

**Request for OMB Review and Approval
Under the Paperwork Reduction Act and 5 C.F.R. § 1320
November 24, 2019**

Supporting Statement: Information Collection for Assurance of Compliance, Form HHS-690

NOTE: OCR is amending this Information Collection Request in light court decisions regarding the recently published rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019) (“the 2019 Rule”). See, e.g., *State v. United States Department of Health & Human Services*, No. 19 Civ. 4676 (PAE), 2019 WL 5781789 (S.D.N.Y. Nov. 6, 2019). Form HHS-690 states that the signatory is providing assurance of compliance with certain conscience laws and 45 C.F.R. Part 88. In light of the court decisions by which the 2019 Rule is not in effect, Part 88 as finalized in 2011 remains in effect at this time. See 76 Fed. Reg. 9,976-77 (February 23, 2011). Accordingly, the form clarifies that assurance of compliance with Part 88 applies to that Part to the extent it is in effect during the term of the award, to ensure it is clear the form does not require assurance with the 2019 Rule at any time such rule is not in effect. Depending on the outcome of the ongoing litigation, the Department may request further revisions to this Information Collection Request, as appropriate, to clarify the scope of the active approval.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Department is requesting Paperwork Reduction Act (PRA) approval for form HHS-690 under OMB number 0945-0008. This information collection is necessary to operationalize HHS’s obligation to communicate and incorporate statutory and public policy requirements in award instruments and obligate the recipient to comply with Federal statutes and “public policy requirements, including . . . those . . . prohibiting discrimination.”¹ Form HHS-690 is entitled “Assurance of Compliance.”²

This collection of information facilitates the Department’s obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal civil rights laws (including conscience protection and associated anti-discrimination laws) and HHS implementing regulations. The Department is accountable to the American public for promoting the integrity of Federal financial assistance and other Federal funds that the Department awards. The Department’s administration of a requirement for an entity at the time of application or reapplication to assure and certify compliance with Federal civil rights laws demonstrates that the entity was aware of its obligations under those laws and respective HHS implementing regulations.

HHS has the authority to place terms and conditions consistent with those statutes in any award instrument HHS issues or to which it is a party (e.g., grants, contracts or other HHS

1 45 C.F.R. § 75.300(a).

2 <https://www.hhs.gov/sites/default/files/hhs-690.pdf>.

agreements). A Department component extending an award must communicate and incorporate statutory and public policy requirements and obligate the recipient to comply with Federal statutes and “public policy requirements, including . . . those . . . prohibiting discrimination.”³ More specifically, the Department component “must communicate . . . all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.”⁴ The Departmental component may require a recipient “to submit certifications and representations required by Federal statutes, or regulations”⁵

Federal laws with which recipients would be required to assure compliance, if applicable, are:

- Title VI of the Civil Rights Act of 1964 (Title VI), Pub. L. 88-352, codified at 42 U.S.C. § 2000d-1 *et seq.*, and its implementing regulation, 45 C.F.R. Part 80, which prohibit discrimination on the grounds of race, color, or national origin by recipients of Federal financial assistance. This encompasses the requirement for recipients to take reasonable steps to provide meaningful access to persons who are limited English proficient (LEP). See Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (2003).
- Section 504 of the Rehabilitation Act of 1973 (Section 504), Pub. L. 93-112, as amended by Pub. L. 93-516, codified at 29 U.S.C. § 794, and its implementing regulation, 45 C.F.R. Part 84, which prohibit discrimination on the basis of disability by recipients of Federal financial assistance. This encompasses the requirement for recipients to provide auxiliary aids and services to persons with disabilities.
- Title IX of the Education Amendments of 1972 (Title IX), Pub. L. 92-318, as amended, codified at 20 U.S.C. § 1681 *et seq.* and its implementing regulation, 45 C.F.R. Part 86, which prohibit discrimination on the basis of sex by recipients of Federal financial assistance in education programs or activities.
- Age Discrimination Act of 1975, Pub. L. 94-135, codified at 42 U.S.C. § 6101 *et seq.*, and its implementing regulation, 45 C.F.R. Part 91, which prohibit discrimination on the basis of age by recipients of Federal financial assistance.
- Section 1557 of the Patient Protection and Affordable Care Act (Section 1557), Pub. L. 111-148, as amended, codified at 42 U.S.C. § 18116, and its implementing regulation, 45 C.F.R. Part 92, which prohibit discrimination on the basis of race, color, national origin, disability, sex and age by recipients of Federal financial assistance and certain health programs and activities administered by HHS. This encompasses the requirement for recipients to take reasonable steps to provide meaningful access to persons who are LEP and to provide auxiliary aids and services to persons with disabilities.

³ 45 C.F.R. § 75.300(a).

⁴ *Id.*

⁵ *Id.* § 75.208.

- Federal conscience and anti-discrimination laws (various U.S. Code and public law citations listed *infra* at 3), and the implementing regulation, 45 C.F.R. Part 88, which collectively prohibit discrimination against individuals and entities that act in accord with their religious beliefs or moral convictions with respect to certain procedures. This collection of information relates to 45 C.F.R. § 88.4 of the rule entitled *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (May 21, 2019) (effective Nov. 22, 2019). The Notice of Proposed Rulemaking was published on January 26, 2018, 83 Fed. Reg. 3880.

The specific Federal conscience and anti-discrimination laws are:

- Conscience protections related to abortion, sterilization, and certain other health services applicable to the Department of Health and Human Services and recipients of certain Federal funds encompassed by 42 U.S.C. 300a-7 (the “Church Amendments”);
- 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 that do not provide, pay for, provide coverage of, or refer for abortions under programs funded by the Department's appropriations acts (*e.g.*, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Div. B., sec. 507(d), Public Law 115-245, 132 Stat. 2981 (Sept. 28, 2018), as extended by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, Pub. L. No. 116-59, Div. A., sec. 101(8), 133 Stat. 1093, 1094 (Sept. 27, 2019) (the “Weldon Amendment”); *id.*, sec. 209);
- Protections from discrimination under the Patient Protection and Affordable Care Act (“ACA”) for health care entities that do not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing, applicable to the Federal Government and any State or local government that receives Federal financial assistance (42 U.S.C. 18113); and conscience protections for providers, organizations, or their employees regarding counseling regarding the same (42 U.S.C. 14406(1));
- Conscience protections regarding exemptions applicable to the ACA's individual mandate (26 U.S.C. 5000A; 42 U.S.C. 18081);
- Conscience protections under the ACA for qualified health plans related to coverage of abortion, and for individual health care providers and health care

facilities that do not provide, pay for, provide coverage of, or refer for abortions (42 U.S.C. 18023(b)(1)(A) and (b)(4));

- o Conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services (42 U.S.C. 1395w-22(j)(3)(B) and 1396u-2(b)(3)(B));
- o Conscience protections related to the performance of advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406(2));
- o Conscience and nondiscrimination protections for organizations related to Global Health Programs, to the extent such funds are administered by the Secretary of HHS (the “Secretary”) (22 U.S.C. 7631(d));
- o Conscience protections attached to Federal funding, to the extent such funding is administered by the Secretary, regarding abortion and involuntarily sterilization (22 U.S.C. 2151b(f), *see, e.g.*, the Consolidated Appropriations Act, 2019, Pub. L. 116-6, Div. F, sec. 7018 (the “Helms, Biden, 1978, and 1985 Amendments”));
- o Conscience protections from compulsory health care or services generally (42 U.S.C. 1396f and 5106i(a)), and under specific programs for hearing screening (42 U.S.C. 280g-1(d)), occupational illness testing (29 U.S.C. 669(a)(5)); vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb-36(f)); and
- o Protections for religious nonmedical health care providers and their patients from certain requirements under Medicare and Medicaid that may burden their exercise of their religious beliefs regarding medical treatment (*e.g.*, 42 U.S.C. 1320a-1(h), 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j-1(b)).

2. Purpose and Use of Information Collection

This information collection serves two purposes. First, through the act of reading and reviewing the statutory requirements to which recipients and applicants assure compliance, recipients and applicants would be apprised of their obligations under the applicable Federal conscience and anti-discrimination laws. Second, a recipient’s awareness of its obligation would increase the likelihood that it would comply with such laws and consequently afford entities and individuals protection under such laws.

The Department and its components (including CMS) awarding Federal financial assistance or other Federal funds and OCR will use the signed assurance and certification as documentation of: (1) a recipient’s or applicant’s awareness of its obligations under the Federal conscience and anti-discrimination laws and this final rule, and (2) a recipient’s commitment to comply with such statutes and implementing regulations via the terms and conditions consistent

with those statutes in instruments that HHS issues or to which it is a party. These uses would most likely occur during an OCR investigation of the recipient's compliance with Federal civil rights laws and as part of an entity's record keeping obligations under such statutes and implementing regulations. The HHS Grants Policy Statement states that "[b]efore an awarding office may make an award to a domestic organization, the authorized organizational representative must assure, by means of the signature on the application, that the organization has on file with OCR an Assurance of Compliance with the statutes enforced by OCR."⁶

3. Use of Improved Information Technology and Burden Reduction

Operationalizing the Assurance of Compliance

The Department is leveraging form HHS-690, which is familiar to Medicare Part A providers and other applicants of Federal financial assistance from HHS. Form HHS-690 previously had OMB approval under the PRA under # 0945-0006 as part of a package OCR used to review prospective Medicare Part A providers' compliance with certain Federal civil rights laws. CMS relied upon OCR's determination in approving providers for participation in Medicare Part A. When OCR, in coordination with CMS, ended the program of compliance reviews for prospective Medicare Part A providers, OCR discontinued the program's PRA package in February 2017, which discontinued the HHS-690 form.

This information collection request reinstates form HHS-690, which is a portion of the collection previously approved under OMB # 0945-0006. Form HHS-690 approved under OMB # 0945-0006 addressed five civil rights laws and the HHS implementing regulations for those laws: Title VI of the Civil Rights Act of 1964 and the HHS implementing regulation at 45 C.F.R. pt. 80, Section 504 of the Rehabilitation Act of 1973 and the HHS implementing regulation at 45 C.F.R. pt. 84, Title IX of the Education Amendments of 1972 and the HHS implementing regulation at 45 C.F.R. pt. 86, the Age Discrimination Act of 1975 and the HHS implementing regulation at 45 C.F.R. pt. 91, and Section 1557 of the Affordable Care Act and its implementing regulation at 45 C.F.R. pt. 92.⁷ The HHS regulations for these laws require applicants and recipients to assure their compliance.⁸

This information collection adds a six set of laws to include Federal conscience and anti-discrimination protections. The new language added to form HHS-690 identifies the major conscience laws by their popular title and their U.S. Code provision (if codified) and references the current version of the conscience implementing regulation currently in effect (45 C.F.R. pt. 88). The new language directs the reader to OCR's Conscience and Religious Freedom webpage

⁶ See HHS Grants Policy Statement I-31 (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

⁷ *Id.*

⁸ See 45 C.F.R. §§ 80.4 (requiring recipients to assure compliance with HHS Title VI regulations), 84.5 (requiring recipients to assure compliance with HHS Section 504 regulations), 86.4 (requiring recipients to assure compliance with HHS Title IX regulations), 91.33 (requiring recipients to assure compliance with the Age Act and HHS implementing regulations), 92.5 (requiring recipients and entities created under Title I of the Affordable Care Act to assure compliance with Section 1557 and the HHS implementing regulation).

for a full listing of the laws.

The form enables an applicant to provide an assurance that it will comply with certain Federal civil rights laws and regulations “in consideration of and for the purpose of obtaining Federal grants, loans, contracts, property, discounts, or other Federal financial assistance” from the Department.⁹ By signing the assurance of compliance, the applicant “agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the Applicant, its successors, transferees and assignees for the period during which such assistance is provided.”¹⁰ Applicants may use an online portal linked to form HHS-690 to provide the assurance rather than mailing a paper form to OCR. All HHS components can use an applicant’s completed HHS-690 form as an assurance of compliance with Federal civil rights laws if an HHS component chooses to use and rely on it.¹¹

Operationalizing the Certification of Compliance Requirement

This information collection request relates to the assurance of compliance in 45 C.F.R. § 88.4(a)(1) of the rule entitled *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (May 21, 2019). This information collection request does not include the related certification of compliance in § 88.4(a)(2) (effective Nov. 22, 2019). For completeness, however, this request summarizes the existing information collections through which the Department is operationalizing the certification requirement.

In calendar year 2019, the Department is operationalizing the certification requirement through the existing signature block of the government-wide Application for Federal Assistance (SF-424) (OMB # 4040-0004),¹² or for research or related grants, through the Application for Federal Assistance for Research and Related (R&R) Series (SF-424 R&R) (OMB # 4040-0001)¹³. The signature block for both applications contains the following statement:

By signing this application, I certify (1) to the statements contained in the list of certifications ** and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances ** and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001).

**The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

9 Form HHS-690 (version accompanying this information collection request).

10 *Id.*

11 See HHS Grants Policy Statement I-31 (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

12 Application for Financial Assistance, SF-424, (OMB # 4040-0004), https://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf (last visited Apr. 11, 2019).

13 Application for Financial Assistance, SF-424 (R&R), (OMB # 4040-0001), https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf (last visited Apr. 11, 2019).

In calendar year 2020, the Department is operationalizing the certification of compliance through the government-wide System for Award Management (SAM)¹⁴ because this system, per an OMB directive, “will become the central repository for common government-wide certifications and representations required of Federal grants recipients.”¹⁵ The certifications and representations through SAM replace the government-wide assurances contained in the Assurances for Non-Construction Programs (SF 424B).¹⁶ “[R]egistration in SAM is required for eligibility for a Federal award and registration must be updated annually”¹⁷ “Federal agencies will use SAM information to comply with award requirements and avoid increased burden and costs of separate requests for such information, unless the recipient fails to meet a Federal award requirement, or there is a need to make updates to their SAM registration for other purposes.”¹⁸

In submitting the general certifications and representations through SAM,¹⁹ the authorized representative certifies to nine paragraphs of statements, two of which the Department interprets as operationalizing § 88.4(b).²⁰ First, paragraph nine states that the authorized representative certifies that it “[w]ill comply with U.S. statutory and public policy requirements which prohibit discrimination, including but not limited to[]” several Federal civil rights statutes.²¹ The Federal conscience and anti-discrimination laws are not listed because the general certifications and representations identified in SAM are government-wide, not agency or multi-agency specific. However, the Department construes the non-exhaustive list as incorporating the Federal conscience and anti-discrimination laws, as applicable, that the final rule implements. Second, paragraph seven states that the authorized representative certifies that it “[w]ill comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies government financial assistance awards and any financial assistance project covered by this certification document.”²² HHS construes this catch-all statement as incorporating the Federal conscience and anti-discrimination laws, as applicable, and 45 C.F.R. pt. 88.

4. Efforts to Identify Duplication and Use of Similar Information

14 U.S. Gen. Servs. Admin., System for Award Management, *Home*, <https://www.sam.gov/SAM/pages/public/index.jsf> (last visited Apr. 11, 2019).

15 Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf>.

16 *See id.*

17 *Id.*

18 *Id.*

19 U.S. Gen. Servs. Admin., System for Award Management, SAM Release Notes Build 2019-02-01, at 3 (Feb. 2, 2019), https://www.sam.gov/SAM/transcript/SAM_Release_Notes_2019_02_01.pdf (describing under “enhancements” that SAM has “a new government-wide Financial Assistance Representations and Certifications module within the SAM entity management registration” and “[a]ll non-federal registrants in SAM will be required to certify to the new Financial Assistance Reps & Certs as part of their registration”).

20 The certifications and representations are not publicly available until an individual creates an account. The list of certifications and representations were obtained from staff at Grants.gov on March 19, 2019, and are on file with OCR.

21 Financial Assistance General Certifications and Representations, at 2, para. 9 (on file with OCR).

22 Financial Assistance General Certifications and Representations, at 1, para. 7 (on file with OCR).

See previous response, which explains the Department’s intention that this information collection reinstates the previously PRA-approved form HHS-690 and modifies it to include Federal conscience and anti-discrimination laws and the version of the conscience implementing regulation at 45 C.F.R. pt. 88 in effect.

5. Impact on Small Businesses or Other Small Entities

The Department assumes that many of the entities affected by this assurance meet the threshold of a small entity 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.²³ Natural persons and States are not included in the definition of a small entity. Small providers that had been impacted by form HHS-690 before its discontinuance in 2017 will again be impacted by this form when it is reinstated.

The assurance requirements at 45 C.F.R. 88.4 (effective Nov. 22, 2019) contain exceptions to relieve many small entities of the requirement to submit an assurance.²⁴ Excepted providers, however, may become subject to section 88.4 if they receive Federal financial assistance or Federal funds from the Department through a mechanism or in a manner not exempted by section 88.4(c). For example, a physician office participating in Medicare Part B, which would be excepted under 88.4(c)(1), may become subject to the assurance requirement by receiving Department funds to conduct clinical research. Such exceptions at 45 C.F.R. 88.4(c) (effective Nov. 22, 2019) do not apply to applicants or recipients submitting an assurance under Title VI, Section 504, Title IX, Section 1557, or the Age Act, which means that small entities exempted under 88.4(c) may still have to respond to this information collection by virtue of their obligations under Title VI, Section 504, Title IX, Section 1557, or the Age Act.

6. Consequences of Collecting the Information Less Frequently

Section 88.4(b)(1)(i)-(ii) of 45 C.F.R. (effective Nov. 22, 2019) requires submission more frequently than at the time of application for HHS Federal financial assistance or other Federal funds if the applicant or recipient fails to meet a requirement of the rule, or OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure. To forgo as needed assurances outside of the application process jeopardizes OCR’s and the Department’s flexibility to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and 45 C.F.R. pt. 88.

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

For information collections required more often than quarterly, an agency must demonstrate that such frequency “is necessary to satisfy statutory requirements or other substantial need.” 5 C.F.R. § 1320.5(d)(2)(i). Although this information collection will not require, *per se*, a respondent to report to the Department more than quarterly, the likely

²³ https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.

²⁴ 45 C.F.R. 88.4(c) (effective Nov. 22, 2019).

frequency with which respondents would apply for new or continued Federal financial assistance or Department funding will likely be more than quarterly. Section 88.4(b)(6) (effective Nov. 22, 2019), and sections 84.5(a) and 92.5(a) of 45 C.F.R. allow an applicant or recipient to incorporate the assurances by reference in subsequent applications to the Department or Department component if prior assurances are initially provided in the same year. This approach is consistent with the HHS Grants Policy Statement.²⁵ Because recipients file an assurance of compliance form “for the organization and . . . not . . . for each application,” a recipient with a signed assurance on file assures through its signature on the award application that it has a signed form HHS-690 on file.²⁶ This approach is also consistent with OMB’s directive on the use of SAM: “[R]egistration in SAM is required for eligibility for a Federal award and registration must be updated *annually*”²⁷ “Federal agencies will use SAM information to comply with award requirements and avoid increased burden and costs of separate requests for such information, *unless the recipient fails to meet a Federal award requirement*, or there is a need to make updates to their SAM registration for other purposes.”²⁸

Thus, the Department expects that each entity applying for funding will sign the assurance once per year. The Department does not have an estimate of how frequently a recipient will fail to meet a requirement of the rule, or how frequently OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure.

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

The Department sought public comment on the new portion of this proposed information collection in the Notice of Proposed Rulemaking entitled *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3880 (January 26, 2018), which had a 60-day comment period.²⁹ The NPRM solicited public comment on the information collection on pages 3,920-21.

The Department sought, but did not receive, comments on whether the exception for Indian Tribes and tribal Organizations Section 88.4(c)(vi) avoids “tribal implications” and does not “impose substantial direct compliance costs on Indian Tribal governments” as stated in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, sec. 5(b) (Nov. 9, 2000).

The Department sought, but did not receive, comments on whether assuring compliance with the Federal conscience and anti-discrimination statutes would constitute a burden exempt

²⁵ See HHS Grants Policy Statement (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

²⁶ *Id.* at I-31.

²⁷ Exec. Office of the President, Memorandum from Mick Mulvaney, Dir., Office of Management & Budget to Heads of Executive Departments and Agencies, Strategies to Reduce Grant Recipient Reporting Burden, at 2 (Sept. 5, 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/M-18-24.pdf> (emphasis added).

²⁸ *Id.* (emphasis added).

²⁹ <https://www.federalregister.gov/documents/2018/01/26/2018-01226/protecting-statutory-conscience-rights-in-health-care-delegations-of-authority>).

from the Paperwork Reduction Act as a usual and customary business practice incurred by recipients during the ordinary course of business.

The Department sought, but did not receive, comments on how the quality, utility, and clarity of the information to be collected in Section 88.4 may be enhanced.

The Department sought, but did not receive, comments on how the manner of compliance with the assurance and certification requirements could be improved, including through use of automated collection techniques or other forms of information technology.

The Department sought, but did not receive, comments regarding the methods used to estimate the scope of exempted recipients under Section 88.4(c)(1)-(4).

The Department sought but did not receive, comments regarding information, data sources, studies, or reports that could assist the Department in improving its approach to calculate the number of sub-recipients of this rule.

The Department sought, but did not receive, comments on the policy for Section 88.4 to apply to recipients but not sub-recipients, noting that the proposed rule took this approach to reduce burden on small entities.

The Department received comments on the burdens associated with the proposed information collection, comments in response to § 88.4, and general comments in support of this section, as discussed *infra*.

The following summary is from the final rule entitled *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (May 21, 2019) and contains the Department's description of public comments received, the Department's responses to the comments, and the changes the Department made in response to certain comments.

Comment: The Department received comments requesting that exemptions for religious or moral convictions, such as for vaccinations, be included in form HHS-690.

Response: The Department's implementation of the assurance and certification of compliance will address the Federal conscience and anti-discrimination laws implicated by this rule. Because none of the statutes that this rule implements create across-the-board rights for exemptions on the basis of religious or moral convictions to vaccination requirements, the assurance and certification of compliance requirement would not function to obligate recipients to certain conduct not covered by the Federal conscience and anti-discrimination laws.

Comment: The Department received comments requesting that any assurance of compliance be acquired through form HHS-690 to avoid the increased administrative burden of adding new forms or procedures.

Response: The Department agrees with this proposal and is working to obtain Paperwork

Reduction Act clearance for updates to the HHS-690 form entitled *Assurance of Compliance*, which now has OMB No. 0945-0008. (The Department’s operationalization of the certification of compliance required in § 88.4(a)(1) is described in the RIA and PRA portions of this rule.)

The HHS-690 form enables an applicant to provide an assurance that it will comply with certain Federal civil rights laws and regulations “in consideration of and for the purpose of obtaining Federal grants, loans, contracts, property, discounts, or other Federal financial assistance” from the Department.³⁰ By signing the assurance of compliance, the applicant “agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the Applicant, its successors, transferees and assignees for the period during which such assistance is provided.”³¹

As finalized 88.4(b)(1) requires entities that are already recipients as of the effective date of the rule and applicants to submit the assurance and the certification as a condition of any application or reapplication for funds to which the rule applies. Pursuant to the finalized § 88.4(b)(6), it would be permissible to incorporate assurances and certifications by reference in subsequent applications, which is consistent with the Department’s Grants Policy Statement, which states that because recipients file an assurance of compliance form “for the organization and . . . not . . . for each application,” a recipient with a signed assurance on file assures through its signature on the award application that it has a signed form HHS-690 on file.³²

The Department proposed to add a provision to paragraph 88.4(b)(1) that would require submission of the assurance more frequently than at the time of application if the applicant or recipient fails to meet a requirement of the rule, or if OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure. For instance, OCR may have reason to suspect through its investigations or the number of complaints received that a particular recipient is not complying with the Federal conscience and anti-discrimination laws or the rule and consequently asks the recipient to sign an assurance of compliance form off-cycle from the normal grants process. To forgo as-needed assurances outside of the application process jeopardizes OCR’s and the Department’s flexibility to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and this rule.

Comment: The Department received a comment requesting that the certification of compliance contain additional language, such as explicit protections for LGBT patients.

Response: The scope of this rule and the certifications of compliance sought herein are limited to the Federal conscience and anti-discrimination laws. Certifications with respect to other topics or laws not the subject of this rule are outside the scope of this rulemaking.

Comment: The Department received a comment stating that conditioning receipt of

30 U.S. Dep’t of Health & Human Servs., Assurance of Compliance, HHS 690, <https://www.hhs.gov/sites/default/files/hhs-690.pdf>.

31 *Id.*

32 U.S. Dep’t of Health & Human Serv., HHS Grants Policy Statement, I-31 (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

Federal financial assistance or Federal funds on receipt of an assurance and certification is unnecessary in light of the proposed enforcement mechanisms provided by § 88.7.

Response: The Department does not agree. This collection of assurances and certifications would facilitate the Department’s obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant with Federal conscience and anti-discrimination laws and this rule. The Department is accountable to the American public for protecting the integrity of Federal financial assistance and other Federal funds that the Department awards. The Department’s administration of a requirement for a person or entity at the time of application or reapplication to assure and certify compliance with Federal conscience and anti-discrimination laws and the final rule demonstrates that the person or entity was aware of its obligations under those laws and the rule.

In addition, this collection of assurances and certifications would operationalize the obligations of persons and entities to comply with applicable Federal conscience and anti-discrimination laws. HHS has the authority to place terms and conditions consistent with the Federal conscience and anti-discrimination laws in any instrument HHS issues or to which it is a party (e.g., grants, contracts, or other HHS agreements). A Department component extending an award must communicate and incorporate statutory and public policy requirements and obligate the recipient to comply with Federal statutes and “public policy requirements, including . . . those . . . prohibiting discrimination.”³³ More specifically, the Department component “must communicate . . . all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.”³⁴ To execute this obligation, the Departmental component may require a recipient “to submit certifications and representations required by Federal statutes, or regulations”³⁵

Furthermore, the proposed requirements of § 88.4 are consistent with the requirements of other Federal civil rights laws and would bring Federal conscience and anti-discrimination laws into parity with those other civil rights laws. Although instituting an enforcement action against an entity is effective in ensuring that the enforced-against entity is aware of its requirements under the statutes implemented through this rule, the requirement of an assurance and certification of compliance would ensure that such awareness is shared by entities subject to proposed § 88.4 before violations occur and may help prevent them.

Comment: The Department received a comment stating that conditioning receipt of Federal financial assistance or Federal funds on receipt of an assurance and certification is unnecessary in light of the proposed enforcement mechanisms provided by § 88.7.

Response: The Department does not agree. This collection of assurances and certifications would facilitate the Department’s obligation to ensure that the Federal financial assistance or other Federal funds that the Department awards are used in a manner compliant

33 45 C.F.R. § 75.300(a).

34 *Id.*

35 *Id.* § 75.208.

with Federal conscience and anti-discrimination laws and this rule. The Department is accountable to the American public for protecting the integrity of Federal financial assistance and other Federal funds that the Department awards. The Department's administration of a requirement for a person or entity at the time of application or reapplication to assure and certify compliance with Federal conscience and anti-discrimination laws and the final rule demonstrates that the person or entity was aware of its obligations under those laws and the rule.

In addition, this collection of assurances and certifications would operationalize the obligations of persons and entities to comply with applicable Federal conscience and anti-discrimination laws. HHS has the authority to place terms and conditions consistent with the Federal conscience and anti-discrimination laws in any instrument HHS issues or to which it is a party (e.g., grants, contracts, or other HHS agreements). A Department component extending an award must communicate and incorporate statutory and public policy requirements and obligate the recipient to comply with Federal statutes and "public policy requirements, including . . . those . . . prohibiting discrimination."³⁶ More specifically, the Department component "must communicate . . . all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award."³⁷ To execute this obligation, the Departmental component may require a recipient "to submit certifications and representations required by Federal statutes, or regulations" ³⁸

Furthermore, the proposed requirements of § 88.4 are consistent with the requirements of other Federal civil rights laws and would bring Federal conscience and anti-discrimination laws into parity with those other civil rights laws. Although instituting an enforcement action against an entity is effective in ensuring that the enforced-against entity is aware of its requirements under the statutes implemented through this rule, the requirement of an assurance and certification of compliance would ensure that such awareness is shared by entities subject to proposed § 88.4 before violations occur and may help prevent them.

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 collection of information requires the name and signature of an authorizing official of the entity seeking funding, the address of the entity, and the date. The collection of information does not request personal identifying information regarding individuals, such as a Social Security number, home address, or other identifiable information. In accordance with the principles of the Freedom of Information Act (FOIA), 5 U.S.C. § 552, the Department will adhere to all applicable rules and provisions in FOIA to which the contents of the assurance and certification are subject.

³⁶ 45 C.F.R. § 75.300(a).

³⁷ *Id.*

³⁸ *Id.* § 75.208.

11. Justification for Sensitive Questions

This information collection does not seek information of a sensitive nature. As described in the prior response, the collection of information requires the name and signature of an authorizing official of the entity seeking funding, the entity’s address, and the date.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

Respondents are the applicants or recipients for Federal financial assistance or Federal funds from the Department. Although section 88.4(c)(1) through (4) (effective Nov. 22, 2019) excludes certain categories of recipients as having to assure compliance with Federal conscience and associated anti-discrimination laws, as described in the response to question 5, these recipients are not excluded from assuring compliance with Title VI, Section 504, Title IX, Section 1557, or the Age Act. Consequently, the estimated annualized burden hours to comply with this information collection, which reinstates form HHS-690, will be substantially greater than the hours estimated in *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (May 21, 2019) (effective Nov. 22, 2019), which merely focused on the burden unique to respondents assuring compliance with Federal conscience and anti-discrimination laws.

Respondents of this information collection include 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 Department estimates the number of respondents at 500,290 persons or entities. This estimate represents the average between the lower-bound (389,692) and upper-bound (610,888) estimates of entities that will have to sign an assurance or a certification.

Table 1: Range of Estimated Respondents

	Low-End Estimate	Upper-Bound Estimate
Persons or Entities Subject to Sign Form HHS-690	392,301	613,497
Sub-Recipients to Which Form HHS-690 Does Not Apply	<u>-2,609</u>	<u>-2,609</u>
Total, Estimate Recipients Subject to Form HHS-690	389,692	610,888

The burden under the PRA for the assurance is the opportunity cost of recipient staff time to review the assurance as well as the requirements of the underlying Federal civil rights laws referenced or incorporated.

The Department estimates that each recipient will spend an average of 5.0 hours reviewing the assurance and certification language as well as the requirements of the underlying Federal civil rights laws referenced or incorporated through a web link. Assuming that it would

take 30 minutes to certify compliance with three laws,³⁹ OCR uses the rough guide of 10 minutes per statutory provision, on average. Given that there are a total of 30 Federal civil rights laws covered by form HHS-690 (Title VI, Section 504, Title IX, Section 1557, the Age Act, and 25 Federal conscience and anti-discrimination statutory provisions), the Department estimates that it would take a total of 300 minutes on average for a respondent to review and sign the form. This estimate equates to a total burden of 5 hours per recipient, per year, for the first five years. Some recipients may spend considerably less time; others may spend considerably more time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses Per Resp.	Avg. Burden / Response (in hours)	Total Burden Hours
States, certain health care providers, other persons and entities	Form HHS-690	500,290	1	5	2,501,450
Total					2,501,450

12B. Estimated Annualized Burden Costs

The labor cost is a function of a lawyer spending 3 hours reviewing the assurance and certification and a chief executive spending one hour to review and sign, as form HHS-690 requires the signature if an individual authorized to commit the applicant to the form’s provisions. The mean hourly wage (not including benefits and overhead) for these occupations is \$67.25 per hour for the lawyer (occupation code 23-1011) and \$93.44 for the chief executive (occupation code 11-1011). 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 weighted mean hourly wage (not including benefits and overhead) of these two occupations is \$73.80 per hour (((\$67.25 x .75) + (\$93.44 x .25)).

Because this estimated annualized burden hours to comply with this information collection, which reinstates form HHS-690, is substantially greater than the hours estimated in *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (May 21, 2019) (effective Nov. 22, 2019), which merely focused on the burden unique to respondents assuring compliance with Federal conscience and anti-discrimination laws, the associated costs will similarly be greater.

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Weighted Hourly Wage Rate	Total Respondent Costs
States, certain health care providers,	2,501,450	\$73.80	\$184,607,010

3973 Fed. Reg. 78072, 78095 (2008 Rule) (estimating that it would take 30 minutes to certify compliance with the Church, Weldon, and Coats-Snowe Amendments).

other persons and entities			
Total			\$184,607,010

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

Not applicable to this collection of information.

14. Annualized Cost to Federal Government

The cost to the Federal Government is the opportunity cost of three categories of actions.

- *One-time burden of OCR staff time to develop a revised HHS-690 form, OMB No. 0945-0008, for this PRA clearance request (4 hours).* An OCR staff member spent two hours reviewing and updating the form and two supervisors spent a total of two hours reviewing the updates and finalizing the form for PRA clearance.
- *Periodic burden of HHS staff time to administer the assurance of compliance more than once per year, per § 88.4(b)(1)(i)-(ii), when the applicant or recipient fails to meet a requirement of this part, or OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure.* An OCR staff member or an HHS staff member would administer the assurance of compliance. It is unclear how frequently this administration of the assurance of compliance would happen outside of the application process for Federal financial assistance from HHS or other Federal funds from the Department.
- *Periodic burden of time spent implementing the assurance and certification of compliance requirements (3 hours).* An HHS Grants Office staff member would spend a total of 3 hours replacing the HHS-690 form with the revised forms and communicating to HHS component grants offices about this rule’s assurance and certification of compliance requirements. Such communication would likely include email alerts to HHS component grants offices, technical assistance on when to begin using the revised forms, and the appropriate point of contact grants offices could contact in OCR if there are any questions on the revised content. OCR, the HHS grants office, and HHS component grants offices would spend an additional amount of time to address ad hoc implementation issues throughout the year, but because OCR does not know the complexity of what those may be, OCR does not have enough information to estimate this portion of the burden.
- *OCR staff time spent reviewing a respondent’s completed forms if that respondent is the subject of an investigation or compliance review.* OCR staff would review completed assurance and certification forms for each of the respondents subject to an investigation or compliance review. OCR cannot estimate the number of complaints alleging violations of Federal conscience and anti-discrimination laws and this rule that are *not* administratively closed (*e.g.*, OCR lacking jurisdiction is an example of an administrative

closure) and result in an investigation. OCR staff members would spend 10 seconds per form to review proper completion. Assuming that OCR staff review each form for each respondent, the total number of hours spent is the number of respondents subject to an investigation multiplied by 10 seconds.

Based on the areas that OCR has enough information to monetize, the total average burden is about 7 hours in the first year for a total of about 2.3 hours per year. The estimated wage rate for the various staff members is likely to range from a GS-11 to a GS-15. For the purpose of these calculations, the Department assumes that the estimated wage rate is the midpoint in this range of a GS-13 step 5 in the DC-MD-VA area, which is \$53.85 per hour. See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB_h.pdf. Based on this wage rate, the annual burden to the Federal government based on the areas of burden that OCR has enough information to monetize is \$123.86 per year in labor costs.

15. Explanation for Program Changes or Adjustments

This is a new requirement.

16. Plans for Tabulation and Publication and Project Time Schedule

None.

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

The expiration date of this OMB control number will be displayed on form HHS-690.

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.

Appendices A through F

Appendix A

45 C.F.R. § 80.4 Assurances Required (HHS implementing regulation for Title VI)

(a) General.

(1) Every application for Federal financial assistance to which this part applies, except an application to which paragraph (b) of this section applies, and every application for Federal financial assistance to provide a facility shall, as a condition to its approval and the extension of any Federal financial assistance pursuant to the application, contain or be accompanied by an assurance that the program will be conducted or the facility operated in compliance with all requirements imposed by or pursuant to this part. In the case of an application for Federal financial assistance to provide real property or structures thereon, the assurance shall obligate the recipient, or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. In the case of personal property the assurance shall obligate the recipient for the period during which he retains ownership or possession of the property. In all other cases the assurance shall obligate the recipient for the period during which Federal financial assistance is extended pursuant to the application. The responsible Department official shall specify the form of the foregoing assurances in the program, and the extent to which like assurances will be required of subgrantees, contractors and subcontractors, transferees, successors in interest, and other participants in the program. Any such assurance shall include provisions which give the United States a right to seek its judicial enforcement.

(2) Where Federal financial assistance is provided in the form of a transfer of real

property or interest therein from the Federal Government the instrument effecting or recording the transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. Where no transfer of property is involved but property is improved with Federal financial assistance, the recipient shall agree to include such a covenant to any subsequent transfer of the property. Where the property is obtained from the Federal Government, such covenant may also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant where, in the discretion of the responsible Department official, such a condition and right of reverter is appropriate to the statute under which the real property is obtained and to the nature of the grant and the grantee. In the event a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on such property for the purposes for which the property was transferred, the responsible Department official may agree, upon request of the transferee and if necessary to accomplish such financing, and upon such conditions as he deems appropriate, to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

(b) Continuing Federal financial assistance. Every application by a State or a State agency for continuing Federal financial assistance to which this regulation applies (including the Federal financial assistance listed in part 2 of appendix A to this part) shall as a condition to its approval and the extension of any Federal financial assistance pursuant to the application (1) contain or be accompanied by a statement that the program is (or, in the case of a new program,

will be) conducted in compliance with all requirements imposed by or pursuant to this regulation, and (2) provide or be accompanied by provision for such methods of administration for the program as are found by the responsible Department official to give reasonable assurance that the applicant and all recipients of Federal financial assistance under such program will comply with all requirements imposed by or pursuant to this regulation.

(c) Elementary and secondary schools. The requirements of paragraph (a) or (b) of this section with respect to any elementary or secondary school or school system shall be deemed to be satisfied if such school or school system (1) is subject to a final order of a court of the United States for the desegregation of such school or school system, and provides an assurance that it will comply with such order, including any future modification of such order, or (2) submits a plan for the desegregation of such school or school system which the responsible Department official determines is adequate to accomplish the purposes of the Act and this part, at the earliest practicable time, and provides reasonable assurance that it will carry out such plan; in any case of continuing Federal financial assistance the responsible Department official may reserve the right to redetermine, after such period as may be specified by him, the adequacy of the plan to accomplish the purposes of the Act and the regulations in this part. In any case in which a final order of a court of the United States for the desegregation of such school or school system is entered after submission of such a plan, such plan shall be revised to conform to such final order, including any future modification of such order.

(d) Assurance from institutions.

(1) In the case of any application for Federal financial assistance to an institution of higher education (including assistance for construction, for research, for special training project, for student loans or for any other purpose), the assurance required by this section shall extend to

admission practices and to all other practices relating to the treatment of students.

(2) The assurance required with respect to an institution of higher education, hospital, or any other institution, insofar as the assurance relates to the institution's practices with respect to admission or other treatment of individuals as students, patients, or clients of the institution or to the opportunity to participate in the provision of services or other benefits to such individuals, shall be applicable to the entire institution.

Appendix B

45 C.F.R. § 84.5 Assurances Required (HHS Implementing Regulation for Section 504)

(a) Assurances. An applicant for Federal financial assistance to which this part applies shall submit an assurance, on a form specified by the Director, that the program or activity will be operated in compliance with this part. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) Duration of obligation.

(1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for the purpose for which Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) In the case of Federal financial assistance extended to provide personal property, the assurance will obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) Covenants.

(1) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the instrument effecting or recording this transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) Where no transfer of property is involved but property is purchased or improved with Federal financial assistance, the recipient shall agree to include the covenant described in paragraph (b)(2) of this section in the instrument effecting or recording any subsequent transfer of the property.

(3) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the covenant shall also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant. If a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on the property for the purposes for which the property was transferred, the Director may, upon request of the transferee and if necessary to accomplish such financing and upon such conditions as he or she deems appropriate, agree to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

Appendix C

45 C.F.R. § 86.4, Assurance Required (HHS implementing regulation for Title IX)

(a) General. Every application for Federal financial assistance for any education program or activity shall as condition of its approval contain or be accompanied by an assurance from the applicant or recipient, satisfactory to the Director, that the education program or activity operated by the applicant or recipient and to which this part applies will be operated in compliance with this part. An assurance of compliance with this part shall not be satisfactory to the Director if the applicant or recipient to whom such assurance applies fails to commit itself to take whatever remedial action is necessary in accordance with § 86.3(a) to eliminate existing discrimination on the basis of sex or to eliminate the effects of past discrimination whether occurring prior or subsequent to the submission to the Director of such assurance.

(b) Duration of obligation. (1) In the case of Federal financial assistance extended to provide real property or structures thereon, such assurance shall obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used to provide an education program or activity.

(2) In the case of Federal financial assistance extended to provide personal property, such assurance shall obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases such assurance shall obligate the recipient for the period during which Federal financial assistance is extended.

(c) Form. The Director will specify the form of the assurances required by paragraph (a) of this section and the extent to which such assurances will be required of the applicant's or recipient's subgrantees, contractors, subcontractors, transferees, or successors in interest.

Appendix D

45 C.F.R. § 91.33(a), Assurance of compliance and recipient assessment of age distinctions

(a) Each recipient of Federal financial assistance from HHS shall sign a written assurance as specified by HHS that it will comply with the Act and these regulations.

Appendix E
45 C.F.R. § 92.5, Assurances Required

(a) Assurances. An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with Section 1557 and this part. A health insurance issuer seeking certification to participate in a Health Insurance MarketplaceSM or a State seeking approval to operate a State-based MarketplaceSM to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health program or activity will be operated in compliance with Section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in a Health Insurance MarketplaceSM or approval to operate a State-based MarketplaceSM.

(b) Duration of obligation. The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing Section 504, 45 CFR 84.5(b).

(c) Covenants. When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing Section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under Section 1557 and this part.

Appendix F

45 C.F.R. § 88.4 (effective Nov. 22, 2019)

84 Fed. Reg. 23,170, 23,269-70 (May 21, 2019) (effective Nov. 22, 2019)

§ 88.4 Assurance and certification of compliance requirements.

(a) *In general.*

(1) *Assurance.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by an assurance that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(2) *Certification.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies, shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by, a certification that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(b) *Specific requirements.*

(1) *Timing.* Entities who are already recipients as of the effective date of this part or any applicants shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section as a condition of any application or reapplication for funds to which this part applies, through any instrument or as a condition of an

amendment or modification of the instrument that extends the term of such instrument or adds additional funds to it.

Submission may be required more frequently if:

- (i) The applicant or recipient fails to meet a requirement of this part, or
- (ii) OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure.

(2) *Form and manner.* Applicants or recipients shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section in the form and manner that OCR, in coordination with the relevant Department component, specifies, or shall submit them in a separate writing signed by the applicant's or recipient's officer or other person authorized to bind the applicant or recipient.

(3) *Duration of obligation.* The assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section will obligate the recipient for the period during which the Department extends Federal financial assistance or Federal funds from the Department to a recipient.

(4) *Compliance requirement.* Submission of an assurance or certification required under this section will not relieve a recipient of the obligation to take and complete any action necessary to come into compliance with Federal conscience and anti-discrimination laws and this part prior to, at the time of, or subsequent to, the submission of such assurance or certification.

(5) *Condition of continued receipt.* Provision of a compliant assurance and certification shall constitute a condition of continued receipt of Federal financial assistance or Federal funds from the Department and is binding upon the applicant or recipient, its successors, assigns, or transferees for the period during which such Federal financial assistance or Federal funds from

the Department are provided.

(6) *Assurances and certifications in applications.* An applicant or recipient may incorporate the assurances and certifications by reference in subsequent applications to the Department or Department component if prior assurances or certifications are initially provided in the same fiscal or calendar year, as applicable.

(7) *Enforcement of assurances and certifications.* The Department, Department components, and OCR shall have the right to seek enforcement of the assurances and certifications required in this section.

(8) *Remedies for failure to make assurances and certifications.* If an applicant or recipient fails or refuses to furnish an assurance or certification required under this section, OCR, in coordination with the relevant Department component, may effect compliance by any of the mechanisms provided in § 88.7.

(c) *Exceptions.* The following persons or entities shall not be required to comply with paragraphs (a)(1) and (2) of this section, provided that such persons or entities are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, other than those set forth in paragraphs (c)(1) through (4) of this section:

(1) A physician, as defined in 42 U.S.C. 1395x(r), physician office, pharmacist, pharmacy, or other health care practitioner participating in Part B of the Medicare program;

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

(i) Medical or behavioral research;

(ii) Health care providers; or

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

(3) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

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

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