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. [FR Doc. E8–19753 Filed 8–25–08; 8:45 am]

BILLING CODE 6560–50–P

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.

Electronic Access

This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web (the Superintendent of Documents’ home page address is http://www.gpoaccess.gov/), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required).

FOR FURTHER INFORMATION CONTACT:

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 employment, promotion, termination of employment, or the extension of staff or other privileges to health care personnel in employment, promotion, termination of employment, or the extension of staff or other privileges because he refused to perform or assist 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, 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 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 postgraduate 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.


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.

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
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 Department for the purposes of this proposed regulation.

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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 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–7(b)(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 Department, the Department proposes 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 conscientious workers within the workplace and, thus, to comply with the Church Amendment and these regulations.
Amendments, PHS Act

required to comply with the Church

recipients of Department funds are

to records set forth in 45 CFR 74.53.

are expected to comply with

collecting the certification. Recipients

are maintained by the recipient, this

become subject to the written

funds for maintenance.

other recipients of Department funds

will be considered for ensuring the compliance of their

sub-recipients as part of ensuring that

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 as 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 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 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 whether the combination of

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; 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

<table>
<thead>
<tr>
<th>Health care entity</th>
<th>Number of entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals (less than 100 beds)</td>
<td>2,403</td>
</tr>
<tr>
<td>Hospitals (100–200 beds)</td>
<td>1,129</td>
</tr>
<tr>
<td>Hospitals (200–500 beds)</td>
<td>1,160</td>
</tr>
<tr>
<td>Hospitals (more than 500 beds)</td>
<td>244</td>
</tr>
<tr>
<td>Nursing Homes (less than 50 beds)</td>
<td>2,388</td>
</tr>
<tr>
<td>Nursing Homes (50–99 beds)</td>
<td>5,819</td>
</tr>
<tr>
<td>Nursing Homes (99–199 beds)</td>
<td>6,877</td>
</tr>
<tr>
<td>Nursing Homes (more than 200 beds)</td>
<td>1,037</td>
</tr>
<tr>
<td>Physicians Offices</td>
<td>234,200</td>
</tr>
<tr>
<td>Offices of Other Health Care Practitioners</td>
<td>115,378</td>
</tr>
<tr>
<td>Outpatient Care Centers</td>
<td>26,901</td>
</tr>
<tr>
<td>Medical and Diagnostic Laboratories</td>
<td>11,856</td>
</tr>
<tr>
<td>Home Health Care Services</td>
<td>20,184</td>
</tr>
<tr>
<td>Pharmacies (chain and independent)</td>
<td>58,109</td>
</tr>
<tr>
<td>Dental Schools</td>
<td>56</td>
</tr>
<tr>
<td>Medical Schools (Allopathic)</td>
<td>125</td>
</tr>
<tr>
<td>Medical Schools (Osteopathic)</td>
<td>20</td>
</tr>
<tr>
<td>Nursing Schools (Licensed practical)</td>
<td>1,138</td>
</tr>
<tr>
<td>Nursing Schools (Baccalaureate)</td>
<td>550</td>
</tr>
<tr>
<td>Nursing Schools (Associate degree)</td>
<td>885</td>
</tr>
<tr>
<td>Nursing Schools (Diploma)</td>
<td>78</td>
</tr>
<tr>
<td>Occupational Therapy Schools</td>
<td>142</td>
</tr>
<tr>
<td>Optometry Schools</td>
<td>17</td>
</tr>
<tr>
<td>Pharmacy Schools</td>
<td>92</td>
</tr>
<tr>
<td>Podiatry Schools</td>
<td>7</td>
</tr>
<tr>
<td>Public Health Schools</td>
<td>37</td>
</tr>
<tr>
<td>Residency Programs (accredited)</td>
<td>8,494</td>
</tr>
<tr>
<td>Health Insurance Carriers and 3rd-Party Administrators</td>
<td>4,578</td>
</tr>
<tr>
<td>Grant awards</td>
<td>76,088</td>
</tr>
<tr>
<td>Contractors</td>
<td>4,245</td>
</tr>
<tr>
<td>State and territorial governments</td>
<td>57</td>
</tr>
<tr>
<td>Total</td>
<td>584,294</td>
</tr>
</tbody>
</table>


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

3 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).

4 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).

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. [Such 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.}
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 × $0.5 × $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 entities × 1 hour × $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.

Papework 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.


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.
§88.3 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 for the proper purposes as provided in paragraph (e) of this section, any such entity shall also comply with §§88.4(a), (b)(1), and (d)(1).

§88.4 Requirements and prohibitions.

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

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

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

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

(iv) To refer for abortions;

(b) Subject any institutional or individual health care entity to discrimination for attending or having attended a post-graduate physician training program in 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;

(c) 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;

(d) Any State or local government that receives federal financial assistance is required to comply with §§88.4(a), (b)(1) 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) 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) 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 to discriminate on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortion, regardless of whether such standard applies shall not:

1. Make its facilities available for 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;

2. Such entity to:

(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;

(b) Any State or local government, any part of any State or local government, or any other public entity must comply with §§88.4(b)(2) and 88.5.

(c) Any entity that receives federal funds appropriated for the proper purposes as provided in paragraph (e) of this section, any such entity shall also comply with §§88.4(a), (b)(1), and (d)(1).

§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 that extends the term of such instrument or adds additional funds to it. 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 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 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 grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding 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 through which they receive Department funding. Entities that are already sub-recipients of the grant, cooperative agreement, contract, grant under a contract, memorandum of understanding or other funding instrument or contract that extends the term of such instrument or adds additional funds to it. Sub-recipients shall submit such certifications to the recipient through which they receive Department funds. (2) The certification. 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 instrument or contract that extends the term of such instrument or adds additional funds to it. Sub-recipients shall submit such certifications to the recipient through which they receive Department funding.
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.

• 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 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

1 See 47 CFR 1.1206(b)(2).