

**Request for OMB Review and Approval
Under the Paperwork Reduction Act and 5 C.F.R. § 1320
January 26, 2018**

Supporting Statement

Information Collection for Assurance and Certification of Compliance (proposed 45 C.F.R. § 88.4)

A. Justification

1. Circumstances Making the Collection of Information Necessary

This collection of information is required by the proposed rule entitled, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, which displayed for public inspection on January 19, 2018, <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-01226.pdf>. This collection of information relates to proposed 45 C.F.R. § 88.4, which appears as an appendix to this statement. Proposed § 88.4 requires each recipient (or applicant to become a recipient), with limited exception, to assure and certify compliance with Federal conscience and associated anti-discrimination laws. Specifically, proposed § 88.4(a) requires each recipient or applicant to include in its application for Federal financial assistance or other Federal funds from the Department, or accompany its application with, an assurance and a certification that it will operate applicable projects or programs in compliance with applicable Federal health care conscience and associated anti-discrimination laws.

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

- 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)).

2. Purpose and Use of Information Collection

Requiring certain recipients and applicants to assure and certify compliance serves two purposes. First, through the act of reading and reviewing the statutory requirements to which recipients or applicants assure and certify compliance, recipients would be apprised of their obligations under the applicable Federal health care conscience and associated anti-discrimination laws. Second, a recipient's or applicant's awareness of its obligation would increase the likelihood that it would comply with such laws and consequently afford entities and individuals protection of their conscience rights and protection from coercion or discrimination. Because of this awareness, the Department anticipates that proposed § 88.4 may generate changes in the policies, procedures, and operations of the persons and entities covered.

The Department and its components awarding Federal financial assistance or other Federal funds and OCR would use the signed assurance and certification as documentation of: (1) a recipient's or applicant's awareness of its obligations under the Federal health care conscience and associated anti-discrimination laws and the proposed rule, and (2) a recipient's

commitment to comply with such statutes and the proposed rule. This second use would most likely occur during an OCR investigation of the recipient's compliance with Federal health care conscience and associated anti-discrimination laws and the proposed rule.

3. Use of Improved Information Technology and Burden Reduction

The Department is committed to leveraging existing grant, contract, and other Departmental forms where possible rather than creating additional, separate forms for recipients to sign. The Department intends to update the HHS-690 Form, OMB No. 0945-0006 (Medicare Part A), which includes several Federal civil rights authorities with which applicants and recipients must assure compliance.¹ The Department would update the form to include a reference to Federal health care conscience and associated anti-discrimination laws, as well as a web link to information about the requirements. The Department also intends to update HHS-5161-1 Form, OMB No. 0930-0367 (HHS Grants Application) (Certification of Compliance) to include a reference to Federal health care conscience and associated anti-discrimination laws, as well as a web link to information about the requirements.

4. Efforts to Identify Duplication and Use of Similar Information

See previous response regarding the Department's intention to modify existing forms.

5. Impact on Small Businesses or Other Small Entities

Consistent with the Regulatory Flexibility Act analysis at page 157 of the proposed rule, the 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.² Natural persons and States are not included in the definition of a small entity.

The assurance and certification requirements in proposed § 88.4 contain exceptions to relieve many small entities of the requirement to submit an assurance and certification, including:

1 HHS regulations implementing each of the following civil rights laws require recipients to assure compliance with applicable implementing regulations: Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 1557 of the Affordable Care Act. *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).

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

- physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program;
- recipients 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, whose purpose is unrelated to health care provision as specified;
- recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, whose purpose is unrelated to health care provision as specified; and
- Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

Requiring the large number of entities in these four categories to submit assurance and certification requirements would pose significant implementation hurdles for Departmental components, programs, and services. Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions. Similarly, certain programs currently administered by the Administration for Children and Families and the Administration on Community Living involve the provision of grants to States and other governments, or cash assistance or vouchers rather than direct services, and they are not likely to involve medical research, the participation of health care providers, or referral to health care providers.

Excepted providers, however, may become subject to the assurance and certification requirement if they receive Federal financial assistance or Federal funds from the Department through a mechanism or in a manner not excepted by § 88.4(c). For example, a physician office participating in Medicare Part B may become subject to the written certification requirement by receiving Department funds to conduct clinical research.

6. Consequences of Collecting the Information Less Frequently

Although proposed § 88.4(a) requires each recipient or applicant to include in its application for Federal funds, or accompany its application with, an assurance and a certification that it will operate applicable projects or programs in compliance with applicable Federal health care conscience and associated anti-discrimination laws, proposed § 88.4(b)(6) allows 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. See HHS Grants Policy Statement (Jan. 2007), <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsqps107.pdf>. 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 690 on file. *Id.* at I-31.

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.” 45 C.F.R. § 75.300(a). 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.” *Id.* In addition, the Departmental component may require a recipient “to submit certifications and representations required by Federal statutes, or regulations . . .” *Id.* at § 75.208.

Given these regulatory requirements, the Department may not be able to reduce the burden of the proposed assurance and certification requirement any further than the exceptions proposed in § 88.4(c) and the authority in § 88.4(b)(6) to incorporate assurances by reference in subsequent applications if prior assurances are initially provided in the same year.

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

No special circumstances are involved in this collection of information.

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

A 60-day Federal Register Notice of Proposed Rulemaking, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, is scheduled for publication in the *Federal Register* on January 26, 2018, vol. 83. The proposed rule seeks public comment on this proposed information collection on pages 163-171 of the version that displayed for public inspection on January 19, 2018, <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-01226.pdf> (also attached as a PDF).

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

The proposed 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 the FOIA to which the contents of the assurance and certification are subject.

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

Respondents are a subset of the recipients, as defined in the proposed amendment of 45 C.F.R. § 88.2, subject to the relevant Federal health care conscience and associated anti-discrimination laws and the proposed rule because proposed § 88.4(c)(1) through (4) excludes certain categories of recipients, as described in the response to question 5 and *infra* Table 1. Respondents 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 123,302 persons or entities. This estimate represents the average between the lower-bound (94,214) and upper-bound (152,389) estimates of entities that will have to sign an assurance or a certification.

Table 1: Range of Recipients Subject to the Proposed Assurance and Certification Requirements (§ 88.4)

	Low-End Estimate	Upper-Bound Estimate
Range of Persons or Entities Subject to the NPRM	364,640	571,412
Range of Recipients Excepted from Proposed § 88.4	<u>-270,361</u>	<u>-418,893</u>
Total , Recipients Subject to the Assurance and Certification Requirements	94,279	152,519

The burden for the assurance and certification is the opportunity cost of recipient staff time (1) to review the assurance and certification language as well as the requirements of the underlying Federal health care conscience and associated anti-discrimination laws referenced or incorporated, (2) to review entity-wide policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws, and (3) to implement any actions to come into compliance.

Review and Sign Assurance and Certification

The Department estimates that each recipient not excepted will spend an average of 4 hours reviewing the assurance and certification language as well as the requirements of the underlying Federal health care conscience and associated antidiscrimination laws referenced or incorporated through a web link. In the 2008 Rule, the Department estimated that it would take 30 minutes to certify compliance with three laws: the Church, Weldon, and Coats-Snowe Amendments. 73 FR 78072, 78095 (2008 Rule). In the proposed rule, there are 22 additional

statutory provisions included. Using the rough guide of 10 minutes per provision, the Department estimates that it would take an additional 3.5 hours on average to review the applicability of the additional laws that this rule proposes to enforce, for a total burden of 4 hours per recipient, per year, for the first five years. Some recipients may spend considerably less time; others may spend considerably more time.

Review Policies and Procedures

The Department estimates that 61,652 recipients, which is half of all recipients required to assure and certify compliance (123,302 entities / 2) will review policies and procedures or take other actions to self-assess compliance with applicable Federal health care conscience and associated anti-discrimination laws each year for the first five years of publication. The Department reasonably estimates such action because § 88.4(c)(4) states that the submission of an assurance and certification will not relieve a recipient of the obligation to take and complete actions to come into compliance prior to or after submission of such assurance or certification. The first step to such actions is reviewing organization-wide safeguards that are, or should be, in place. The Department estimates that recipients that review policies and procedures or otherwise self-assess compliance will spend an average of 4 hours doing so. Some entities will spend more time and others will spend less time.

Update Policies and Procedures; Train Workforce

The Department estimates that approximately 5% of entities will take an organization-wide action to improve compliance in the first year and 0.5% will take a similar action annually each year in years two through five. This percentage equates to 23,406 recipients in year 1 and 2,341 recipients annually in years two through five. The annualized number of recipients is 6,805. The Department estimates that these recipients would spend 4 hours annually, on average, to take remedial efforts. The Department estimates that recipients will spend an average of 4 hours to update policies and procedures, implement staffing or scheduling practices that respect an exercise of conscience rights under Federal law, or train staff on relevant Federal law or the recipient's policies and procedures.

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 care providers, other persons and entities	88.4(a) (Review and sign assurance and certification)	123,302	1	4	493,208
States, certain health care providers, other persons and entities	88.4(a) (Review Policies and Procedures)	61,639	1	2	123,278
States, certain health care providers, other persons and entities	88.4(a) (Update Policies and Procedures; Train Workforce)	6,805	1	4	27,220
Total					643,706

12B. Estimated Annualized Burden Costs

With respect to reviewing and signing the assurance and certification, 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 proposed § 88.4(b)(2) requires a signature by an individual authorized to bind the recipient. With respect to the remain activities (reviewing and updating policies and procedures), the labor cost function of a lawyer spending 3 hours and a chief executive spending one hour for the activities.

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 (($\$67.25 \times .75$) + ($\$93.44 \times .25$)).

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	493,208	\$73.80	\$36,398,750
States, certain health care providers, other persons and entities	123,278	\$73.80	\$9,097,916
States, certain health care providers, other persons and entities	27,220	\$73.80	\$2,008,836

Total			\$47,505,503
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13. Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs

Not applicable to this proposed collection of information.

14. Annualized Cost to Federal Government

Of the three types of activities generated by § 88.4(a), only one—the review and signing of the assurance and certification—has costs to the Federal Government. The cost to the Federal Government is the opportunity cost of four categories of actions.

- *One-time burden of HHS staff time to develop revised forms on which the respondents will assure and certify compliance (16 hours).* An OCR Civil Rights Analyst and an HHS Grants Office Program Analyst would spend a total of 14 hours to draft updates to the HHS 690 Form, OMB No. 0945-0006 (Medicare Part A), which requires applicants to assure compliance, and to the HHS-5161-1 Form, OMB No. 0930-0367 (HHS Grants Application). An attorney in the HHS General Counsel’s office would spend two hours reviewing and consulting on the forms.
- *One-time burden of HHS staff time spent implementing the revised forms (3 hours).* An HHS Grants Office Program Analyst (or Management Analyst) would spend a total of 3 hours replacing the old forms with the revised forms online and communicating to HHS component grants offices on the revised forms. Such communication would likely include email alerts to HHS component grants offices, technical assistance on when to begin using the revised forms, and who grants offices could contact in OCR if there are any questions on the revised content.
- *OCR staff time spent reviewing a respondent’s completed forms if that respondent is the subject of an investigation or compliance review (10 minutes).* OCR Civil Rights Analysts would review completed assurance and certification forms for each of the respondents subject to an investigation or compliance review. OCR expects to handle 30 investigation or compliance reviews of Federal health care conscience and associated anti-discrimination laws per year. OCR staff members would spend 10 seconds per form to review proper completion of the items pertaining to Federal health care conscience and associated anti-discrimination laws. Assuming that OCR staff review each form for each respondent, the total number of hours spent is 1/6 of an hour, or ten minutes (30 respondents X 2 forms X 10 seconds).

The total average burden is about 20 hours in the first year and 1/6 of an hour (10/60 minutes) in the out-years for an annualized total of 4 hours per year. The estimated wage rate for the various staff members (e.g., Civil Rights Analyst, Program Analyst, Attorney, etc.) 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 mid-point in this range of a GS-13 step 5, which is \$48.53 per hour. See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/GS_h.pdf. Based on this wage rate, the annual burden to the Federal government is \$194 per year in labor costs.

15. Explanation for Program Changes or Adjustments

Please see the response to question one, which outlines the proposed requirement at 45 C.F.R. § 88.4.

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.

Appendix: Proposed 45 C.F.R. § 88.4 - Assurance and certification of compliance requirements

As provided for public inspection

<https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-01226.pdf>.

(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 health care conscience and associated 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 health care conscience and associated anti-discrimination laws and this part.

(b) *Specific requirements*. (1) *Timing*: Applicants or recipients who are already recipients as of the effective date of this part 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 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 the applicant or recipient fails to meet a requirement of this part.

(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 health care conscience and associated anti-discrimination laws and this part prior to, or 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 in applications.* An applicant or recipient may incorporate the assurances by reference in subsequent applications to the Department or Department component if prior assurances are initially provided in the same year.

(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 remedies 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, 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.