

state law. For that reason, this proposed action:

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, pertaining to the Philadelphia County RACT under the 8-hour ozone NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 18, 2008.

William T. Wisniewski,

Acting Regional Administrator, Region III.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 88

RIN 0991–AB48

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

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services proposes to promulgate regulations to ensure that Department funds do not support morally coercive or discriminatory practices or policies in violation of federal law, pursuant to the Church Amendments (42 U.S.C. 300a–7), Public Health Service (PHS) Act § 245 (42 U.S.C. 238n), and the Weldon Amendment (Consolidated Appropriations Act, 2008, Pub. L. 110–161, § 508(d), 121 Stat. 1844, 2209). This notice of proposed rulemaking proposes to define certain key terms. Furthermore, in order to ensure that recipients of Department funds know about their legal obligations under these nondiscrimination provisions, the Department proposes to require written certification by certain recipients that they will comply with all three statutes, as applicable.

DATES: Submit written or electronic comment on the regulations proposed by this document by September 25, 2008.

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

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

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

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

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

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

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

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

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of

the Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m.

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FOR FURTHER INFORMATION CONTACT:

Brenda Destro, (202) 401-2305, Office of Public Health and Science, Department of Health and Human Services, Room 728E, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

SUPPLEMENTARY INFORMATION:

I. Background

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

federal funds from discriminating against individuals and institutions that refuse to, among other things, provide, refer for, pay for, or cover, abortion.

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

The conscience provisions contained in 42 U.S.C. 300a-7 (collectively known as the "Church Amendments") were enacted at various times during the 1970s in response to debates over whether receipt of federal funds required the recipients of such funds to provide abortions or sterilizations. The first conscience provision in the Church Amendments, 42 U.S.C. 300a-7(b), provides that "[t]he receipt of any grant, contract, loan, or loan guarantee under [certain statutes implemented by the Department of Health and Human Services] * * * 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 a sterilization procedure or an abortion, if it would be contrary to his/her religious beliefs or moral convictions; (2) the entity to make its facilities available for sterilization procedures or abortions, if the performance of sterilization procedures or abortions in the facilities is prohibited by the entity on the basis of religious beliefs or moral convictions; or (3) the entity to provide personnel for the performance of sterilization procedures or abortions, if it would be contrary to the religious beliefs or moral convictions of such personnel.

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

The third conscience provision, contained in 42 U.S.C. 300a-7(c)(2), prohibits any entity which receives a grant or contract for biomedical or behavioral research under any program

administered by the Department from discriminating against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges "because he performed or assisted in the performance of any lawful health service or research activity," or "because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity."

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

The final conscience provision contained in the Church Amendments, 42 U.S.C. 300a-7(e), prohibits any entity that receives a grant, contract, loan, or loan guarantee under certain Departmentally implemented statutes 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, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions."

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, Public Law 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, Public Law 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, Public Law 109-149, § 508(d), 119 Stat. 2833, 2879-80; Revised Continuing Appropriations Resolution of 2007, Public Law 110-5, § 2, 121 Stat. 8, 9; Consolidated Appropriations Act, 2008, Public Law No. 110-161, Div. G, § 508(d), 121 Stat. 1844, 2209. The Weldon Amendment provides that "[n]one of the funds made available under this Act [making appropriations for the Departments of Labor, Health and Human Services, and Education] may be made available to a federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." It also defines "health care entity" to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan."

The Laws in the Courts

The federal courts have recognized the breadth and importance of statutory and other conscience protections for health care professionals and workers.

Shortly after its passage, a federal appellate court decision characterized the importance of conscience protections contained in the Church Amendments. Faced with the question of a denominational hospital's right to refuse to perform sterilization procedures, the Ninth Circuit affirmed a lower court decision protecting the hospital's right to refuse to perform sterilizations and abortions on religious or moral grounds: "If [a] hospital's refusal to perform sterilization [or, by implication, abortion] infringes upon any constitutionally cognizable right to privacy, such infringement is outweighed by the need to protect the freedom of religion of denominational hospitals 'with religious or moral scruples against sterilizations and abortions.'" *Taylor v. St. Vincent's Hospital*, 523 F.2d 75, 77 (9th Cir. 1975) (citations omitted).

The Problem

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

Despite the fact that several conscience statutes protecting health care entities from discrimination have been in existence for decades, the Department is concerned that the public and many health care providers are largely uninformed of the protections afforded to individuals and institutions under these provisions. This lack of knowledge within 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.

The Department's Response

In general, the Department is concerned that the development of an environment in the health care field that is intolerant of individual conscience, certain religious beliefs, ethnic and cultural traditions, and moral convictions may discourage individuals

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

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

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

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>.

inclusive, tolerant environment in the health care industry than may currently exist.

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

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

II. Summary of the Proposed Rule

This proposed rule sets out, and provides further definition of, the rights and responsibilities created by the federal nondiscrimination provisions. It clarifies the scope of nondiscrimination protections to applicable members of the Department's workforce, as well as and health care entities and members of the workforces of entities receiving Department funds. This proposed rule would also require certain recipients of Department funds to certify compliance with these requirements. In order to ensure proper enforcement, this proposed rule would define certain terms for the purposes of this proposed regulation.

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

paid out in violation of nondiscrimination provisions under 45 CFR 74, and other measures.

III. Statutory Authority

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

The statutory provisions discussed above require that the Department and recipients of Department funds (including State and local governments) refrain from discriminating against institutional and individual health care entities for their participation or refusal to participate in certain medical procedures or services, including certain health services, or research activities funded in whole or in part by the Federal Government. The Department has authority to promulgate regulations to enforce these prohibitions. Finally, the Department also has the legal authority to require that recipients certify their compliance with these proposed requirements and to require their sub-recipients to likewise certify their compliance with these proposed requirements. In addition, 5 U.S.C. 301 empowers the head of an Executive department to prescribe regulations "for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property."

IV. Provisions of the Proposed Rule

Section 88.1 Purpose

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

Section 88.2 Definitions

Assist in the Performance: The Department, in considering how to interpret the term "assist in the performance," seeks to provide broad protection for individuals' consciences. The Department seeks to avoid judging whether a particular action is genuinely offensive to an individual. At the same time, the Department wishes to guard against potential abuses of these

protections by limiting the definition of "assist in performance" only to those actors who have a reasonable connection to the procedure, health service or health service program, or research activity to which they object.

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

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

In keeping with the definitions in PHS Act § 245 and the Weldon Amendment, the Department proposes to define "health care entity" to include the specifically mentioned organizations from the two statutes, as well as other types of entities referenced in the Church Amendments. It is important to note that the Department does not intend for this to be a comprehensive list of relevant organizations for

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

purposes of the regulation, but merely a list of examples.

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

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

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

Instrument: We propose to use “instrument” to mean the variety of

means by which the Department conveys funding and resources to organizations, including: grants, cooperative agreements, contracts, grants under a contract, and memoranda of understanding. The definition of “instrument” is intended to include all means by which the Department conveys funding and resources.

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

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

Workforce: We propose to define “workforce” as including employees, volunteers, trainees, and other persons whose conduct, in the performance of work for an entity, is under the control or authority of such entity, whether or not they are paid by the Department-funded entity. The definition is drawn from the “Administrative Data Standards and Related Requirements” rules implementing Health Insurance Portability and Accountability Act (HIPAA), 45 CFR Parts 160, 162, and 164 (2006) at 45 CFR 160.103. In keeping with this definition, persons and organizations under contract with an entity, if they are under the control or authority of the entity, would be considered members of the entity’s workforce.

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

Section 88.3 Applicability

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

Section 88.4 Requirements and Prohibitions

The “Requirements and Prohibitions” section explains the obligations that the Church Amendments, PHS Act § 245, and the Weldon Amendment impose on entities which receive funding from the Department. These provisions are taken from the relevant statutory language and make up the elements of the certification provided by the entities. We intend for the proposed requirements and prohibitions to be interpreted using the definitions proposed in section 88.2.

Section 88.5 Written Certification of Compliance

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

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

The proposed regulation requires that entities certify in writing that they will operate in compliance with the Church Amendments, PHS Act § 245, and the Weldon Amendment as applicable. Certification provides a demonstrable way of ensuring that the recipients of such funding know of, and attest that they will comply with, the applicable nondiscrimination provisions. Sub-recipients of federal funds—entities that will receive federal funds indirectly through another entity (a recipient or other sub-recipient)—are required to provide certification as set out in the “Sub-recipient” subsection of the “Certification of Compliance” section, and submit them to the recipients

through which they receive Department funds for maintenance.

Although it is collected and maintained by the recipient, this certification by sub-recipients is a certification addressed to the Department, not to the recipients collecting the certification. Recipients are expected to comply with requirements for retention of and access to records set forth in 45 CFR 74.53.

While all recipients and sub-recipients of Department funds are required to comply with the Church Amendments, PHS Act § 245, and the Weldon Amendment, as applicable, section 88.5(e) contains three important exceptions from the requirement to provide the written certification: (1) Physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program; (2) physicians, physician offices, or other health care practitioners which participates in Part B of the Medicare program, when such individuals or organizations are sub-recipients of Department funds through a Medicare Advantage plan; and (3) sub-recipients of state Medicaid programs (i.e., any entity that is paid for services by the state Medicaid program). While other providers participating in the Medicare program as well as state Medicaid programs would be required to submit written certification of compliance to the Department, the large number of entities included in these three categories poses significant implementation hurdles for Departmental components and programs. Furthermore, the Department believes that, due primarily to their generally smaller size, the excepted categories of recipients and sub-recipients of Department funds are less likely to encounter the types of issues sought to be addressed in this regulation. However, excepted providers may become subject to the written certification requirement by nature of their receiving Department funds under a separate agency or program. For example, a physician office participating in Medicare Part B may become subject to the written certification requirement by receiving Department funds to conduct clinical research. We note, however, that the State Medicaid programs are responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions. The Department is considering whether other recipients of Department funds from programs that do not involve the provision of health care should also be

excepted from the certification requirement and we seek comment on this issue.

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

V. Request for Comment

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

- Comment on all issues raised by the proposed regulation.
- Information with regard to general knowledge or lack thereof of the protections established by these nondiscrimination provisions, including any facts, surveys, audits, reports, or any other evidence of knowledge or lack of knowledge on these matters in the general public, as well as within the healthcare industry and educational institutions.
- In the past, there has been some confusion about whether the receipt of federal funds permitted public officials to require entities to provide abortions or perform sterilizations. The debate was resolved, and statutory provisions like section (b) of the Church Amendments [42 U.S.C. 300a-7(b)] were promulgated to protect entities from public authorities who would claim that the receipt of federal funds creates a legal obligation for the entity to provide abortions or sterilization procedures. The Department seeks information, including any facts, surveys, audits, or reports on whether this remains an issue, that is, do public authorities continue to claim that the receipt of federal funds is sufficient basis for entities to be required to provide abortions or perform sterilizations? If so, how should the Department address this problem?
- Comment on whether written certification of compliance with nondiscrimination provisions should contain language specifying that the certification is a material prerequisite to the payment of Department funds.
- The Department also seeks comment on what constitutes the most effective methods of educating recipients of Department funds, their

employees, and participants of the protections against discrimination found in the Church Amendments, PHS Act § 245, and the Weldon Amendment. What is the best method for communicating to the public the protections afforded by these statutes, and any regulation implementing them?

○ One option is to require the physical posting of notices of nondiscrimination protections in conspicuous places within the buildings of recipients of funds, and on applications to educational programs that are recipients of funds. Have notices been effective educational tools with respect to individuals' rights under federal law?

○ Another option is to require inclusion of nondiscrimination protections in notice of applications for training, residency, and educational programs.

○ Another option is requiring notice of nondiscrimination protections on websites and in employee/volunteer handbooks of recipients.

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

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

VI. Impact Analysis

Executive Order 12866—Regulatory Planning and Review

HHS has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. HHS has

determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

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

The statutes mandating the requirements for protecting health care entities and individuals in the health care industry as discussed in this rule have been in effect for a number of years and the proposed regulations are consistent with prior Departmental interpretations of these nondiscrimination statutes;³ therefore, the regulatory burden associated with this rule, if finalized, is largely associated with the incremental costs of a recipient certifying compliance to the federal government and the cost of collecting and maintaining records of certification statements from sub-recipients. We estimate the universe and number of entities that would be required to certify to be, at most,

584,294 (see Table I). We do not distinguish between recipients and sub-recipients of HHS funding. Each entity could be a recipient, a sub-recipient, or both. 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; however, a high estimate of the number of physician offices and offices of other health care practitioners who may be required to certify as recipients or sub-recipients of Department funds through other programs, instruments, or mechanisms is included.

TABLE I—AFFECTED ENTITIES

Health care entity	Number of entities
Hospitals (less than 100 beds) ¹	2,403
Hospitals (100–200 beds) ⁴	1,129
Hospitals (200–500 beds) ⁴	1,160
Hospitals (more than 500 beds) ⁴	244
Nursing Homes (less than 50 beds) ²	2,388
Nursing Homes (50–99 beds) ⁵	5,819
Nursing Homes (99–199 beds) ⁵	6,877
Nursing Homes (more than 200 beds) ⁵	1,037
Physicians Offices ³	234,200
Offices of Other Health Care Practitioners ^{6,4}	115,378
Outpatient Care Centers ^{6,5}	26,901
Medical and Diagnostic Laboratories ⁶	11,856
Home Health Care Services ⁶	20,184
Pharmacies (chain and independent) ⁶	58,109
Dental Schools ⁷	56
Medical Schools (Allopathic) ⁴	125
Medical Schools (Osteopathic) ⁴	20
Nursing Schools (Licensed practical) ⁸	1,138
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) ⁹	8,494
Health Insurance Carriers and 3rd-Party Administrators ¹⁰	4,578
Grant awards ¹¹	76,088
Contractors ¹²	4,245
State and territorial governments	57
Total	584,294

¹ 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.

² Nursing Home Data Compendium, 2007 edition. U.S. Dept. of Health and Human Services, Centers for Medicaid and Medicare Services.

³ NPRM: Modification to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS.

⁴ 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).

⁵ 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).

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 FR 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.

⁶ 2005 NCPA-Pfizer Digest: Total, Prescription Sales Increase At Nation's Independent Pharmacies. National Community Pharmacies Association Press Release, May 12, 2005.

⁷ Dental Education At-A-Glance, 2004. American Dental Education Association. Available at: http://www.adea.org/CEPR/Documents/2004_Dental_Ed_At_A_Glance.pdf.

⁸ 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.

⁹ Number of Accredited Programs by Academic Year (7/1/2007—6/30/2008). Accreditation Council for Graduate Medical Education. Available at: http://www.acgme.org/adspublic/reports/accredited_programs.asp.

¹⁰ U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May 2007.

¹¹ HHS Grants Statistics, 2007. Available at <http://www.hhs.gov/grantsnet>.

¹² General Services Administration (estimated).

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

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

be \$2 million ($77,333 \text{ entities} \times 1 \text{ hour} \times \30).

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

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

Regulatory Flexibility Act

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.

Executive Order 13132—Federalism

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.

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

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

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires cost-benefit and other analyses before any rulemaking if the rule would

include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is approximately \$130 million. The Department has determined that this proposed rule would not constitute a significant rule under the Unfunded Mandates Reform Act.

Assessment of Federal Regulation and Policies on Families

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

Paperwork Reduction Act of 1995

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

List of Subjects in 45 CFR Part 88

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

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

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

- Sec.
88.1 Purpose.
88.2 Definitions.
88.3 Applicability.

- 88.4 Requirements and prohibitions.
88.5 Written certification of compliance.

Authority: 42 U.S.C. 300a–7, 42 U.S.C. 238n, Pub. L. 120–161, Div. G, section 508(d), 121 Stat. 1884, 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), and 42 U.S.C. 1396u–2(b)(3).

§ 88.1 Purpose.

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

§ 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.

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 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.

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.

Individual means a member of the workforce of an entity/health care entity.

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

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

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

Workforce includes employees, volunteers, trainees, and other persons whose conduct, in the performance of

work for a Department-funded entity, is under the control or authority of such entity, whether or not they are paid by the Department-funded entity.

§ 88.3 Applicability.

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

(b) Any State or local government that receives federal funds appropriated through the appropriations act for the Department of Health and Human Services is required to comply with §§ 88.4(b)(1) and 88.5.

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

(d) Any State or local government that receives federal financial assistance is required to comply with §§ 88.4(a) and 88.5.

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

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

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

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

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

§ 88.4 Requirements and prohibitions.

(a) Entities to whom this paragraph (a) applies shall not:

(1) Subject any institutional or individual health care entity to discrimination for refusing:

(i) To undergo training in the performance of abortions, or to require, provide, refer for, or make arrangements for training in the performance of abortions;

(ii) To perform, refer for, or make other arrangements for, abortions; or

(iii) To refer for abortions;

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

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

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

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

(c) Entities to whom this paragraph (c) applies shall not:

(1) Discriminate against any physician or other health care professional in the employment, promotion, termination, or extension of staff or other privileges because he performed or assisted in the performance, or refused to perform or assist in the performance of a lawful sterilization procedure or abortion on the grounds that doing so would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions concerning abortions or sterilization procedures themselves;

(2) Discriminate against or deny admission to any applicant for training

or study because of reluctance or willingness to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions.

(d) Entities to whom this paragraph (d) applies shall not:

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

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

(e) Entities to whom this paragraph (e) applies shall not, on the basis that the individual or entity has received a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000, require:

(1) Such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions, or

(2) Such entity to:

(i) Make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or

(ii) Provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedure or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

§ 88.5 Written certification of compliance.

(a) *Certification requirement.* Except as provided in paragraph (e) of this

section, recipients shall include the written certifications as set forth in paragraph (c)(4) of this section in the application for the grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding or employment instrument or contract, as applicable. Except as provided in paragraph (e) of this section, sub-recipients must provide the Certification of Compliance as set out in paragraph (d)(3) of this section, submitted as part of its original agreement with the recipient in the execution of its grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding instrument, or in a separate writing, signed by the sub-recipients' officer or other person authorized to bind the sub-recipient. Certifications shall be made by an officer or other individual authorized to bind the recipient or sub-recipient. All certifications shall be addressed directly to the Department; recipients are required to submit their certifications directly to the Department. Recipients shall be in full compliance with all applicable certification requirements by no later than the beginning of the federal fiscal year following the effective date of this regulation.

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

(c) *Certification by recipients.*

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

(2) Recipients must file with the Department a renewed certification upon any renewal, extension, amendment, or modification of the grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding or

employment instrument or contract that extends the term of such instrument or adds additional funds to it. Recipients that are already recipients as of the effective date of this regulation must file a certification upon any extension, amendment, or modification of the grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding instrument that extends the term of such instrument or adds additional funds to it.

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

(4) *The certification.* Except as provided in paragraph (e) of this section, all recipients shall provide the following certification:

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

I further certify that the recipient acknowledges that any violation of these certifications shall be grounds for termination by the Department of any grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding or employment instrument or contract prior to the end of its term and recovery of appropriated funds expended prior to termination. I further certify that, except as provided in 45 CFR 88.5(e), the recipient will include this certification requirement in any [instrument] to a sub-recipient of funds made available under this instrument, and will require, except as provided in 45 CFR 88.5(e), such sub-recipient to provide the same certification that the recipient organization or entity provided. I further certify the recipient organization will collect and maintain sub-recipient certifications for as long as the relationship between the recipient and the sub-recipient lasts, and for a reasonable time after the relationship ends, for the purpose of investigations, litigation, or other purposes.

(d) *Certification by sub-recipients.*

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

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

(3) *The certification.* Except as provided in paragraph (e) of this section, all sub-recipients of Department funds shall provide the following certification:

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

I further certify that the sub-recipient acknowledges that these certifications by the sub-recipient of funds are certifications made directly to the Department and that any violation of these certifications shall be grounds for termination by the Department of the recipient's grant, cooperative agreement,

contract, grant under a contract, memorandum of understanding or other funding or employment instrument or contract prior to the end of its term and recovery of appropriated funds expended prior to termination. I further certify that the sub-recipient will submit all certifications to the recipient entity through which it received Department funds.

(e) *Exceptions.* Provided that such individuals or organizations are not recipients or sub-recipients of Department funds through another instrument, program, or mechanism, other than those set forth in paragraphs (e)(1) through (3) of this section, the following individuals or organizations shall not be required to comply with the written certification requirement set forth in this section:

(1) A physician, as defined in 42 U.S.C. 1395(r), physician office, or other health care practitioner participating in Part B of the Medicare program;

(2) A physician, as defined in 42 U.S.C. 1395(r), physician office, or other health care practitioner which participates in Part B of the Medicare program, when such individuals or organizations are sub-recipients of Department funds through a Medicare Advantage plan; or

(3) A sub-recipient of Department funds through a State Medicaid program.

Dated: August 20, 2008.

Michael O. Leavitt,
Secretary.

[FR Doc. E8-19744 Filed 8-21-08; 2:00 pm]

BILLING CODE 4150-28-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[MD Docket No. 08-65; FCC 08-182]

Assessment and Collection of Regulatory Fees for Fiscal Year 2008

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, we seek comment on changes to the regulatory fee schedule and methodology.

DATES: Comments are due September 25, 2008, and reply comments are due October 27, 2008.

ADDRESSES: You may submit comments, identified by MD Docket No. 08-65, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site:* <http://www.fcc.gov/cgb/ecfs>. Follow the instructions for submitting comments.

• *E-mail:* ecfs@fcc.gov. Include MD Docket No. 08-65 in the subject line of the message.

• *Mail:* Commercial overnight mail (other than U.S. Postal Service Express Mail, and Priority Mail, must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

• *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: (202) 418-0530 or TTY (202) 418-0432.

FOR FURTHER INFORMATION CONTACT: CORES Helpdesk at (877) 480-3201, option 4 or ARINQUIRIES@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking, MD Docket No. 08-65, FCC 08-182 adopted on August 1, 2008 and released on August 8, 2008. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554. The full text may also be downloaded at <http://www.fcc.gov>.

Pursuant to sections 1.1206(b), 1.1202 and 1.1203 of the Commission's rules, CFR 1.1206(b), 1.1202, 1.1203, this is as a "permit-but-disclose" proceeding. *Ex parte* presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, *ex parte* or otherwise, are generally prohibited. Persons making oral *ex parte* presentations are reminded that a memorandum summarizing a presentation must contain a summary of the substance of the presentation and not merely a listing of the subjects discussed. More than a one- or two-sentence description of the views and arguments presented is generally required.¹ Additional rules pertaining to oral and written presentations are set forth in section 1.1206(b).

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before the dates

indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System ("ECFS"), (2) the Federal Government's eRulemaking Portal, or (3) procedures for filing paper copies. See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998), 13 FCC Rcd 11322 (1998).

• *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://www.fcc.gov/cgb/ecfs> or the Federal eRulemaking Portal: <http://www.regulations.gov>. Filers should follow the instructions provided on the Web site for submitting comments. For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to ecfs@fcc.gov, and include the following words in the body of the message, "get form." A sample form and directions will be sent in response.

• *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

¹ See 47 CFR 1.1206(b)(2).