

**Request for OMB Review and Approval
Under the Paperwork Reduction Act and 5 C.F.R. § 1320
February 8, 2018**

Supporting Statement

Information Collection for Notice Requirement (proposed 45 C.F.R. § 88.5)

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal health care conscience and associated anti-discrimination laws that the Department proposes to implement in the proposed rule *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 FR 3880 (January 26, 2018), are as follows:

- Conscience protections related to abortion, sterilization, and certain other health services to participants in programs—and their personnel—funded by the Department (the Church Amendments, 42 U.S.C. 300a-7);
- Conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion (the Coats-Snowe Amendment, 42 U.S.C. 238n);
- Protections from discrimination for health care entities and individuals who object to furthering or participating in abortion under programs funded by the Department’s yearly appropriations acts (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d), 131 Stat. 135 (the Weldon Amendment) and at Div. H, Tit. II, sec. 209 (Weldon language applied to Medicare Advantage);
- Certain provisions of the Affordable Care Act applying Federal conscience protections (42 U.S.C. 18023(c)(2)(A)(i)-(iii), (b)(1)(A), and (b)(4)), regarding assisted suicide (42 U.S.C. 18113), and providing a conscience exemption to the individual mandate (26 U.S.C. 5000A(d)(2));
- Certain laws governing provider counseling, referral, and implementation of directives (counseling and referral in Medicare Advantage ((42 U.S.C. 1395w-22(j)(3)(B)), counseling and referral in Medicaid (42 U.S.C. 1396u-2(b)(3)(B)), and performance of advanced directives in the Medicare and Medicaid programs (42 U.S.C. 1396a(w)(3), 1395cc(f), and 14406);
- Conscience and anti-coercion laws applicable to Global Health Programs for HIV/AIDS Prevention, Treatment, or Care (22 U.S.C. 7631(d)) and certain funds appropriated to the U.S. Department of State and USAID (the Helms Amendment (*e.g.*, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, sec. 7018));

- Laws providing for patient objections to receiving health care services, including medical screening, examination, diagnosis, treatment, or other health care (42 U.S.C. 1396f), occupational illness testing (29 U.S.C. 669(a)(5)), pediatric vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), youth suicide prevention and treatment (42 U.S.C. 290bb-36(f)), and newborn health screening (42 U.S.C. 280g-1(d)); and
- Laws protecting religious nonmedical health care by exempting religious nonmedical institutions from health facility review (42 U.S.C. 1320a-1), peer review (42 U.S.C. 1320c-11), certain health standards (42 U.S.C. 1396a(a)(83) (referencing 1396a(a)(9) (A)), medical evaluation (42 U.S.C. 1396a(a)(83) (referencing 1396a(a)(31)), medical licensing review (42 U.S.C. 1396a(a)(83) (referencing 1396a(a)(33))), and from utilization review plan requirements (42 U.S.C. 1396b(i)(4)), and protecting the exercise of religious nonmedical health care in the Elder Justice Block Grant Program (42 U.S.C. 1397j-1(b)) and in the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106i(a) (2)).

The proposed rule at § 88.5 would require that each recipient and the Department must post a notice that appraises persons, entities, and health care entities of their rights under the above Federal health care conscience and associated anti-discrimination laws.

2. Purpose and Use of Information Collection

Notice serves three primary purposes. First, persons become apprised of their rights under the applicable Federal health care conscience and associated anti-discrimination laws, including the right to file a complaint with HHS OCR. Second, a person's awareness of his or her rights increases the likelihood that the person will exercise those rights. Third, recipients and their managers and employees will be reminded and be made aware of their own obligations under these laws.

In the event that the OCR Director investigates or initiates a compliance review of a recipient, the OCR Director will consider as one of many factors whether the recipient posted the notice in the documents described in § 88.5(c)(1) through (3), as applicable.

3. Use of Improved Information Technology and Burden Reduction

Proposed § 88.5(b)(1) requires that the notice appear on the Department's and each recipient's website(s). A recipient that voluntarily posts the notice in the documents described in § 88.5(c)(1) through (3), as applicable, may post the notice in such documents even if they are only available electronically or maintained on recipients' websites.

4. Efforts to Identify Duplication and Use of Similar Information

Current 45 C.F.R. part 88 does not require the posting of a notice pertaining to applicable Federal health care conscience and associated anti-discrimination laws. OCR is unaware of any

other information collection that would require such notice.

5. Impact on Small Businesses or Other Small Entities

Consistent with the Regulatory Flexibility Act analysis in the proposed rule at page 157, Department assumes that most, if not all, of the entities affected by the proposed rule would meet the threshold of a small entity. The entities that would be affected by the proposed rule, in the industries described in detail in the Regulatory Impact Analysis, pages 104-132, are considered small by virtue of either nonprofit status or having revenues of less than between \$7.5 million and \$38.5 million in average annual revenue, with the threshold varying by industry.¹ Natural persons and States are not included in the definition of a small entity.

Although proposed § 88.5 will apply to and thus affect small entities, the burden would generally be proportional to the size of an entity, suggesting that the smallest affected entities will face lower average costs. The annualized burden hours and associated costs described *infra* for question 12 assume that each establishment of an entity maintains its own web site and thus would bear the labor cost for a web developer to post the notice on the establishment's web site. For the purpose of this PRA, the Department has erred on the side of overestimating the burden. Therefore, the Department assumed that a web developer at each physical location would incur the labor cost to post the notice online. A key uncertainty with respect to this labor cost is the degree to which each recipient maintains one web site for all of its establishments. If this is the case, a web developer at the firm-level, rather than web developers at each establishment, would bear the labor costs to post the notice online. In contrast to 611,372 establishments bearing the labor costs of the web developer, about 464,792 recipients at the firm-level would bear this cost. The Department outlines these assumptions because the smallest affect entities with one establishment would bear less of a burden to update the website than relatively larger of the smallest affected entities with multiple establishments where web developers at each establishment would bear a burden to update the establishment web sites.

In addition, in an effort to further reduce burden, proposed § 88.5 requires recipients to post the text of the notice in appendix A to proposed 45 C.F.R. part 88. This approach leverages economies of scale by requiring recipients to post the exact text from the notice in Appendix A and avoids the recipients having to bear the labor costs of consulting with counsel and executives.

6. Consequences of Collecting the Information Less Frequently

Respondents' posting of the notice and physical spaces and online is a one-time posting. Thus, the notice cannot be posted any less frequently.

7. Special Circumstances Relating to the Guidelines of 5 C.F.R. § 1320.5

¹ https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.

No special circumstances are involved in this collection of information.

8. Comments in Response to the Federal Register Notice/Outside Consultation

The proposed rule seeks public comment on this proposed information collection in the Notice of Proposed Rulemaking entitled *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 FR 3,880, 3,921-22 (January 26, 2018), which has a 60-day comment period.

9. Explanation of any Payment/Gift to Respondents

No such payments or gifts are foreseen to the respondents, and none have been given.

10. Assurance of Confidentiality Provided to Respondents

This proposed collection of information does not request personal identifying information regarding individuals, such as a Social Security number, home address, or other identifiable information.

11. Justification for Sensitive Questions

This proposed information collection would not seek information of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, race/ethnicity, social security numbers, or other matters that are commonly considered private and sensitive.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

The respondents are recipients, as defined in proposed 45 C.F.R. § 88.2. Respondents include, but are not limited to, hospitals, research institutions, health professions training programs, qualified health plan issuers, Health Insurance Marketplaces, home health agencies, community mental health centers, and skilled nursing facilities. The number of respondents required to post the notice in physical locations and online is estimated at 611,372 establishments. This estimate represents the average between the lower and upper-bound estimates of how many recipient establishments must post notices. Respondents are a subset (99.5%) of the total scope of entities subject to the proposed rule because the notice requirement does not apply to sub-recipients.

As described in the response to question 5, this PRA assumes that each establishment of an entity maintains its own web site and thus would bear the labor cost for a web developer to post the notice on the establishment's web site. This assumption, however, reflects a key uncertainty that affects burden. If each recipient maintains one web site for all of its establishments, then a web developer at the firm-level, rather than web developers at each

establishment, would bear the labor costs to post the notice online. Consequently, in contrast to 611,372 establishments bearing the labor costs of the web developer, about 464,792 recipients at the firm-level would bear this cost. For the purpose of this PRA analysis, the Department has erred on the side of overestimating the burden and assumes that a web developer at each establishment will bear the labor cost of updating an establishment web site.

The number of respondents likely to voluntarily post the notice in the first year, as § 88.5(c)(1) through (3) permits, is 305,686 establishments which is half of all establishments subject to the notice requirement (611,372 establishments X 50%). In years 2 through five, approximately 152,843 establishments (305,686 establishments / 2) will annually undertake such voluntary posting. The annualized number of respondents for the voluntary posting across five years is 185,245.

Mandatory Posting

The Department estimates that the burden for the notice is represented in terms of opportunity costs of staff time to download, print, and post the notice. The Department estimates that it would take 1/3 of an hour for an administrative assistant to download the notice, print notice(s) and post them in physical locations of the establishment where notices are commonly posted. To post the notice on the web, the Department estimates that it will take 2 hours for a web developer to execute the design and technical elements to post the notice online. For some establishments, it may take an administrative assistant or web developer longer to perform these functions; for other establishments, it may take less time.

The total burden hours per establishment to post the notice in physical locations and online is 2.33 hours, or 140 minutes, in the first year of the proposed rule’s implementation and zero in years two through five. Annualized across five years, the total burden hours per establishment for mandatory posting is 0.5 hours, or 30 minutes.

Voluntary Posting

The proposed notice provision at § 88.5(c)(1) through (3) includes language designed to incentivize recipients to include the OCR-drafted notice in certain types of documents or publications. The Department assumes that an administrative assistant would identify documents in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with paper documents. The assistant may spend a total of 2 hours in year one and 1 hour annually in years 2 through 5. Annualized across five years, the total burden hours per establishment for voluntary posting is 1.2 hours, or 73 minutes.

Estimated Annualized Burden Hours

Type of Respondent	Proposed regulatory provision	No. of Respondents	No. Responses Per Resp.	Avg. Burden / Response (in hours)	Total Burden Hours
States, certain health	88.5(a)	611,372	1	30/60	305,686

care providers, other persons and entities	(mandatory posting)				
States, certain health care providers, other persons and entities	88.5(c)(1)-(3) (voluntary posting)	185,245	1	73/60	225,381
Total					531,067

12B. Estimated Annualized Burden Costs

The weighted hourly wage (not including benefits and overhead) used to calculate the labor costs of the mandatory posting is \$32.50 per hour ((1/7 hour X \$19.39/hr. for an administrative assistant (occupation code 43-6010)) + (6/7 hour X \$34.69 per hour for a web developer (occupation code 15-11134)). See Bureau of Labor Statistics, Occupational and Employment Statistics, Occupational Employment and Wages, May 2016, https://www.bls.gov/oes/current/oes_nat.htm. The hourly wage used to calculate the labor costs of the voluntary posting is \$19.39 / hour for an administrative assistant.

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Weighted Hourly Wage Rate	Total Respondent Costs
States, certain health care providers, other persons and entities	305,686	\$32.50	\$9,934,795
States, certain health care providers, other persons and entities	225,381	\$19.39	\$4,370,146
Total			\$14,304,941

13. Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs

The non-labor costs include the cost of materials (paper and ink) at \$0.05 per page that recipients post in physical spaces, as § 88.5(b)(2) requires, or that recipients voluntarily include in certain documents, as § 88.5(c)(1) through (3) incentivizes.

Materials Cost Associated with the Mandatory Posting

With respect to the mandatory posting in physical spaces, which proposed § 88.5(b)(2) requires, the number of locations where notices are commonly posted in an establishment will vary based on multiple factors. These factors may include the type of recipient, floor plans of the building, the square footage of the common areas, the square footage of the building, the number of floors, the size of the workforce, and the number of ultimate beneficiaries, among other variables. The Department assumes that the average establishment will print and post five notices; larger entities might post more and smaller entities post fewer.

Based on this assumption, the first-year cost to post 5 notices across all establishments would be (611,372 establishments X \$.05 per page X 5 pages), which amounts to about \$152,843. Because the Department assumes that this cost is a one-time, upfront cost, it will not recur in the out-years. Annualized across five-years, the cost of materials associated with posting the notice is \$32,403 per year.

Materials Cost Associated with Voluntary Posting

With respect to voluntary posting that proposed § 88.5(c)(1) through (3) incentives, the Department anticipates that there may be some additional printing costs where inclusion of the notice adds a page to the underlying document. There is a high degree of uncertainty as to the average number of documents in which a recipient may proactively include the notice. There is also uncertainty as to whether a recipient would print the publications or house them online. The Department estimates that a recipient that voluntarily includes the notice in publications may print some publications and house others online; on balance, the recipient might print approximately 100 extra pages. With these assumptions, the cost of voluntarily included notices, as proposed § 88.5(c) incentivizes, will cost approximately \$1.5 million in the first year (305,686 entities X 100 pages X \$.05 per page) and \$764,216 annually in years two through five. Annualized across five-years, the cost of materials associated with posting the notice is \$926,226 per year.

14. Costs to Federal Government

The annual burden to the Federal government includes the labor cost associated with implementing the notice requirement and the materials cost associated with the paper and ink for posting the notice in physical locations or documents.

Labor Costs

- *One-time burden of HHS OCR staff time developing the content of the notice.* An OCR Civil Rights Analyst would spend 8 hours developing the content of the notice that appears in appendix A of the proposed rule. Annualized across five years, the total hours per year is two.
- *HHS component staff time for posting the notice to comply with the mandatory and voluntary posting provisions.*

The burden to the Federal Government for the mandatory and voluntary posting provisions is represented in terms of opportunity costs of staff time to download, print, and post the notice. The Department estimates that it would take 1/3 of an hour for an administrative assistant to download the notice, print notice(s) and post them in physical locations of the applicable Department component where notices are commonly posted. There is a high degree of uncertainty regarding the number of locations that would have a

posted notice; thus, the estimated number of hours likely underestimates the actual burden. To post the notice on the web, the Department estimates that it will take 2 hours for a web developer to execute the design and technical elements to post the notice online. The total burden hours to post the notice in physical locations and online is 2.33 hours, or 140 minutes, in the first year of the proposed rule's implementation and zero in years two through five. Annualized across five years, the total burden hours for mandatory posting is 0.5 hours, or 30 minutes, for each of the 11 HHS Operating Divisions and the HHS Office of the Secretary, resulting in 360 hours per year.

The Department anticipates that its own components, in contrast to regulated persons and entities, are more likely to post notices voluntarily to set an example for the regulated community. Consequently, the Department anticipates that each of the 11 HHS Operating Divisions and the HHS Office of the Secretary would voluntarily post notices in the types of documents outlined as § 88.5(c)(1)-(3) incentives and would do so each year. The Department assumes that an administrative assistant would identify documents in which to include the notice, revising the documents or their layouts to include the notice, or otherwise printing an insert to include with paper documents. The assistant may spend a total of 2 hours in year one and 1 hour annually in years 2 through 5. Annualized across five years, the total burden hours for voluntary posting is 1.2 hours, or 73 minutes for each of the 11 HHS Operating Divisions and the HHS Office of the Secretary, resulting in about 15 hours per year.

The average hourly wage rate for the staff members who implement the notice requirement will likely range from a GS-3 to a GS-11. For the purpose of these calculations, the Department uses the hourly wage rate of the mid-point – a GS-7 step 5, which is \$19.47 per hour. See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/GS_h.aspx.

The estimated annualized labor cost is about \$7,340 per year for the mandatory and voluntary notice provisions ($\$19.47 \times (2 \text{ hours} + 360 \text{ hours} + 15 \text{ hours})$).

Materials Costs

With respect to the mandatory posting in physical spaces, which proposed § 88.5(b)(2) requires, the number of locations where notices are commonly posted in an applicable Department component will vary based on the applicable programs that the Department administers with respect to the proposed rule, the floor plans of the building, the square footage of the common areas, the square footage of the building, the number of floors, the size of the workforce, and the number of ultimate beneficiaries, among other variables. The average Department component would print and post 50 notices; larger establishments might post more and smaller establishments might post fewer notices. Based on this assumption, the first-year cost to post 5 notices across all establishments would be (12 HHS Components \times 50 pages \times \$.05 per page), which amounts to about \$30. Because the Department assumes that this cost is a one-time, upfront cost, it will not recur in the out-years. Annualized across five-years, the cost

of materials associated with posting the notice to comply with the mandatory provision is \$6 per year.

There is a high degree of uncertainty as to the average number of documents in which a Department component may proactively include the notice. There is also uncertainty as to whether a Department component would print the publications or house them online. The Department estimates that a recipient that voluntarily includes the notice in publications may print some publications and house others online; on balance, the component might print approximately 50 times the number of pages recipients printed (100) given the Department's national scope, which results in 5,000 extra pages per year. With these assumptions, the cost of voluntarily including notices, as proposed § 88.5(c) incentivizes, will cost approximately \$ 3,000 per year (12 entities X 5,000 pages X \$.05 per page).

The total materials cost for the mandatory and voluntary notice requirement is \$3,006 per year. The total annual cost to the Federal government is \$10,346 per year, which is the sum of the total annualized labor costs (\$7,340 per year) plus the total annualized materials costs (\$3,006 per year).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

None.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

None.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

No statistical methods are employed in relation to the information collected.