

How to File a Patient Safety Confidentiality Complaint

About Patient Safety Confidentiality

OCR enforces the confidentiality provisions of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and the Patient Safety and Quality Improvement Rule (Patient Safety Rule). Together, [the Patient Safety Act and Rule](#) establish a voluntary system for Patient Safety Organizations (PSOs) to collect and analyze medical error and patient safety event data. To encourage provider reporting, the Patient Safety Act and Rule include Federal privilege and confidentiality protections for patient safety work products (PSWP). Information submitted to, and developed by, these PSOs is protected as PSWP.

What is PSWP?

PSWP is any information:

- Assembled or developed by a health care provider for reporting to a Patient Safety Organization (PSO) that is listed by the HHS Agency for Healthcare Research and Quality (AHRQ) and is documented as being within the provider's patient safety evaluation system for reporting to a PSO
- Developed by a PSO for the conduct of patient safety activities
- Identifies or constitutes the deliberations, or analysis of, or identifies the fact of reporting pursuant to a patient safety evaluation system

PSWP may identify patients, health care providers and individuals that report medical errors or other patient safety events. This PSWP is confidential and may only be disclosed in certain very limited situations.

Complaint Requirements

Anyone can file a patient safety confidentiality complaint. If you believe that a person or organization shared PSWP, you may file a complaint with OCR. Your complaint must:

- Be filed in writing: sent by mail, fax or e-mail
- Name the person that is the subject of the complaint and describe the act or acts believed to be in violation of the Patient Safety Act requirement to keep PSWP confidential

- Be filed within 180 days of when you knew or should have known that the act complained of occurred, however OCR may waive the 180-day time limit for “good cause” shown

File a Patient Safety Confidentiality Complaint

File a Complaint Using the Patient Safety Confidentiality Complaint Form Package

Open and fill out the [Patient Safety Confidentiality Complaint Form \[PDF, 298 KB\]](#) and [Consent Form Package \[PDF, 272 KB\]](#) in PDF format. You will need Adobe Reader software to fill out the complaint and consent forms. You may either:

- Print and mail or fax the completed complaint and consent forms to the appropriate [OCR regional office](#)
- Email the completed complaint and consent forms to OCRComplaint@hhs.gov (Please note that communication by unencrypted email presents a risk that personally identifiable information contained in such an email, may be intercepted by unauthorized third parties)

File a Complaint Without Using Our Patient Safety Confidentiality Complaint Package

If you prefer, you may submit a written complaint in your own format by either:

- Mail or fax to the appropriate [OCR regional office](#)
- Email to OCRComplaint@hhs.gov

Be sure to include:

- Your name
- Full address
- Telephone numbers (include area code)
- E-mail address (if available)
- Name, full address and telephone number of the person, agency, or organization you believe violated your (or someone else’s) health information privacy rights or committed another violation of the Privacy or Security Rule
- Brief description of what happened, including how, why, and when you believe a person impermissibly disclosed patient safety work product
- Any other relevant information
- Your signature and date of complaint

You may also include:

- If you need special accommodations for us to communicate with you about this complaint

- Contact information for someone who can help us reach you if we cannot reach you directly
- If you have filed your complaint somewhere else and where you've filed

How OCR Investigates Your Complaint

OCR will investigate complaints that allege potential violations of the Rule. To the extent practicable, OCR will provide technical assistance and seek informal resolution of complaints involving the inappropriate sharing of PSWP through voluntary compliance from the responsible person, entity, or organization. When OCR is unable to achieve an informal resolution of an indicated violation through such voluntary compliance, the Secretary may impose a civil money penalty of up to \$14,960 for each knowing and reckless disclosure of PSWP that is in violation of the confidentiality provisions.

HIPAA FAQs for Individuals

[What does the HIPAA Privacy Rule do?](#)

[Does the HIPAA Privacy Rule expand the ability of providers, plans, marketers and others to use my protected health information to market goods and services to me? Does the Privacy Rule make it easier for health care businesses to engage in door-to-door sales and marketing efforts?](#)

[Can telemarketers obtain my health information and use it to call me to sell good and services?](#)

[How does the HIPAA Privacy Rule affect my rights under the Federal Privacy Act?](#)

[If I believe that my privacy rights have been violated, when can I submit a complaint?](#)

[If I do not object, can my health care provider share or discuss my health information with my family, friends, or others involved in my care or payment for my care?](#)

[If I am unconscious or not around, can my health care provider still share or discuss my health information with my family, friends, or others involved in my care or payment for my care?](#)

[If my family or friends call my health care provider to ask about my condition, will they have to give my provider proof of who they are?](#)

[Can I have another person pick up my prescription drugs, medical supplies, or x-rays?](#)

[Can my health care provider discuss my health information with an interpreter?](#)

[Since the HIPAA Privacy Rule protects a decedent's health information only for 50 years following the individual's death, does my family health history recorded in my medical record lose protection when it involves family members who have been deceased for more than 50 years?](#)

[Does the HIPAA Privacy Rule require my doctor to send my medical records to the government?](#)

[Will this HIPAA Privacy Rule make it easier for police and law enforcement agencies to get my medical information?](#)

[Under HIPAA, may an individual request that a covered entity restrict how it uses or discloses that individual's protected health information \(PHI\)?](#)

Filing a Health Information Privacy Complaint

You may file a complaint with the Office for Civil Rights (OCR) if you believe:

- **A HIPAA covered entity or its business associate violated your (or someone else's) health information privacy rights** or committed another violation of the Privacy, Security, or Breach Notification Rules.
- **A substance use disorder (SUD) treatment program violated your confidentiality rights** under 42 CFR part 2 (called "Part 2").

OCR can investigate health information privacy complaints against covered entities (health plans, health care clearinghouses, or health care providers that conduct certain transactions electronically) and their business associates. OCR can also investigate complaints of Part 2 violations against a Part 2 program or its qualified service organization; a lawful holder of Part 2 records, such as a HIPAA covered entity or its business associate; or another person holding Part 2 records.

Complaint Process

Anyone can file a complaint if they believe there has been a violation of the HIPAA Rules or Part 2. Learn what you'll need to submit your complaint online or in writing.

[learn more](#)

File a Complaint Online

File your HIPAA or Part 2 complaint electronically via the OCR Complaint Portal.

[learn more](#)

Filing a Patient Safety Confidentiality Complaint

Read about the Patient Safety Confidentiality Act and Rule and how to file a complaint online or in writing.

[learn more](#)

What to Expect

Learn how OCR investigates your complaint and what happens after the investigation is complete.

[learn more](#)

How to File a Health Information Privacy or Security Complaint

Complaint Requirements

Anyone can file a complaint about noncompliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules or 42 CFR part 2 (“Part 2”), Confidentiality of Substance Use Disorder Patient Records.

Your complaint must:

- Be filed in writing by mail, fax, e-mail, or via the [OCR Complaint Portal](#).

- Name the entity involved:
 - For a HIPAA complaint, name the covered entity or business associate
 - For a Part 2 complaint, name the Part 2 program, Qualified Service Organization, lawful holder of Part 2 records, or other person holding Part 2 records
- Describe the acts or omissions you believed violated the requirements of the Privacy, Security, or Breach Notification Rules or Part 2.
- Be filed within 180 days of when you knew that the act or omission complained of occurred. OCR may extend the 180- day period if you can show "good cause"

HIPAA and Part 2 Prohibit Retaliation

Under HIPAA and Part 2, an entity cannot retaliate against you for filing a complaint. You should notify OCR immediately in the event of any retaliatory action.

File a Health Information Privacy or Security Complaint Online

Open the [OCR Complaint Portal](#) and select the type of complaint you would like to file. Complete as much information as possible, including:

- Information about you, the complainant
- Details of the complaint
- Any additional information that might help OCR when reviewing your complaint

You will then need to electronically sign the complaint and complete the consent form. After completing the consent form, you will be able to print out a copy of your complaint to keep for your records

File a Health Information Privacy or Security Complaint in Writing

File a Complaint Using the HIPAA Privacy and Security Complaint Form Package or the Part 2 Complaint Form Package

Open and fill out the [HIPAA Privacy and Security Complaint Form Package \[PDF, 408 KB\]](#) or the [Part 2 Complaint Form Package \[PDF, 617 KB\]](#) in PDF format. You will need Adobe Reader software to fill out the complaint and consent forms. You may either:

- Print and mail the completed complaint and consent forms to:
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.

Room 509F HHH Bldg.
Washington, D.C. 20201

- Email the completed complaint and consent forms to OCRComplaint@hhs.gov (Please note that communication by unencrypted email presents a risk that personally identifiable information contained in such an email, may be intercepted by unauthorized third parties)

File A Complaint Without Using Our Health Information Privacy Complaint Package

If you prefer, you may submit a written complaint in your own format by either:

- Print and mail the completed complaint and consent forms to:
Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, D.C. 20201
- Email to OCRComplaint@hhs.gov

Be sure to include:

- Your name
- Full address
- Telephone numbers (include area code)
- E-mail address (if available)
- Name, full address and telephone number of the person, agency, or organization you believe violated your (or someone else's) health information privacy rights or committed another violation of the HIPAA Privacy, Security, or Breach Notification Rules or Part 2.
- Brief description of what happened. How, why, and when do you believe your (or someone else's) health information privacy rights were violated, or how the Privacy, Security, or Breach Notification Rules or Part 2 were otherwise violated
- Any other relevant information
- Your signature and date of complaint

If you are filing a complaint on someone's behalf, also provide the name of the person on whose behalf you are filing.

You may also include:

- If you need special accommodations for us to communicate with you about this complaint
- Contact information for someone who can help us reach you if we cannot reach you directly
- If you have filed your complaint somewhere else and where you've filed

Before You File a HIPAA Complaint

[Review these questions before filing a HIPAA complaint with OCR.](#)

Are you filing a complaint against an entity that is required by law to comply with the HIPAA Privacy, Security, or Breach Notification Rules?

Not all entities are required to comply with the Privacy and Security Rules. OCR can only investigate the **covered entities** that must comply with these rules. **Covered entities** include most:

- Doctors
- Clinics
- Hospitals
- Psychologists
- Chiropractors
- Nursing Homes
- Pharmacies
- Dentists
- Health Insurance Companies
- Company Health Plans
- Medicare, Medicaid, and other government programs that pay for health care

Does your complaint describe an activity that might violate the Privacy or Security Rule?

If you are not sure, go ahead and file your complaint. But, OCR can only investigate complaints that allege an action or omission that fails to comply with the Privacy, Security, or Breach Notification Rules. For example, a doctor can send your medical test results to another doctor without your permission if the doctor needs the information to treat you; this is not a violation of the Privacy Rule, so we would not investigate a complaint that described this situation.

Are you willing to give OCR your name and contact information?

OCR does not investigate complaints filed without a name and contact information on the complaint. If you want OCR to keep your name and contact information confidential during the investigation, you may specify that on the consent form.