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June 2, 2016

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Office of the Secretary:
Nondiscrimination in Health Programs and Activities*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services (HHS), Office of the Secretary entitled "Nondiscrimination in Health Programs and Activities" (RIN: 0945-AA02). We received the rule on May 13, 2016. It was published in the *Federal Register* as a final rule on May 18, 2016. 81 Fed. Reg. 31,376.

The final rule implements section 1557 of the Patient Protection and Affordable Care Act (PPACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. According to HHS, the final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by HHS and entities established under title I of PPACA.

Enclosed is our assessment of HHS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that HHS complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas
Regulations Coordinator
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
OFFICE OF THE SECRETARY
ENTITLED
"NONDISCRIMINATION IN HEALTH PROGRAMS
AND ACTIVITIES"
(RIN: 0945-AA02)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) included a cost-benefit analysis in the final rule. HHS summarized the costs attributable to the final rule that covered entities may incur following enactment of the final regulation in a table in the rule. HHS assumed that half of the training costs and changes to policies and procedures on the prohibition of discrimination on the basis of sex will be incurred in the first year and the second half will be expended in the second year. For covered entities that will be printing and distributing notices to their patients and policy holders, HHS assumed that all of the estimated printing and distribution costs will be expended in the first year after the effective date of the rule. Familiarization costs, information collection requirements, and paperwork burden costs would be incurred within the first year after the effective date of the final regulation. According to HHS, the cost of enforcement, by contrast, will increase over the course of the first 5 years. HHS concluded that the annualized cost of this rule over the first 5 years following its publication is \$192.5 million using a discount rate of 3 percent, and \$197.8 million using a discount rate of 7 percent.

HHS states that in most respects, the final rule clarifies existing obligations under existing authorities and noted in the cost analysis that it does not expect that covered entities will incur costs related to the clarification of those existing obligations in the final rule. HHS states that recipients are already required to take reasonable steps to ensure meaningful access to their programs and activities by persons with limited English proficiency. HHS noted that the additional provisions related to serving individuals with limited English proficiency in the final rule may create some additional costs but will also create substantial benefits to patients and providers by improving access to quality care. Further, HHS referenced studies that show that individuals with limited English proficiency experience barriers to receiving regular and adequate health care, but that when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decisionmaking, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance. According to HHS, additional intangible benefits may include retention of cultural information, exchange of information, greater satisfaction with care, and enhanced privacy and autonomy of individuals with limited English proficiency who may have previously had to rely on family members for language assistance. HHS stated that health service providers also benefit from providing language assistance services for individuals with limited English proficiency. For example, providers can more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are understood by patients. HHS cited studies that found that language assistance services aid clinicians in establishing an empathic connection with patients which benefit both patients and providers alike. HHS cited a study that stated that ensuring effective communication can also help providers avoid costs associated with damages paid to patients, legal fees, the time lost when defending a lawsuit, the loss of reputation and patients, the fear of possible monetary loss, and the stress and distraction of litigation. HHS cited an additional study noting the costs of litigation.

HHS states that it expects that the prohibition of sex discrimination in the final rule will also result in benefits. According to HHS, many women and transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities. Continued discrimination, according to HHS,

demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

HHS states that for transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them. HHS states that another potential barrier to care for transgender individuals is that covered entities' nondiscrimination policies often do not include gender identity. HHS also stated that another barrier for transgender individuals is the process of obtaining health insurance coverage. Ultimately, according to HHS, transgender individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care, which may lead to negative health consequences. HHS cited studies in the final rule in support of all of these statements. HHS stated that by prohibiting discrimination on the basis of sex, Section 1557 would result in more women and transgender individuals obtaining coverage and accessing health services. HHS stated that declines in the rates of the uninsured are attributable to many factors; among these factors may be provisions in PPACA prohibiting discriminatory practices in insurance. HHS expects that the Section 1557 final rule may contribute to a continued reduction in the number of individuals who are uninsured, but concluded that the reduction would be much more modest. As a representative example, HHS described a State of California economic impact assessment of state practices prohibiting gender discrimination in health care, which cited the following benefits: (1) reduced violence against affected individuals; (2) reduced depression and suicide attempts among the affected population; and (3) overall declines in substance abuse, smoking and alcohol abuse rates, and improvements in mental health among treated individuals in lesbian, gay, bisexual, or transgender (LGBT) populations who receive appropriate medical treatment. Moreover, HHS states that because discrimination contributes to health disparities, the prohibition of sex discrimination in health care under Section 1557 can help reduce health disparities. HHS said that while it is not possible to quantify the benefits of the reduction in health disparities, the benefits would include more people receiving adequate health care, regardless of their sex, including gender identity. HHS states that it believes that the Section 1557 regulation will likewise contribute to a decrease in payments by the federal government for uncompensated care by promoting an increase in the number of individuals who have coverage when they receive care. Finally, HHS concluded that aside from the specific benefits and transfers that women and transgender individuals, and the health care community can be expected to gain from the enactment of the regulation, there are additional benefits that are intangible and unquantifiable that can be derived from providing equal access to health care for all.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

HHS certified that the final rule will not have a significant impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

HHS conducted an impact analysis under the Unfunded Mandates Reform Act and provided a summary of the conclusions in the final rule. The impact analysis states that the burden associated with training staff working for covered entities will be spread widely across health care entities, state and local governmental entities, and a substantial number of health insurance issuers. The analysis estimates the unfunded burden will be about \$422 million in training and familiarization costs. HHS projected that for the first few years following promulgation of the final rule, private sector costs for investigating discrimination complaints may amount to \$87 million per year. Within the first 5 years following the final rule's promulgation, HHS anticipates that complaints will increase and then eventually drop off as covered entities modify their policies and practices in response to the final rule.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On August 1, 2013, HHS's Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the *Federal Register* to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from

individuals. On September 8, 2015, HHS issued a proposed rule, "Nondiscrimination in Health Programs and Activities," in the *Federal Register*, and invited comment on the proposed rule by all interested parties. 80 Fed. Reg. 54,172. The comment period ended on November 9, 2015. In total, HHS received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of commenters, including, but not limited to: civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving LGBT individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; state and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. According to HHS, the great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups. HHS summarized and responded to the relevant public comments in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

HHS stated that the final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under PRA. The final rule estimates four categories of information collection: (1) submission of an assurance of compliance form, per § 92.5 of the final rule; (2) posting of a nondiscrimination notice and posting of taglines, under § 92.8 of the final rule; (3) development and implementation of a language access plan, anticipated per § 92.201 of the final rule; and (4) designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees, per § 92.7 of the final rule.

HHS states that it will use this information to ensure covered entities' adherence to the statutory requirements imposed under Section 1557 and this final rule. HHS will enforce the requirements by verifying during investigations of covered entities that an entity has submitted an assurance of compliance and posted the notice and taglines and, for each covered entity that employs 15 or more persons, that an individual has been designated to coordinate its compliance efforts and that appropriate grievance procedures have been adopted, as required.

HHS provided an explanation of the respondents and an estimated number of covered entities. Respondents are: HHS, each entity that operates a health program or activity, any part of which receives federal financial assistance, and each entity established under title I of PPACA that administers a health program or activity, which includes such entities as hospitals, home health agencies, community mental health centers, skilled nursing facilities, and health insurance issuers. The number of respondents was estimated to include the 275,002 covered entities affected by the final rule.

HHS provided an estimate of the burden to comply with the requirements. The total estimated annual burden costs for the proposed information collection requirements will be approximately \$86.0 million in the first year, \$76.2 million in the second year, and \$97.5 million per year in years 3 through 5 following publication of the final rule.

Statutory authorization for the rule

HHS states that the final rule was promulgated under the authority of section 1557 of the Patient Protection and Affordable Care Act (PPACA), 42 U.S.C. § 18116, and under 5 U.S.C. § 301.

Executive Order No. 12,866 (Regulatory Planning and Review)

HHS states that OMB determined that the final rule is a "significant regulatory action" under Executive Order 12,866. Accordingly, OMB reviewed this final rule.

Executive Order No. 13,132 (Federalism)

HHS concluded that the regulation does have federalism implications but preempts state law only where the exercise of state authority directly conflicts with the exercise of federal authority under the federal statute.