

EXHIBIT A

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DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the Secretary 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

Part VI

73 FR 78072

DATE: Friday, December 19, 2008

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing a final rule 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, Public Law 110-161, Div. G, § 508(d), *121 Stat. 1844, 2209*). This final rule defines certain key terms. In order to ensure that recipients of Department funds know about their legal obligations under these federal health care conscience protection laws, the Department is requiring written certification by certain recipients that they will comply with all three statutes, as applicable. Finally, this final rule assigns responsibility for complaint handling and investigation among the Department's Office for Civil Rights and Department program offices.

EFFECTIVE DATE: This rule is effective January 20, 2009.

FOR FURTHER INFORMATION CONTACT: For further information regarding this rule, 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. For information regarding how to file a complaint with the Office for Civil Rights, U.S. Department of Health and Human Services, contact: Vernell Lancaster, (202) 260-7180, Office for Civil Rights, Department of Health and Human Services, Room 533F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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Several provisions of federal law 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 statutory provision that prohibits the federal government 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 (and reenacted or incorporated into every appropriations act since the appropriations act for Fiscal Year 2005) 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. These statutes are collectively referred to as the "federal health care conscience protection statutes." This rule is intended to ensure that, in the delivery of health care and other health services, recipients of Department funds do not support coercive or discriminatory practices in violation of these laws.

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 perform 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." [*78073]

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. For the purposes of this protection, the statute defines "financial assistance" as including, "with respect to a government program," "governmental payments provided as reimbursement for carrying out health-related activities." 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 would be accredited, but for the reliance on an accrediting standard that, regardless of whether such standard provides exceptions or exemptions, 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 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 110-161, Div. G, § 508(d), *121 Stat. 1844, 2209*; Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, Public Law 110-329, Div. A, § 101, *122 Stat. 3574, 3575*. 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 Proposed Rule

On August 26, 2008 (*73 FR 50274*), the Office of the Secretary, Department of Health and Human Services, published a Notice of Proposed Rulemaking (proposed rule) entitled, "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices In Violation of Federal Law." The proposed rule set forth the purpose of the proposed rule, proposed definitions to clarify the meaning of statutory requirements, and proposed to require certain recipients and sub-recipients of Departmental funds to certify their compliance with the statutory requirements.

The Comment: period closed on September 25, 2008.

The Final Rule

As noted in the preamble to the proposed rule, the Department is concerned about the development of an environment in sectors of the health care field that is intolerant of individual objections to abortion or other individual religious beliefs or moral convictions. Such developments may discourage individuals from entering health care professions. Such developments also promote the mistaken belief 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. Such institutions may have traditions of issuing clear public guidance which informs the members of their workforces, including physicians having privileges at their institutions, of the parameters under which they should operate in accordance with the organization's overall mission and ethics. 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 and regions of the country.

The Department is committed to its mission of expanding patient access to necessary health care services.

Americans can enjoy healthier, happier, and more productive lives through access to, and appropriate utilization of, all of the life-saving and life-improving procedures and services produced by medical innovation. The Department has a long history of demonstrated success in facilitating the improvement of lives in this way.

A necessary element in ensuring the best possible care for patients is protecting the integrity of the doctor-patient relationship. Patients need full access to their health care provider's best judgment as informed by practice, knowledge, and experience. This [*78074] relationship requires open communication between both parties so patients can be confident that the care they seek and receive is endorsed by their health care provider. It is one of the reasons for the common practice of patients meeting with several health care providers in order to find the one in whom they are most confident about entrusting their care. This helps ensure patients receive the care they believe is appropriate, and that doctors provide care that they are comfortable providing.

The doctor-patient relationship requires a balancing of interests. The patient has an interest in obtaining legal health care services--and, in the context of federally funded health care programs, an eligible patient may have the right to obtain certain health care services from certain entities. This must be balanced against the statutory right of the provider in the context of a federally funded entity to not be discriminated against based on a refusal to participate in a service to which they have objections, such as abortion. As stated above, Congress recognized those provider rights in several statutes.

The Department seeks to ensure this balance through raising awareness of federal health care conscience protection 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. It also seeks to provide for Departmental enforcement of these three statutes.

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 health care conscience protection laws through the various Department mechanisms currently in existence, 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 health care field, and between providers and patients, fostering a more inclusive, tolerant environment in the health care industry than may currently exist.

The ability of patients to access health care services, including abortion and reproductive health services, is long-established and is not changed in this rule. Instead, this rule implements federal laws protecting health care workers and institutions from being compelled to participate in, or from being discriminated against for refusal to participate in, health services or research activities that may violate their consciences, including abortion and sterilization, by entities that receive certain funding from the Department. (It also implements the provisions of federal law which protect health care personnel from being discriminated against for their participation in any lawful health service or research activity, including abortion and sterilization, by entities that receive certain funding from the Department.) Delivery of health care services is significantly improved when patients and health care providers have full, open, and honest conversations about the services they request and provide. These conversations are particularly useful at the beginning of a patient-provider relationship. This rule should help generate greater transparency between patients and providers and foster open discussion, which should strengthen relationships between patients and providers, as well as those between entities and their employees.

This final rule sets out, and provides further definition of, the rights and responsibilities created by the federal health care provider conscience provisions. It clarifies the scope of protections to applicable members of the Department's workforce, as well as health care entities and members of the workforces of entities receiving Department funds. This final rule also requires certain recipients and sub-recipients of Department funds to certify compliance with

these federal requirements. In order to ensure proper enforcement, this final rule defines certain terms for the purposes of this final rule.

As was stated in the preamble to the proposed rule, the Office for Civil Rights (OCR) of the Department of Health and Human Services has been designated to receive complaints of discrimination and coercion based on the healthcare conscience protection statutes and this regulation. OCR 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 (*i.e.*, Department funding component). Enforcement of the requirements set forth in this regulation will be conducted by staff of the Department funding component through the usual and ordinary program mechanisms. Compliance with the requirements promulgated herein will 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 have undertaken activities that could lead to violation of, or may actually be in violation of, the requirements or prohibitions promulgated herein, the Department will work with such government or entity to assist such government or entity to comply or 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 health care conscience protection provisions under 45 CFR parts 74, 92, and 96, as applicable.

II. Comments on the Proposed Rule

On August 26, 2008 (73 FR 50274), Department of Health and Human Services published the proposed rule. The Department received a large volume of Comments on the proposed rule, both from Commenters supporting the proposed rule, as well as from those opposing the proposed rule. Comments came from a wide variety of individuals and organizations, including private citizens, individual and institutional health care providers, religious organizations, patient advocacy groups, professional organizations, universities and research institutions, consumer organizations, and State and federal agencies and representatives. Comments dealt with a range of issues surrounding the proposed rule, including the need for the rule; what kinds of workers would be protected by the proposed rule; what services are covered by the proposed rule; whether health care workers use the regulation to discriminate against patients; what significant implementation issues could be associated with the rule; legal arguments; and the cost impacts of the proposed rule. Many Comments from health care providers, members of the public, and others confirmed the need to promulgate this regulation to raise awareness of federal conscience protections and provide for their enforcement.

A summary of the substantive Comments, and the Department's Responses to those Comments, follows. [*78075]

A. Comments on Proposed New § 88.1--Purpose

No Comments were received pertaining to this section.

B. Comments on Proposed New § 88.2--Definitions

Assist in the Performance

Comment: Many Comments suggested that the proposed definition of "assist in the performance" was too broad. These Comments focused primarily on the inclusion of referral, training, and other arrangements within the ambit of this statutory term, claiming that this would allow an individual or institution to refuse to provide information or counseling about an objectionable procedure to which he or it objected. Commenters also expressed concern that the definition was too broad because, they asserted, a health care provider has an obligation to provide or assist patients with a referral or other information that allows the patient to receive health care services, regardless of the health care provider's conscientious objection.

Response: Commenters raising these concerns may lack understanding of the context in which the term "assist in the performance" is used in the statutes and in this regulation. The term is only used in the Church Amendments and in

the provisions of this regulation that implement those statutory provisions. As noted above (see section I), all provisions of the Church Amendment use the term "assist in the performance" to ensure that individuals are protected from being required to assist in the performance of certain health care services or research activities, and from being discriminated against on the basis that the individual (1) assisted in the performance of a legal health service or research activity, or (2) refused to assist in the performance of such a health service or research activity because it would be contrary to his religious beliefs or moral conviction. Given that context, in interpreting the term "assist in the performance," the Department has sought to provide broad protection for individuals, consistent with the plain language of the statutes. As a policy matter, the Department believes that limiting the definition of the statutory term "assist in the performance" only to those activities that constitute direct involvement with a procedure, health service, or research activity, falls short of implementing the protections Congress intended under federal law. However, we recognized the potential for abuse if the term was unlimited. Accordingly, we proposed--and here finalize--a definition of "assist in the performance" that is limited to "any activity with a reasonable connection to a procedure, health service or health service program, or research activity." We also finalize the limitation in the definition that required the individual involved to be "a part of the workforce of a Department-funded entity."

We wish to clarify here the scope of federal law respecting the protections afforded with respect to "assist[ing] in the performance" of a procedure, health service, or research activity. Whether the relevant provision of the Church Amendments uses the term "individual" (42 U.S.C. 300a-7(b)(1), (d)), "personnel" (42 U.S.C. 300a-7(b)(2)(B)), "any physician or other health care personnel" (42 U.S.C. 300a-7(c)(1)-(2)), or applicant [] for training or study" (42 U.S.C. 300a-7(e)), the term "assist in the performance" of a procedure, health service, or research activity applies to people. Thus, the protections of the Church Amendments with respect to "assist[ing] in the performance" of a procedure, health service, or research activity are afforded only with respect to people. To the extent such entities' or institutions' refusal to assist in the performance of such an activity would not be protected by PHS Act § 245, the Weldon Amendment, or the Church Amendments at section 300a-7(b)(2), such entities or institutions would have to arrange to provide any information or service otherwise required by law.

Individual and Workforce

Comment: Some Comments questioned whether the proposed definitions of the terms "individual" and "workforce" are too broad. Comments suggested that the definitions of these two terms would require a health care facility to apply the protections to all of its employees and contractors, no matter how removed their involvement is from the delivery of abortion or sterilization services. Other Comments expressed concern that the proposed definition of "workforce" would extend the conscience protections to volunteers and trainees. Commenters were also concerned that physicians, hospitals, and other health care institutions may find the definition burdensome in various areas of their operation (e.g., janitorial services, medical recordkeeping, security, reception services). Lastly, Comments asserted that the definition of "workforce" needs to be changed to provide a complete list of the types of individuals who fall within it.

Response: The Department believes that its proposed definition of "individual" is consistent with the statutory language and the intent of Congress as gleaned from an examination of the provisions in context. We had proposed to define "individual" as "a member of the workforce of an entity/health care entity."

As noted above, the term "individual" is used in two provisions of the Church Amendments: 42 U.S.C. 300a-7(b)(1) n1 and 42 U.S.C. 300a-7(d). n2 In other provisions of the Church Amendments, Congress chose to use more clearly limiting terms: "personnel" (42 U.S.C. 300a-7(b)(2)(B)), "any physician or other health care personnel" (42 U.S.C. 300a-7(c)(1)&(2)), or "applicant [] for training or study" (42 U.S.C. 300a-7(e)). In addition, those other provisions are explicitly limited to discrimination in the employment/privileging or education/training contexts, while 42 U.S.C. 300a-7(d) is not so limited: It 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 [HHS]" if doing so "would be contrary to his religious beliefs or moral convictions." Given this context, we believe that Congress did not intend that the term "individual" be limited to employees or health care personnel with privileges at a Department-funded entity, and that it is reasonable to include volunteers and trainees in

the definition of "workforce." These laws are intended to protect the conscience rights of all individuals participating in health care services, and research programs and activities receiving certain federal funds, or that are administered by the Department. The Department provides a definition of the term "workforce" to serve as a limiting criterion to ensure that individuals that are not under the control of an entity receiving Department funds do not claim the protection afforded by the statutes. We further note that, where the individual is assisting in the performance of a sterilization procedure or abortion (or [*78076] any other health service or research activity) in which the provisions of the Church Amendments are relevant, the definition of "assist in the performance" further limits the protection to "any activity with a reasonable connection to a procedure, health service or health program, or research activity * * *." Thus, we disagree with the Comment that the definitions would require a health care facility to apply protections to all of its employees and contractors no matter how far removed from the performance of sterilization procedures or abortion. The Department acknowledges that these definitions would include volunteers and trainees. It is clear that the statutes specifically envision that these protections apply to training programs, students, and applicants for training or study in the health professions. Regarding the Comment that physicians, hospitals or other providers may find it difficult or burdensome to comply with this requirement, the Department points to the fact that these requirements are not new, but are rather existing conditions on certain federal funds that recipients should be following already.

n1 42 U.S.C. 300a-7(b)(1) provides that the "[t]he receipt of any grant, contract, loan, or loan guarantee under [certain statutes implemented by HHS] * * * by any individual * * * does not authorize any court or any public official or other public authority to require" 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.

n2 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 [HHS]" if doing so "would be contrary to his religious beliefs or moral convictions."

The Department agrees with the Comment that the term "workforce" should provide a complete identification of covered individuals, and will therefore replace the word "includes" with the word "means", to provide a clearer and more definitive definition.

As indicated in the proposed rule--and consistent with the scope of the Church Amendments, which include physicians and other health care providers that have privileges with an entity receiving funding from the Department--we intended the concept of "workforce" to include physicians and other health care providers who have privileges at the entity funded by the Department. After publication of the proposed rule, it came to the Department's attention that the language of the "workforce" definition may not be clear on this issue. Accordingly, to ensure clarity on this point, we are revising the definition of "workforce" by adding at the end "or health care providers holding privileges with the entity." The definition now reads: "workforce" means employees, volunteers, trainees, contractors, 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, or health care providers holding privileges with the entity.

Health Care Entity/Entity

Comment: A number of Comments suggested that the definitions of "health care entity" and "entity" are too broad and go beyond those in the Public Health Service Act and the Weldon Amendment. They assert that the Department exceeded its rule-making authority when it applied the legal standard enunciated in the Weldon Amendment and Public Health Service Act to "health care entities" that are not encompassed by the definitions set forth in those statutes. Comments also requested that the Department clarify whether a health care entity includes pharmacists, nurses, occupational therapists, public-health workers, janitors working for health care entities, and technicians, as well as psychiatrists, psychologists, counselors, and other mental health workers, while others suggested that pharmacists should not be included. Lastly, one Commenter expressed concern that the proposed rule did not specify what amount of Departmental funding would place an entity under the purview of these regulations.

Response: The Department believes the definitions proposed in the proposed rule and adopted herein are appropriate and within its authority. In providing definitions of the term "health care entity" in their statutes, the Weldon Amendment and Public Health Services Act use the word "include." As a matter of statutory drafting and construction, the use of that word indicates that the list following it is not exhaustive. In seeking to issue this regulation, the Department thought it would be beneficial to provide a clear and consistent definition that it would apply when implementing any of the three statutes. In proposing the definition, the Department intended it to be appropriately broad, but did not attempt to specifically list every possible entity or health profession classification, to avoid the situation that new health care professional classifications--or current health care professions inadvertently not listed--were not protected. As such, the Department used the terms "health care professional" and "health care personnel" to cover other professions such as pharmacists, nurses, occupational therapists, public-health workers, and technicians, as well as psychiatrists, psychologists, counselors, and other mental health workers. The Department rejects the suggestion that pharmacists or pharmacies be specifically excluded from the definition because that would seem inconsistent with both the text and the purpose of the statutes. Lastly, the Department is concerned that some Commenters may incorrectly believe that there is a minimum financial threshold below which entities may receive a certain amount of Departmental funds without being subject to the statutory provisions and these implementing regulations. As in other cases, such as Title VI of the Civil Rights Act of 1964, when an entity elects to receive any amount of federal funds, that entity agrees to follow all conditions and rules that apply to the use of those funds or upon which receipt of the funds is conditioned.

Health Service/Health Service Program

Comment: Several Comments declared that the definitions of "health service" and "health service program" inappropriately expand the scope of the conscience provisions to all medical treatments or services, biomedical and behavioral research, activities related to providing medicine, health care, or other services related to health or wellness (including programs such as Medicare and Medicaid). Some observed that the definitions include certain public health programs, such as vaccinations and family planning. Lastly, other Comments on these proposed definitions suggested that the definition of "health service program" be expanded to specifically include assisted suicide, transgender-related surgery and assisted reproductive technologies.

Response: Commenters' objections to this definition are fundamentally an objection to the Department's interpretation of the scope of the statutory protections themselves. We proposed to define "health service program" as including 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, which may include components of programs operated by State or local governments. There is nothing in the statute to suggest that the term "health service program" in 42 U.S.C. 300a-7(d) is to be read narrowly. Moreover, given the context of the provision in which it appears, while individuals and health care personnel are protected with respect to their participation in research activities, it would not be the result of a broad understanding of "health service," but because such individuals and healthcare personnel are engaged in performing or assisting in the performance of research activities funded under programs administered by the Department, which are subject to statutory protection. See 42 U.S.C. 300a-7(d). The definition and [*78077] the statutory protections apply to health services and research activities that are funded in whole or in part by the Department. For the Department to adopt a definition that removes protection from entire programs that are appropriately included in the definition, given the statutory context, would be inconsistent with our understanding of the purpose of the statutory provisions. The observation that some of these programs may involve important public health issues that may be controversial or objectionable to some is not a justification to eliminate the statutory protections. The Comment that seeks the inclusion of "assisted suicide" and other procedures in the definition of "health service program" is misinformed. This definition does not set out a list or description of the types of procedures to which a protected individual may or may not object, but the types of programs under which such protection exists.

While the Department had proposed to define the term "health service," the Department has determined that the term is self-explanatory, and that a definition is not necessary, or may potentially confuse recipients. Accordingly, we

do not finalize a definition of the term.

Recipient/Sub-Recipient

Comment: Several Comments expressed concern over extending the applicability of the proposed definitions of "recipient" and "sub-recipient" to foreign non-governmental organizations or international organizations (such as agencies of the United Nations) without reference to existing federal law governing U.S. foreign policy. These Comments claimed that it could create confusion among federal agencies about which laws to follow and could lead to unforeseen foreign policy complications. They added that it may also create confusion for entities that receive United States funding, but are located outside of the United States.

Response: The Department does not believe a conflict exists between these statutory requirements and U.S. foreign policy related to the use of federal funds abroad. To reduce any potential confusion among federal agencies, we proposed and here finalize a definitions of recipient and sub-recipient which permit the Department awarding agency to exercise discretion as to whether the terms include foreign or international organizations (such as agencies of the United Nations).

Other Definitions

Comment: Many Commenters asserted the term "abortion" should be defined in the regulation, some believing that, without such definition, the proposed rule does not provide sufficient information to direct health care providers to meet the obligations of the requirements. The main division among Commenters regarding the definition of abortion was whether certain contraceptive methods or services that have the potential to terminate a fertilized egg after conception but before implantation are considered abortion under the proposed rule. Several Commenters claimed that the proposed rule would seriously jeopardize Title X programs and Medicaid services if "abortion" is not clearly defined to exclude contraceptive services.

Response: After the full consideration of Comments on this issue, the Department declines to add a definition of abortion to the rule. As indicated by the Comments, such questions over the nature of abortion and the ending of a life are highly controversial and strongly debated. The Department believes it can enforce the federal health care conscience protection laws without an abortion definition just as the Department has enforced Hyde Amendment, Consolidated Appropriations Act, 2008, Public Law 110-161, Div. G, §§ 507, 508(a)-(c), *121 Stat. 1844, 2208* (Dec. 26, 2007), abortion funding restrictions without a formal definition. Additionally, nothing in this rule alters the obligation of federal Title X programs to deliver contraceptive services to clients in need as authorized by law and regulation.

Comment: Comments requested that the Department define many other terms or phrases that are used in the regulation. Some Comments suggested that the Department adopt a narrow definition of the term "discrimination" and make clear that the reassignment of an employee who states a religious or moral objection to a certain activity (such as abortion) does not constitute discrimination.

Response: The Department believes that these terms are sufficiently clear, and do not need further definition. The Department does not believe that a definition of the statutory term "discrimination" is necessary. The term "discrimination" is widely understood, and significant federal case law exists to aid entities in knowing what types of actions do or do not constitute unlawful discrimination. The Department expressly rejects the suggestion that the reassignment of an employee who states a religious or moral objection to a certain activity (such as abortion) may not constitute discrimination in all cases. Like most discrimination cases, the outcomes are dependent on the facts. It seems likely that there are situations where the reassignment of an employee for the refusal to perform a specific procedure could constitute unlawful discrimination. Likewise, the Department recognizes that circumstances exist where the reassignment of such an employee would not constitute unlawful discrimination. We encourage employers subject to the rule to have discussions with their employees that lead to mutually agreeable resolutions.

Comment: Some Comments asked that the Department define the terms "religious belief" and "moral conviction" to ensure that they would not be interpreted broadly.

Response: The Department declines to adopt particular definitions of these terms because the common definitions are plainly understood, and the Department intends that common sense interpretations apply. A well-defined body of federal law exists in this general topic, and the U.S. Supreme Court has repeatedly clarified that these terms are to be read broadly.

C. Comments: on Proposed New § 88.3--Applicability

No Comments were received specifically pertaining to this section.

D. Comments on Proposed New § 88.4--Requirements and Prohibitions

No Comments were received specifically pertaining to this section.

E. Comments on Proposed New § 88.5--Written Certification of Compliance

Comment: Several Comments stated that the requirement for written certification in proposed section 88.5 would be duplicative or unnecessary because current regulations already require written certification of compliance with federal nondiscrimination and civil rights laws. Other Comments suggested that the certifications be modified in order to avoid confusion on the part of recipients and sub-recipients.

Response: We find that a specific written certification is necessary to protect institutions under these laws. Many recipients (and sub-recipients) of Department funds currently must certify compliance with certain listed federal nondiscrimination laws, yet federal health care conscience protection laws are separate laws not specifically mentioned in existing forms. As part of a broad effort to raise awareness in the public, in the health care community, among recipients of Department funds, and among protected individuals and institutions, of their rights and responsibilities under existing federal [*78078] health care conscience protection laws, as well as to facilitate enforcement of these laws, the regulation requires certain recipients and sub-recipients of Department funds to certify their compliance in writing. Wherever possible, Department programs will attempt to integrate certifications required under this regulation into existing forms.

The Department has modified the certifications in section 88.5. They have been made clear so that recipients and sub-recipients know, by means of the certifications themselves, with which provisions they must comply based on the type of entity the recipient is or the type of funding mechanism through which they receive funds.

Comment: Comments asserted that the Department is overstepping its authority by making compliance with the federal health care conscience protection statutes a condition of payment, stating Congress has not made compliance a condition of payment and would have said so if that were its intent.

Response: The Department disagrees that the proposed rule exceeds its authority. It is important to emphasize that the Department and recipients of Department funds, including State and local governments, are obligated to comply with the health care protection conscience laws that have been in effect for many years, which prohibit federal funds from being used in a discriminatory or coercive manner against institutional and individual health care entities and workers for their participation or refusal to participate in abortions, other certain medical procedures, health services, or research activities that they find objectionable on religious or moral grounds. By employing existing regulatory enforcement measures to ensure compliance with such statutory requirements under 45 CFR parts 74, 92, and 96, as well as other measures, the Department does not exceed its authority, but rather is carrying out its obligation to enforce existing laws.

*F. Comments Received in Response: Specific Requests for Comments in the Proposed Rule***Current Awareness of and Compliance With Provider Conscience Protections**

Comment: This regulation implements existing federal health care conscience protection laws contained in the Church Amendments, the Public Health Service Act § 245 and the Weldon Amendment. Several Comments objected to the regulation on the grounds that these laws were sufficient in themselves and that their implementation by regulation was unnecessary or redundant. Generally, these Comments suggested that the health care field is sufficiently aware of the statutory protections available for provider conscience, and that no further regulatory effort was required in order to provide awareness of these laws or to assure compliance with them. Several other Comments, however, reported widespread lack of knowledge regarding these laws and inconsistent application of them. These Comments generally supported the regulation as a necessary and useful mechanism to support statutory protection. In addition, numerous Comments reported what they believed to be individual instances of violation of conscience, including health care providers suffering loss of employment, adverse actions during medical training, and discrimination in residency placement, among other consequences, due to their assertion of their conscience rights. Some Commenters also reported pressure to perform certain procedures from State authorities, professional organizations, or employers that appeared to the Commenters to be inconsistent with federal conscience protections.

Response: The Comments received in Response to the proposed rule support the Department position that the regulation is necessary to implement the statutes. While many people in the health care field may have general knowledge that conscience protections exist for providers, the scope of these protections is not always widely understood. Because Congress has enacted several different protections, an individual or organization may be aware that, for instance, a physician may not be compelled to perform abortions, but may not be aware of other aspects of the statutes providing conscience protection. Others may become aware of these laws, at least in detail, only when a dispute arises and a provider or entity attempts to assert their conscience rights; there may be subsequent disagreement over the nature of the rights asserted. The Department believes that coordinating the several related statutory protections, by incorporating their various requirements into this regulation, will allow for greater clarity and awareness of these protections within the health care field, in conjunction with other public education efforts connected with this regulation. In addition, the issuance of a regulation will allow for greater ease of administration, provide a Departmental point of contact for complaints regarding violations of the statutes and this regulation, and provide a uniform mechanism for investigating complaints of noncompliance. The types of noncompliance reported by Commenters are expected to be reduced as a result of this regulation.

Methods To Address Compliance Problems and Increase Awareness

Comment: Commenters who supported and opposed the rule both noted that the Department must increase awareness of health care provider conscientious objection rights, and the obligations this rule may pose for employers, entities, and States. Some Commenters also responded to the Department's request for Comments on methods which may be used by the Department and others to increase awareness among health care providers of their rights under laws protecting providers from discrimination for exercising their conscience rights.

Commenters who opposed the rule suggested that, as an alternative to further federal regulation, the Department should prepare and distribute informational materials to individual and institutional health care providers and State and local governments, and make these materials available on the HHS Web site. A Commenter also proposed that the Department develop continuing education courses for health care practitioners and attorneys, and that existing certifications that recipients of Departmental funds must currently sign could be modified to achieve the objectives of the rule.

Response: The Department agrees that the suggestions offered by Commenters of mechanisms for improving awareness of conscience rights among health care providers would increase the effectiveness of the rule. However, the rule seeks to achieve not only greater awareness of provider conscience rights, but also a more consistent understanding

of the scope of these rights (and the corresponding obligations), greater ease of administration, provision of a Departmental point of contact for complaints regarding violations of the statutes and this regulation, a uniform mechanism for investigating complaints of noncompliance, and, as a result, greater compliance with the laws protecting these rights.

Comment: Commenters who supported the rule also offered suggestions on how both the Department and covered entities could increase awareness of the legal protections for health care provider conscience. Among the suggested activities were posting notices in high-traffic areas of buildings receiving [*78079] Department funds, providing information within educational programs that receive Department funds, including information in applications for training, applications for residency programs, and private insurance plans benefit descriptions, posting information on the Department or provider Web sites, including of information in employee handbooks, and sending e-mail or postal communications directly to providers. Comments were made on how to best attract attention to such postings by making them distinct from other materials in which they might be included.

Response: The Department agrees that these suggestions would contribute to significantly greater public awareness of health care provider conscience protections. The Department encourages covered entities to undertake such public awareness activities. The Department also recognizes that it must undertake reasonable outreach efforts in order for the rule to be effective at increasing awareness of, and compliance with, provider conscience protections in the statutes and this implementing regulation. Thus, the Department will consider all avenues available for increasing public awareness of health care conscience protection laws. Requiring certification of compliance by entities receiving Department funds provides an important vehicle for increasing awareness of health care conscience protection laws and ensuring compliance with them.

Comment: Some Comments declared that the description of notice/posting of health care provider conscience protections in the proposed rule should be enhanced. One argued that posting of notices on bulletin boards, where they appear among multiple notices, is not a very effective way of communicating the protections afforded under the regulation and statutes. Other Comments requested that notices of federal health care conscience protection statutes should be conspicuous and posted in such locations as provider offices and pharmacies and in such public communications as advertising, health plan promotion materials, Medicaid literature, Web sites, as well as applications for training, residency, and educational programs, and in employee/volunteer handbooks.

Response: The Department agrees that informing health care entities of their rights and responsibilities under federal health care provider conscience provisions is important to ensuring institutional and individual conscience rights are protected. Consequently, the Department encourages covered entities to undertake such educational/public awareness activities. Within its statutory authorities, the Department is exploring a number of options, including many of those suggested by Comments as well as others, to provide further public education and notice of federal health care conscience protection laws and this regulation.

Exceptions to the Written Certification Requirement in Proposed New § 88.5

Comment: Several Comments expressed concern that the certification requirement would create an administrative burden, and one Commenter suggested that the Department should not impose the certification requirements of the regulation on every Department grantee regardless of the grant's purpose.

Response: In its Notice of Proposed Rule Making, the Department solicited Comments on whether further exceptions should be made from certification requirements for recipients or sub-recipients of federal funds, where such recipients or sub-recipients receive Department funds for purposes unrelated to the provision of health care or medical research. Because there is concern among Commenters over any burden of a certification, including that stemming from certifications required without regard to a grant's purpose, and because there appears to be little objection to limiting the certification requirement in the way put forth for Comments in the proposed rule, the Department has determined to make further exceptions to the certification requirement for Departmental programs whose purpose is unrelated to

health care provision, including certain programs currently administered by the Administration for Children and Families and the Administration on Aging. These programs often involve the provision of grants to States and other governments, or cash assistance or vouchers rather than direct services, and they are not likely to involve medical research, the participation of health care providers, or referral to health care providers. These programs are unlikely to encounter the circumstances contemplated by this regulation, and therefore the assurance of compliance represented by a certification is not considered necessary by the Department for such programs. The regulatory text has been changed by addition of sections 88.5(e)(4) and (e)(5), together with associated language and example programs in the preamble. Finally, in section 88.5(e)(6), we provide an exception from the written certification requirement for Indian tribes and tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act. Of course, these entities must still comply with the relevant statutes, even if they are not under an obligation to make a certification.

Should Language Specify Written Certification Is a Material Prerequisite to Payment of Department Funds

Comment: The Department requested Comments 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 received a number of Comments in Response to this request, both in favor of and against including such language in the written certification of compliance. Those in favor of including material prerequisite language felt that such language was important as part of the written certification process to protect individuals and institutions from discriminatory treatment. Others stated that certification should not be a prerequisite for Department funding, noting that explicitly tying payment to compliance with the certification requirement would subject the certification process to the federal False Claims Act. One Commenter stated that, absent more explicit guidance on the policies and practices that will satisfy compliance, written certification should not be a material prerequisite to payment of Department funds.

Response: The Department does not consider the written certification of compliance to be a material prerequisite to the payment of Department funds any more than in any other similarly worded statute or regulation. As stated above, the Department intends to work with recipients and sub-recipients of Department funds to ensure compliance with the requirements or prohibitions promulgated in this regulation, and, if such assistance fails to achieve compliance, the Department will consider all legal options, including termination of funding and return of funds paid out in violation of health care conscience protection provisions under 45 CFR parts 74, 92, and 96, as applicable.

G. General Comments

Comment: Many Comments stated concern that the proposed regulation could serve as a pretext for health care workers to claim religious beliefs or moral objections under the protections [*78080] of the fourth provision of the Church Amendments, 42 U.S.C. 300a-7(d), in order to discriminate against certain classes of patients, including illegal immigrants, drug and alcohol users, patients with disabilities or patients with HIV, or on the basis of race or sexual preference.

Response: Comments offered a number of hypothetical situations where individual health care workers might attempt to discriminate against individuals on a variety of grounds, using provider conscience as a pretext, and have suggested that the proposed regulation would permit such activity. Many of the described hypothetical situations are vague or lack substantial detail, but to the extent that the Comments suggest that the regulation permits unlawful discrimination, we disagree. It is important to emphasize that the health care provider conscience protection provisions have existed in law for many years, and that this regulation only implements these existing requirements. As a result, there is nothing in this regulation that newly permits the types of actions described in Comments. It is also important to emphasize that the health care conscience protection laws exist as one part of a number of federal laws that address discrimination on a variety of grounds, and that the actions described in the hypothetical situations that violate federal civil rights laws, continue to violate federal civil rights laws.

We do not believe there is a conflict between the operation of health care conscience protection laws and other federal laws. Congress has enacted a network of laws that govern different activities, and we believe proper meaning can be given to all of them. There are several federal civil rights laws intended to protect individuals from discrimination in programs receiving federal financial assistance or in public accommodations based on their individual characteristics (e.g., race, color, national origin, disability, age, sex and religion). In the former, the individuals protected by these laws typically are beneficiaries of, or applicants for, services and activities provided through federally funded programs. The health care conscience protection laws have a different purpose, protecting individual health care workers and entities from discrimination in connection with particular practices such as abortion, or from compulsion to perform health care activities that they find religiously or morally objectionable. As such, these two sets of laws are intended to protect different populations and on different grounds. On their face, there is no inherent inconsistency or conflict between these laws.

How various federal laws would apply to any particular situation depends largely on the facts of the situation. Thus, it is inappropriate to make definitive statements about legal outcomes in Response to the many scenarios raised in Comments. Entities subject to these laws are responsible for ensuring against illegal discrimination in providing health care services to the public, while also protecting the conscience rights of the health care workers who are affiliated with these entities. Because these laws do not on their face conflict, we believe it is possible in most situations for entities to act without violating any applicable federal laws. In many cases, for example, entities may accommodate health care worker conscience rights--while ensuring that all eligible patients are served, including members of federally protected classes--by managing the workforce to ensure sufficient coverage.

Many of the scenarios raised in Comments involved health care workers hypothetically discriminating against particular individuals on legally impermissible grounds (e.g., race or disability). To the extent these scenarios implied that the health care conscience protection laws protect workers who object to providing services based on an individual's federally protected characteristics, we disagree. We believe such actions are outside of the scope of the health care provider conscience protections. Those laws protect health care workers' conscience rights with respect to particular actions or activities, not with respect to an individual's characteristics that are protected by federal law. To the extent there are actual conflicts between any of the health care conscience protection laws and federal civil rights laws, an entity would be required to comply with federal civil rights requirements.

Where the federal health care conscience protection laws and the civil rights laws are both conditioned on the receipt of federal funding, application of rules of statutory construction require continued compliance with federal civil rights laws. The health care conscience protection laws would not be interpreted to impliedly repeal federal civil rights requirements. Moreover, given the strong national policies embodied in federal civil rights laws that protect individuals from unlawful discrimination based on their federally protected individual characteristics, and that ensure that federally supported programs are available to all without discrimination, we believe that federal civil rights protections prevail.

Comment: A number of Comments argued that the proposed regulation would limit patient access to basic reproductive health care services, including contraceptive services. Many Comments also asserted that the proposed regulation would disproportionately affect certain sub-populations, including low-income patients, minorities, the uninsured, patients in rural areas, the Medicaid population, or other medically underserved populations. Some Comments further warned of health consequences, such as an increase in unintended pregnancy, should the proposed rule be promulgated. Finally, several Comments expressed concern that the proposed rule would limit access to emergency procedures, such as emergency contraception for rape victims, surgery for ectopic pregnancies, and other services.

Response: The Department recognizes that access to health care services is a challenge facing the entire health care system, and that it is not a challenge restricted to the context of reproductive health services. In recent years, the Department has proposed or implemented several important initiatives aimed at increasing access to quality health care, including by providing health care services for the poor, elderly and disabled; increasing access to quality medical care through expansion of the federal Community Health Center program; proposing to support and encourage States' efforts

to work with the private marketplace to help ensure affordable health insurance; and supporting the enactment of proven medical liability reforms that increase patient access to quality medical care. The Department supports continuing such efforts into the future in addressing barriers to affordable, quality health care.

We disagree that this regulation would create new limitations on health care access, including basic reproductive health care services, services provided by publicly funded clinics, and health care services provided in emergency situations. First, this regulation does not expand the scope of existing federal laws, some of which have been in place for many years, protecting health care entities from discrimination on the basis of provider conscience with respect to abortion and certain other services to which a provider may have religious or moral objections. The Department has a duty to enforce these laws applying to recipients of Department funds. Even absent the issuance of this final rule, [*78081] recipients of Department funds are still required to comply with these laws; this regulation is intended to raise awareness of the laws among the public, protected health care entities, and recipients of Department funds, as well as to provide for enforcement of federal conscience protections.

Second, the current shortage of health care providers in certain areas of the country provides additional justification for protecting conscience rights. Many Comments we received, including those of many health care providers, stated that forcing providers to perform or participate in procedures that violate their consciences discourages individuals from entering or remaining in careers in the health professions. One Commenter wrote, "by insisting that those who are willing to violate their consciences in the delivery of health care are the only persons who should enter the health care field, one contributes to the creation of a health care delivery system of professionals who blindly follow directives rather than conscience, putting society at risk." Unlike some Commenters, we believe that problems of access to health care can be resolved without requiring health care providers to violate their conscience. By protecting conscience rights in accord with federal law, we wish to encourage more individuals and institutions to participate in Department-funded health service programs in accord with their consciences and, thereby, increase access to quality health care services.

Third, with regard to contraceptive services, the Department continues to support efforts to make safe and effective contraceptives and family planning services available to women--and men--who cannot otherwise afford them. This regulation will ensure that such programs are carried out in a way that is consistent with existing federal health care conscience protection laws. While Comments posed many hypothetical situations in which they claimed access to contraceptive services would be limited, we have found no evidence that issuing these regulations to better ensure compliance with existing federal health care conscience protection laws will create additional barriers to accessing contraceptive services.

Fourth, we note that many Commenters who believed that this rule will significantly restrict access to contraceptives or increase teen pregnancies also submitted Comments stating that the rule was unnecessary because health care provider conscience protection laws are being followed and no provider rights are currently being violated. These two statements are contradictory. If access to any service significantly declined with the implementation of this rule and all other factors remained unchanged, that fact could be evidence that health care providers in question had previously been compelled to deliver the service over their conscience objections.

Comment: Comments argued that any revised rule should include guidance discussing ways to balance the rights of providers and patients, and one Commenter stated that any final rule should contain "a forceful statement of patients' rights to receive health care services in accordance with their religious beliefs or conscience." The Commenter also argued that any certification should require health care entities to certify that the rights of patients are respected to the extent required by law.

Response: Patients' ability to access health care services, including abortion and reproductive health services, is long-established and is not changed in this rule. In issuing regulations implementing federal laws protecting health care entities' conscience rights, we recognize that many current or prospective recipients of Department funds must already certify or assure their compliance with certain federal nondiscrimination laws as a part of existing funding applications. We also encourage all participants in the health care system, including patients, health care providers, and those entities

receiving Department funds, to review existing laws, regulations, and guidance, including the U.S. Constitution and federal laws enacted by Congress prohibiting discrimination by health care entities receiving certain federal funds. (For more information on these issues, visit the Web site of the Office for Civil Rights of the Department of Health and Human Services at <http://www.hhs.gov/ocr>.) We also encourage full and open communication between patients and providers on sensitive issues surrounding the provision of health care services, including issues of morality and conscience. Patients are best served when their providers communicate clearly and early about any services they decline to provide or participate in. We similarly encourage full and open communication between providers and their employers or the entities with which they have privileges on issues concerning the services the provider may be unwilling to perform. This would facilitate the appropriate accommodation of a provider's religious or moral objections to particular services, while at the same time enabling the employer/institution to meet the needs of its patients.

The Department seeks to strike a careful balance between the health care provider conscience protections provided in federal law, on the one hand, and patients' needs and the needs of the health care system on the other hand. A health care system that is intolerant of individual conscience, certain religious beliefs, ethnic and cultural traditions, or moral convictions serves to discourage individuals with diverse backgrounds and perspectives from entering the health care professions, further exacerbating health care access shortages and reducing quality of care. It is more likely to lead to situations in which a patient is receiving services or procedures from a provider who is not fully committed to the choice of care. We seek a health care field in which patients can be more confident that their provider shares their views and concerns as identified through mutually open communication. The final regulation takes a cautioned and balanced approach to ensure compliance with federal health care conscience protection laws by defining key terms, stating requirements and prohibitions, and requiring certain recipients and sub-recipients of Department funds to provide written certification of compliance. In so doing, we wish to promote diversity in the health professions, increasing access to health care services.

Comment: Some Comments expressed concern that the proposed rule could restrict access to contraceptives which are being used for purposes other than preventing pregnancy or are being used in conjunction with other medical treatments.

Response: According to 42 U.S.C. 300a-7(d), which applies to any program funded in whole or in part under a program administered by the Department, no protected individual may be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or part under a program implemented by HHS contrary to that individual's religious beliefs or moral convictions; the motivation of the patient or intended use of the service is irrelevant under the statute. We note that nothing in this rule changes the obligations of the federal Title X program or Medicaid to deliver contraceptives to eligible patients in need. However, we reiterate that we have found no evidence that these regulations will create new barriers in accessing contraception unless those contraceptives are currently delivered over the religious or moral objections of [*78082] the provider in such programs or research activities.

Comment: Some Comments requested the creation of a hotline to report patient access to care problems.

Response: Again, we do not anticipate a reduction in access to legal health services as a result of this regulation, much less a significant enough change to warrant the creation of a hotline. As a result, we decline to create a specific hotline solely to report patient access to care problems as part of this regulation. However, we encourage members of the public to visit <http://www.hhs.gov/about/referlst.html> for a list of available hotlines and information resources regarding Department programs and activities.

Comment: Comments asserted that the proposed rule, if finalized, would disrupt the ethical and legal requirements of providers to obtain informed consent from their patients. Commenters argued that principles of informed consent require health care providers to inform patients about all treatment options or reasonable alternatives, including those to which they object or refuse to perform because it would violate their consciences.

Response: We recognize that informed consent is crucial to the provision of quality health care services. This final rule raises awareness and provides for the enforcement of federal laws, some of which have been in effect for many years, protecting the conscience rights of health care entities. We are aware that nearly all States have laws protecting health care practitioners' rights of conscience to some degree or another, many providing full exemptions to any health care practitioner who conscientiously refuses to participate in an abortion. Over the last four decades, medical professional associations, such as the American Medical Association (AMA), have reaffirmed the rights of physicians and other health care personnel to practice medicine without violating their moral principles.ⁿ³ Despite the widespread and sustained existence of federal and State laws protecting the consciences of health care providers, we have found no evidence that protecting conscience rights disrupts the informed consent process between providers and patients. Rather, we believe the provider-patient relationship is best served by open communication of conscience issues surrounding the provision of health care services, including any conscientious objections providers or patients may have to providing, assisting, participating in, or receiving certain services or procedures.

ⁿ³ See, e.g., AMA House of Delegates Policy H-5.995 (issued 1973; reaffirmed 1986, 1996, 1997, and 2000).

To avoid potential conflicts from occurring, we emphasize the importance of and strongly encourage early, open, and respectful communication between providers and patients surrounding sensitive issues of health care, including issues of conscience, so that both parties' consciences are respected as patients are provided with necessary information to make informed decisions about their health care and choice of provider. We disagree that health care providers' consciences must be violated in order to meet requirements of informed consent in the provision of medical services.

Comment: Several Comments asserted that the proposed regulation could negatively impact and potentially hinder scientific research, arguing that hospital, academic, nonprofit, and corporate research activities that receive Department funds could have difficulty fulfilling their research contracts if workers were allowed to refuse participation. Offering several research activities as examples, Comments argued that Department-funded research institutions could be compromised because of personnel objections to conducting or supporting the research conducted there. Other Comments argued that health care quality and safety will be compromised by the proposed regulation because of the refusal of staff to do their jobs. Similarly, some Comments expressed concern that the regulation will adversely impact the academic rigor of medical education. They argued that professors at publicly funded medical schools could refuse to teach medical procedures or information they find morally objectionable, which would reduce the quality and breadth of medical education.

Response: The Department does not find evidence supporting the Comments' assertions. In enacting federal health care conscience protection laws, including the Church Amendments, PHS Act § 245, and the Weldon Amendment, Congress has clearly stated a policy that Department funding should not support coercive or discriminatory practices that violate individual conscience. The Church Amendments contain specific provisions relating to scientific research, while both the Church Amendments and PHS Act § 245 contain provisions applying to physician training and other training programs in the health professions regarding abortion and sterilization. Some provisions of the Church Amendments, for instance, which specifically mention scientific research (42 U.S.C. 300a-7(c)(2), "biomedical or behavioral research," "research activity"; 42 U.S.C. 300a-7(d), "research activity") and discrimination against applicants for training or study (42 U.S.C. 300a-1(e)), have been in effect for over three decades. PHS Act § 245 has been in effect since the mid-1990s. The Department is unaware of evidence showing a negative impact of federal conscience provisions on Department-funded scientific research, health services programs, training, or instruction in the health professions; nor have Comments provided evidence supporting the claim that regulations implementing existing federal conscience protections and requirements would hinder such activities. We also disagree with the Commenters' assertions to the extent that Commenters suggest that institutions must require health care providers to violate their consciences in order to conduct health services, training, or research activities.

Comment: Comments expressed concern that the proposed regulation will expand the ability of insurers to refuse to provide health care services, information, and referrals to patients. Other Comments expressed concern that the regulation could impact funding for programs that benefit immigrants or victims of domestic violence.

Response: As previously stated, this regulation does not expand the scope of existing federal conscience protections for health care entities, including health insurance plans. Rather, it provides for Departmental implementation and enforcement of existing federal health care conscience protection laws and educates the public and the health care community about laws protecting the consciences of health care entities that refuse to participate in abortions or other services in the case of Departmental grantees. We are unaware of any way in which the regulation could impact funding for programs that benefit immigrants or victims of domestic violence.

Comment: One Commenter thought the rule would increase spending and add a significant strain on Medicaid.

Response: We have not found evidence supporting the Commenter's assertion that the final rule would increase spending in Medicaid, in part because this final rule does not expand the scope of existing federal health care conscience protection laws, some of which have been in place for over thirty years.

Comment: Several Comments disagreed with the Department's assertion in the proposed rule that the [*78083] regulation will not have an impact on family well being. Another Commenter stated that the Treasury and General Government Appropriations Act of 1999 requires the Department to determine if the proposed rule would affect family well-being. The Commenter stated that, if family well-being is affected, the Department must provide an impact assessment of these effects. The Commenter also stated that the proposed rule does not adequately address the impact on family well-being.

Response: As stated in the proposed rule, the Department has determined that the final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Pub. L. 105-277, 112 Stat. 2681). This final rule defines certain key terms, ensures that recipients of Department funds know about their legal obligations under existing federal health care provider conscience protection provisions, and requires written certification by certain recipients that they will comply with such provisions, as applicable.

Comment: Some Comments asserted that the proposed regulation follows from general laws restricting religious discrimination, such as Title VII of the Civil Rights Act of 1964, or the religious exercise clause of the First Amendment to the United States Constitution. Commenters on this topic disagreed over whether this suggested connection made the regulation necessary to implement core constitutional principles, or unnecessary because these rights are protected in other ways. Commenters pointed out current grantees, for instance, already certify to obey all nondiscrimination laws, and that a specific certification on conscience protection, as contemplated in the proposed regulation, would not be necessary.

Response: The Department agrees with Comments noting that federal health care conscience protections are consistent with constitutional and other statutory protections of religious belief and moral conviction. However, Congress has enacted specific and detailed legislation in the area of health care provider conscience applicable to recipients of certain federal funds which is broader in scope than protections afforded under Title VII and the other examples cited by some Commenters. Because they implement health care-specific statutory provisions applicable to recipients of certain federal funds, these regulations offer more administrable and directive guidance than do other existing laws prohibiting religious discrimination. Many organizations and individuals may not be aware of the scope of the conscience protections or their relationship to other federal nondiscrimination laws when certifying compliance with the latter. The Department believes that the responsibilities of certifying entities will be made clearer by a certification that explains federal health care conscience protection laws explicitly.

Comment: A few Comments suggested that the Department should gather more evidence of noncompliance before regulating in this area, for example, by commissioning a national survey to determine the prevalence of civil rights violations of provider conscience, and that, in the absence of statistical evidence that a significant number of violations are occurring, refrain from issuing implementing regulations.

Response: The Department disagrees that such a survey is a necessary precondition to issuing this regulation. The basis for the regulation is the existence of the several federal health care conscience protection laws. There are a number of purposes served by regulating in this area, including, but not limited to, making the health care community more aware of these rights and clarifying their scope through the exercise of agency expertise, as well as assuring compliance. The Department has good reason to believe that there are risks of non-compliance. By their nature, civil rights protections create responsibilities for entities such as recipients of federal funds or employers to do things they otherwise may not do. It has been the Department's experience that, in the absence of a clear statement of responsibilities, civil rights are less effectively exercised. Commenters did not indicate what they believed would be an "acceptable" level of civil rights violations preventable by this regulation. The Department's goal is compliance with federal law. In Response to the proposed rule, numerous Comments were received, including from those in the health care community, that indicated serious misunderstandings regarding statutory health care provider conscience protections, or which expressed a narrower view of the scope of these protections than is consistent with the Department's interpretation. Especially in light of the additional Comments alleging violations of conscience protection, this Commentary reinforces the Department's view that, in the absence of a clear statement of responsibilities, there is a serious risk that, either from misunderstanding or from a groundless and overly narrow view of health care provider conscience rights, these conscience rights will not be fully protected. How often these violations occur is not known, and it is unclear whether a valid survey could be conducted to determine this figure. Some health care providers may not at this time be aware their rights are being violated when they are compelled to act against their conscience, or they may not attempt to report such violations. As a result of this regulation, a procedure will be put in place to receive and compile complaints, extend protection to those who make them, and the complaints will be reviewed for validity. Consequently, a more reliable estimate of the prevalence of actual violations is likely to be obtained, which will enable the Department to track the extent of noncompliance over time.

Comment: Several Comments were concerned about the absence of implementation guidance in the proposed rule for communication of a provider's individual conscience objections to entities and to patients. Commenters presented a variety of suggestions for additional guidance in the rule concerning communication of a health care provider with his or her employer and patients. Several Comments recommended a requirement that employees submit a written statement of their conscience objection or objections. Some Comments suggested a requirement for posting or providing notice of limitations to health care services provided at a facility or office. One Commenter pointed out that the State of Illinois requires pharmacies that do not carry emergency contraception to post a sign directing patients to other pharmacies that do.

Response: We strongly encourage early, open, and mutually respectful communication of conscience concerns that may arise in the provision of medical services, including between employees and employers as well as between providers and patients. However, we concluded that it was neither feasible nor prudent in this final rule to provide specific guidance on methods and means for such communication given the vast array of circumstances and settings in which communications regarding conscience are likely to take place.

Comment: Comments stated that the proposed rule did not clarify what safeguards health care facilities were required to have in place when a medical professional refused to provide a particular service. [*78084]

Response: In general, the Department acknowledges that not every institutional or individual health care provider offers every legal health service, and requiring them to do so would be neither appropriate nor prudent. At the same time, we encourage and expect health care facilities to take measures to protect conscience rights while ensuring access to health care services. The myriad number of circumstances occurring across different health care settings where the need to protect conscience rights may arise leads us to decline to prescribe particular measures in this final rule. Because federal health care conscience protection laws have been in place for many years, we fully expect health care entities to take the necessary steps to protect conscience rights while meeting the needs of their patients.

Comment: Another Commenter stated that the proposed rule does not address whether refusal to perform a service must be a consistent, across-the-board refusal, or whether it can be a "graded refusal." For example, the proposed rule

does not clarify if an employee can refuse to schedule sterilizations for young or single women but not for married women.

Response: We reiterate here that, for abortion-related activities as covered by the Weldon Amendment and Public Health Service Act § 245, a health care entity's refusal can be on any ground. (42 U.S.C. 300a-7(d), which applies to any program funded in whole or in part under a program administered by the Department, requires that no individual may be required to perform or assist in the performance of any part of a health service program or research activity contrary to that individual's religious beliefs or moral convictions. For involvement in abortion and sterilization as covered by the rest of 42 U.S.C. 300a-7, again, provisions require that no health care personnel be discriminated against for, among other reasons, his/her refusal to perform or assist in the performance of a sterilization procedure (or abortion) contrary to that professional's religious beliefs or moral convictions. Thus, in the case of these statutes, it is the individual's religious beliefs or moral convictions that will control in a particular case, rather than the frequency of the objection.

In addition, as we have previously noted, if the decision is being made based on an individual's characteristics that are federally protected, that is impermissible.

Comment: Comments argued that if a provider is unwilling to provide a certain service, it should give the patient a referral for that service. One Commenter asserted that providers should give patients a "meaningful referral that will ensure that the patients receive continuity of care without facing an undue burden, such as traveling long distances or encountering additional barriers to obtaining the desired services."

Response: Providers who object to participation in abortion or a particular health service may provide information on other options, if asked, but are under no obligation to do so. First, with respect to abortion, both PHS Act § 245 and the Weldon Amendment (among other things) specifically prohibit discrimination by the federal government and State and local governments, and federal agencies and programs, and State and local governments, respectively, against health care entities who refuse to refer for abortion. The Department could not enforce such a referral requirement without violating these provisions. With respect to entities imposing requirements on their employees or members of their workforces, the Church Amendments, while not identifying specific medical practices or services, uses very broad language to characterize the wide array of practices and services to be protected. For example, 42 U.S.C. 300a-7(d) states that individuals may not be required to perform or assist in the performance of "any part of" an objectionable health service program or research activity. For many health care providers, including many who Commented on the proposed rule, referral means assisting in the performance of objectionable procedures or services such as abortion and would violate their consciences. One health care practitioner Commenting on the proposed rule stated that referrals are a form of participation in objectionable acts, and forcing providers to provide referrals would effectively circumvent their moral objection. Federal law recognizes and protects the conscience rights of individuals and entities when it comes to referral for certain objectionable services. Taking the Church Amendments, the Weldon Amendment, and Public Health Service Act § 245 together, the regulation interprets these three federal laws in a way that is consistent with both the letter and the spirit of the law.

Comment: Some Comments argued that the proposed regulation seems to run counter to the Hippocratic Oath's admonition to "do no harm" to patients. Comments pointed out that health care providers must take this oath and agree to treat patients without judgment and provide patients with the care they need.

Response: According to the National Institutes of Health's National Library of Medicine (NLM), the Hippocratic Oath is an ancient medical text requiring new physicians to swear oaths by a number of deities to uphold several professional ethical imperatives, the most widely known of which is "to do no harm." Notably, the NLM translation of the Hippocratic Oath also includes the prohibitions, "I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan, and similarly I will not give a woman a pessary to cause an abortion." The NLM further states that most medical schools do not require graduates to take the Hippocratic Oath. For those physicians who take the Hippocratic Oath or other similar oaths, federal law protects health care providers whose consciences lead them to

recognize that participation in certain activities, such as abortion, harms others. Conscience is consistent with and is a necessary part of quality care.

Comment: Commenters expressed concern about impacts on health care delivery, burdens and costs (particularly on small employers), and overlap with existing protections afforded to protect religious conscience of healthcare workers under Title VII of the Civil Rights Act of 1964, and suggested that the Department adopt elements of Title VII jurisprudence in enforcing these laws. Commenters also stated that health care providers must be able to address staffing issues and otherwise appropriately screen job applicants to determine if they are capable and willing to perform the core services required of the job.

Response: We do not believe that it is necessary or appropriate to incorporate elements of Title VII jurisprudence into this provider conscience regulation. Title VII was enacted nine years before the first of the health care conscience protection laws was passed; it includes specific language with respect to reasonable accommodation and undue hardship with respect to religion. In contrast, the Church Amendment, the first of the health care conscience protection laws, is specific as to its prohibitions, and contains none of the reasonable accommodation or undue hardship language Congress elected to include in Title VII. This is also true of the additional health care conscience protection laws that Congress subsequently enacted. Notwithstanding the existence of Title VII, Congress passed a series of laws to explicitly protect provider conscience without using Title VII's formulation. Moreover, where Title VII is restricted to the [*78085] employment context, the provider conscience provisions are not so limited. As a result, we believe it is a reasonable interpretation of the statutes that Congress sought to ensure provider conscience protections that are distinct from, and extend beyond, those under Title VII. The Department's enforcement of the provider conscience laws will be informed, for example, by comparison to Title VII religious discrimination jurisprudence.

Congress enacted Title VII of the Civil Rights Act of 1964 to protect employees from discrimination by their employers with respect to certain individual characteristics, including religion. It applies to all employers of a certain size, regardless of whether the employer receives federal funding. In the context of the Title VII prohibition on employment discrimination on the basis of religion, Congress in 1972 limited the protection afforded to employees by defining "religion" as "all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the employer's business." Under the Title VII standard, an employer is, thus, only required to attempt to reasonably accommodate its current or prospective employee's religious objections if it would not place an undue burden on the employer. In contrast, the health care conscience protection provisions apply only to recipients of federal funding, and primarily to recipients of funding from the Department, regardless of size. Congress was capable of incorporating an express balancing of interests in health care conscience protection provisions, but it chose not to, in spite of its general familiarity with the balancing test in the Civil Rights Act religious nondiscrimination provision. We believe that it is reasonable to interpret this action by Congress to impose higher standards for provider conscience on employers in the health care and medical research that receives Departmental funding than is imposed on employers in general. Thus, we believe it is a reasonable interpretation that Congress in this context imposed a choice not between reasonable accommodations and undue burden, but between accommodation of religious belief or moral convictions and federal funding. Where an employer will not accommodate an employee's sincere religious belief or moral conviction, it may cease being eligible for federal funds and lose certain federal funding.

While it is a reasonable interpretation of the statutes that Congress did not intend to limit provider conscience protections to those provided to employees under the Title VII legal framework for religious accommodation requests, we also interpret nothing in the provider conscience statutes as preventing employers from accommodating employees' sincerely held religious beliefs, observances, and practices when requested as a means of accomplishing the same protections for provider conscience. As long as employees in the health care field are free from being discriminated against or required to participate in abortions or services they find religiously or morally objectionable, employers are free to balance employee rights with other interests in conducting their business operations. We envision that, through open communication between employees and employers about each other's respective needs and requirements, and by

employers providing accommodations of employees' religious beliefs and moral convictions, full compliance with the health care conscience protection laws and organizational objectives can best be achieved.

Similarly, we do not foresee that the health care conscience protection laws and this regulation would necessarily constrain employers in the health care field to hire individuals or accept volunteers who, due to their religious beliefs or moral convictions, refuse to perform job duties that comprise the significant majority or the entirety of duties required by the position.

There are a number of reasons why these and other staffing concerns might not be constrained by protections afforded to health care workers on the basis of conscience. First, employers have no obligation under the health care conscience protection laws to employ persons who are unqualified to perform the functions required of the jobs that they seek to fill. A job applicant must be qualified or, typically among a pool of qualified applicants, the best qualified, to perform the core services of a job for which he/she is applying. It is difficult to conceive of a circumstance in which an applicant who is fundamentally opposed on religious or moral grounds to a particular medical procedure, health service program, or research activity, would be among the best qualified to perform that procedure, service, or activity. Additionally, a job applicant with a sincerely held religious belief or moral conviction against a lawful health service or activity would be unlikely to apply for a job in which that precise health service or activity constitutes a significant majority or the entirety of the job. That said, employers are to be expected to make rational hiring decisions based on due consideration of an applicant's knowledge, skills, ability, and desire to perform the essential functions of a job. To the extent a health care employer's adverse decision is based on an applicant's inability to perform the essential functions of a job, the decision would not typically constitute discrimination under the regulation even if the applicant had expressed an unwillingness to perform those functions on conscience grounds. However, an adverse decision predicated on an applicant's alleged "inability" could constitute unlawful discrimination if the employer's stated reasons are pretextual; for example, if the employer is using the definition of essential functions as a pretext for excluding applicants with certain religious beliefs or moral convictions. In applying this standard, the Department will remain vigilant against discrimination and the potential for employers to use an applicant's qualifications as a pretext for unlawful discrimination.

Comment: Comments requested clarification regarding the application of the written certification requirement in the proposed rule to programs receiving federal funding under the President's Emergency Plan for AIDS Relief (PEPFAR).

Response: PEPFAR funding is distributed to several federal agencies, including the federal Centers for Disease Control and Prevention (CDC) within the Department. If the activities of CDC under PEPFAR are funded from the annual Labor, Health and Human Services appropriations act, the Weldon Amendment would apply, as would certain provisions of the Church Amendments.

To the extent that CDC's PEPFAR programs are funded solely from the Department of State appropriations, the Weldon Amendment would not apply because the funds for PEPFAR would come from the Department of State's appropriations act. The Weldon Amendment applies to funds appropriated under the Labor/HHS appropriations act to which the Weldon Amendment is a rider. PHS Act § 245, 42 U.S.C. 238n, would not apply because section 245 applies to the federal government and to State and local governments receiving federal financial assistance. The Church Amendments at 42 U.S.C. 300a-7(b), (c)(1) and (e) apply to activities funded and carried out under the PHS Act, the Community Mental Health Centers Act, [*78086] and/or the Developmental Disabilities Assistance and Bill of Rights Act of 2000, and, thus, would not be applicable.

There are two provisions of the Church Amendments that apply more broadly. The Church Amendments at 42 U.S.C. 300a-7(c)(2) applies to grants or contracts for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services. CDC's PEPFAR programs do not customarily involve such research.

The Church Amendments at 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 part under a program administered by the 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." 42 U.S.C. 300a-7(d) (emphasis added). PEPFAR is a program administered, in part, by HHS. PEPFAR funds are appropriated under the State Department's authorities and then transferred to HHS and fund grant programs that are developed, administered and implemented by HHS/CDC which provide health services, including HIV prevention, treatment, and care. Accordingly, CDC's PEPFAR programs would be subject to the requirements/prohibitions in 42 U.S.C. 300a-7(d), and foreign or international organizations (such as agencies of the United Nations) which are recipients or sub-recipients under CDC's PEPFAR programs may be recipients or sub-recipients for the purposes of this rule at CDC's discretion. We note that these requirements are consistent with a conscience protection clause already existing in the PEPFAR authorizing statute.

Comment: One Commenter requested clarification on the Office for Civil Rights' (OCR) experience and knowledge of employment discrimination and how OCR would handle a potential increase in workload associated with its role in the proposed rule as the office designated to receive complaints of discrimination.

Response: With a Headquarters office in Washington, DC, ten regional and two field offices located throughout the United States, OCR promotes and ensures that individuals have equal access to, and opportunity to participate in, and receive services from, all relevant Department-funded programs without facing unlawful discrimination, and that the privacy of their health information is protected. OCR is the sole agency within the Department charged with responsibility for enforcing these important federal protections. Through the enforcement work of its Headquarters policy staff and regional investigators, OCR annually resolves more than 12,000 citizen complaints alleging discrimination or a violation of the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA). OCR provides training and technical assistance annually to individuals and health care entities nationwide that receive certain funds from the Department through its public education and compliance activities to promote and ensure compliance with applicable federal laws requiring nondiscriminatory access to Department programs and services and protection of the privacy of individually identifiable health information under the HIPAA Privacy Rule. OCR is therefore well-positioned within the Department to fulfill its designated role as the point of contact to receive, and coordinate with the Department-funding components the handling of, complaints from individual and institutional health care providers and entities seeking protection from discrimination in connection with particular practices, or from compulsion to perform health care activities, that they find religiously or morally objectionable. The Department-funding components will bear the actual responsibility for enforcement of the health care conscience protection laws through their usual and ordinary program mechanisms, which include termination of funding and return of funds paid out in violation of the health care provider conscience protection provisions under 45 CFR parts 74, 92, and 96.

OCR also has considerable experience working collaboratively with the Department-funding components to identify barriers and implement practices that can avoid potential discrimination in services, and also in supporting funding components' enforcement responsibilities. For example, OCR conducts fully coordinated investigations with the Administration for Children and Families (ACF) in its enforcement of the Multiethnic Placement Act (MEPA) of 1994, as amended by section 1808 of the Small Business Job Protection Act of 1996, which provides that state agencies may not delay or deny the placement of a child for adoption or into foster care on the basis of the race, color, or national origin of the adoptive or foster parent, or the child involved. OCR and ACF act collaboratively concerning the conduct of MEPA investigations and in resolution of MEPA complaints. Pursuant to a memorandum of understanding between OCR and ACF, OCR takes the lead in investigating violations; when OCR finds a violation of MEPA, ACF determines whether to require a monetary payment by the state as part of the resolution agreement and whether to require that the payment be an integral part of the resolution. In these ways, OCR routinely works with the staff of Departmental programs and brings its expertise to bear to ensure compliance with federal nondiscrimination requirements.

With respect to OCR's experience and knowledge in the area of employment discrimination complaints, OCR has

served as the designated entity within the Department to receive a variety of discrimination complaints for over 40 years, including employment discrimination complaints. OCR's authority covers discrimination based on race, color, national origin, age, disability, sex, and religion. OCR's designated responsibilities under the provider conscience regulation to receive and coordinate the handling of discrimination complaints under the statutes and this implementing regulation, with the Departmental programs funding the entities at issue in any complaint, therefore, fall clearly within OCR's area of expertise and responsibility within the Department.

Comment: One Commenter noted that designating OCR as the office to receive complaints appears to overlap with EEOC jurisdiction, and could confuse employees as to when and where to file complaints.

Response: OCR, EEOC, and other federal agencies have developed procedures over the years to ensure appropriate handling of federal nondiscrimination complaints where there is overlapping jurisdiction.

The agencies responsible for federal nondiscrimination laws, including OCR and EEOC, coordinate to ensure these procedures are working and also confer on a case-by-case basis when needed to work out instances where there may be shared jurisdiction. As part of this coordination, federal agencies, including OCR, use a variety of methods, including consumer brochures, fact sheets, grassroots meetings, and the Internet, to get information to the public about their federal civil rights and when, where, and how to file discrimination complaints depending upon the facts of the complaint. The Department will continue to use appropriate means to educate the public about their rights and [*78087] how to file a complaint under the provider conscience regulation.

The Department agrees that it will be important to ensure that the regulated entities and their employees are aware that the EEOC retains its primary jurisdiction in the area of enforcing protections under Title VII prohibiting employment discrimination based on religion. The Department will explore all avenues available, in coordination with the EEOC, for increasing public awareness of both health care conscience protection laws and Title VII's protections against employment discrimination based on religion. Where there are overlapping interests between the EEOC and the Department with respect to enforcement of protections against religious discrimination in employment, the EEOC and OCR roles and responsibilities are set forth in a federal regulation which has been in effect for 25 years, 29 CFR part 1691, 48 FR 3574 (January 25, 1983) (as amended) (*Procedures for Complaints of Employment Discrimination filed against Recipients of Federal Financial Assistance*). This regulation provides for coordination between EEOC and OCR for review, investigation, and resolution of certain overlapping employment discrimination complaints, including those based on religion.

Comment: Several Comments questioned the authority of the Secretary to issue this regulation. They pointed out that several of the statutory provisions such as the Church amendments lacked an explicit delegation of rulemaking authority to the Department. Several of these Commentators also stated the "housekeeping statute," 5 U.S.C. 301, does not authorize the Department to promulgate standards for entities outside the agency, and that this rule is, therefore, *ultra vires*.

Response: The Supreme Court has recognized the best, but not only, means by which an agency may promulgate binding legislative rules is through the issuance of regulations through notice and Comment rulemaking pursuant to delegated rulemaking authority. *United States v. Mead*, 533 U.S. 218 (2000). The Court has also found Chevron deference applicable where an agency has considerable expertise over a complex area and has given the issue careful consideration. *Barnhart v. Walton*, 535 U.S. 212 (2002); *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Lower courts have also recognized binding deference to the Department in determining whether recipients of federal funds are complying with myriad federal requirements. *Pharmaceutical Manfs. v. Thompson*, 362 F.3d 817 (DC Cir. 2004). All these deference factors are applicable here, and in addition to the notice and Comment the Secretary has conducted here.

Regardless of the Department's authority to promulgate legislative rules in this instance, it is well settled in case law that every agency has the inherent authority to issue interpretive rules and rules of agency practice and procedure.

Pierce, *Administrative Law* at 306 (4th ed. 2002). The compliance requirements set forth in this rule do not substantively alter or amend the obligations of the respective statutes. *JEM Broadcasting v. FCC*, 22 F3d 320 (DC Cir. 1994). While specific certification of compliance for the health care conscience protection laws is new, recipients of federal funding have long certified compliance with other applicable federal laws, including civil rights laws. While this needed change in procedures may prompt a minor increase in the costs of compliance for some entities, that does not alter the procedural nature of the rule. *Hurson v. Glickman*, 229 F3d 277 (DC Cir. 2000).

Furthermore, provisions of the rule which do no more than define terms are reasonably drawn from the existing statutes. *Hector v. Dept. of Agriculture*, 82 F3d 165 (7th Cir. 1996). Particularly as Congress intended the conscience protections to apply broadly across institutions and individuals, the Department has ample authority to issue these interpretive provisions.

Comment: Several Comments raised the question of how this regulation may conflict with rules governing other Department programs. Some expressed concerns that the rule was inconsistent with program requirements of the Medicaid, Community Health Center, and Title X Family Planning programs, as well as the treatment requirements under the Emergency Medical Training and Active Labor Act (EMTALA). Specifically, Comments assert that this regulation is inconsistent with the requirement that institutions provide care in an emergency, a requirement that includes no exception for religious or moral objections to the needed service, and that the regulatory requirements for family planning clinics under Title X of the Public Health Service Act require Title X projects to offer pregnant women non-directive counseling, and referrals upon request for prenatal care and delivery, infant care, foster care or adoption, and abortion.

Response: The Department does not operate its programs in conflict with the existing federal protections being further implemented by this rule. The Department believes that many Commenters are confused as to the programmatic requirements of various Departmental programs, and suggests that concerned parties seek clarification from individual program offices as appropriate. Similarly, the Department believes that Commenters mistakenly confuse certain legal requirements on institutions or health care entities as requirements on individual providers. With respect to emergency treatment, the obligations of EMTALA are imposed on hospital under 1867 of the Social Security Act only if they elect to operate an emergency room and are also limited to the capabilities of the particular hospital. The requirement under EMTALA that such hospitals treat and stabilize patients who present in an emergency is not in conflict with the Church Amendments' requirement that certain recipients of Department funds not force any individual to participate in a health service program that they object to based on a religious belief or moral conviction. While this and other hypothetical situations were raised in the Comments, the Department is not aware of any instance where a facility required to provide emergency care under EMTALA was unable to do so because its entire staff objected to the service on religious or moral grounds. With regards to the Title X program, Commenters are correct that the current regulatory requirement that grantees must provide counseling and referrals for abortion upon request (42 CFR 59.5(a)(5)) is inconsistent with the health care provider conscience protection statutory provisions and this regulation. The Office of Population Affairs, which administers the Title X program, is aware of this conflict with the statutory requirements and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants.

Comment: Multiple Comments questioned the balance between provisions in the Department's proposed rule and requested clarification on EMTALA requirements and how they will be upheld if the Department's proposed rule is promulgated.

Response: The Department notes that this Comment would only be relevant where a hospital, as opposed to an individual, has an objection to performing abortions that are necessary to stabilize the mother, as that term has been interpreted in the context of EMTALA. The Department is unaware of any hospital that has such a policy. Furthermore, the laws this regulation supports have existed alongside [*78088] EMTALA for many years. Thus, we do not anticipate any actual conflict between EMTALA and this regulation.

Comment: Some Comments expressed concern that this rule could interfere with existing state laws that regulate

contraceptive coverage mandates in insurance policies, access to emergency contraception, and access to birth control at pharmacies. Commenters were also concerned that this regulation would impact a State's ability to enforce these laws and upset the balance that state and local laws already strike between the religious freedom of health care providers and a patient's need to access health care services.

Response: As mentioned above, this rule was issued to help define the rights and responsibilities created by the existing federal health care provider conscience protection provisions, clarify the scope of the existing protections, require certain recipients of Department funds to certify compliance with these requirements, and define certain terms for the purposes of this rule. This rule does not change federal policy regarding the conscience rights of health care providers, or create new rights, but simply seeks to ensure that recipients of Department funds are aware of the existing conditions that apply to the receipt of these funds. As such, States should already be aware of these existing protections, and should ensure that they do not take actions that would violate these established federal protections. By accepting federal funds, States accept the conditions that the Congress has imposed on the receipt of those funds. In this case, Congress has seen fit to include broad conscience protections for health care entities that apply to a wide array of Department activities. As this rule implements existing law, if States wish to adopt or enforce policies that seek to ensure that patients have proper access to health care services, they would be expected to do so, but they should avoid policies that interfere with federally protected rights, or risk the loss of federal funds. While the Department is aware that some States may have laws that, if enforced, depending on the factual circumstances, might violate these federally protected rights, the Department is not aware of any particular instance where a State has done so in an inappropriate fashion. The Department's objective is to protect the conscience rights established in federal law, not to penalize States that adopt laws that, if enforced against an objecting individual or entity, could violate federal law. The Department is committed to working cooperatively with States to help ensure that they do not violate the federal protections.

Comment: Several Comments claimed that the proposed rule is covered under existing federal laws, which makes the new proposed rule unnecessary.

Response: The Department agrees that the provider conscience regulation's purpose is to implement existing federal laws by providing definitions to clarify the scope of those laws and to adopt certification mechanisms that will be used to increase awareness of, and compliance with, those laws. For reasons stated above, the Department disagrees that the rule is unnecessary.

Comment: Several Comments noted that the rule supports the First Amendment right of freedom of religion.

Response: The Department agrees. It is clear that Congress intended these statutes--the Church Amendment in particular--to further protect, in part, the First Amendment right to free exercise of one's religion in the context of healthcare provided by recipients of Departmental funds.

Comment: Commenters claimed that the rule, if promulgated, would violate the "constitutionally protected right to choose."

Response: We disagree. The Supreme Court has read the Constitution to include rights to privacy and bodily integrity broad enough to protect a woman's choice to procure an abortion. The case law enshrining this interpretation of the Constitution does not create or identify a corresponding duty on the part of any provider to be involved in the procedure in any way. In contrast, many protections, including principles established in court cases n4 and ethical principles found in State and federal laws, n5 are in place to ensure that no such duty is imposed on providers. The regulations implementing the Church Amendments, PHS Act § 245, and the Weldon Amendment merely interpret these federal health care conscience protection provisions and encourage compliance.

n4 "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).

n5 See, e.g., S.D. Codified Laws § 36-11-70 (2003); Miss. Code Ann. § 41-107-5 (2004).

Comment: Comments stated that Congress upheld the access-to-care rights of pregnant women in the Education Appropriations Act beginning in 1997. The Comments declared that the proposed rule would contradict 42 CFR 59.5(a)(5), which states women are to receive "neutral, factual information and nondirective counseling, and referral upon request," regarding prenatal care and delivery, as well as adoption and termination options.

Response: The Department is unsure which provision in the Education Appropriations Act the Commenter was referencing, and cannot respond except to say that we are unaware of any federal law that imposes a positive duty on doctors to provide services to which the provider objects.

This rule is consistent with 42 CFR 59.5 with respect to an individual provider's right to refuse to counsel or refer for abortion, as explained in the preamble to the final rule that promulgated that requirement:

The corollary suggestion, that the requirement to provide options counseling should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds, is likewise rejected. In addition to the foregoing considerations, 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. However, in such cases the grantees must make other arrangements to ensure that the service is available to Title X clients who desire it. 65 FR 41270, 41274 (2000).

As is always the case, requirements and prohibitions contained in a regulation cannot be enforced in derogation of conflicting statutes. Thus, under section 245 of the Public Health Service Act and the Weldon Amendment, the Department cannot and does not enforce 42 CFR 59.5(a)(5) against an otherwise eligible grantee or applicant who objects to the requirement to counsel on or refer for, abortion. See *Nat'l Family Planning & Reprod. Health Ass'n v. Gonzales*, 468 F.3d 826, 828 (DC Cir. 2006) ("* * * the government notes, and plaintiff doesn't contest, that in the event of conflict the regulation must yield to a valid statute.").

Comment: A number of Comments stated that the proposed rule is unnecessary in part because of the National Research Act, which created protection within biomedical and behavioral research organizations and formed a commission to ensure these rights are protected.

Response: The Department disagrees. The Department has identified several instances that suggest that providers, employers, and employees are unaware of the protections found in federal law. Hundreds of Comments have confirmed this lack of awareness. This rule is an [*78089] important step in ensuring knowledge of, and compliance with, the provider conscience provisions found in these statutes.

Comment: One Commenter argued that the regulation was needed and there are no court rulings, including *Roe v. Wade* and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), that compel an individual or institutional health care provider to participate in the provision of abortions, so the regulation does not contradict the cases.

Response: The Department agrees. Although these cases interpret the Constitution to include a right to abortion, they do not create an affirmative duty on the part of any provider to perform or participate in the provision of such an abortion.

Comment: A Commenter cited the Supreme Court case of *Griswold v. Connecticut*, 381 U.S. 479 (1965), that addressed the privacy of a married couple to engage in the use of birth control versus the State's law which declared contraception illegal.

Response: The Department notes that the Supreme Court in *Griswold* affirmed a married couple's right to use

contraception as against a State law that prohibited such access. It did not impose upon any provider an affirmative duty to prescribe or dispense contraception.

Comment: One Commenter stated that *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220 (3d Cir. 2000), clearly shows that in times of emergency professional ethical obligations to care for the sick and injured outweigh their conscience.

Response: The Department disagrees with this reading of *Shelton*. The sole issue in that case was "whether a state hospital reasonably accommodated the religious beliefs and practices of a staff nurse who refused to participate in what she believed to be abortions." *Shelton v. University of Med. & Dentistry*, 223 F.3d 220, 222 (3d Cir. 2000). Her employer offered her a lateral transfer, which she refused. The court held that this offer of a lateral transfer was a reasonable accommodation under the Civil Rights Act of 1964. The court said nothing of ethical obligations to care for the sick and injured outweighing conscience.

Comment: One Commenter argued that the rule does not make clear that the providers' religious objection has to be to the activity or procedure, not to the patient and stated that in a recent decision (*North Coast Women's Care Medical Group v. Benitez*, 44 Cal. 4th 1145 (2008)), the California Supreme Court ruled that doctors are barred from refusing medical care to homosexuals based on the doctors' religious beliefs about homosexuals.

Response: In *Benitez*, the California Supreme Court was interpreting State, not federal, law. The Court's analysis is inapplicable to this situation. Further, the Department believes the statutes and this rule are sufficiently clear as to applicability.

Comment: One Commenter suggested that the proposed rule violates a White House directive that executive departments and agencies submit all proposed rules by June 1, 2008, except in "extraordinary circumstances." The Commenter stated the Department should explain those extraordinary circumstances or withdraw its proposal.

Response: The memorandum issued by the Chief of Staff to the President was solely for purposes of management and coordination of the Executive Branch, conferred no rights on anyone outside the Executive Branch, did not create any legal requirements, and by its own terms authorized the exercise of discretion and exceptions to timing guidelines where appropriate. The Department has solicited and carefully evaluated public Comment as required by the Administrative Procedure Act. Nothing in applicable law precluded issuance of the proposed rule, just as nothing in applicable law precludes the issuance of this final rule.

Comment: Some Comments requested that the 30-day Comment period be extended.

Response: We decline to extend the 30-day Comment period. The purpose of extending the Comment period would be to provide additional opportunity to Comment on the proposed rule. We note that, as demonstrated by the volume of Comments received by the Department, Commenters had ample opportunity to submit Comments and did so. The Department received Comments discussing a wide range of issues, including potential impact of the proposed rule, from stakeholders including hospitals, health care providers, professional associations, trade groups, advocacy organizations, private citizens, and others. The Department has had sufficient opportunity to weigh the issues posed by public Comments, including the impact of the proposed rule and its interaction with State and federal laws, and has taken such Comments into account in issuing this final rule.

Comment: One Commenter stated that the interests protected in the regulation are only specific concerns of providers in particular situations or locations, and the only thing needed to remedy the conflict is to change the situation or location to accommodate the employee.

Response: The Department agrees that employers should strive for accommodation of religious beliefs, moral convictions, or convictions against involvement in abortions or sterilizations. However, the Department believes that regulations are necessary to ensure that employers opt to accommodate their employees' objections rather than to

engage in intimidation or discrimination.

Comment: One Comment asserted that HHS's concern about the development of an environment in which individuals from diverse backgrounds are discouraged from entering health care professions contrasts with the accreditation requirements of The Liaison Committee on Medical Education (LCME) and The Accreditation Council for Graduate Medical Education (ACGME). That is, these organizations have standards that are "designed to ensure that the education of physicians provides an environment that embraces a diversity of views and values for both health care providers and patients."

Response: The Department disagrees. Although the requirements are certainly useful as future physicians are educated, the Department thinks it would be uncontroversial to suggest that over time, as physicians and other professionals are trained and begin practicing medicine, their attitudes and demeanor may change. Thus, these regulations are needed to protect against coercion and discrimination across the span of a professional's education and career.

Comment: One Commenter claimed that the regulation would require the American Medical Association to rewrite its code of ethics.

Response: As noted before, this regulation simply enforces federal law. The American Medical Association code of ethics--which, in any event, does not appear to conflict with federal law--is not binding law, so it may not matter if there is a conflict. Insofar as problems may arise as a result of conflict between any code of ethics and federal law, the proper solution is to rewrite the relevant code of ethics.

Comment: One Commenter recommended that the Department set up a process by which providers ensure patients receive care from another provider when they have objections to the requested procedure.

Response: While the Department suspects that such referrals may be how many providers will handle these types of situations, it declines to impose such a requirement in the rule, since such a requirement would constitute "making arrangements for", "referring for", or [*78090] "assisting in the performance" of an abortion or other objectionable procedure in violation of the health care provider conscience protection statutes.

III. Legal Authority

On the basis of the following statutory authority, the Secretary promulgates these regulations, requiring certification of compliance with anti-discrimination statutes.

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."

The Church Amendments, 42 U.S.C. 300a-7 (2000), prohibit recipients of Department funding under the PHS Act and several other statutes from discriminating against employees and others who participate in health service programs or research activities funded in whole or part by the Department who refuse to perform certain medical services, including sterilization, abortion, or research activities because of religious or moral beliefs. Specifically, section 300a-7(c)(1)(A) and (B) provides that recipients may not discriminate in the employment of or the extension of staff privileges to any health care professional because he refused, because of his religious beliefs or moral convictions, to perform or assist in the performance of any sterilization or abortion procedures. Section 300a-7(d) provides that no individual shall be required to perform or assist in the performance of *any* health service program or research activity funded in whole or part by the Department contrary to his religious beliefs or moral convictions. n6

n6 Section 300a-7(c)(1) provides that "[n]o entity which receives a grant, contract, loan, or loan guarantee under the [Act] * * * may (A) discriminate in the employment, promotion, or termination of employment of any physician or

other health care personnel, or (B) * * * in the extension of staff or other privileges to any physician or other health care personnel * * * because he refused to perform or assist in the performance of * * * [an] abortion" on the grounds that doing so "would be contrary to his religious beliefs or moral convictions." 42 U.S.C. 300a-7(c)(1). Section 300a-7(c)(2) provides that "[n]o entity which receives * * * a grant or contract for biomedical or behavioral research under any program administered by [HHS]" may discriminate in the employment of or the extension of staff privileges to any health care professional "because he refused to perform or assist in the performance of" "any lawful health service" based on religious belief or moral conviction. 42 U.S.C. 300a-7(c)(2). Section 300a-7(d) provides that "[n]o individual [may] be required to perform or assist in the performance of any part of a health service program * * * funded in whole or in part under a program administered by the Secretary of Health and Human Services" if doing so "would be contrary to his religious beliefs or moral convictions." 42 U.S.C. 300a-7(d). Section 300a-7(e) prohibits any entity that receives funding under the PHS Act from denying admission to, or otherwise discriminating against, "any applicant (including for internships and residencies) for training or study because of the applicant's reluctance * * * to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions * * * contrary to or consistent with the applicant's religious beliefs or moral convictions." 42 U.S.C. 300a-7(e). In addition, section 300a-7(b) provides in part that "[t]he receipt of any grant, contract, loan, or loan guarantee under the [PHS Act] * * * by any individual or entity does not authorize any court or any public official or other public authority to require" (1) the individual to perform or assist in an abortion if it would be contrary to his/her religious beliefs or moral convictions; or (2) the entity to make its facilities available for abortions, if the performance of abortions in the facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or provide personnel for the performance of abortions if it would be contrary to the religious beliefs or moral convictions of such personnel. 42 U.S.C. 300a-7(b).

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

The Weldon Amendment, Consolidated Appropriations Act, 2008, Public Law 110-161, § 508(d), 121 Stat. 1844, 2209 (2008), prohibits a federal agency or program, or any State or local government from receiving Department funds 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.

These statutory provisions require that the Department and recipients of Department funds refrain from discriminating against institutional and individual health care entities for their participation or refusal to participate in certain medical services or research activities funded 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.

We respond to the Comment on the Department's legal authority to promulgate these regulations in section H (General Comments) of the Comments section above.

IV. Section-by-Section Description of the Final Rule

Section 88.1 Purpose

Proposed Rule: In the proposed rule, the "Purpose" section set forth the objective that this final rule provides 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.

The Department received no Comments on this section.

Final Rule: The Department adopts this provision as recommended in the proposed rule without modification.

Section 88.2 Definitions

Assist in the Performance

Proposed Rule: The Department, in considering how to interpret the term "assist in the performance," sought to provide broad protection for individuals. At the same time, the Department sought to guard against potential abuses of these protections by limiting the definition of "assist in the performance" to only those individuals who have a reasonable connection to the procedure, health service or health service program, or research activity to which they object.

Therefore, the Department proposed 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 proposed that the term be limited to participation in any activity with a reasonable connection to the objectionable procedure, including referrals, training, and other arrangements for the procedure, health service, or research activity. For example, an operating room nurse would assist in the performance of surgical procedures; an employee whose task it is to clean the instruments used in a particular procedure would also be considered to assist in the performance of the particular procedure under the proposed rule.

The Department responds to Comments on the proposed definition of this term above. [*78091]

Final Rule: The Department adopts the above definition as proposed.

Health Care Entity/Entity

Proposed Rule: 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 a matter of statutory construction as well as long-standing Departmental interpretation, the definition of "health care entity" in PHS Act § 245 also encompasses institutional entities, such as hospitals and other entities. 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 proposed to define "health care entity" to include the specifically mentioned types of individuals and organizations from the two statutes, as well as other types of entities referenced in the Church Amendments.

The Department responds to Comments on the proposed definition of this term above.

Final Rule: The Department adopts the proposed definition without modification. It is important to note that the Department does not intend for this to be a comprehensive list of relevant types of individuals and organizations for purposes of the regulation, but merely a list of examples.

Health Service/Health Service Program

Proposed Rule: One of the provisions in the Church Amendments uses the term "health service," another uses the term "health service program." The Church Amendments do not define these terms, nor does the Public Health Service Act define "health service program." In developing an appropriate definition for "health service program," the proposed rule 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, it was proposed 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 benefit programs where federal funds are used to provide access to health coverage (e.g., SCHIP, Medicaid, and Medicare Advantage).

The Department responds to Comments on the proposed definition of this term above.

Final Rule: Upon further reflection, the Department has determined that the meaning of the term "health service" is self-evident, and so we do not adopt a definition for "health service" in this final rule.

Final Rule: The Department adopts the above definition without modification.

Individual

Proposed Rule: For the purposes of the new proposed part, the proposed rule defined "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.)

The Department responds to Comments on the proposed definition of this term above.

Final Rule: The Department adopts the above definition as proposed.

Instrument

Proposed Rule: The proposed rule uses the term "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 proposed definition of "instrument" was intended to include all means by which the Department conveys funding and resources.

No Comments were received on the definition of this term.

Final Rule: The Department adopts the above definition without modification.

Recipient

Proposed Rule: The proposed rule defined this term to mean any entity that receives Department funds directly.

The Department responds to Comments on the proposed definition of this term above.

Final Rule: The Department adopts this definition as proposed.

Sub-recipient

Proposed Rule: The proposed rule defined this term to mean any entity that receives Department funds indirectly through a recipient or sub-recipient.

The Department responds to Comments on the proposed definition of this term above.

Final Rule: The Department adopts this definition as proposed.

Workforce

Proposed Rule: In the proposed rule we defined the term "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 was drawn from the "Administrative Data Standards and Related Requirements" rules implementing the 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.

The Department responds to Comments on the proposed definition of this term above.

Final Rule: In response to public Comments on this issue, we have provided an exclusive definition of the [*78092] term "workforce" by changing "includes" to "means" in the definition. In defining both "individual" and "workforce," the Department promulgates 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 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.

As indicated in the proposed rule--and consistent with the scope of the Church Amendments, which include physicians and other health care providers that have privileges with an entity receiving funding from the Department--we intended the concept of "workforce" to include physicians and other health care providers who have privileges at the entity funded by the Department. After publication of the proposed rule, it came to the Department's attention that the language of the "workforce" definition may not be clear on this issue. Accordingly, to ensure clarity on this point, we are revising the definition of "workforce" by adding at the end "or health care providers holding privileges with the entity".

Section 88.3 Applicability

Proposed Rule: The "Applicability" section of the proposed rule directs individuals and entities receiving funds from the Department to the appropriate sections of proposed section 88.4 that set forth the relevant requirements, drawn from the three statutes that form the basis of this regulation, that are applicable to them and also directed to the provisions regarding certifications that the various recipients of federal monies must provide.

Final Rule: In this final rule, we have included a technical correction in section 88.3 clarifying that educational institutions, teaching hospitals, and programs for the training of health care professionals or health care workers shall

comply with section 88.4(c)(2), which prohibits discrimination against or denial of admission to applicants "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" in accordance with PHS Act § 245. 42 U.S.C. 300a-7(e). Apart from this change, we have adopted this provision as recommended in the proposed rule.

Section 88.4 Requirements and Prohibitions

Proposed Rule: The "Requirements and Prohibitions" section in the proposed rule explains the obligations that the Church Amendments, PHS Act § 245, and the Weldon Amendment impose on entities which receive funding from the Department, depending on the type of entity and the program or statute under which the funding is received. These provisions are taken from the relevant statutory language and make up the elements of the certification provided by the entities. The proposed rule states that we intend for the requirements and prohibitions to be interpreted using the definitions contained in section 88.2.

Final Rule: The final rule adopts this provision without change.

Section 88.5 Written Certification of Compliance

Proposed Rule: In the "Written Certification of Compliance" section of the proposed rule, the Department proposed 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 nondiscrimination provisions. Under the 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 would require 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)--would be 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 would be collected and maintained by the recipient, this certification by sub-recipients would be a certification addressed to the Department, not to the recipients collecting the certification. Recipients would be 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), as proposed, would contain several important exceptions to the proposed requirement to provide the written certification, including individual physicians, physician offices, other health care practitioners, and other participants in Part B of the Medicare program; (2) physicians, physician offices, or other health care practitioners participating in Part C 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 the categories of providers listed above (e.g., individual physicians, physician offices, other health care practitioners, and sub-recipients of State Medicaid programs) would have posed significant implementation hurdles for Departmental components and programs. Furthermore, the Department believed that, due primarily to their generally smaller size, the excepted categories of recipients and sub-recipients of Department funds in the above categories would be less likely to encounter the types of issues sought to be addressed in this regulation. [*78093] However, we noted in the proposed rule that excepted providers may become subject to the proposed written certification requirement by receiving Department funds under a separate agency or program. For example, under the proposed rule, a physician office participating in Medicare Part B may become subject to the proposed written certification requirement by receiving Department funds to conduct clinical research. We noted, however, that the State Medicaid programs would be responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistent with applicable nondiscrimination provisions.

Final Rule: Partly in Response to suggestions received in Response to solicitation of public Comment on this issue (see the Department Responses to the Comments on the proposed certification requirement above), HHS has determined to make further exceptions to the certification requirements in section 88.5 in the final rule. Exceptions from the written certification requirement are included for Departmental grant programs whose purpose is unrelated to health care provision, including economic assistance, and which do not involve medical research or the involvement of health care providers, and which are unlikely to involve referral for provision of health care. These programs often involve funding to States and other governments for non-health care purposes, and/or cash assistance or vouchers, rather than direct services by a funded entity, to individuals. These programs are unlikely to involve Department funds being used for medical research, the participation of health care providers or referral to health care providers. As a consequence, these programs are also unlikely to encounter the circumstances contemplated by this regulation, and therefore the assurance of compliance represented by a certification is not considered necessary by the Department for such programs. Programs excepted under this provision include certain current programs administered by the Administration for Children and Families, including Low-Income Home Energy Assistance Program, Assets for Independence, the Child Care and Development Fund, Job Opportunities for Low-Income Individuals, Mentoring Children of Prisoners, and programs overseen by the Office of Child Support Enforcement, as well as certain current programs administered by the Administration on Aging. Finally, an exception to the written certification requirement of section 88.5 has been included for Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

As stated in the proposed rule, individual Department components have been 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 have been 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.

Finally, we have reorganized the wording of the written certifications in section 88.5 for purposes of clarity and to more closely track the language of the health care conscience protection laws. Recipients are expected to comply with the records retention and access requirements in 45 CFR 74.53, 45 CFR 92.42, 45 CFR 96.30, and any other applicable requirements.

Section 88.6 Complaint Handling and Investigating

Proposed Rule: This section did not appear in the proposed rule.

Final Rule: We have included a new section 88.6 to clarify, as was stated in the preamble to the proposed rule, that the HHS Office for Civil Rights (OCR) has been designated to receive complaints of discrimination and coercion based on the health care conscience protection statutes and this regulation. OCR will coordinate handling of complaints with the staff of the Departmental programs from which the entity, with respect to which a complaint has been filed, receives funding (i.e., Department funding component).

IV. Analysis of Economic Impacts

Executive Order 12866--Regulatory Planning and Review

HHS has examined the economic implications of this final 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, although this final rule is not economically significant, it is a significant regulatory action as defined by Executive Order 12866.

Comment: One Comment stated that HHS did not provide an adequate cost-benefit analysis as required by E.O. 12866. The Comment pointed out that the Department concluded that the rule is a significant regulatory action but did not undertake a more formal analysis.

Response: HHS disagrees. Our conclusion, based on the analysis of impacts of the proposed rule, was that the rule was not economically significant. Therefore, the assessment of potential costs and benefits provided was sufficient to meet the requirements of the Executive Order.

Comment: Two Comments stated HHS's analysis was inadequate in that it did not consider the costs of additional health care or other impacts on patients and employers because various definitions had been broadened. Another Comment stated that HHS did not assess the effects on public health resulting from a decrease in access to care.

Response: HHS disagrees. As stated previously, the Department does not agree that the interpretation of the terms used in this rule have been broadened or that the scope of the laws were expanded. Nor does HHS agree that this rule would cause changes in staffing or other processes beyond those changes entities have already incurred in order to comply with existing statutes. This final rule does not limit patient access to health care, but rather implements existing federal laws. Thus, we have not changed our analysis in Response to this Comment.

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 from many different faiths 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 is confident that the future benefits will exceed the costs of complying with the regulation. [*78094]

Comment: One Comment suggested that the number of affected entities suggests that the benefits will not exceed the costs of complying with the regulation. The Commenter provided no clarification and no data to support this statement.

Response: The Department has not revised its analysis in Response to this Comment.

The statutes mandating the requirements for protecting health care workers as discussed in this rule have been in effect for a number of years. Therefore, the regulatory burden associated with this rule is largely associated with the incremental costs of certifying 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 571,947 (see Table I). This estimate has been revised from the proposal to reflect new exceptions to the certification requirement for recipients of ACF, AOA, and IHS funds. We do not distinguish between recipients and sub-recipients of HHS funding. Each entity could be a recipient, a sub-recipient, or both.

Table--Affected Entities

Health care entity	Number of entities
Hospitals (less than 100 beds) n7	2,403
Hospitals (100-200 beds) n17	1,129
Hospitals (200-500 beds) n17	1,160
Hospitals (more than 500 beds) n17	244
Nursing Homes (less than 50 beds) n8	2,388
Nursing Homes (50-99 beds) n18	5,819
Nursing Homes (99-199 beds) n18	6,877
Nursing Homes (more than 200 beds) n18	1,037
Physicians Offices n9	234,200
Offices of Other Health Care Practitioners n18 10	115,378
Outpatient Care Centers n11 19	26,901
Medical and Diagnostic Laboratories n19	11,856
Home Health Care Services n19	20,184
Pharmacies (chain and independent) n12	58,109
Dental Schools n13	56
Medical Schools (Allopathic) n17	125
Medical Schools (Osteopathic) n17	20
Nursing Schools (Licensed practical) n14	1,138
Nursing Schools (Baccalaureate) n22	550
Nursing Schools (Associate degree) n22	885
Nursing Schools (Diploma) n22	78
Occupational Therapy Schools n17	142
Optometry Schools n17	17
Pharmacy Schools n17	92
Podiatry Schools n17	7
Public Health Schools n17	37
Residency Programs (accredited) n15	8,494

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Health Insurance Carriers and 3rd-Party Administrators n16	4,578
Grant awards n17	63,741
Contractors n18	4,245
State and territorial governments	57
Total	571,947

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.

n7 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.

n8 Nursing Home Data Compendium, 2007 edition. U.S. Dept. of Health and Human Services, Centers for Medicaid and Medicare Services.

n9 See HIPAA Administrative Simplification NPRM: Modification to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS; Proposed Rule, 73 FR 49796-49872, August 22, 2008.

n10 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.

n11 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.

n12 2005 NCPA-Pfizer Digest: Total, Prescription Sales Increase At Nation's Independent Pharmacies. National Community Pharmacies Association Press Release, May 12, 2005.

n13 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.

n14 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.

n15 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.

n16 U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May 2007.

n17 HHS Grants Statistics, 2007. Available at <http://www.hhs.gov/grantsnet>.

n18 General Services Administration (estimated).

In the analysis to the proposed rule, we explained that indirect costs associated with the certification requirement might include costs for such actions as staffing/scheduling changes and internal reviews to assess compliance. We

further explained that there is insufficient data to estimate the number of funding recipients not [*78095] currently compliant with the Church Amendments, PHS Act § 245, or the Weldon Amendment. We received no Comments indicating that there were any funding recipients not currently compliant. Therefore, we continue to assume that, because together these three federal statutes have been in existence for many years, the incremental indirect costs of certification will be minimal for Department funding recipients.

Comment: Four Commenters argued against our administrative cost estimates associated with the certification process. These Comments stated that the analysis of the proposed rule did not sufficiently account for the cost of collecting, maintaining, and submitting written certifications. However, the Comments provided no new information or data.

Response: HHS disagrees. In determining the costs associated with collecting and maintaining the certification, we reviewed the analysis and regulatory costs associated with or conducted for several other similar certification requirements for HHS programs. The Comments did not provide any new information or data nor did they suggest any activities for which we did not already account in the analysis. Thus, we have not changed the analysis in Response to these Comments.

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 571,947 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, the cost associated with the act of certification is \$ 41.6 million ($571,947 \times .5 \times \$ 145.54$).

The direct cost of collecting and maintaining certifications made by sub-recipients is estimated as the labor cost. We assume that each of the 63,741 grant awardees 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 ($67,986 \text{ entities} \times 1 \text{ hour} \times \$ 30$).

Comment: One Comment suggested the analysis should consider the legal fees likely to flow from litigation over the proposed regulations.

Response: HHS disagrees. In assessing the costs and benefits of regulations, the government assumes compliance. Thus, the amount of litigation is assumed to be minimal and very difficult to predict.

The total quantifiable costs of the regulation are estimated to be \$ 43.6 million each year.

Congressional Review Act

The Congressional Review Act defines a "major rule" as "any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in--(A) an annual effect on the economy of \$ 100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets." 5 U.S.C. 804(2). Based on OMB's review of the rule under Executive Order 12866, the Administrator of OIRA has determined that this

rule is not a major rule for purposes of the Congressional Review Act. This finding of the Administrator is not subject to judicial review. 5 U.S.C. 805.

Regulatory Flexibility Act

HHS has examined the economic implications of this final 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 requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This 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.

Comment: One Comment suggested HHS should assess the impact on small entities who will incur costs to hire new staff and make staffing changes to accommodate objections by workforce members.

Response: HHS acknowledges that there may be indirect costs associated with the certification requirement including costs for such actions as staffing/scheduling changes and internal reviews to assess compliance. As stated in the proposed rule, there continues to be insufficient data to estimate the number of funding recipients not currently compliant with the Church Amendments, PHS Act § 245, or the Weldon Amendment. 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. HHS received no Comments on this assumption. Therefore, we continue to conclude that these indirect costs of certification will be minimal.

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 about \$ 115 million. HHS has determined that this final rule would not constitute a significant rule under the Unfunded Mandates Reform Act.

Federalism

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

All three statutes implemented through this 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 in addition to those impacts caused by the statutory provisions, they do so only to the extent that States and local governments are required to submit certifications of compliance with the statutes and this [*78096] regulation, 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 certification requirement to be negligible.

The Department received Comments from a number of States, State officials, or components of State governments on the proposed rule. The Department considered those Comments in finalizing the rule.

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.

Comment: Several Comments disagreed with the Department's assertion in the proposed rule that the regulation will not have an impact on family well-being. Another Commenter stated that the Treasury and General Government Appropriations Act of 1999 requires the Department to determine if the proposed rule would affect family well-being. The Commenter stated that if family well-being is affected, the Department must provide an impact assessment of these effects. The Commenter also stated that the proposed rule does not adequately address the impact on family well-being.

Response: The Department disagrees. This final rule defines certain key terms, ensures that recipients of Department funds know about their legal obligations under existing federal health care provider conscience protection provisions, and requires written certification by certain recipients that they will comply with such provisions, as applicable. As stated above, the rule does not expand the scope of existing federal health care conscience protection laws, nor does it create new barriers to health care access that might have an impact on family well-being. The Department finds that this rule does not affect family well-being within the meaning of meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Pub. L. 105-277, *112 Stat. 2681*).

V. Paperwork Reduction Act of 1995

HHS received Comments on the burden associated with the written certification requirements contained in sections 88.5(a), (c) and (d) of this final rule and are therefore soliciting Comments on the information collection requirements associated with this rule, consistent with the Paperwork Reduction Act of 1995.

To obtain or retain federal funding for various activities, the Department requires the certification of all recipients and sub-recipients of Department funding. The certification and associated documents are necessary to ensure that recipients and sub-recipients of federal funds comply with federal anti-discrimination law.

Likely respondents to this certification requirement include all entities required to certify as estimated in the EO 12866 analysis listed above, which provides a high estimate of 571,947 recipients and sub-recipients. As outlined above, it will take an estimated 30 minutes for each recipient and sub-recipient to review the relevant language and provide the relevant certifications as well as, in the case of recipients, to collect and maintain certifications by sub-recipients, as applicable. The Department therefore estimates the annual aggregate burden to collect the information to be as follows:

The Department is seeking public Comments on the proposed data collection associated with this final rule through a 60-day **Federal Register** notice. Interested persons are invited to send Comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

This final rule becomes effective 30 days after publication. However, affected parties do not have to comply with the information collection requirements in the final rule until the Department of Health and Human Services publishes in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved these information collection 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*, the Weldon Amendment, Consolidated Appropriations Act, 2008, Public Law 110-161, Div. G, § 508(d), *121 Stat. 1844, 2209*, and *5 U.S.C. 301*, and for the reasons set forth in the preamble, the Department of Health and Human Services is amending 45 CFR Subtitle A, Subchapter A by adding 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.

88.6 Complaint handling and investigating.

Authority: *42 U.S.C. 300a-7*, *42 U.S.C. 238n*, Public Law 110-161, Div. G, § 508(d), *121 Stat. 1884, 2209, 31*, *42 U.S.C. 1395w-22(j)(3)(B)*, *42 U.S.C. 1396u-2(b)(3)*, and *5 U.S.C. 301*.

§ 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 110-161, Div. G, § 508(d), *121 Stat. 1844, 2209* (collectively referred to as the federal healthcare conscience protection statutes). These statutory provisions protect the rights of health care entities/entities, both individuals and institutions, to refuse to perform health care services and research activities to which they may object for religious, moral, ethical, or other [*78097] 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 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 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 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 means employees, volunteers, trainees, contractors, 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, or health care providers holding privileges with the entity.

§ 88.3 Applicability.

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

(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 of this part.

(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 of

this part.

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

(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) of this part.

(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 of this part.

(2) In addition to complying with the provisions set forth in § 88.4(c)(1) of this part, 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(c)(2) of this part.

(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 of this part.

(2) In addition to complying with the provisions set forth in (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) of this part.

§ 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 [*78098] 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 the sub-recipient's 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 contract, or in a separate writing, signed by the sub-recipient's officer or other person authorized to bind the sub-recipient. All certifications shall be addressed directly to the Department; recipients are required to submit their certifications directly to the Department. Recipients and sub-recipients shall be required to 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 contract 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 or contract 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 [*78099] 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) 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 [check all that are appropriate]:

__[if recipient is a state or local government receiving federal funds appropriated through the appropriations act for the U.S. Department of Health and Human Services] 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.

__[if recipient is an entity receiving federal funds appropriated through the appropriations act for the U.S. Department of Health and Human Services to implement any part of any federal program] 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.

__[if recipient is a State or local government that receives federal financial assistance]

(1) Subject any institutional or individual health care entity to discrimination for refusing: (a) To undergo training in the performance of abortions, or to require, provide, refer for, or make arrangements for training in the performance of abortions; (b) to perform, refer for, or make other arrangements for, abortions; or (c) 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.

_[if recipient is a State or local government, any part of any State or local government, or any other public entity] 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 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 such entity to 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 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.

_[if recipient is 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] 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.

_[if recipient is 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 that is an educational institution, teaching hospital, or program for the training of health care professionals or health care workers] 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.

_[if recipient is an 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 U.S. Secretary of Health and Human Services] require any individual to perform or assist in the performance of any part of a health service program or research activity funded by the U.S. Department of Health and Human Services if such service or activity would be contrary to his religious beliefs or moral convictions.

_[if recipient is an entity that receives grants or contracts for biomedical or behavioral research under any program

administered by the U.S. Secretary of Health and Human Services] 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."

_[All recipients] I further certify that the recipient acknowledges that any violation of these certifications may result in 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, and may be used as such at the Department's discretion. 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, [*78100] contract, grant under a contract, memorandum of understanding or other funding instrument or contract 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 or contract 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) 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 [check all that are appropriate]:

_[if sub-recipient is a State or local government receiving federal funds appropriated through the appropriations act for the U.S. Department of Health and Human Services] 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.

_[if sub-recipient is an entity receiving federal funds appropriated through the appropriations act for the U.S. Department of Health and Human Services to implement any part of any federal program] 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.

[if sub-recipient is a State or local government that receives federal financial assistance]

(1) Subject any institutional or individual health care entity to discrimination for refusing: (a) To undergo training in the performance of abortions, or to require, provide, refer for, or make arrangements for training in the performance of abortions; (b) to perform, refer for, or make other arrangements for, abortions; or (c) 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, the recipient will not 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.

[if sub-recipient is a State or local government, any part of any State or local government, or any other public entity] 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 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 such entity to 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 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.

[if sub-recipient is any entity (including a state or local government) that receives these funds through a recipient which received them through 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] 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.

[if sub-recipient is any entity (including a State or local government) that receives these funds through a recipient which received them through 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 that is an educational institution, teaching hospital, or program for the training of health care professionals or health care workers] 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.

[if sub-recipient is an 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 U.S. Secretary of Health

and Human Services] require any individual to perform or assist in the performance of any part of a health service program or research activity funded by the U.S. Department of Health & Human Services if such service or activity would be contrary to his religious beliefs or moral convictions.

[if sub-recipient is an entity that these funds through a recipient which received them through receives grants or contracts for biomedical or behavioral research under any program administered by the U.S. Secretary of Health and Human Services] 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."

[All sub-recipients] 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 may result in termination by the Department of the recipient's grant, cooperative agreement, contract, grant [*78101] 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, and may be used as such at the Department's discretion. 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 paragraph (e)(1) through (e)(6) of this section, the following individuals or organizations shall not be required to comply with the written certification requirements 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 C of the Medicare program, when such individuals or organizations are sub-recipients of Department funds through a Medicare Advantage plan;

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

(4) A recipient or sub-recipient of Department funds awarded under certain grant programs currently administered by the Administration for Children and Families, whose purpose is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve--

(i) Medical or behavioral research;

(ii) The involvement of health care providers;

(iii) Any significant likelihood of referral for the provision of health care;

(5) A recipient or sub-recipient of Department funds awarded under certain grant programs currently administered by the Administration on Aging, whose purpose is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve--

(i) Medical or behavioral research;

(ii) The involvement of health care providers;

(iii) Any significant likelihood of referral for the provision of health care; and

(6) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

§ 88.6 Complaint handling and investigating.

The Office for Civil Rights (OCR) of the Department of Health and Human Services has been designated to receive complaints of discrimination and coercion based on the health care conscience protection statutes and this regulation. OCR will coordinate handling of complaints with the staff of the Departmental programs from which the entity, with respect to which a complaint has been filed, receives funding (i.e., Department funding component).

Dated: December 3, 2008.

Michael O. Leavitt,

Secretary.

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