

Requests for OMB Review and Approval Under the Paperwork Reduction Act and 5 CFR 1320

Supporting Statement for HHS Office for Civil Rights and Conscience and Privacy, Security, and Breach Notification Complaint Forms

Department of Health and Human Services
Office of the Secretary/Office for Civil Rights
Harold Henderson
Strategic Planning Division Paperwork Reduction Act Official
Office for Civil Rights
Office: (202) 868-9407
200 Independence Avenue, S.W.
Washington, DC 20201

Date: March 5, 2026

Background - Please explain the purpose of this collection.

OCR is requesting a revision of the previously approved collection 0945-0002 that is expiring in December 2025 which include two forms titled: (1) Health Information Privacy & Security Complaint, and (2) Civil Rights and Conscience Complaint. This request revises these complaint forms and retitles Health Information Privacy Complaint to Health Information Privacy, Security, & Breach Notification Complaint.

The purpose of this revision is to allow OCR to collect the minimum information needed from individuals filing complaints with OCR as the basis for the initial processing of those complaints.

A. Justification

1. *Need and Legal Basis*: What is the need and legal basis for this information collection? What does the law say?

OCR enforces federal nondiscrimination and HIPAA statutes and regulations. Specifically, OCR is authorized to solicit information for enforcement purposes under the following:

(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d et seq.), Section 504 and 508 of the Rehabilitation Act of 1973 (29 U.S.C. §§ 794 § 794(d)), the Age Discrimination Act of 1975 (42 U.S.C. § 6101 et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), Sections

794 and 855 of the Public Health Service Act (42 U.S.C. §§ 295m and 296g); and Section 1557 of the Affordable Care Act (42 U.S.C. § 18116), Religious Nondiscrimination Provisions of Block Grant Programs for Maternal and Child Health Services, 42 U.S.C. § 708; Preventive Health and Health Services, 42 U.S.C. § 300w-7; and Community Mental Health Services, 42 U.S.C. § 300x-57, Equal Treatment Regulations, 45 C.F.R. pt. 87, among others;

(ii) Federal laws protecting rights of conscience in health and human services programs, such as Sections 1303(b)(1)(A), (b)(4) and (c)(2)(A), and 1411(b)(5)(A) and 1553 of the Affordable Care Act (42 U.S.C. §§ 18023(b)(1)(A), (b)(4) and (c)(2)(A), 18081(b)(5)(A), and 18113), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C. § 238n), and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act, 2024, Public Law 118–47, div. H, tit. V, sec. 507(d)(1), 138 Stat. 460, 703 (Mar. 23, 2024));

(iii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§ 291 et seq. and 300s et seq.) and 42 Code of Federal Regulations (C.F.R.) Part 124, Subpart G (Community Service obligations of Hill-Burton facilities);

(iv) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS;

(v) Title II of the Americans with Disabilities Act (42 U.S.C. § 12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS “designated agency” authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and human services agencies of state and local governments, regardless of whether they receive federal financial assistance; and

(vi) Health Insurance Portability and Accountability Act of 1996 (HIPAA) Standards for Privacy of Individually Identifiable Health Information (Privacy Rule), 45 C.F.R. Part 160 and subparts A and E of part 164, Health Insurance Reform: Security Standards (Security Rule), 45 C.F.R. Part 160 and Subparts A and C of Part 164, Breach Notification for Unsecured Protected Health Information (Breach Notification Rule), 45 C.F.R. Part 160 and Subparts A and D of part 164, and Administrative Simplification: Enforcement, 45 C.F.R. part 160, Subparts C, D, and E, which contains provisions relating to compliance and investigations, the imposition of civil money penalties, and procedures for hearings related to violations of HIPAA (42 U.S.C. § 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note))); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279).

Under OCR’s authorities, individuals may file written or electronic complaints with OCR when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from HHS or if they believe that their rights to privacy or security of protected health information have been violated. To fulfill OCR’s statutory obligation and authority to respond to these complaints, OCR must collect a limited set of information sufficient to allow processing of such complaints. The complaint forms in this Paperwork Reduction Act submission request the basic information needed by OCR.

2. *Information Users: Who uses this information and for what purpose?*

OCR has collected similar information through complaint forms for many years to help in the initial assessment of a complaint. OCR provides two complaint forms – one for civil rights or conscience discrimination complaints, and one for complaints alleging violation of the privacy or security of protected health information or the Breach Notification Rules. Use of these forms is voluntary. Alternatively, a complainant may choose to submit a complaint in the form of a letter, or electronically.

The mandatory fields for the existing forms are: name; contact information; whether the complaint is being filed on behalf of someone else; the basis for the complaint (e.g., race/color/national origin, pregnancy, age, sex (male/female), disability, religion or conscience, or violation of the privacy or security of protected health information or the Breach Notification Rules); the name and/or contact information of the entity against which the complaint is being filed; when the incident(s) occurred; a brief description of what happened; and the complainant’s signature. OCR will generally need the signed consent of that person to proceed with an investigation unless the person is a minor or is not legally competent. The two forms generally request similar information, with the main substantive difference being the basis for the complaint.

In addition, each form includes several voluntary fields to assist OCR in processing the complaint and to provide appropriate customer service. Those fields are an alternate person to contact if the complainant cannot be reached; whether this complaint has been filed with other agencies or is the basis of a lawsuit and, if so, to identify where else the complaint has been filed; and whether the complainant needs special accommodations for OCR to communicate with them (e.g., Braille, TDD). OCR has also included a limited number of fields to be answered on a voluntary basis to help OCR better assess whether OCR is adequately reaching out and providing service to populations whose rights are covered by OCR’s statutory authorities. These fields concerning the complainant or the person on whose behalf a complaint has been filed request information about ethnicity, race, and primary language spoken (if other than English). Failure to answer the voluntary questions does not affect OCR’s decision to process a complaint.

OCR intends to continue requiring this same small set of mandatory fields and to request the voluntary information as described above; however, we are proposing to delete certain categories to be consistent with the [Provisional Guidance for the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity](#) and the addition of a new option – “decline to specify”.

3. *Improved Information Technology: Was there any consideration of using technology to reduce burden? How can the Office of the Secretary (OS) use technology to improve this information collection?*

In addition to paper submission of complaints, OCR facilitates the electronic submission of complaints. An electronic complaint can be submitted on the OCR's Website at:

<https://www.hhs.gov/sites/default/files/ocr-cr-complaint-form-package.pdf>

<https://www.hhs.gov/sites/default/files/ocr-hip-security-complaint-form-package.pdf>

The forms themselves are available to be downloaded electronically to a user's own computer in a fillable format, should they choose. The form can also be printed and mailed or submitted electronically via electronic mail. Actual burden time would be reduced only marginally by using electronic methods since the bulk of the estimated average effort relates to the assembling and recording of a set of factual information.

Since access to computers and the internet, as well as computer proficiency, still varies widely, these different methods allow complainants to use the method with which they are most comfortable (or to which they have access) without increasing burden on any class of individuals.

4. *Duplication of Similar Information:* Identify whether this information is duplicative of another information collection.

The information being collected is not duplicative of another information collection. It is case and individual specific, so OCR does not already have this information. If a person has filed a previous complaint with OCR, then data on the individual may already be in OCR's records, but confidentiality considerations would restrict OCR's ability to display that information to the complainant since it might in fact relate to another person with the same name. Use of PIN numbers and other methods that allow individuals to return to the same web site without having to re-enter personal information have not been adopted because they are not cost effective given the limited number of multiple complaints filings by the same individual.

5. *Small Businesses:* How were the information collection requirements minimized for small businesses?

Complainants are primarily individuals or, in rare instances, advocacy organizations filing complaints on behalf of a class of individuals. Small businesses are not required to provide any of this information unless they are filing a complaint.

6. *Less Frequent Collection:* What will happen if this information is collected less frequently?

Since OCR needs the mandatory information on these forms to begin an investigation, inability to collect this information in each instance of a complaint would prevent OCR from carrying out OCR's statutorily mandated law enforcement authority to conduct complaint investigations and rectify instances of civil rights discrimination and violations

of conscience, health information privacy, security, and/or breach notification rules. Further, lack of a standardized form would hinder OCR's ability to fully and effectively comply with the requirements of the Government Paperwork Elimination Act to support electronic communication with OCR's stakeholders.

The forms also include two sets of voluntary questions: those intended to help OCR communicate with the complainant in processing the complaint, and those designed to help OCR better assess whether OCR is adequately reaching and providing service to our various target populations.

If the first set of voluntary questions (i.e., Does the complainant need OCR to communicate using Braille or an alternate format or language? Is there an alternate person to contact if the complainant cannot be reached? etc.) were removed from the form, the complaint process could proceed. However, this would be at the cost of effective customer service for individuals with special communication needs and would not meet OCR's legal requirements to provide effective communication and meaningful access. Initial contact from OCR may prove to be extremely frustrating for the complainant in such an instance, and the potential for missed communications would be increased.

If the second set of voluntary questions (i.e., questions concerning the complainant's ethnicity, race, primary language spoken, etc.) were removed from the form, again, the complaint process could proceed. However, over the long term, OCR's effectiveness in reaching those populations most in need of our services would be impaired by the lack of data on who does, and by implication, who does not, avail themselves of OCR's services.

7. *Special Circumstances*: Describe special circumstances for collecting this information.

There are no additional special circumstances for collecting this information.

8. *Federal Register Notice/Outside Consultation*: When was the notice published in the *Federal Register*?

The Department published [notice of the proposed revisions to the complaint forms in the Federal Register on December 31, 2025](#) to give the public an opportunity to review and comment on the proposed revisions. The public will have an additional opportunity to comment on the proposed revisions for 30 days during the Office of Management and Budget's review of the revisions.

We received comments on the proposed revisions to the complaint forms in response to the December 31, 2025 notice from four commenters:

Comment: Three commenters addressed the proposed removal of data fields from the revised complaint forms for complainants to identify sexual orientation, gender identity, and gender-neutral pronouns. Two commenters supported this removal, pointing to the

removal's consistency with federal civil rights statutes, Administration positions, and the safeguards in the Paperwork Reduction Act to ensure the appropriateness of the collection. Another commenter recommended that OCR retain these data fields, suggesting that their removal will limit OCR's ability to investigate cases.

Response: The Department appreciates the commenters' views on this issue. The Department believes that its complaint forms should be crafted in a way to provide investigators from OCR with the most relevant information for determining possible violations of health information privacy and security and civil rights laws, while also providing information to the complainants on the specific categories of discrimination cognizable under those authorities. OCR permits complainants to provide additional information not specifically requested in the complaint form. In addition, OCR investigators may contact complainants for additional information that is relevant to the investigation of a complaint. The enforcement of the Department's civil rights authorities is guided by and necessarily limited by court orders; in this case, a court has issued a final order restricting OCR from interpreting its sex discrimination authorities in a manner that would include gender identity, among other limitations. See *Tennessee v. Kennedy*, No. 1:24-cv-161-LG-BWR (S.D. Miss., Oct. 22, 2025).

The third commenter made two recommendations about the Health Information Privacy, Security, & Breach Notification Complaint form and one recommendation about the Civil Rights and Conscience Complaint form:

Comment: The commenter recommended that the Health Information Privacy, Security, & Breach Notification Complaint form be combined with OCR's new complaint form for reporting potential violations of the confidentiality of substance use disorder patient records.

Response: The authority and applicability of the HIPAA and Breach Notification Rules vary significantly from 42 CFR part 2. Both complaint forms are drafted for ease of use of a complainant for the respective authority with the use of key terms appropriate for the specific complaint. Combining forms would create confusion among filers and cause additional burden for OCR when assessing complaints, which would result in greater administrative burden for OCR.

Comment: The commenter also suggested that the Department could simplify the Health Information Privacy, Security, & Breach Notification Complaint form, making the form less legalistic, and adding language addressing next steps. The commenter provided alternative forms modified by artificial intelligence tools.

Response: The proposed form is drafted to balance the ability of a complainant to provide relevant information about a potential violation with the need for OCR to obtain sufficient information from a complainant to accurately assess the nature and scope of a potential violation. Certain key terms are used to avoid confusion by complainants that OCR has authority to address actions that a complainant may believe are violations.

OCR has information on its website about the complaint process, including what OCR does after receiving a complaint. We believe this information is best kept separate from a complaint to minimize the length of and burden associated with filing a complaint.

Comment: The commenter’s final recommendation suggested OCR should simplify the Civil Rights and Conscience Complaint form. The commenter suggested combining the questions that ask for details about the nature of the complaint into one unified question, such as: “Why do you believe your conscience rights were violated and what resolution do you seek.” The commentator also included an AI-generated proposed form that would seek to simplify the number of questions asked.

Response: The Department appreciates the suggestion. However, each question on the form assists OCR in efficiently handling the complaint based on OCR’s extensive experience. When filled out completely, each question or field about the allegation provides meaningful details that OCR has found valuable, based on its investigative experience. Under the commenter’s proposal, complainants would likely be contacted for additional information more frequently than if the separate questions about the allegations were not asked, providing a net burden to OCR staff and complainants. OCR will continue to work on efforts to use clear and simple language in keeping with the Plain Writing Act of 2010 and other relevant authorities.

9. *Payment/Gift to Respondent:* Explain any decisions to provide payments or gifts to the respondents.

OCR does not provide any payments or gifts to respondents or any form of remuneration to any contractors or grantees.

10. *Confidentiality:* Does OS assure the public that this information will be confidential?

The information received from complainants is collected pursuant to an approved Privacy Act System of Records (67 Fed Reg. 57011-57014 (September 6, 2002)). Pursuant to the Act and to that notice, disclosure of information collected is strictly for investigatory purposes or for a limited set of routine uses consistent with those investigatory purposes contained in OCR’s System of Records Notice. Information compiled for investigated purposes is also subject to The Freedom of Information Act ([5 U.S.C. § 552](#)).

11. *Sensitive Questions:* Provide justification for any sensitive questions in this information collection.

OCR collects sensitive information for purposes of fact finding and demographics for outreach with options to decline. Filing a complaint with OCR is voluntary. However, without the information requested, OCR may be unable to proceed with a complaint. The information received from complainants is collected pursuant to an approved Privacy Act System of Records (67 Fed Reg. 57011-57014 (September 6, 2002)). Pursuant to the Act and to that notice, disclosure of information collected is strictly for investigatory

purposes or for a limited set of routine uses consistent with those investigatory purposes contained in OCR’s System of Records Notice. Information compiled for investigated purposes is also subject to The Freedom of Information Act ([5 U.S.C. § 552](#)).

12. *Burden Estimate (Total Hours & Wages):* Total burden hours for this information collection and the cost associated with those hours.

OCR estimates that the average time needed to complete a complaint form is 45 minutes (.75 hours), which has not increased since the forms were last revised. Based on examination of actual complaint levels over the past two years, OCR projects that OCR will average 15,468 civil rights related complaints per year and 31,985 privacy related complaints per year. The National Average Salary for Workers according to the Bureau of Labor Statistics is \$29.90 per hour for the second quarter of 2025 ([Occupation Finder : Occupational Outlook Handbook: U.S. Bureau of Labor Statistics](#)) and used as the basis for the wage calculation below. The overall burden estimate is calculated as follows:

Estimated Annualized Burden Table

Written Forms/ Electronic Forms	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per response (minutes)	Wage burden	Total Burden Hours
Civil Rights and Conscience Complaint	Individuals or households, Not-for-profit institutions	15,468	1	45	\$22.43 p/hr	11,601
Health Information Privacy, Security, & Breach Notification Complaint	Individuals or households, Not-for-profit institutions	31,985	1	45	\$22.43 p/hr	23,989
Total		47,453		45	\$22.43 p/hr	35,576

13. *Capital Costs (Maintenance of Capital Costs):* Total cost of capital and cost of maintaining capital associated with this information collection. These capital items only refer to systems that the respondent would not purchase or maintain in the absence of this information collection.

In most situations, this information is submitted by individuals at one time. Therefore, there are no capital and startup costs, or ongoing operation and maintenance or purchase of services in order to complete this form.

14. *Annualized Cost to the Federal Government:*

The Department will incur no additional costs from collecting data pursuant to the revised complaint forms.

15. *Program or Burden Changes:* Explain any program or burden changes. Please consider any burden reductions that may be applicable.

The complaint filing process has not changed and the requested revisions do not involve a program or burden change. Depending on changes in complaint volume estimates, the burden estimates in paragraph 12 could fluctuate.

Changes to Civil Rights and Conscience Complaint Form:

- To be consistent with E.O. 14168 on “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government” and the court order in *Texas v. Becerra*, No. 6:24-CV-211-JDK, 2024 WL 4490621, at *2 (E.D. Tex. Aug. 30, 2024) (staying nationwide the Section 1557 Final Rule definition of sex discrimination as including “pregnancy or related conditions” “sexual orientation” and “gender identity”):
 - Deleted “Mx” option for complainant.
 - Deleted field for “Preferred Pronoun”.
 - Deleted “other” option next to “Sex” discrimination option as a basis for discrimination.
 - Removed language referring to “sexual orientation” and “gender identity”.
- Moved “limited English proficiency” from a free-standing potential basis for discrimination to a parenthesis after national origin- changes include: (including ancestry, ethnicity, and language spoken).
- Substituted “discrimination” for “violation” with respect to conscience allegations for consistency.
- Revised narrative question requesting identity of regulated entity to better clarify that OCR does not have enforcement authority over individual workforce members who allegedly have committed discriminatory acts.
- Revised question on date of alleged violation to remove the 180-day timeframe as conscience complaints are not time barred.
- Removed question related to reasonable modifications to reduce the number of questions.
- Removed the question related to desired resolution to reduce the number of questions.
- Revised Privacy Act Notice to Complainants to include updated authorities.
- Made conforming edits in revised narrative on filing and rights under the Privacy Act and FOIA.

- Updated statutory and regulatory citations.

Changes to Health Information Privacy & Security Complaint Form:

- Changed the title of the complaint form to add “Breach Notification” so that the Form is now called “Health Information Privacy, Security, & Breach Notification Complaint.”
- Made conforming edits (deleted Mx. and preferred pronouns) for consistency with E.O. 14168 on “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government” and court orders.
- Revised question about relationship between the complainant, or the person on whose behalf the complainant is filing, and the regulated entity. The change consolidates prior questions for clarity and spacing considerations. “Person” was added to agency/organization named as covered entity.
- Made conforming edits in revised narrative question requesting identity of regulated entity to better clarify that OCR does not have enforcement authority over individual workforce members.
- Removed specific questions related to the right of access to reduce the number of questions.
- Revised complainant information request notification language by removing references to non-HIPAA authorities that are not relevant to the HIPAA complaint form.
- Revised Privacy Act Notice to Complainants to include updated authorities and be consistent with Civil Rights form.
- Made conforming edits in revised narrative on filing and rights under the Privacy Act and FOIA.
- Updated statutory and regulatory citations.

16. *Publication and Tabulation Dates:* If there is any possibility that these information collection requirements may be published, tabulated, or manipulated (i.e., the results are summarized, segmented, or altered), please discuss. This includes hard copies and, most important, publication on the Internet.

The Department of Health and Human Services reports general deidentified information collected in these forms and tabulated to Congress. [OCR Reports to Congress | HHS.gov](#)

17. *Expiration Date:* If seeking approval to not show an expiration date, explain why.

OCR does not request such approval.

18. *Certification Statement:* Explain each exception to the second page of the 83-I.

None.

B. Collection of Information Employing Statistical Methods

The collection of information does not use a statistical methodology. Rather, the mandatory questions on the complaint forms, as well as the voluntary questions, are designed to assist OCR in processing the complaint and are specific to the individual filing the complaint and the circumstances associated with that complaint. OCR needs the unique information provided to respond to the complaint.