



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
OFFICE FOR CIVIL RIGHTS (OCR)
**CONFIDENTIALITY OF SUBSTANCE USE
DISORDER PATIENT RECORDS
COMPLAINT**

Form Approved: OMB No. 0945-0014
Expiration Date: 02/28/2029

Please indicate one of the following boxes: ☐ Mr. or ☐ Ms.

FIRST NAME

LAST NAME

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PHONE (Please include area code)

PREFERRED DAYS/TIMES TO RECEIVE PHONE CALLS

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STREET ADDRESS

CITY

--	--

STATE

ZIP

EMAIL ADDRESS

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Have you previously filed a complaint with OCR? ☐ Yes ☐ No **If yes**, please provide OCR Transaction No(s):

Are you filing this complaint for someone else? ☐ Yes ☐ No _____

If yes, who was affected by the alleged violation of 42 CFR part 2, the Confidentiality of Substance Use Disorder (SUD) Patient Records?

FIRST NAME

LAST NAME

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If filing on behalf of someone else, what is your relationship to that person?

☐ Parent/Legal Guardian

☐ Attorney

☐ Family Friend

☐ Personal Representative

☐ Other (specify) _____

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. If you have documentation showing that you are legally authorized to act on behalf of the person, please provide that documentation (e.g., health care power of attorney, court appointed legal guardian).

Who (e.g., person or organization) do you believe violated the 42 CFR part 2 requirements?

For organizations, please do not include contact information for an individual workforce member in the following fields.

You may provide individual workforce member information in the witness(es) section of this form.

NAME OF THE PERSON (first name, last name) / ORGANIZATION

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STREET ADDRESS

CITY

--	--

STATE

ZIP

PHONE (Please include area code)

EMAIL ADDRESS

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What is the relationship between the patient affected by the alleged violation of 42 CFR part 2 and the organization or person named above?

(Please check all that apply.)

☐ Patient/Client

☐ Employee

☐ None

☐ Other (specify): _____

☐ Patient is the subject of Investigation or Civil, Criminal, Administrative, or Legislative Proceeding

When do you believe that the violation of 42 CFR part 2 occurred?

LIST DATE(S) ALLEGED VIOLATION OCCURRED

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When did you learn about the alleged violation? A complaint must be filed no later than 180 days from when the complainant knew, or should have known, that the act or omission complained of occurred, unless OCR waives the time limit for good cause

LIST DATE(S) YOU LEARNED ABOUT THE ALLEGED VIOLATION

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CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS COMPLAINT

How and why do you believe the requirements of 42 CFR Part 2 were violated? Please include information about why the information is a record protected by 42 CFR part 2 (concerning SUD prevention, referral, or treatment). Does the record identify a patient as having or having had a SUD, either directly or through verification by another person? Does the record contain SUD information obtained by a SUD program? Please be as specific as possible.

(Attach additional pages as needed)

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Have you attempted to resolve this matter with the person or organization against which you are filing?..... ☐ Yes ☐ No

(If yes, please describe your efforts below and provide copies of any relevant documents.)

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Is there anyone with knowledge about the potential violation whom we should contact? If so, please provide name(s) and contact information below.

WITNESS NAME(S)	EMAIL ADDRESS	PHONE (Please include area code)

Please sign and date the complaint. (You do not need to sign if submitting this form by email because submission by email represents your signature.)

SIGNATURE	DATE (mm/dd/yyyy)

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under the authority of the Confidentiality of Substance Use Disorder Patient Records (42 CFR part 2) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Enforcement Rule (45 CFR part 160). Part 2 programs and other entities may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual for filing a complaint or participating in an investigation (42 CFR 2.4 and 45 CFR 160.316). We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on or through this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974 and 42 CFR part 2, as applicable. Names or other identifying information about individuals may be disclosed when it is necessary for the investigation, for internal systems operations, or for routine uses, which include disclosure of information outside the HHS for purposes associated with statutory compliance and as permitted by law. You are not required to use this form. You may also write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's online Complaint Portal at: <https://ocrportal.hhs.gov/ocr/smartscreen/main.jsf>. To mail a complaint, please see page 3 of this form for the mailing address.

CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS COMPLAINT

The remaining information on this form is **optional**.
(Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.)

Do you need special accommodations for OCR to communicate with you about this complaint? (Check all that apply)

<input type="checkbox"/> Braille	<input type="checkbox"/> Large Print	<input type="checkbox"/> TDD	<input type="checkbox"/> Other (specify): <input type="text"/>
<input type="checkbox"/> Interpreter (specify language): <input type="text"/>			

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME	
<input type="text"/>	<input type="text"/>	
PHONE (Please include area code)		
<input type="text"/>		
STREET ADDRESS		
<input type="text"/>		
CITY		
<input type="text"/>		
STATE	ZIP	EMAIL ADDRESS
<input type="text"/>	<input type="text"/>	<input type="text"/>

Have you filed a complaint anywhere else? If so, please provide the following.

NAME(S) OF AGENCY / ORGANIZATION / COURT	
<input type="text"/>	
DATE(S) FILED	CASE NUMBER(S) (If known)
<input type="text"/>	<input type="text"/>

Has your complaint been accepted by the other agency/organization/court? ☐ Yes ☐ No

Has there been a decision or a determination? ☐ Yes ☐ No
(If yes, please submit a copy of that decision or determination.)

To help us better serve the public, please provide the following optional information for the patient whose confidentiality rights were believed to be violated. (This is you or the person on whose behalf you are filing.)

ETHNICITY (select one)

RACE (select one or more)

- | | | |
|---|---|--|
| <input type="checkbox"/> Decline to Specify | <input type="checkbox"/> Decline to Specify | <input type="checkbox"/> Black or African American |
| <input type="checkbox"/> Hispanic or Latino | <input type="checkbox"/> American Indian or Alaska Native | <input type="checkbox"/> Native Hawaiian or Pacific Islander |
| <input type="checkbox"/> Not Hispanic or Latino | <input type="checkbox"/> Asian | <input type="checkbox"/> White |

PRIMARY LANGUAGE SPOKEN (if other than English):

To submit a complaint, please type or print, sign, and return the completed complaint form package (including consent form) to the OCR Headquarters address below.

U.S. Department of Health and Human Services
Office for Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W. Suite 515F, HHH Building
Washington, D.C. 20201
Customer Information Line: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: OCRComplaint@hhs.gov

Public Burden Statement (Paperwork Reduction Act):

The public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail your complaint form to this address.**



CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about an individual, including personnel and medical records, when they are relevant to its investigation.

To investigate a complaint, OCR may need to disclose the individual's name and other identifying information about the individual to persons at the organization under investigation or to other persons, agencies, or entities. In some circumstances, OCR may refer a complaint to another government agency, as warranted.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information and, with your consent, allows OCR to use an individual's name or other personal information, if necessary, to investigate a complaint.

Consent is voluntary, and it is not always needed in order to investigate a complaint; however, failure to give consent is likely to impede the investigation of a complaint and may result in the closure of the case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer a complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of a complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled [*Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights*](#) and [*Protecting Personal Information in Complaint Investigations*](#) for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of this complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- I understand that in the course of the investigation of this complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the organization under investigation or to other persons, agencies, or entities.
- I am also aware of the obligations of OCR to honor requests under FOIA. I understand that it may be necessary for OCR to disclose information which it has gathered as part of its investigation of this complaint.
- In addition, I understand that I may be covered by HHS's regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because the individual has made a complaint, testified, assisted, in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS's investigation, conciliation, or enforcement process.



After reading the above information, please check ONLY ONE of the following boxes:

☐ **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me to persons at the organization or person under investigation or to other relevant persons, agencies, or entities during any part of HHS's investigation, conciliation, or enforcement process.

☐ **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of this complaint and may result in closure of the investigation.

Signature: _____ Date:

*Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

Name (Please print):

Address:

Telephone Number:



NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 United States Code (U.S.C.) § 552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:

- (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 of the Rehabilitation Act of 1973 (29 U.S.C. § 794), 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); Section 1557 of the Affordable Care Act (42 U.S.C. § 18116);
- (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.*, American Relief Act, 2025, , P.L. 118-158, div. A, section 101 (Dec. 21, 2024), extending Continuing Appropriations and Extensions Act, 2025, P.L. 118-83, div. A, section 102 (Sept. 26, 2024), extending “Further Consolidated Appropriations Act, 2024, P.L. 118-47, div. D, title V, General Provisions, section 507(d) (Mar. 23, 2024).), among others, and applicable regulations (45 C.F.R. Part 88);
- (iii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§ 291 *et seq.* and 300 *et seq.*) and 42 Code of Federal Regulations (C.F.R.) Part 124, Subpart G (Community Service obligations of Hill- Burton facilities); 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;
- (iv) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
- (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 service agencies of state and local governments, regardless of whether they receive federal financial assistance.
- (vi) Health Insurance Portability and Accountability Act of 1996 (HIPAA) Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule), 45 C.F.R. Part 160 and Subparts A and E of Part 164, Health Insurance Reform: Security Standards (The Security Rule), 45 C.F.R. Part 160 and Subparts A and C of Part 164, Breach Notification for Unsecured Protected Health Information (The Breach 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



(vii) civil money penalties, and procedures for hearings related to violations of the 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.).

(viii) Confidentiality of Substance Use Disorder Patient Records (42 C.F.R. part 2); 42 U.S.C. 290dd–2 and 42 U.S.C. 290dd-2 note.

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws referenced above.

OCR has the authority to disclose personal information collected during an investigation without the individual’s consent for the following routine uses:

- (i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
- (ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
- (iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
- (iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. § 552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. § 5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction, and notification requirements.

Freedom of Information Act

A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. § 552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements

Federal law, at 18 U.S.C. § 1001, authorizes prosecution and penalties of fine or imprisonment for conviction of “whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry.”



PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate a complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of medical records or other personal information. This fact sheet explains how OCR protects personal information that is part of an investigative case file.

HOW DOES OCR PROTECT PERSONAL INFORMATION?

OCR is required by law to protect personal information. The Privacy Act of 1974 (Privacy Act) protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Under the Privacy Act, OCR will disclose an individual's name or other personal information with a signed consent, and only when it is necessary to complete the investigation of the complaint or to enforce civil rights laws, health information privacy laws, or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate a complaint; however, failure to give consent is likely to impede the investigation of a complaint and may result in the closure of the case.

CAN THE COMPLAINANT SEE OCR's CASE FILE?

Under the Freedom of Information Act (FOIA), an individual can request a copy of the individual's case file once the case has been closed; however, OCR may, in some circumstances, withhold information in order to protect the identities of witnesses and other sources of information. Additionally, some records may be withheld to protect OCR's deliberative process privilege or any other legally protected privilege.

CAN OCR GIVE A COMPLAINT FILE TO ANYONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without the individual's permission.

If an individual files a complaint with OCR, and we decide we cannot help the individual, we may refer the complaint to another agency, such as the Department of Justice.



CAN ANYONE ELSE SEE THE INFORMATION IN A COMPLAINT FILE?

Public access to OCR's files and records is controlled by FOIA. Under FOIA, OCR may be required to release general information about this case upon public request. In the event that OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals.

If OCR receives protected health information about an individual in connection with a HIPAA investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under FOIA and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages, please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed \$100.00. For details, see HHS's FOIA page.