participating in
13 Part B of the Medicare program; (2) physicians, physician office, or other health care
14 practitioners which participates in Part B of the Medicare program, when such individuals or
15 organizations are sub-recipients of Department funds through a Medicare Advantage plan; and (3)
16 sub-recipients of state Medicaid programs (i.e., any entity that is paid for services by the state
17 Medicaid program). While other providers participating in the Medicare program as well as state
18 Medicaid programs would be required to submit written certification of compliance to the
19 Department, the large number of entities included in these three categories poses significant
20 implementation hurdles for Departmental components and programs. Furthermore, the
21 Department believes that, due primarily to their generally smaller size, the excepted categories of
22 recipients and sub-recipients of Department funds are less likely to encounter the types of issues
23 sought to be addressed in this regulation. However, excepted providers may become subject to

1 the written certification requirement by nature of their receiving Department funds under a
2 separate agency or program. For example, a physician office participating in Medicare Part B
3 may become subject to the written certification requirement by receiving Department funds to
4 conduct clinical research. We note, however, that the State Medicaid programs are responsible
5 for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid
6 program is operated consistently with applicable nondiscrimination provisions. The Department
7 is considering whether other recipients of Department funds from programs that do not involve
8 the provision of health care should also be excepted from the certification requirement and we
9 seek comment on this issue.

10 When finalized, individual Department components will be tasked with determining how
11 best to implement the written certification requirements set out in this regulation in a way that
12 ensures efficient program operation. To this end, Department components will be given
13 discretion to phase in the written certification requirement by no later than the beginning of the
14 next federal fiscal year following the effective date of the regulation.

15

16 **V. Request for Comment**

17 The Department, in order to craft its final rule to best reflect the environment within the
18 health care field, seeks comment on this Proposed Rule. In particular, the Department seeks the
19 following:

- 20 • Comment on all issues raised by the proposed regulation.
- 21 • Information with regard to general knowledge or lack thereof of the protections
22 established by these nondiscrimination provisions, including any facts, surveys, audits,

1 reports, or any other evidence of knowledge or lack of knowledge on these matters in the
2 general public, as well as within the healthcare industry and educational institutions.

- 3 • In the past, there has been some confusion about whether the receipt of federal funds
4 permitted public officials to require entities to provide abortions or perform sterilizations.
5 The debate was resolved, and statutory provisions like section (b) of the Church
6 Amendments [42 U.S.C. § 300a-7(b)] were promulgated to protect entities from public
7 authorities who would claim that the receipt of federal funds creates a legal obligation for
8 the entity to provide abortions or sterilization procedures. The Department seeks
9 information, including any facts, surveys, audits, or reports on whether this remains an
10 issue, that is, do public authorities continue to claim that the receipt of federal funds is
11 sufficient basis for entities to be required to provide abortions or perform sterilizations?
12 If so, how should the Department address this problem?

- 13 • Comment on whether written certification of compliance with nondiscrimination
14 provisions should contain language specifying that the certification is a material
15 prerequisite to the payment of Department funds.

- 16 • The Department also seeks comment on what constitutes the most effective methods of
17 educating recipients of Department funds, their employees, and participants of the
18 protections against discrimination found in the Church Amendments, PHS Act §245, and
19 the Weldon Amendment. What is the best method for communicating to the public the
20 protections afforded by these statutes, and any regulation implementing them?

- 21 ○ One option is to require the physical posting of notices of nondiscrimination
22 protections in conspicuous places within the buildings of recipients of funds, and
23 on applications to educational programs that are recipients of funds. Have notices

1 been effective educational tools with respect to individuals’ rights under federal
2 law?

- 3 ○ Another option is to require inclusion of nondiscrimination protections in notice
4 of applications for training, residency, and educational programs.
- 5 ○ Another option is requiring notice of nondiscrimination protections on websites
6 and in employee / volunteer handbooks of recipients.

7 The Department seeks further comment on this matter—both on the merit of the options
8 mentioned, and on any other means of educating the public with respect to the
9 nondiscrimination protections under federal law.

- 10 • Comment on whether there are recipients of Department funds that should be excepted
11 from the proposed certification requirement, for example because the program under
12 which such recipients receive Department funds is unrelated to the provision of health
13 care or medical research.

15 **VI. Impact Analysis**

16 *Executive Order 12866—Regulatory Planning and Review*

17 HHS has examined the economic implications of this proposed rule as required by
18
19 Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits
20 of available regulatory alternatives and, when regulation is necessary, to select regulatory
21 approaches that maximize net benefits (including potential economic, environmental, public
22 health and safety, and other advantages; distributive impacts; and equity). Executive Order
23 12866 classifies a rule as significant if it meets any one of a number of specified conditions,
24 including: having an annual effect on the economy of \$100 million, adversely affecting a sector
25

1 of the economy in a material way, adversely affecting competition, or adversely affecting jobs.
2 A regulation is also considered a significant regulatory action if it raises novel legal or policy
3 issues. HHS has determined that this proposed rule is a significant regulatory action as defined
4 by Executive Order 12866.

5 An underlying assumption of this regulation is that the health care industry, including
6 entities receiving Department funds, will benefit from more diverse and inclusive workforces by
7 informing health care workers of their rights and fostering an environment in which individuals
8 and organizations from many different faiths, cultures, and philosophical backgrounds are
9 encouraged to participate. As a result, we cannot accurately account for all of the regulation's
10 future benefits, but the Department believes the future benefits will exceed the costs of
11 complying with the regulation.

12 The statutes mandating the requirements for protecting health care entities and
13 individuals in the health care industry as discussed in this rule have been in effect for a number
14 of years and the proposed regulations are consistent with prior Departmental interpretations of
15 these nondiscrimination statutes;³ therefore, the regulatory burden associated with this rule, if
16 finalized, is largely associated with the incremental costs of a recipient certifying compliance to
17 the federal government and the cost of collecting and maintaining records of certification
18 statements from sub-recipients. We estimate the universe and number of entities that would be
19 required to certify to be, at most, 584,294 (see Table I). We do not distinguish between
20 recipients and sub-recipients of HHS funding. Each entity could be a recipient, a sub-recipient,

³ 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* (emphasis added). 65 Fed. Reg. 41270 (July 3, 2000) [codified at 42 CFR § 59 (2008)]; see also Letter from Secretary Tommy G. Thompson to Hon. W.F. Tauzin, September 24, 2002.

1 or both. In accordance with subsection 88.5(e) below, physicians, physician offices, and other
 2 health care practitioners participating in Medicare Part B or who are sub-recipients assisting in
 3 the implementation of a State Medicaid program are not subject to the written certification
 4 requirement; however, a high estimate of the number of physician offices and offices of other
 5 health care practitioners who may be required to certify as recipients or sub-recipients of
 6 Department funds through other programs, instruments, or mechanisms is included.

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 8 **Table 1: Affected Entities**
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| Health Care Entity | Number of Entities |
|---|---------------------------|
| Hospitals (less than 100 beds) ⁴ | 2403 |
| Hospitals (100-200 beds) ⁴ | 1129 |
| Hospitals (200-500 beds) ⁴ | 1160 |
| Hospitals (more than 500 beds) ⁴ | 244 |
| Nursing Homes (less than 50 beds) ⁵ | 2388 |
| Nursing Homes (50-99 beds) ⁵ | 5819 |
| Nursing Homes (99-199 beds) ⁵ | 6877 |
| Nursing Homes (more than 200beds) ⁵ | 1037 |
| Physicians Offices ⁶ | 234200 |
| Offices of Other Health Care Practitioners ^{6,7} | 115378 |
| Outpatient Care Centers ^{6,8} | 26901 |
| Medical and Diagnostic Laboratories ⁶ | 11856 |
| Home Health Care Services ⁶ | 20184 |
| Pharmacies (chain and independent) ⁹ | 58109 |
| Dental Schools ¹⁰ | 56 |
| Medical Schools (Allopathic) ⁴ | 125 |

⁴ Health, United States, 2007. U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. Nov. 2007.

⁵ Nursing Home Data Compendium, 2007 edition. U.S. Dept. of Health and Human Services, Centers for Medicaid and Medicare Services.

⁶ NPRM: Modification to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS.

⁷ From the NAICS Code 6213--Office of Other Health Care Practitioners (including Chiropractors, Optometrists, non-Physician Mental Health Practitioners, Physical Occupational and Speech Therapists, Podiatrists, and all other Miscellaneous Health Care Practitioners.

⁸ From the NAICS Code 6214--Outpatient Care Centers (including Family Planning Centers, Outpatient Mental Health and Substance Abuse Centers, Other Outpatient Care Centers, HMO Medical Centers, Kidney Dialysis Centers, Freestanding Ambulatory Surgical and Emergency Centers, and all Other Outpatient Care Centers.

⁹ 2005 NCPA-Pfizer Digest: Total, Prescription Sales Increase At Nation's Independent Pharmacies. National Community Pharmacies Association Press Release, May 12, 2005.

¹⁰ Dental Education At-A-Glance, 2004. American Dental Education Association. Available at: www.adea.org/CEPR/Documents/2004_Dental_Ed_At_A_Glance.pdf

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| Medical Schools (Osteopathic) ⁴ | 20 |
| Nursing Schools (Licensed practical) ¹¹ | 1138 |
| Nursing Schools (Baccalaureate) ¹¹ | 550 |
| Nursing Schools (Associate degree) ¹¹ | 885 |
| Nursing Schools (Diploma) ¹¹ | 78 |
| Occupational Therapy Schools ⁴ | 142 |
| Optometry Schools ⁴ | 17 |
| Pharmacy Schools ⁴ | 92 |
| Podiatry Schools ⁴ | 7 |
| Public Health Schools ⁴ | 37 |
| Residency Programs (accredited) ¹² | 8494 |
| Health Insurance Carriers and 3rd-Party Administrators ¹³ | 4578 |
| Grant awards ¹⁴ | 76088 |
| Contractors ¹⁵ | 4245 |
| State and territorial governments | 57 |
| Total | 584294 |

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The Department envisions three sub-categories of potential costs for recipients and sub-recipients of Department funds: (1) direct costs associated with the act of certification; (2) direct costs associated with collecting and maintaining certifications made by sub-recipients, and (3) indirect costs associated with certification.

The direct cost of certification is the cost of reviewing the certification language, reviewing relevant entity policies and procedures, and reviewing files before signing. We estimate that each of the 584,294 entities will spend an average of 30 minutes on these activities. Although some entities may need to sign a certification statement more than once, we assume that the entity will only carefully review the language, procedures and their files before signing the initial statement each year. We assume the cost of signing subsequent statements to be small.

¹¹ National Center for Health Workforce Analysis: U.S. Health Workforce Personnel Factbook. U.S. Dept. of Health and Human Services, Health Resources and Services Administration.
¹² Number of Accredited Programs by Academic Year (7/1/2007 - 6/30/2008). Accreditation Council for Graduate Medical Education. Available at: www.acgme.org/adspublic/reports/accredited_programs.asp.
¹³ U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May, 2007.
¹⁴ HHS Grants Statistics, 2007. Available at <http://www.hhs.gov/grantsnet>.
¹⁵ General Services Administration (estimated).

1 Some existing HHS certification forms specify the certification statement should be signed by
2 the CEO, CFO, direct owner, or Chairman of the Board. According to Bureau of Labor Statistics
3 wage data, the mean hourly wage for occupation code 11-1011, Chief Executives, is \$72.77. We
4 estimate the loaded rate to be \$145.54. Thus, assuming that the recipient chooses to have a high-
5 level employee such as a Chief Executive certify on its behalf, the cost associated with the act of
6 certification is \$42.5 million (584,294 x .5 x \$145.54).

7 The direct cost of collecting and maintaining certifications made by sub-recipients is
8 estimated as the labor cost. We assume that each of the 73,088 grant awards and 4,245
9 contractors doing business with HHS have at least one sub-recipient. We also assume that, on
10 average, each grant awardee and contractor will spend one hour collecting and maintaining
11 certifications made by sub-recipients. The mean hourly wage for office and administrative
12 support occupations, occupation code 43-0000, is \$15.00, or \$30 loaded. Thus, the cost of
13 collecting and maintaining records is estimated to be \$2 million (77,333 entities x 1 hour x \$30).

14 Indirect costs associated with the certification requirement might include costs for such
15 actions as staffing/scheduling changes and internal reviews to assess compliance. There is
16 insufficient data to estimate the number of funding recipients not currently compliant with the
17 Church Amendments, PHS Act § 245, or the Weldon Amendment. However, because together
18 these three federal statutes have been in existence for many years, we expect the incremental and
19 indirect costs of certification to be minimal for Department funding recipients. We specifically
20 request comment on this assumption.

21 The total quantifiable costs of the proposed regulation, if finalized, are estimated to be
22 \$44.5 million each year.

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1 *Regulatory Flexibility Act*

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HHS has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. §§ 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, by virtue of either nonprofit status or having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. While the proposed rule will affect a number of small entities, we preliminarily conclude that the costs of compliance are not economically significant (see discussion above). Moreover, in accordance with subsection 88.5(e) below, physicians, physician offices, and other health care practitioners participating in Medicare Part B or who are sub-recipients assisting in the implementation of a State Medicaid program are not subject to the written certification requirement. Thus, we conclude that this proposal, if finalized, will not impose significant costs on small entities. Therefore, the Secretary certifies that this rule will not result in a significant impact on a substantial number of small entities.

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20 *Executive Order 13132—Federalism*

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

1 All three acts enforced in this proposed regulation— the Church Amendments, PHS Act
2 §245, and the Weldon Amendment—impose restrictions on states, local governments, and public
3 entities receiving funds from the Department, including under certain Department-implemented
4 statutes. Insofar as these regulations impact state and local governments, they do so only to the
5 extent that States and local governments would be required to submit certifications of
6 compliance with the statutes and these regulations, as applicable. Since we expect the recipients
7 of Department funds to comply with existing federal law, we anticipate the impact on States and
8 local governments of the proposed certification requirement to be negligible.

9 The Department will consult with States and local governments to seek ways to minimize
10 any burden imposed on the States and local governments by these proposed regulations,
11 consistent with meeting the Department’s objectives of ensuring: (1) knowledge of the
12 obligations imposed, and the rights and protections afforded, by these federal nondiscrimination
13 provisions; and (2) compliance with the nondiscrimination provisions.

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16 *Unfunded Mandates Reform Act of 1995*

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18 Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-
19 benefit and other analyses before any rulemaking if the rule would include a “Federal mandate
20 that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by
21 the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The
22 current inflation-adjusted statutory threshold is approximately \$130 million. The Department
23 has determined that this proposed rule would not constitute a significant rule under the Unfunded
24 Mandates Reform Act.

1 *Assessment of Federal Regulation and Policies on Families*

2
3 Section 654 of the Treasury and General Government Appropriations Act of 1999
4 requires federal departments and agencies to determine whether a proposed policy or regulation
5 could affect family well-being. If the determination is affirmative, then the Department or
6 agency must prepare an impact assessment to address criteria specified in the law. These
7 regulations will not have an impact on family well-being, as defined in the Act.

8
9 *Paperwork Reduction Act of 1995*

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11 This proposed rule does not create any new requirements under the Paperwork Reduction
12 Act of 1995.

13

14 **LIST OF SUBJECTS IN 45 CFR Part 88**

15 Abortion, Civil rights, Colleges and universities, Employment, Government contracts,
16 Government employees, Grant programs, Grants administration, Health care, Health insurance,
17 Health professions, Hospitals, Insurance companies, Laboratories, Medicaid, Medical and dental
18 schools, Medical research, Medicare, Mental health programs, Nursing homes, Public health,
19 Religious discrimination, Religious liberties, Reporting and recordkeeping requirements, Rights
20 of conscience, Scientists, State and local governments, Sterilization, Students.

21

22 Therefore, under the Church Amendments, 42 U.S.C. § 300a-7, Public Health Service Act § 245,
23 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2008, Pub. L.
24 No. 110-161, Div. G, § 508(d), 121 Stat. 1844, 2209, the Department of Health and Human
25 Services proposes to adopt 45 CFR Part 88 as follows:

26

1 **PART 88—ENSURING THAT DEPARTMENT OF HEALTH AND HUMAN SERVICES**
2 **FUNDS DO NOT SUPPORT COERCIVE OR DISCRIMINATORY POLICIES OR**
3 **PRACTICES**

4
5 1. The authority citation for 45 CFR part 88 is adopted to read as follows: Authority: 42
6 U.S.C. § 300a-7, 42 U.S.C. § 238n, Pub. L. 120-161, Div. G, § 508(d), 121 Stat. 1884,
7 2209, 31 U.S.C. 6306, 41 U.S.C. § 253, 40 U.S.C. § 471, 42 U.S.C. § 1395w-22(j)(3)(B),
8 and 42 U.S.C. § 1396u-2(b)(3).

9 2. Section 88.1 is adopted to read as follows:

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11 Section 88.1 Purpose

12 The purpose of this Part is to provide for the implementation and enforcement of the
13 Church Amendments, 42 USC 300a-7, section 245 of the Public Health Service Act, 42 USC
14 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2008, Pub. L. No. 110-
15 161, Div. G, § 508(d), 121 Stat. 1844, 2209. These statutory provisions protect the rights of
16 health care entities/entities, both individuals and institutions, to refuse to perform health care
17 services to which they may object for religious, moral, ethical, or other reasons. Consistent with
18 this objective to protect the conscience rights of health care entities/entities, the provisions in the
19 Church Amendments, section 245 of the Public Health Service Act and the Weldon Amendment,
20 and the implementing regulations contained in this Part are to be interpreted and implemented
21 broadly to effectuate their protective purposes.

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23 3. Section 88.2 is adopted to read as follows:

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Section 88.2 Definitions

For the purposes of this part:

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

“*Health Care Entity*” includes an individual physician or other health care professional, health care personnel, a participant in a program of training in the health professions, an applicant for training or study in the health professions, a post graduate physician training program, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, laboratory or any other kind of health care organization or facility. It may also include components of State or local governments.

“*Entity*” includes an individual physician or other health care professional, health care personnel, a participant in a program of training in the health professions, an applicant for training or study, a post graduate physician training program, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, laboratory or any other kind of health care organization or facility. It may also include components of State or local governments.

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

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

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

5 “*Recipient*” means an organization or individual receiving funds directly from the
6 Department or component of the Department to carry out a project or program. The term
7 includes State and local governments, public and private institutions of higher education, public
8 and private hospitals, commercial organizations, and other quasi-public and private nonprofit
9 organizations such as, but not limited to, community action agencies, research institutes,
10 educational associations, and health centers. The term may include foreign or international
11 organizations (such as agencies of the United Nations) which are recipients, sub-recipients, or
12 contractors or subcontractors of recipients or sub-recipients at the discretion of the Department
13 awarding agency.

14 “*Sub-recipient*” means an organization or individual receiving funds indirectly from the
15 Department or component of the Department through a recipient or another sub-recipient to carry
16 out a project or program. The term includes State and local governments, public and private
17 institutions of higher education, public and private hospitals, commercial organizations, and
18 other quasi-public and private nonprofit organizations such as, but not limited to, community
19 action agencies, research institutes, educational associations, and health centers. The term may
20 include foreign or international organizations (such as agencies of the United Nations) which are
21 recipients, sub-recipients, or contractors or subcontractors of recipients or sub-recipients at the
22 discretion of the Department awarding agency.

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

4
5 4. Section 88.3 is adopted to read as follows:

6
7 Section 88.3 Applicability

8 (a) The Department of Health and Human Services is required to comply with sections 88.4(a),
9 (b)(1), and (d)(1), below.

10 (b) Any State or local government that receives federal funds appropriated through the
11 appropriations act for the Department of Health and Human Services is required to comply with
12 sections 88.(b)(1) and 88.5 below.

13 (c) Any entity that receives federal funds appropriated through the appropriations act for the
14 Department of Health and Human Services to implement any part of any federal program is
15 required to comply with sections 88.4(b)(2) and 88.5 below.

16 (d) Any State or local government that receives federal financial assistance is required to
17 comply with sections 88.4(a) and 88.5, below.

18 (e) Any State or local government, any part of any State or local government, or any other
19 public entity must comply with section 88.4(e) below.

20 (f)(1) Any entity, including a State or local government, that receives a grant, contract, loan, or
21 loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act,
22 or the Developmental Disabilities Assistance and Bill of Rights Act of 2000, must comply with
23 sections 88.4(c)(1) and 88.5.

1 (2) In addition to complying with the provisions set forth in 88.4(c)(1), any such entity that is
2 an educational institution, teaching hospital, or program for the training of health care
3 professionals or health care workers shall also comply with section 88.4(a)(2) below.

4 (g)(1) Any entity, including a State or local government, that carries out any part of any health
5 service program or research activity funded in whole or in part under a program administered by
6 the Secretary of Health and Human Services must comply with sections 88.4(d)(1) and 88.5
7 below.

8 (2) In addition to complying with the provisions set forth in (g)(1), any such entity that
9 receives grants or contracts for biomedical or behavioral research under any program
10 administered by the Secretary of Health and Human Services shall also comply with section
11 88.4(d)(2) below.

12

13 5. Section 88.4 is adopted to read as follows:

14

15 Section 88.4 Requirements and Prohibitions

16 (a) Entities to whom this subsection 88.4 (a) applies shall not:

17 (1) subject any institutional or individual health care entity to discrimination for refusing: (A)
18 to undergo training in the performance of abortions, or to require, provide, refer for, or make
19 arrangements for training in the performance of abortions; (B) to perform, refer for, or make
20 other arrangements for, abortions; or (C) to refer for abortions;

21 (2) subject any institutional or individual health care entity to discrimination for attending or
22 having attended a post-graduate physician training program, or any other program of training in
23 the health professions, that does not or did not require attendees to perform induced abortions or

1 require, provide, or refer for training in the performance of induced abortions, or make
2 arrangements for the provision of such training;

3 (3) For the purposes of granting a legal status to a health care entity (including a license or
4 certificate), or providing such entity with financial assistance, services or benefits, fail to deem
5 accredited any postgraduate physician training program that would be accredited but for the
6 accrediting agency's reliance upon an accreditation standard or standards that require an entity to
7 perform an induced abortion or require, provide, or refer for training in the performance of
8 induced abortions, or make arrangements for such training, regardless of whether such standard
9 provides exceptions or exemptions;

10 (b)(1) Any entity to whom this subsection 88.4(b)(1) applies shall not subject any institutional or
11 individual health care entity to discrimination on the basis that the health care entity does not
12 provide, pay for, provide coverage of, or refer for, abortion.

13

14 (b)(2) Entities to whom this subsection 88.4(b)(2) applies shall not subject any institutional or
15 individual health care entity to discrimination on the basis that the health care entity does not
16 provide, pay for, provide coverage of, or refer for abortion as part of the federal program for
17 which it receives funding.

18

19 (c) Entities to whom this subsection 88.4(c) applies shall not:

20 (1) discriminate against any physician or other health care professional in the employment,
21 promotion, termination, or extension of staff or other privileges because he performed or assisted
22 in the performance, or refused to perform or assist in the performance of a lawful sterilization
23 procedure or abortion on the grounds that doing so would be contrary to his religious beliefs or

1 moral convictions, or because of his religious beliefs or moral convictions concerning abortions
2 or sterilization procedures themselves;

3 (2) discriminate against or deny admission to any applicant for training or study because of
4 reluctance or willingness to counsel, suggest, recommend, assist, or in any way participate in the
5 performance of abortions or sterilizations contrary to or consistent with the applicant's religious
6 beliefs or moral convictions.

7

8 (d) Entities to whom this subsection 88.4(d) applies shall not:

9 (1) require any individual to perform or assist in the performance of any part of a health
10 service program or research activity funded by the Department if such service or activity would
11 be contrary to his religious beliefs or moral convictions.

12 (2) discriminate in the employment, promotion, termination, or the extension of staff or other
13 privileges to any physician or other health care personnel because he performed, assisted in the
14 performance, refused to perform, or refused to assist in the performance of any lawful health
15 service or research activity on the grounds that his performance or assistance in performance of
16 such service or activity would be contrary to his religious beliefs or moral convictions, or
17 because of the religious beliefs or moral convictions concerning such activity themselves.

18

19 (e) Entities to whom this subsection 88.4(e) applies shall not, on the basis that the individual or
20 entity has received a grant, contract, loan, or loan guarantee under the Public Health Service Act,
21 the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and
22 Bill of Rights Act of 2000, require (1) such individual to perform or assist in the performance of
23 any sterilization procedure or abortion if his performance or assistance in the performance of

1 such procedure or abortion would be contrary to his religious beliefs or moral convictions, or (2)
2 such entity to (A) make its facilities available for the performance of any sterilization procedure
3 or abortion if the performance of such procedure or abortion in such facilities is prohibited by the
4 entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the
5 performance or assistance in the performance of any sterilization procedure or abortion if the
6 performance or assistance in the performance of such procedure or abortion by such personnel
7 would be contrary to the religious beliefs or moral convictions of such personnel.

8

9 6. Section 88.5 is adopted to read as follows:

10

11 Section 88.5 Written Certification of Compliance:

12 (a) **Certification Requirement.** Except as provided in subsection 88.5(e) below, recipients shall
13 include the written certifications as set forth in section 88.5(c)(4) in the application for the grant,
14 cooperative agreement, contract, grant under a contract, memorandum of understanding or other
15 funding or employment instrument or contract, as applicable. Except as provided in subsection
16 88.5(e) below, sub-recipients must provide the Certification of Compliance as set out in section
17 88.5(d)(3) of this regulation, submitted as part of its original agreement with the recipient in the
18 execution of its grant, cooperative agreement, contract, grant under a contract, memorandum of
19 understanding or other funding instrument, or in a separate writing, signed by the sub-recipients'
20 officer or other person authorized to bind the sub-recipient. Certifications shall be made by an
21 officer or other individual authorized to bind the recipient or sub-recipient. All certifications
22 shall be addressed directly to the Department; recipients are required to submit their
23 certifications directly to the Department. Recipients shall be in full compliance with all

1 applicable certification requirements by no later than the beginning of the federal fiscal year
2 following the effective date of this regulation.

3

4 **(b) Notification of Certification Requirement.** The Department shall notify recipients of
5 funding of the certification requirement at the time of award through the Request for Proposal,
6 Request for Agreement, Provider Agreement, contract, guidance, or other public announcement
7 of the availability of funding. Recipients shall not construe anything in this paragraph to mean
8 that an entity or organization is in any way exempt from providing the certification in the event
9 the Department should fail to provide notification.

10

11 **(c) Certification by recipients.**

12 (1) Except as provided in subsection 88.5(e) below, all recipients through any instrument must
13 provide the Certification of Compliance as set out in Section 88.5(c)(4) of this regulation,
14 submitted as part of the recipient's application for the grant, cooperative agreement, contract,
15 grant under a contract, memorandum of understanding or other funding instrument or in a
16 separate writing signed by the recipients' officer or other person authorized to bind the recipient.

17 (2) Recipients must file with the Department a renewed certification upon any renewal,
18 extension, amendment, or modification of the grant, cooperative agreement, contract, grant under
19 a contract, memorandum of understanding or other funding or employment instrument or
20 contract that extends the term of such instrument or adds additional funds to it. Recipients that
21 are already recipients as of the effective date of this regulation must file a certification upon any
22 extension, amendment, or modification of the grant, cooperative agreement, contract, grant under

1 a contract, memorandum of understanding or other funding instrument that extends the term of
2 such instrument or adds additional funds to it.

3 (3) Recipients shall require certifications and re-certifications by all sub-recipients that receive
4 funding through their association with the recipient. Recipients shall require these certifications
5 and re-certifications as often as recipients are required to sign or amend the instrument, for as
6 long as the relationship between the recipient and the sub-recipient lasts. Recipients shall collect
7 and maintain sub-recipient certifications for as long as the relationship between the recipient and
8 the sub-recipient lasts, and for a reasonable time after the relationship ends, for the purpose of
9 investigations, litigation, or other purposes.

10 (4) **The Certification.** Except as provided in subsection 88.5(e) below, all recipients shall
11 provide the following certification:

12 “As the duly authorized representative of the recipient I certify that the recipient of funds made
13 available through this [instrument] will not discriminate on the basis of an entity’s past
14 involvement in, or refusal to assist in the performance of, the practices of abortion or
15 sterilization, and will not require involvement in procedures that violate an individual’s
16 conscience as part of any part of any health service program, in accord with all applicable
17 sections of 45 CFR part 88.

18

19 I further certify that the recipient acknowledges that any violation of these certifications shall be
20 grounds for termination by the Department of any grant, cooperative agreement, contract, grant
21 under a contract, memorandum of understanding or other funding or employment instrument or
22 contract prior to the end of its term and recovery of appropriated funds expended prior to
23 termination. I further certify that, except as provided in 45 CFR 88.5(e), the recipient will

1 include this certification requirement in any [instrument] to a sub-recipient of funds made
2 available under this instrument, and will require, except as provided in 45 CFR 88.5(e), such
3 sub-recipient to provide the same certification that the recipient organization or entity provided. I
4 further certify the recipient organization will collect and maintain sub-recipient certifications for
5 as long as the relationship between the recipient and the sub-recipient lasts, and for a reasonable
6 time after the relationship ends, for the purpose of investigations, litigation, or other purposes.”

7
8 **(d) Certification by Sub-recipients.**

9 (1) Except as provided in subsection 88.5(e), organizations or entities that are sub-recipients of
10 the organization or entity providing the initial Certification of Compliance must submit to the
11 recipient for maintenance by the recipient through which the sub-recipient receives Department
12 funds Certification of Compliance as set out in Section 88.5(d)(3) of this regulation, as part of
13 the grant, cooperative agreement, contract, grant under a contract, memorandum of
14 understanding or other funding instrument between the recipient and the sub-recipient or in a
15 separate writing signed by the sub-recipients’ officer or other person authorized to bind the sub-
16 recipient.

17 (2) Except as provided in subsection 88.5(e), sub-recipients of funds shall renew certification
18 to the recipient through which it receives Department funds upon any renewal, extension,
19 amendment, or modification of the grant, cooperative agreement, contract, grant under a
20 contract, memorandum of understanding or other funding or employment instrument or contract
21 that extends the term of such instrument or adds additional funds to it. Sub-recipients shall
22 submit such renewals to the recipient entities through which they receive Department funding.
23 Entities that are already sub-recipients as of the effective date of this regulation must certify

1 upon any extension, amendment, or modification of the grant, cooperative agreement, contract,
2 grant under a contract, memorandum of understanding or other funding instrument that extends
3 the term of such instrument or adds additional funds to it, and shall submit such certifications to
4 the recipient entity through which they receive Department funding.

5 (3) **The Certification.** Except as provided in subsection 88.5(e) below, all sub-recipients of
6 Department funds shall provide the following certification:

7 “As the duly authorized representative of the sub-recipient I certify that the sub-recipient of
8 funds made available through this [instrument] will not discriminate on the basis of an entity’s
9 past involvement in, or refusal to assist in the performance of, the practices of abortion or
10 sterilization, and will not require involvement in procedures that violate an individual’s
11 conscience as part of any part of any health service program, in accord with all applicable
12 sections of 45 CFR part 88.

13

14 I further certify that the sub-recipient acknowledges that these certifications by the sub-recipient
15 of funds are certifications made directly to the Department and that any violation of these
16 certifications shall be grounds for termination by the Department of the recipient’s grant,
17 cooperative agreement, contract, grant under a contract, memorandum of understanding or other
18 funding or employment instrument or contract prior to the end of its term and recovery of
19 appropriated funds expended prior to termination. I further certify that the sub-recipient will
20 submit all certifications to the recipient entity through which it received Department funds.”

21

22 (e) **Exceptions.** Provided that such individuals or organizations are not recipients or sub-
23 recipients of Department funds through another instrument, program, or mechanism, other than

1 those set forth in (1)-(3) below, the following individuals or organizations shall not be required
2 to comply with the written certification requirement set forth in this section: (1) a physician, as
3 defined in 42 U.S.C. § 1395(r), physician office, or other health care practitioner participating in
4 Part B of the Medicare program; (2) a physician, as defined in 42 U.S.C. § 1395(r), physician
5 office, or other health care practitioner which participates in Part B of the Medicare program,
6 when such individuals or organizations are sub-recipients of Department funds through a
7 Medicare Advantage plan; or (3) a sub-recipient of Department funds through a State Medicaid
8 program.