



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. OS-0945-New-60D]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the Information Collection Request (ICR) must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to Conner O'Brien at OCRPrivacy@hhs.gov.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, such as a free copy of the form to be used for the information collection, please include the document identifier OS-0945-New-60D and project title for reference, to Conner O'Brien, email: OCRPrivacy@hhs.gov, or call (202) 240-3110.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Confidentiality of Substance Use Disorder Patient Records Complaint

Type of Collection: New Collection.

OMB No. 0945-New: Office for Civil Rights (OCR)—Health Information Privacy, Data, and Cybersecurity Division.

Abstract: OCR is requesting Office of Management and Budget (OMB) approval for a new information collection. Under OCR’s delegated civil enforcement authority, a person may file a complaint with OCR for alleged noncompliance with 42 CFR part 2 (“Part 2”). OCR will collect information from individuals using the form, Confidentiality of Substance Use Disorder Patient Records Complaint, to allow OCR to collect the minimum information needed from individuals who file complaints with OCR to form the basis for the initial processing of such complaints to satisfy the right for an individual to file a complaint under 42 CFR 2.4(b).

I. Authority

OCR has delegated civil enforcement authority under 42 U.S.C. 290dd-2(f), as amended by section 3221 of the Coronavirus Relief, Aid, and Economic Security Act, that applies section 1176 of the Social Security Act (“the Act”), 45 U.S.C. 1320d-5, to a violation of Part 2 in the same manner as it applies to a violation of part C of title XI of the Act, Administrative Simplification. The Administrative Simplification provisions were added to the Act by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). OCR currently applies its HIPAA enforcement authority under section 1176 of the Act in accordance with 45 CFR part 160. To implement 42 U.S.C. 290dd-2, the Department published a final rule modifying Part 2, 89 FR 12472 (February 16, 2024) (“2024 Part 2 Final Rule”), that included, among other provisions, a new right to file complaints of noncompliance and applied 45 CFR part 160, subparts C, D, and E, as the enforcement regulation for Part 2.

II. Method of Collection

Individuals will be able to submit a Part 2 complaint using the HHS OCR online complaint portal or by filling out a copy of the form obtained from OCR’s website and submitting it to OCR electronically or by postal mail.

III. Estimated Burden

The estimated burden on individuals for gathering information and completing the Part 2 complaint form is 45 minutes per complaint based on the hourly burden for HIPAA complaints. Assuming that 1 in every 1,000 patients treated for SUD would file a Part 2 complaint, the Department estimates a total of 1,398 burden hours for 1,864 complaints annually (1,864,367 patients/1,000 x .75 hours = 1,398).

Likely Respondents: Patients of substance use disorder treatment programs who believe that a Part 2 program, covered entity, business associate, qualified service organization, or other lawful holder of Part 2 records is noncompliant with 42 CFR part 2.

Annualized Burden Hour Table

Forms (If necessary)	Respondents (If necessary)	Number of Respondents	Number of Responses per Respondents	Average Burden per Response	Total Burden Hours
Complaint Form	Patients of Substance Use Disorder Treatment Programs	1,864	1	45 minutes	1,398
Total		1,864			1,398

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer,

Department of Health and Human Services,

Office of the Secretary.