

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 88

RIN 0991-AB49

Rescission of the Regulation Entitled “Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law”; Proposal

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services proposes to rescind 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 Department believes it is important to have an opportunity to review this regulation to ensure its consistency with current Administration policy and to reevaluate the necessity for regulations implementing the Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment.

DATES: Submit written or electronic comment on the regulatory changes proposed by this document by [insert date 30 days from publication].

ADDRESSES: In commenting, please refer to “Rescission Proposal.” To better manage the comment process, we will not accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.Regulations.gov> or via email to proposedrescission@hhs.gov. To submit electronic comments to <http://www.Regulations.gov>, go to the Web site and click on the link “Comment or Submission” and enter the keywords “Rescission Proposal.”

[Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.]

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Office of Public Health and Science, Department of Health and Human Services, Attention: Rescission Proposal Comments, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Room 716G, Washington, DC 20201.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Office of Public Health and Science, Department of Health and Human Services, Attention: Rescission Proposal Comments, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Room 716G, Washington, DC 20201.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to the following address: Room 716G, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the documents being filed.)

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

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

Electronic Access

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

FOR FURTHER INFORMATION CONTACT: Mahak Nayyar, (240) 276-9866, Office of Public Health and Science, Department of Health and Human Services, Room 716G, Hubert E. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201.

SUPPLEMENTARY INFORMATION:

I. Background

Statutory Background

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.

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 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), 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), 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 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

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). 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.”

Rulemaking

No statutory provision requires the promulgation of rules to implement the requirements of the Church Amendments, Public Health Service (PHS) Act Sec. 245, and the Weldon Amendment. Nevertheless, on August 26, 2008, the Department exercised its discretion and issued a 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,” (73 FR 50274). Citing concerns that the development of an environment in the health care field that is intolerant of individual conscience, certain religious beliefs, ethnic and cultural traditions, and moral convictions may discourage individuals from diverse backgrounds from entering health care professions, 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 Church Amendments, PHS Act Sec. 245, and the Weldon Amendment; (3) when such compliance efforts prove unsuccessful, enforce these nondiscrimination laws through the various Department mechanisms, to ensure that

Department funds do not support coercive or discriminatory practices, or policies in violation of federal law; and (4) otherwise take an active role in promoting open communication within the healthcare industry, and between providers and patients, fostering a more inclusive, tolerant environment in the health care industry than may currently exist.

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, commented on the proposed rule. 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, the rule's relationship to Title VII of the Civil Rights Act and other statutes and protections, what services are covered by the rule, whether health care workers might use the regulation to discriminate against patients, what significant implementation issues could be associated with the rule, legal arguments, the cost impacts and the public health consequences of the rule.

On December 19, 2008, the Department issued a final rule (73 FR 78072). The Department saw a need to balance the rights of patients in obtaining legal health care services against the statutory rights of providers in the context of federally funded entities not to be discriminated against based on a refusal to participate in a service to which they have objections. Thus, the Department imposed an additional certification requirement

by specifically including a reference to the nondiscrimination provisions contained in the Church Amendments, PHS Act Sec. 245, and the Weldon Amendment in certifications currently required of most existing and potential recipients of Department funds. The final rule went into effect on January 20, 2009, except that 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. Furthermore, the certification requirement is not effective pending completion of the information collection process under the Paperwork Reduction Act. The 60-day comment period on the information collection expired on February 27, 2009, and OMB approval for the information collection has not yet been sought.

II. Proposed Rule

The Department is proposing to rescind in its entirety the 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,” published in the Federal Register on December 19, 2008 (73 FR 78072, 45 CFR Part 88). Commenters asserted that the rule would limit access to patient care and raised concerns that individuals could be denied access to services, with effects felt disproportionately by those in rural areas or otherwise underserved. The Department believes that the comments on the August 2008 proposed rule raised a number of questions that warrant further careful consideration. It is important that the Department have the opportunity to review this regulation to ensure its consistency with current Administration policy.

Accordingly, we believe it would benefit the Department to review this rule, accept further comments, and reevaluate the necessity for regulations implementing the statutory requirements. Thus, the Department is proposing to rescind the December 19, 2008 final rule, and we are soliciting public comment to aid our consideration of the many complex questions surrounding the issue and the need for regulation in this area.

III. Statutory Authority

The Secretary proposes to rescind 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.” As discussed above, the Church Amendments, section 245 of the PHS Act, 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. No statutory provision, however, requires promulgation of a rule such as that published on December 19, 2008. This proposed 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.”

IV. Request for Comment

The Department, in order to determine whether or not to rescind the final rule in part or in its entirety, seeks comments. In particular, the Department seeks 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 December 19, 2008 final rule reduces access to information and health care services, particularly by low-income women;
3. Comment on whether the December 19, 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 December 19, 2008 final rule might also be accomplished through non-regulatory means, such as outreach and education.

V. Impact Analysis

Executive Order 12866 – Regulatory Planning and Review

HHS has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and

equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a single sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. This proposed rule is not significant under these economic standards. However, under Executive Order 12866, a regulation is also considered a significant regulatory action if it raises novel legal or policy issues. Because HHS previously determined that the December 19, 2008 final rule was a significant regulatory action under this standard, HHS will assume that the proposed rescission of the December 19, 2008 final rule is also a significant regulatory action.

The December 19, 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 rule would therefore result in a cost savings of \$43.6 million each year to the health care industry.

Regulatory Flexibility Act

HHS has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (RFA). If a rule has a significant economic burden on a substantial number of small entities, the RFA requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small

governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities by virtue of either nonprofit status or having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. The position of the Department has long been that the RFA requirements for regulatory flexibility analysis only apply to rules that create significant adverse impacts on small entities. Rescission of the final rule may create positive impacts on small entities by removing any burdens imposed by that rule. Accordingly, we certify that this proposed rule will not have a significant effect on a substantial number of small entities.

Executive Order 13132 – Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has federalism implications. This proposed rule would not require additional steps to meet the requirements of Executive Order 13132 because it removes any burden imposed by the December 19, 2008 final rule.

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 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. The Department has determined that this proposed rule would not constitute a significant rule under the Unfunded Mandates Reform Act, because it would rescind rather than impose mandates.

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

Paperwork Reduction Act of 1995

This proposed rule does not create any new requirements under the Paperwork Reduction Act of 1995. Instead, it proposes to eliminate requirements that would be imposed by the final rule issued on December 19, 2008. The 60-day comment period on the information collection requirements of the December 19, 2008 final rule expired on

February 27, 2009, and OMB approval for the information collection requirements has not yet been sought.

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: March 5, 2009

Charles E. Johnson

Acting Secretary

Part 88 – [Removed and Reserved]

Therefore, under 5 U.S.C. 301, the Department of Health and Human Services proposes to remove and reserve 45 CFR part 88.

Billing Code: 4150-28

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