

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 88

RIN 0991-AB76

**Regulation for the Enforcement of Federal Health Care Provider Conscience
Protection Laws**

AGENCY: Office of the Secretary, HHS.

ACTION: Final Rule.

SUMMARY: The Department of Health and Human Services issues this Final Rule which provides that enforcement of the federal statutory health care provider conscience protections will be handled by the Department’s Office for Civil Rights, in conjunction with the Department’s funding components. This Final Rule rescinds, in part, and revises, the December 19, 2008 Final 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 “2008 Final Rule”). Neither the 2008 final rule, nor this Final Rule, alters the statutory protections for individuals and health care entities under the federal health care provider conscience protection statutes, including

the Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment. These federal statutory health care provider conscience protections remain in effect.

DATES: This rule is effective [insert date that is 30 days after publication].

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I. Introduction

The Department supports clear and strong conscience protections for health care providers who are opposed to performing abortions. While federal health care provider conscience statutes have been in effect for decades, the Department has received comments suggesting that the 2008 final rule attempting to clarify the federal health care provider conscience statutes has instead led to greater confusion. The comments received suggested that there is a need to increase outreach efforts to make sure providers and grantees are aware of these statutory protections. It is also clear that the Department needs to have a defined process for health care providers to seek enforcement of these protections.

The Department seeks to strengthen existing health care provider conscience statutes by retaining that part of the 2008 Final Rule that established an enforcement process. At the same time, this Rule rescinds those parts of the 2008 Final Rule that were unclear and potentially overbroad in scope. This partial rescission of the 2008 Final Rule does not alter or affect the federal statutory health care provider conscience protections.

Finally, the Department is beginning an initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated. The Department's Office for Civil Rights will lead this initiative, and will collaborate with the funding components of the Department to determine how best to inform health care providers and grantees about health care conscience protections, and the new process for enforcing those protections.

II. Background

Statutory Background

The Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment, collectively known as the "federal health care provider conscience protection statutes," prohibit recipients of certain federal funds from discriminating against certain health care providers based on their refusal to participate in health care services they find religiously or morally objectionable. Most of these statutory protections have existed for decades. Additionally, the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (collectively referred to as the "Affordable Care Act") includes new health care provider conscience protections within the health insurance exchange system.

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 to make clear that receipt of federal funds did not require 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 the receipt by an individual or entity of any grant, contract, loan, or loan guarantee under certain statutes implemented by the Department of Health and Human Services does not authorize a court, 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 the individual’s 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 or assistance in 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), extends protections to personnel decisions and prohibits any entity that 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 “performed or assisted in the performance of a lawful sterilization procedure or abortion, 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), goes beyond abortion and sterilization and prohibits any entity that 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, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.”

The fourth conscience provision, 42 U.S.C. 300a-7(d), provides that “[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by

[the Department] if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.”

The final conscience provision contained in the Church Amendments, 42 U.S.C. 300a-7(e), prohibits any entity that receives a grant, contract, loan, loan guarantee, or interest subsidy under certain Departmentally implemented statutes from denying admission to, or otherwise discriminating against, “any applicant (including applicants 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 Sec. 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 undergo training in the performance of induced 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 program of training in the health professions, that does not (or did not) 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.

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 sec. 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), the federal government and any state or local government receiving federal financial assistance shall deem accredited any postgraduate 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

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, 118 Stat. 2809, 3163 (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, Sec. 508 (d), 119 Stat. 2833, 2879-80 (Dec. 30, 2005); Revised Continuing Appropriations Resolution of 2007, Public Law 110-5, Sec. 2, 121 Stat. 8, 9 (Feb. 15, 2007); Consolidated Appropriations Act, 2008, Public Law 110-161, Div. G, Sec. 508(d), 121 Stat. 1844, 2209 (Dec. 26, 2007); Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, Public Law 110-329, Div. A, Sec.101, 122 Stat. 3574, 3575 (Sept. 30, 2008); Consolidated Appropriations Act, 2010, Public Law 111-117, Div. D, Sec. 508(d), 123 Stat. 3034, 3279-80 (Dec. 16, 2009). The Weldon Amendment provides that “[n]one of the funds made available in 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.”

Affordable Care Act

The Affordable Care Act includes new health care provider conscience protections within the health insurance Exchanges. Section 1303(b)(4) of the Act provides that “No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.” Like the other statutory health care provider conscience protections, this provision of law does not require rulemaking to take effect, and continues to apply notwithstanding this partial rescission of the 2008 Final Rule.

A recent Executive Order affirms that under the Affordable Care Act, longstanding federal health care provider conscience laws remain intact, and new protections prohibit discrimination against health care facilities and health care providers based on their unwillingness to provide, pay for, provide coverage of, or refer for abortions. Executive Order 13535, “Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act” (March 24, 2010).

Regulatory Background

No regulations were required or necessary for the conscience protections contained in the Church Amendments, PHS Act, sec. 245, and the Weldon Amendment to take effect. Nevertheless, on August 26, 2008, nearly forty years after enactment of the Church Amendments, the Department issued a proposed interpretive 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” (73 Fed. Reg. 50274).

In the preamble to the 2008 Final Rule, the Department concluded that regulations were 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 federal health care provider conscience protection statutes;
3. when such compliance efforts prove unsuccessful, enforce these nondiscrimination laws through the various Department mechanisms, to ensure that Department funds do not support 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 industry, and between providers and patients, fostering a more inclusive, tolerant environment in the health care industry than may currently exist.

(“Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law,” 73 Fed. Reg. 78072, 78074, 45 C.F.R. Part 88 (Dec. 19, 2008)).

The 2008 Final Rule was published in the Federal Register on December 19, 2008. The Rule contained definitions of terms used in the federal health care provider conscience statutes, discussed their applicability, noted the prohibitions and requirements of the statutes, and created an enforcement mechanism. The 2008 Final Rule also imposed a new requirement that all recipients and subrecipients of Departmental funds had to submit written certification that they would operate in compliance with the provider conscience statutes. This new requirement was based on a concern that there was a lack of knowledge in the health care community regarding the rights and obligations created by the federal health care provider conscience protection statutes. The Department received a number of comments expressing concern that this new certification would impose a substantial burden. The 2008 Final Rule went into effect on January 20, 2009 except that its certification requirement never took effect, as it was subject to the information collection approval process under the Paperwork Reduction Act, which was never completed.

Pending Litigation

In a consolidated action filed in the U.S. District Court for the District of Connecticut, eight states and several organizations challenged and sought to enjoin enforcement of the

2008 Final Rule by the Department. According to plaintiffs, in promulgating the 2008 Final Rule, HHS exceeded its statutory authority, violated the Administrative Procedure Act (APA) by failing to respond adequately to public comments, and conditioned the receipt of federal funds on compliance with vague and overly broad regulations. The Court granted a stay of all proceedings in this litigation pending the issuance of this Final Rule. *Connecticut v. United States*, No. 3:09-CV-054-RNC (D. Conn).

III. Proposed Rule

On March 10, 2009, the Department proposed rescinding, in its entirety, the 2008 Final 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” (74 FR 10207). The Department sought public comment in order to determine whether or not to rescind the 2008 Final Rule in part or in its entirety. In particular, the Department sought comment addressing the following:

1. information, including specific examples where feasible, addressing the scope and nature of the problems giving rise to the need for federal rulemaking and how the current rule would resolve those problems;
2. information, including specific examples where feasible, supporting or refuting allegations that the 2008 Final Rule reduces access to information and health care services, particularly by low-income women;

3. comment on whether the 2008 Final Rule provides sufficient clarity to minimize the potential for harm resulting from any ambiguity and confusion that may exist because of the rule; and
4. comment on whether the objectives of the 2008 Final Rule might also be accomplished through non-regulatory means, such as outreach and education.

IV. Comments on the Proposed Rule

A. Scope of Comments

The Department received more than 300,000 comments addressing its notice of proposed rulemaking proposing to rescind in its entirety the 2008 Final Rule. A wide range of individuals and organizations, including private citizens, health care workers, health care providers, religious organizations, patient advocacy groups, professional organizations, universities and research institutions, consumer organizations, state and local governments, and members of Congress, submitted comments regarding the notice of proposed rulemaking. The large number of comments received covered a wide variety of issues and points of view responding to the Department's request for comments on the four issues mentioned above, and the Department reviewed and analyzed all of the comments. The overwhelming majority of comments, both in support of and against rescission of the 2008 Final Rule, were form letters organized by various groups. In this

section, which provides an overview of the comments received, and in the following sections, which provide a more detailed response to these comments, we respond to comments by issue, rather than by individual comment, as necessitated by the number of comments received and by the issues posed by them.

More than 97,000 individuals and entities submitted comments generally supportive of the proposal to rescind the 2008 Final Rule. Approximately one-fifth of the comments in favor of rescinding the 2008 Final Rule indicated that the 2008 Final Rule was not necessary, because existing law, including Title VII of the Civil Rights Act of 1964 and the federal health care provider conscience protection statutes, already provided protections to individuals and health care entities. An overwhelming number of these commenters expressed concern that the 2008 Final Rule unacceptably impacted patient rights and restricted access to health care and conflicted with federal law, state law, and other guidelines addressing informed consent. Additionally, commenters in support of rescinding the 2008 Final Rule contended that this new regulation imposed additional costs and administrative burdens, through the certification requirement, on health care providers when there are already sufficient laws on the books to protect their rights.

A large number of commenters also expressed concern that the 2008 Final Rule created ambiguities regarding the rights of patients, providers, and employers. Specifically, a number of commenters noted that the 2008 Final Rule created ambiguities that could expand the provider conscience protections beyond those established in existing federal statutes. Several groups commented that during rulemaking for the 2008 Final Rule,

proponents failed to provide evidence that the long-standing statutory protections were insufficiently clear or that a problem currently exists for providers.

Nearly 187,000 comments expressed opposition to the Department's proposal to rescind the 2008 Final Rule. Nearly 112,000 of these comments stated that health care workers should not be required to perform procedures that violate their religious or moral convictions. Nearly 82,000 of the comments in opposition expressed concern that without the 2008 Final Rule, health care providers would be forced to perform abortions in violation of their religious or moral convictions. Many of these commenters also speculated that eliminating provider conscience protections would cause health care providers to leave the profession, which would reduce access to health care services.

Additionally, thousands of commenters suggested that rescinding the 2008 Final Rule would violate the First Amendment religious freedom rights of providers or the tenets of the Hippocratic Oath, and would impact the ethical integrity of the medical profession. While the Department carefully considered these comments, we do not specifically address them because this partial rescission does not alter or affect the existing federal statutory health care provider conscience protections.

Finally, numerous commenters opposing rescission of the 2008 Final Rule expressed concern that if the 2008 Final Rule was rescinded in its entirety, there would be no regulatory enforcement scheme to protect the rights afforded to health care providers,

including medical students, under the federal health care provider conscience protection statutes.

B. Comments Addressing Awareness and Enforcement

Need For Enforcement Mechanism

Comment: The Department received numerous comments against rescission of the 2008 Final Rule expressing concern that if the 2008 Final Rule were rescinded in its entirety, there would be no regulatory enforcement scheme to protect the rights afforded to health care providers, including medical students, under the federal health care provider conscience protection statutes.

Response: The Department shares the concerns expressed in these comments, and agrees there must be a clear process for enforcement of the health care provider conscience protection statutes. While the longstanding federal health care provider conscience protection statutes have provided protections for health care providers, there was no clear mechanism for a health care provider who believed his or her rights were violated to seek enforcement of those rights. To address these comments, this final rule retains the provision in the 2008 Final Rule that designates the Office for Civil Rights (OCR) of the Department of Health and Human Services to receive complaints of discrimination and coercion based on the federal health care provider conscience protection statutes.

OCR will lead an initiative across the Department that will include staff from the Departmental programs that fund grants, in order to develop a coordinated investigative and enforcement process. OCR is revising its complaint forms to make it easier for health care providers to understand how to utilize the complaint process, and will coordinate the 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 statutory conscience protections will be conducted by staff of the Department funding component, in conjunction with the Office for Civil Rights, through normal program compliance mechanisms. If the Department becomes aware that a state or local government or an entity may have undertaken activities that may violate the statutory conscience protections, 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 provider conscience protection provisions under 45 CFR parts 74, 92, and 96, as applicable.

Need for Education and Outreach

Comment: The Department's notice of proposed rulemaking for this final rule requested comment on the need for an education and outreach program in addition to the

promulgation of a regulatory enforcement scheme. 74 Fed. Reg. 10207, 10210. The Department received many comments expressing concern about the lack of knowledge about the federal health care provider conscience protection statutes in the health care industry. Many commenters opposed to rescission related anecdotes of hospitals and other health care entities failing to respect the conscience rights of health care providers. The commenters opined that if the 2008 Final Rule was rescinded in its entirety, health care entities receiving federal funding would not honor the rights provided health care providers under the federal health care provider conscience protection statutes.

Response: The Department is concerned about the number of comments it received that were opposed to rescission of the 2008 Final Rule based on a belief that rescission of the rule would abolish the long-standing statutory provider conscience protections as these comments reflect a lack of understanding that the statutory protections are in effect irrespective of Department regulations or the 2008 final rule. The Department believes it is important to provide outreach to the health care community about the federal health care provider conscience protection statutes. To address this need, the Department's Office for Civil Rights will work with the funding components of the Department to determine how best to raise grantee and provider awareness of these longstanding statutory protections, and the newly created enforcement process.

The Department's Office for Civil Rights currently engages in outreach and education efforts and works closely with health care entities to educate them about all of the federal authorities that the Office for Civil Rights enforces. The Office for Civil Rights will

include information on the federal health care provider conscience protection statutes in such outreach, and will also include information so that health care entities understand the new process for enforcement of the federal health care provider conscience protection statutes. The Office for Civil Rights provides a web portal for the receipt of complaints on its website. See Office for Civil Rights, U.S. Department of Health and Human Services, *How to File a Complaint* (2010) (<http://www.hhs.gov/ocr/civilrights/complaints/index.html>). Combining the above education and outreach programs with the enforcement provision in this final rule should ensure that providers can take advantage of these protections.

The Department is also amending its grant documents to make clear that recipients are required to comply with the federal health care provider conscience protection laws.

C. Comments Addressing the Underlying Statutes and Other Laws

Status of Underlying Statutory Conscience Protections

Comment: The Department received a large number of comments, both in favor of and in opposition to rescinding the 2008 Final Rule, which expressed concern regarding the effect of the 2008 Final Rule on protections for providers. Many commenters advocated leaving the final rule in place, stating that rescinding the 2008 Final Rule would eliminate the protections for providers established under the federal health care provider conscience protection statutes. On the other hand, many commenters advocated rescission of the

2008 Final Rule based on the mistaken belief that its rescission would eliminate the ability of certain providers to refuse to provide requested medical services that were contrary to their moral or religious beliefs.

Response: These comments underscore the misconceptions that exist regarding the proposed partial rescission of the 2008 Final Rule, and highlight the need for continued education and training of health care providers regarding the longstanding statutory protections. The federal health care provider conscience protection statutes, including the Church Amendments, the Section 245 of the PHS Act, and the Weldon Amendment, have long provided statutory protections for providers. Neither the 2008 Final Rule, nor this Final Rule, which rescinds, in part, and revises the 2008 Final Rule, alters the statutory protections for individuals and health care entities under the federal health care provider conscience protection statutes. Departmental funding recipients must continue to comply with the federal health care provider conscience protection statutes.

Interaction between Provider Conscience Statutes and Other Federal Statutes

Comment: Several other comments raised questions and identified ambiguities with respect to the interaction between the 2008 Final Rule and statutes governing other Department programs, including: the Medicaid program, pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (2006); the Community Health Centers program, pursuant to section 330 of the PHS Act, 42 U.S.C. § 264(b)(2008); the Title X Family Planning program, pursuant to Title X of the Public Health Service Act, 42

U.S.C. §§ 300-300a-6 (2006); and the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd (2003), as well as the federal civil rights statutes enforced by the Department in its programmatic settings, which include Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d (1964); Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (2002); Title II of the Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12131-12134 (1990); and the Age Discrimination Act of 1975, 42 U.S.C. §§ 6101-6107 (1998). Specifically, commenters expressed concern that the 2008 Final Rule conflicts with the requirements of these other federal statutes.

Response: Health care entities must continue to comply with the long-established requirements of the statutes above governing Departmental programs. These statutes strike a careful balance between the rights of patients to access needed health care, and the conscience rights of health care providers. The conscience laws and the other federal statutes have operated side by side often for many decades. As repeals by implication are disfavored and laws are meant to be read in harmony, the Department fully intends to continue to enforce all the laws it has been charged with administering. The Department is partially rescinding the 2008 final rule in an attempt to address ambiguities that may have been caused in this area. The approach of a case by case investigation and, if necessary, enforcement will best enable the Department to deal with any perceived conflicts within concrete situations.

Interaction with Title VII of the Civil Rights Act of 1964

Comment: Several comments raise questions about the overlap between the federal health care provider conscience protection statutes and the protections afforded under Title VII of the Civil Rights Act of 1964, as amended (Title VII), 42 U.S.C. § 2000e *et seq.*.

Response: The relationship between the protections contained under the federal health care provider conscience protection statutes and the protections afforded under Title VII fall outside the scope of this final rule. Under the final rule, the Department's Office for Civil Rights (OCR) will continue to receive complaints alleging violations of the federal health care provider conscience protection statutes. The Equal Employment Opportunity Commission (EEOC) enforces Title VII, which prohibits employers – including health care providers – from discriminating against any applicant or employee in hiring, discipline, promotion, termination, or other terms and conditions of employment based on religious beliefs.

Guidance for handling complaints involving Title VII issues can be found in *Procedures for Complaints of Employment Discrimination Filed Against Recipients of Federal Financial Assistance*, 29 C.F.R. Part 1691 (Aug. 4, 1989). The Procedures provide for coordination between the EEOC and other federal departments for review, investigation, and resolution of employment discrimination complaints, including those based on religion.

Informed Consent

Comment: Many comments expressed concern that the 2008 Final Rule would prevent a patient from being able to give informed consent, because the health care provider might not advise the patient of all health care options.

Response: The doctrine of informed consent requires that a health care provider inform an individual patient of the risks and benefits of any health care treatment or procedure. In order to give informed consent, the patient must be able to understand and weigh the treatment or procedure's risks and benefits, and must understand available alternatives. Additionally, a patient must communicate his or her informed consent to the provider, which is most commonly done through a written document. State laws generally treat lack of informed consent as a matter of negligence on the part of the health care provider failing to disclose necessary information to the patient. Provider association and accreditation association guidelines set forth additional requirements on members and member entities.

We recognize that informed consent is crucial to the provision of quality health care services. The provider-patient relationship is best served by open communication of conscience issues surrounding the provision of health care services. The Department emphasizes the importance of and strongly encourages early, open, and respectful communication between providers and patients surrounding sensitive issues of health care, including the exercise of provider conscience rights, and alternatives that are not being recommended as a result.

Partial rescission of the 2008 Final Rule should clarify any mistaken belief that it altered the scope of information that must be provided to a patient by their provider in order to fulfill informed consent requirements.

D. Comments Addressing Whether the 2008 Final Rule Clarified the Provider Conscience Statutes

Comment: The Department sought information regarding whether the 2008 Final Rule provided the clarity that it intended to provide. The comments received in response to this question tended to focus on whether or not the definitions contained in the 2008 Final Rule were too broad. Commenters supporting rescission of the 2008 Final Rule indicated that the definitions were far broader than the scope of the federal provider conscience statutes. Commenters opposing rescission of the 2008 Final Rule did not believe the definitions were too broad. Many comments indicated that the 2008 Final Rule created confusion that the federal provider conscience protections authorized refusal to treat certain kinds of patients rather than to perform certain medical procedures. Numerous comments on both sides questioned whether the 2008 Final Rule expanded the scope of the provider conscience statutes by suggesting that the term “abortion” included contraception.

Response: The comments reflected a range of views regarding whether the 2008 Final Rule added clarity to the federal health care conscience statutes. The comments received illustrated that there is significant division over whether the definitions provided by the

2008 Final Rule are in line with the longstanding federal health care provider conscience protection statutes.

The Department agrees with concerns that the 2008 Final Rule may have caused confusion as to whether the federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs. The federal provider conscience statutes were intended to protect health care providers from being forced to participate in medical procedures that violated their moral and religious beliefs. They were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable.

The 2008 Final Rule did not provide that the term “abortion,” as contained in the federal health care provider conscience protection statutes, includes contraception. However, the comments reflect that the 2008 Final Rule caused significant confusion as to whether abortion also includes contraception. The provision of contraceptive services has never been defined as abortion in federal statute. There is no indication that the federal health care provider conscience statutes intended that the term “abortion” included contraception.

The Department rescinds the definitions contained in the 2008 Final Rule because of concerns that they may have caused confusion regarding the scope of the federal health care provider conscience protection statutes. The Department is not formulating new

definitions because it believes that individual investigations will provide the best means of answering questions about the application of the statutes in particular circumstances.

E. Comments Addressing Access to Health care

Concerns the 2008 Final Rule Would Limit Access

Comment: The Department received several comments suggesting that the 2008 Final Rule could limit access to reproductive health services and information, including contraception, and could impact a wide range of medical services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services. Additionally, a number of commenters expressed concern that the 2008 Final Rule could disproportionately affect access to health care by certain sub-populations, including low-income patients, minorities, the uninsured, patients in rural areas, Medicaid beneficiaries, or other medically-underserved populations.

Response: The Department agrees with comments that the 2008 Final Rule may negatively affect the ability of patients to access care if interpreted broadly. As noted above, in the litigation filed shortly after issuance of the 2008 Final Rule, eight states sought to enjoin implementation of the Rule, arguing that it would prevent them from enforcing their state laws concerning access to contraception. *Connecticut v. United States*, No. 3:09-CV-054-RNC (D. Conn). Additionally, while there are no federal laws compelling hospitals to provide contraceptive services, the Medicaid Program does

require that States provide contraceptive services to Medicaid beneficiaries. The Department is concerned that the breadth of the 2008 Final Rule may undermine the ability of patients to access these services, especially in areas where there are few health care providers for the patient to choose from. As we state above, entities must continue to comply with their Title X, Section 330, EMTALA, and Medicaid obligations, as well as the federal health care provider conscience protection statutes. Accordingly, the Department partially rescinds the 2008 Final Rule based on concerns expressed that it had the potential to negatively impact patient access to contraception and certain other medical services without a basis in federal conscience protection statutes.

Concerns that Rescission of the 2008 Final Rule Would Limit Access

Comment: A substantial number of comments in opposition to rescinding the 2008 Final Rule maintained that Roman Catholic hospitals would have to close, that rescission of the rule would limit access to pro-life counseling, and that providers would either leave the health care industry or choose not to enter it, because they believed that they would be forced to perform abortions. As such, these commenters concluded that rescinding the 2008 Final Rule would limit access to health care services or information.

Response: Under this partial rescission of the 2008 Final Rule, Roman Catholic hospitals will still have the same statutory protections afforded to them as have been for decades. The Department supports the longstanding federal health care provider conscience laws, and with this Final Rule provides a clear process to enforce those laws. As discussed

above, the federal health care provider conscience statutes have provided protections for decades, and will continue to protect health care providers after partial rescission of the 2008 Final Rule. Entities must continue to comply with the federal health care provider conscience protection statutes. Moreover, under this Final Rule, health care providers who believe their rights were violated will now be able to file a complaint with the Department's Office for Civil Rights in order to seek enforcement of those rights.

F. Comments Addressing Costs to Providers

Comment: The Department received several comments addressing the costs to providers of the 2008 Final Rule. Commenters stated that the new certification requirement imposed substantial additional responsibilities on health care entities, and that the burden analysis did not sufficiently account for the cost of collecting information for, submitting, and maintaining the written certifications required by the 2008 Final Rule. Additionally, the Department received several comments outlining various estimates regarding the burdens, including time and cost, on health care entities to comply with certification requirements of the 2008 Final Rule.

Response: The federal health care provider conscience protection statutes mandating requirements for protecting health care providers have been in effect for decades. The stated reason for enacting the certification requirement was a concern that there is a lack of knowledge on the part of states, local governments, and the health care industry of the federal health care provider conscience protections. The Department believes it can raise

awareness of these protections by amending existing grant documents to specifically require that grantees acknowledge they must comply with the laws.

The Department estimated that 571,947 health care entities would be required to comply with the certification requirements. The Department also stated in the preamble to the 2008 Final Rule that it estimated the total quantifiable costs of the regulation, including direct and indirect costs, as \$43.6 million each year. See 73 Fed. Reg. 98095, Dec. 18, 2009.

The Department agrees with these commenters, and believes that the certification requirements in the 2008 Final Rule are unnecessary to ensure compliance with the federal health care provider conscience protection statutes, and that the certification requirements created unnecessary additional financial and administrative burdens on health care entities. The Department believes that amending existing grant documents to require grantees to acknowledge that they will comply with the provider conscience laws will accomplish the same result with far less administrative burden. While proposed, the certification requirements were never finalized under the previous rule, and they are deleted in this rule. The Department emphasizes, however, that health care entities remain responsible for costs associated with complying with the federal health care provider conscience protection statutes, in the same way that health care entities were before the promulgation of the 2008 Final Rule. Additionally, health care providers can now seek enforcement of their conscience protections through the Department's Office for Civil Rights.

V. Statutory Authority

The Secretary hereby rescinds, in part, redesignates, and revises the 2008 Final 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,” in accordance with the following statutory authority. As discussed above, the federal health care provider conscience protection statutes, including the Church Amendments, the PHS Act Sec. 245, and the Weldon Amendment, require, among other things, that the Department and recipients of Department funds (including state and local governments) refrain from discriminating against institutional and individual health care entities for their participation in certain medical procedures or services, including certain health services, or research activities funded in whole or in part by the federal government. However, none of these statutory provisions require promulgation of regulations for their interpretation or implementation. The provision of the 2008 Final Rule establishing that the Office for Civil Rights is authorized to receive and investigate complaints regarding violations of the federal health care provider conscience statutes is being retained. This Final Rule is being issued pursuant to the authority of 5 U.S.C. § 301, which empowers the head of an Executive department to prescribe regulations “for the government of his department, the conduct of his employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.”

VI. Overview and Section-by-Section Description of the Final Rule

Section 88.1 describes the purpose of the Final Rule. The language is revised slightly from the 2008 Final Rule, and states that the purpose of Part 88 is to provide for the 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, 2010, Public Law 111-117, Div. D, Sec. 508(d), 123 Stat. 3034, 3279-80, referred to collectively as the “federal health care conscience protection statutes.”

Sections 88.2 through 88.5 of the 2008 Final Rule have been removed. Section 88.2 contains definitions of terms used in the federal health care provider conscience statutes. Section 88.3 describes the applicability of the 2008 Final Rule. Section 88.4 describes the requirements and prohibitions under the 2008 Final Rule. Section 88.5 contains the certification requirement. The preamble to the August 26, 2008 Notice of Proposed Rulemaking (73 FR 50274) and the preamble to the December 19, 2008 Final Rule (73 FR 78072) addressing these sections are neither the position of the Department, nor guidance that should be relied upon for purposes of interpreting the federal health care provider conscience protection statutes.

Section 88.6 has been re-designated as Section 88.2. Section 88.2 provides that the Department’s Office for Civil Rights (OCR) is designated to receive complaints of discrimination and coercion based on the health care provider conscience protection statutes, and that OCR will coordinate the handling of complaints with the HHS Departmental funding component(s) from which the entity complained about receives

funding. This language is revised slightly from the 2008 Final Rule to clarify that “Department funding component” is not a defined term.

VII. Impact Statement and Other Required Analyses

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (5 U.S.C. § 601 et seq.), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. § 1532), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. § 804(2)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). The 2008 Final Rule estimated the quantifiable costs associated with the certification requirements of the proposed regulation to be \$43.6 million each year.

Rescinding the certification requirements of the final rule would therefore result in a cost savings of \$43.6 million each year to the health care industry.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. With this final rule the Department is rescinding the certification requirements which will reduce the

potential burden to small businesses. We have examined the implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a single sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. This final rule is not economically significant under these standards.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule would not require additional steps to meet the requirements of Executive Order 13132.

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analysis before any rulemaking if the rule includes a “Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is approximately \$130 million. We have determined that this final rule does not create an

unfunded mandate under the Unfunded Mandates Reform Act, because it does not impose any new requirements resulting in expenditures by state, local, and tribal governments, or by the private sector.

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. This final rule will not have an impact on family wellbeing, as defined in the Act, because it affects only regulated entities and eliminates costs that would otherwise be imposed on those entities.

VIII. Paperwork Reduction Act Information Collection

This final rule eliminates requirements that would be imposed by the 2008 Final Rule. The 60-day comment period on the information collection requirements of the 2008 Final Rule expired on February 27, 2009, and OMB approval for the information collection requirements will not be sought.

New Paperwork Collection Act Information for Complaints

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

1. The need for the information collection and its usefulness in carrying out the proper functions of our agency.
2. The accuracy of our estimate of the information collection burden.
3. The quality, utility, and clarity of the information to be collected.
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to

the PRA requirements summarized in this section. To comment on this collection of information or to obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your comment or request, including your address and phone number to sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

45 CFR Part 88, Section 88.2 provides that individuals or entities may file written complaints with the Department's Office for Civil Rights if they believe they have been discriminated against under the federal health care provider conscience protection statutes by programs or entities that receive Federal financial assistance from the Department. The new information collection provisions associated with this final rule will not go into effect until approved by OMB. HHS will separately post a notice in the Federal Register at that time.

The table below reflects the Office for Civil Rights current complaint receipts under its other civil rights enforcement authorities. HHS does not expect the burden to increase measurably as a result of this provision.

Estimated Annualized Burden Table

Individuals may file written complaints with the Office for Civil Rights when they believe they have been discriminated against on the basis of race, color, national origin, age, disability, and, in certain circumstances, sex and religion by programs or entities that receive Federal financial assistance from the Department of Health and Human Services. The table below includes: the annual number of respondents to the Office for Civil Rights regarding all the authorities that it enforces; the frequency of submission, including record keeping and reporting on occasion; and the affected public, including not-for-profit entities and individuals.

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
Civil Rights Complaint Form	Individuals or Not-for-profit entities	3037	1	45/60	2278
Total		3037			2278

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.

Dated: February 17, 2011

Kathleen Sebelius,
Secretary.

For the reasons set forth in the preamble, the Department amends 45 CFR Part 88, as set forth below:

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

1. The authority citation for part 88 is revised to read as follows:

Authority: 5 U.S.C. 301.

2. The heading of part 88 is revised to read as set forth above.

3. Revise § 88.1 to read as follows:

§ 88.1 Purpose.

The purpose of this Part is to provide for the 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, 2010, Public Law 111-117, Div. D, Sec. 508(d), 123 Stat. 3034, 3279-80, referred to collectively as the “federal health care provider conscience protection statutes.”

4. Remove §§ 88.2 through 88.5.

5. Redesignate § 88.6 as § 88.2.

6. Revise newly designated § 88.2 to read as follows:

§ 88.2 Complaint handling and investigating.

The Office for Civil Rights (OCR) of the Department of Health and Human Services is designated to receive complaints based on the federal health care provider conscience protection statutes. OCR will coordinate the handling of complaints with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding.

