

# LEGAL UPDATE 2025



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(11.25)

# Disclaimer

This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.

# Compliance Programs



# OIG General Compliance Program Guidance

<https://oig.hhs.gov/compliance/general-compliance-program-guidance/>



U.S. Department of Health and Human Services  
**Office of Inspector General**



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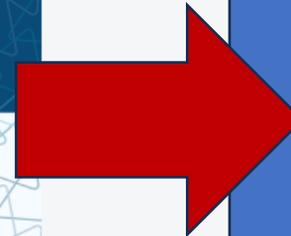
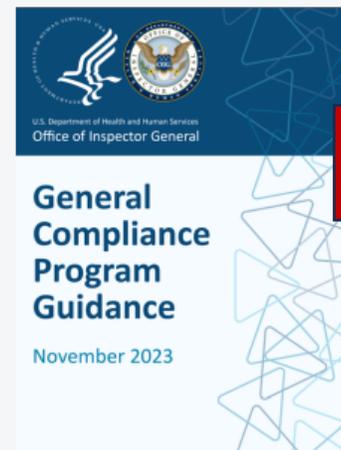
## General Compliance Program Guidance

The General Compliance Program Guidance (GCPG) is a reference guide for the health care compliance community and other health care stakeholders. The GCPG provides information about relevant Federal laws, compliance program infrastructure, OIG resources, and other information useful to understanding health care compliance.

The GCPG is voluntary guidance that discusses general compliance risks and compliance programs. The GCPG is not binding on any individual or entity. Of note, OIG uses the word “should” in the GCPG to present voluntary, nonbinding guidance.

**You may download the guidance in whole, or access individual sections below.**

[Download Complete Guidance](#)



OIG focuses on key statutes, e.g.,

1. Anti-Kickback Statute
2. Physician Self-Referral Law (Stark)
3. False Claims Act
4. Civil Monetary Penalty Authorities
  - Beneficiary Inducements
  - Information Blocking
  - Exclusion Authority
5. HIPAA Privacy and Security Rules

### Individual Sections

<https://oig.hhs.gov/compliance/compliance-guidance/>



According to  
OIG website,  
industry-specific  
guides are  
expected in  
2025 for:

- Hospital
- Clinical Labs
- Medicare Advantage

## Compliance Guidance

Below are OIG's existing CPGs and supplemental CPGs, available for use as an ongoing resource to help identify risk areas in particular industry segments as we develop new ICPGs. Existing CPGs will be archived but still available on our website when new ICPGs are issued.

The CPGs are listed below.

### Industry Segment-Specific Compliance Program Guidance (ICPG)

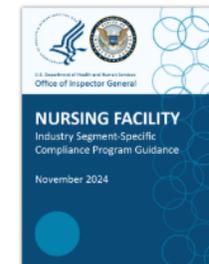
- Nursing Facility
- Medicare Advantage
- Hospital
- Clinical Laboratory
- Pharmaceutical Manufacturer
- Hospice

**GENERAL  
COMPLIANCE  
PROGRAM  
GUIDANCE**

### GCPG



### ICPGs



# Fraud and Abuse



- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Eliminating Kickbacks in Recovery Act (EKRA)
- Ethics in Patient Referrals Act (Stark)
- Civil Monetary Penalties Law (CMPL)
  - Inducements to program beneficiaries
  - Excluded Entities
- State fraud and abuse laws.

# False Claims Act

- Prohibits knowingly and improperly avoiding an obligation to pay or transmit money or property to the govt.

(31 USC 3729(a)(1)(G))

- “Obligation” = means a duty to repay the govt arising from statute or contract or “retention of any overpayment.”

(31 USC 3729(b)(3))

- Statute of limitations:
  - 6 years from false claim or failure to pay, or
  - 3 years from the time the govt knew about it, but no more than 10 years from false claim.

(31 USC 3731)

## Penalties

- Up to \$24,947\* per violation.
  - Each overpayment constitutes a separate violation.
- 3x damages incurred by govt.
- Costs of litigation.
- *Qui tam* lawsuit.
  - But see *U.S. ex rel. Zafirov v. Florida Medical Associates* (11<sup>th</sup> Cir. 2025)

(31 USC 3729; 45 CFR 102.3\*)

# CMS Report and Repay Rule

In December 2024, CMS modified the report and repay rule:

- A person who has received an overpayment must report and return the overpayment by the later of either:
  - The date any corresponding cost report is due, if applicable, or
  - The date which is 60 days after the date on which the overpayment was “identified”, i.e., the person
    - has actual knowledge of the info; or
    - acts in deliberate ignorance of the truth or falsity of the information.
- 60-day reporting period suspended for up to 180 days during timely, good faith investigation.

(42 CFR 401.305; see 89 FR 98553 (12/9/24))

# HIPAA and Patient Privacy



# HIPAA

## ~~Reproductive Health Rule~~

- ~~• If reproductive healthcare is legal, covered entities may not disclose reproductive healthcare PHI for purposes of criminal, civil or administrative liability or investigation.  
(45 CFR 502(a)(5))~~
- ~~• Must obtain attestation from persons seeking reproductive healthcare PHI.  
(45 CFR 509)~~

- Texas federal district court enjoined enforcement. (*Purl v. HHS*, No. 2:24-cv-00228-Z (N.D. Tex., June 18, 2025)).
- Trump administration did not challenge court decision.

OCR HIPAA Website,  
<https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html>

Change Healthcare Cybersecurity Incident FAQs

HIPAA and COVID-19

**HIPAA and Reproductive Health**

HIPAA and Final Rule Notice

HIPAA and Telehealth

HIPAA and FERPA

Research

Public Health

Emergency Response

Health Information Technology

Health Apps

# HIPAA and Reproductive Health

Per a court order, HHS is required to restore this website as of [February 11, 2025 at 11:59 p.m]. Any information on this page promoting gender ideology is extremely inaccurate and disconnected from the immutable biological reality that there are two sexes, male and female. The Trump Administration rejects gender ideology and condemns the harms it causes to children, by promoting their chemical and surgical mutilation, and to women, by depriving them of their dignity, safety, well-being, and opportunities. This page does not reflect biological reality and therefore the Administration and this Department rejects it.

On June 18, 2025, the U.S. District Court for the Northern District of Texas issued an order declaring unlawful and vacating most of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy at 89 Federal Register 32976 (April 26, 2024). With regard to the modifications to the HIPAA Privacy Rule Notice of Privacy Practices (NPP) requirements at 45 CFR 164.520, the court vacated only the provisions that were deemed unlawful, namely 164.520(b)(1)(ii)(F), (G), and (H). The remaining modifications to the NPP requirements are undisturbed and remain in effect, *see Carmen Purl, et al. v. U.S. Department of Health and Human Services, et al.*, No. 2:24-cv-00228-Z (N.D. Tex. June 18, 2025). Compliance with the remaining NPP modifications is required by February 16, 2026. HHS will determine next steps after a thorough review of the court's decision.

## Final Rule HIPAA Privacy Rule to Support Reproductive Health Care Privacy



# HIPAA

## Disclosures per Administrative Requests

- HIPAA allows disclosures for certain law enforcement requests, including but not limited to:
  - “(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:
    - “(1) The information sought is relevant and material to a legitimate law enforcement inquiry;
    - “(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
    - “(3) De-identified information could not reasonably be used.”

(45 CFR 164.512(f)(1)(C))

- ✓ *Clarifies that “administrative request” exception only applies if the response is required by law, not just because the agent requests the info.*

# HIPAA Patient's Right of Access



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[Home](#) > [Press Room](#) > HHS' Office for Civil Rights Settles HIPAA Right of Access Investigation with Concentra, Inc.



**FOR IMMEDIATE RELEASE**

**December 16, 2025**

**Contact: HHS Press Office**

202-690-6343

[Submit a Request for Comment](#)

## HHS' Office for Civil Rights Settles HIPAA Right of Access Investigation with Concentra, Inc.

*OCR Settlement Marks OCR's 54<sup>th</sup> HIPAA Right of Access Enforcement Action to Advance Individual Access to Medical Records*

**WASHINGTON— December 16, 2025** — Today, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) announced a settlement with Concentra, Inc., (Concentra), an occupational health services provider headquartered in Texas, for a potential violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The settlement resolves an investigation of a complaint alleging a failure to provide timely access to an individual's protected health information (PHI). OCR's investigation determined Concentra failed to provide timely access to

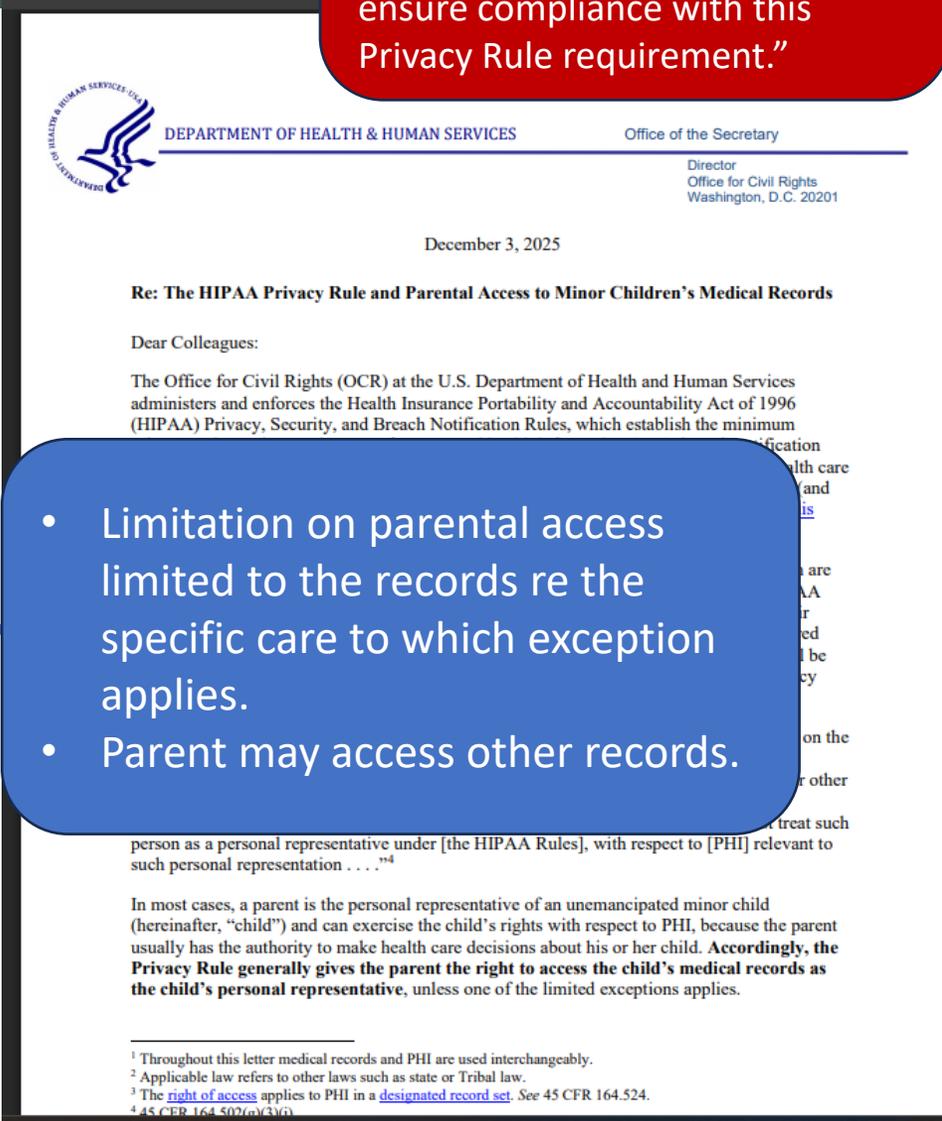
- OCR's Right of Access Initiative is alive and well.
- Provider paid \$112,500 for failing to provide access in response to multiple requests.

# HIPAA Parent's Access to Minor Child's Info

- If a parent or guardian has authority under applicable law to make healthcare decisions for the minor, the parent is the personal representative for purposes of HIPAA and has the right to access the minor's PHI.
- Exceptions:
  - Minor has authority to consent to her/his own care.
  - Minor's care is directed by a court.
  - Parent agrees minor and provider may have confidential relationship.
  - Abuse, neglect, or danger to minor.

(45 CFR 164.502(g); <https://www.hhs.gov/sites/default/files/ocr-letter-hipaa-privacy-rule-and-parental-access-to-minor-childrens-medical-records.pdf> )

“OCR is making parental access to children’s medical records an enforcement priority and will use all civil remedies available, including civil money penalties, to ensure compliance with this Privacy Rule requirement.”



- Limitation on parental access limited to the records re the specific care to which exception applies.
- Parent may access other records.

person as a personal representative under [the HIPAA Rules], with respect to [PHI] relevant to such personal representation . . . .<sup>4</sup>

In most cases, a parent is the personal representative of an unemancipated minor child (hereinafter, “child”) and can exercise the child’s rights with respect to PHI, because the parent usually has the authority to make health care decisions about his or her child. **Accordingly, the Privacy Rule generally gives the parent the right to access the child’s medical records as the child’s personal representative**, unless one of the limited exceptions applies.

<sup>1</sup> Throughout this letter medical records and PHI are used interchangeably.  
<sup>2</sup> Applicable law refers to other laws such as state or Tribal law.  
<sup>3</sup> The [right of access](#) applies to PHI in a [designated record set](#). See 45 CFR 164.524.  
<sup>4</sup> 45 CFR 164.502(a)(3)(i).

# HIPAA

## Parent's Access to Minor Child's Info

- “With respect to electronic access to PHI, covered entities should work with any business associates involved in facilitating such access (e.g., electronic health record or patient portal vendors) to ensure that parents who are their children’s personal representatives have electronic access to their children’s PHI to the full extent required by the Privacy Rule. This includes establishing electronic access configurations to allow parents access to their children’s PHI in accordance with the Privacy Rule. For example, if the default configurations of electronic information systems that maintain a child’s PHI result in the improper denial of a parent’s right, as the child’s personal representative, to timely access the information, the covered entity should modify, or work with their business associate (if applicable) to modify, the default configurations to allow such access as required by the Privacy Rule. A covered entity that denies such access may be in violation of the Privacy Rule.”

(<https://www.hhs.gov/sites/default/files/ocr-letter-hipaa-privacy-rule-and-parental-access-to-minor-childrens-medical-records.pdf>)

- See also Information Blocking Rule...

# HIPAA: Patient's Right of Access



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## Health Information Privacy

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Newsroom

HHS > HIPAA Home > For Professionals > Privacy > Guidance Materials > Individuals' Right under HIPAA to Access their Health Information



HIPAA for Professionals

Regulatory Initiatives

Privacy +

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Breach Notification +

Compliance & Enforcement +

Special Topics +

## Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524

This guidance remains in effect only to the extent that it is consistent with the court's order in Ciox Health, LLC v. Azar, No. 18-cv-0040 (D.D.C. January 23, 2020), which may be found at <https://ecf.dcd.uscourts.gov/cgi->

See Guidance at  
<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>

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# HIPAA

## Proposed Privacy Rule Changes



Proposed rule published 1/21/21; still waiting...

- Strengthens individual's right of access.
  - Individuals may take notes or use other personal devices to view and capture images of PHI.
  - Must respond to requests to access within 15 days instead of 30 days.
  - Must share info when directed by patient.
  - Additional limits to charges for producing PHI.
- Facilitates individualized care coordination.
- Clarifies the ability to disclose to avert threat of harm.
- Not required to obtain acknowledgment of Notice of Privacy Practices.
- Modifies content of Notice of Privacy Practices.

(86 FR 6446 (1/21/21))

# Substance Use Disorder Records: 42 CFR part 2



## New 42 CFR part 2:

- Effective 4/16/24.
  - **Enforced 2/16/26.**
- (89 FR 12472)

- **SUD Programs:**

- Generally, may not disclose SUD records (i.e., info) without consent.
  - May obtain single consent for treatment, payment and healthcare operations.
- Consent forms must satisfy requirements.
- If disclose SUD records, send copy of consent + notice of Part 2 duties.
- Execute agreements with qualified service organizations.
- Secure SUD records.
- Provide notice of patient rights.
- Update and provide notice of privacy practices.

- **Recipients of SUD records:**

- Maintain confidentiality of SUD info received.
- Do not redisclose unless allowed by Part 2.
- Secure SUD records.

(42 CFR part 2)

# “Federally Assisted” SUD Program

- “Federally assisted” =
  - Carried out under license or authorization granted by U.S. dept or agency (*e.g.*, participating in Medicare; DEA registration; or authorization to conduct maintenance treatment or withdrawal management).
  - Supported by funds provided by a U.S. department or agency (*e.g.*, receiving federal financial assistance, Medicaid, grants, etc., even if federal money does not pay directly for SUD services);
  - Program is tax-exempt or claims tax deductions relating to program; or
  - Conducted directly or by contract or otherwise by any dept or agency of the United States.
    - Special rules for VA or armed forces.

(42 CFR 2.12(b))

- Not purely private pay programs, but HIPAA likely applies.

# Federally Assisted “SUD Program”

Individual or Entity; <u>Not</u> General Medical Facility	General Medical Facility	
	Identified Unit	Medical Personnel or Staff
<ol style="list-style-type: none"> <li>1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, <i>and</i></li> <li>2. Provides SUD diagnosis, treatment, or referral for treatment</li> </ol>	<ol style="list-style-type: none"> <li>1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, <i>and</i></li> <li>2. Provides SUD diagnosis, treatment, or referral for treatment</li> </ol>	<ol style="list-style-type: none"> <li>1. Primary function is to provide SUD diagnosis, treatment or referral for treatment, <i>and</i></li> <li>2. Identified as such providers</li> </ol>

*Beware: 42 CFR part 2 also applies to most recipients of SUD records*

# Substance Use Disorder Records: Enforcement



- HIPAA penalties and enforcement applies to Part 2:
  - Criminal penalties of up to \$250,000 and 10 years in prison.
  - Civil penalties of \$141\* to \$2,134,831\* per violation.
  - Must self-report breaches.
- On 8/27/25, Sec. Kennedy delegated enforcement of Part 2 to OCR.
  - Complaints and investigations.
  - Settlements and agreements.
  - Civil penalties.

(90 FR 41833)

- May signal greater enforcement.

# HIPAA and SUD Rules: Notice of Privacy Practices

- Reproductive Health Rule: modified NPP requirements to accommodate SUD Rule changes as required by 45 CFR 164.520.
- SUD Rule: Covered entities creating or maintaining SUD records subject to Part 2 must provide the notice to the patient as required by 42 CFR 2.22.
  - Uses and disclosures.
  - Patient rights.
  - Covered entities' duties.
- Other covered entities must update their NPP.  
(45 CFR 164.520(a)(2))
- Must comply by **2/16/26**.

- **Check applicable regs when drafting updated NPP.**
- **Watch for new NPP requirements when final HIPAA rules are published.**
- **OCR plans to publish model NPP.**

# NPP v. Website Privacy Terms

## HIPAA NOTICE OF PRIVACY PRACTICES

- Usually prepared by privacy officer or compliance.
- Must contain required terms.
- Describes permissible uses and disclosures.
- Prohibits others.



## WEBSITE PRIVACY TERMS

- Often prepared by marketing, website developer or IT without considering HIPAA implications.
- May purportedly allow uses or disclosures that are not permitted by HIPAA.

# HIPAA and Data Security



# Recent HIPAA Resolutions

<https://www.hhs.gov/hipaa/newsroom/index.html>

Security Rule breaches make up majority of HIPAA settlements and have highest dollar values

Date	Conduct	Resolution
4/17/25	Hospital hit with ransomware attack + improper access.	\$25,000
4/4/25	Radiology group data subject to unauthorized access.	\$350,000
3/21/25	Business associate's PHI exposed to webcrawlers on internet.	\$227,816
2/20/25	Eyeglasses company hacked.	\$1,500,000
1/15/25	Neurosurgery group hit with ransomware attack.	\$10,000
1/14/25	Medical supply company data breached following phishing scheme.	\$3,000,000
1/8/25	Business associate's PHI deleted by unauthorized third party.	\$337,750
1/7/25	Business associate hit with ransomware attack.	\$80,000
12/10/24	Health care clearinghouse data available through Google search.	\$250,000
10/31/24	Ambulance services hit with ransomware attack.	\$90,000
10/31/24	Plastic surgeons hit with ransomware attack.	\$500,000
10/17/24	Dentist office failed to provide timely access to records.	\$70,000
10/3/24	Hospital hit with ransomware attack.	\$240,000
9/26/24	Eye and Skin Center hit with ransomware attack	\$250,000
8/1/24	EMS provider failed to provide timely access to records.	\$115,200
7/1/24	Health system hit with ransomware attack.	\$950,000
4/1/24	Essex Residential Care failed to provide personal rep timely access to records.	\$100,000
3/29/24	Phoenix Healthcare failed to provide personal representatives timely access to records.	\$35,000

[https://ocrportal.hhs.gov/ocr/breach/breach\\_report.jsf](https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf)

Of the 749 cases currently under investigation by the OCR, 95%+ are due to “Hacking/IT Incident”

## Cases Currently Under Investigation

This page lists all breaches reported within the last 24 months that are currently under investigation by the Office for Civil Rights.

[Show Advanced Options](#)

Breach Report Results							
Expand All	Name of Covered Entity	State	Covered Entity Type	Individuals Affected	Breach Submission Date	Type of Breach	Location of Breached Information
>	City of St. Joseph, MO Health Department	MO	Healthcare Provider	11538	09/22/2025	Hacking/IT Incident	Network Server
>	UNC Hospitals	NC	Healthcare Provider	6377	09/19/2025	Hacking/IT Incident	Email
>	People Encouraging People	MD	Healthcare Provider	13083	09/19/2025	Hacking/IT Incident	Network Server
>	The University of North Carolina at Chapel Hill - School of Medicine	NC	Healthcare Provider	799	09/19/2025	Hacking/IT Incident	Email
>	Health & Palliative Services of the Treasure Coast, Inc d/b/a Treasure Coast Hospice (“Treasure Health ”)	FL	Healthcare Provider	13234	09/19/2025	Unauthorized Access/Disclosure	Email
>	Sturgis Hospital	MI	Health Plan	77771	09/18/2025	Hacking/IT Incident	Network Server
>	Sturgis Hospital	MI	Healthcare Provider	77771	09/18/2025	Hacking/IT Incident	Network Server

# Costs of Data Breach

Plaintiff's lawyers  
fishing for cases

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& ASSOCIATES, P.C.  
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SEARCH



Average cost of data breach in  
healthcare industry: \$7.42 million

- Detection and investigation
- System and infrastructure recovery
- Lost revenue
- Regulatory penalties
- Legal fees
- Damage control, e.g., notification, credit monitoring, communication, etc.
- Settlements
- Payments to bad actors

POSTED ON JUNE 13, 2023 [CONSUMER PRIVACY & DATA BREACHES](#)

## Idaho Falls Community Hospital and Mountain View Hospital Data Breach Investigation





**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Office for Civil Rights**

April 17, 2025

**HHS Office for Civil Rights Settles HIPAA Ransomware Cybersecurity Investigation with Public Hospital**

*Settlement marks OCR's 11th ransomware enforcement action and 7th enforcement action in OCR's Risk Analysis Initiative*

“OCR recommends that health care providers, health plans, ... and business associates that are covered by HIPAA take the following steps to mitigate or prevent cyber-threats:

- Identify where ePHI is located in the organization, including how ePHI enters, flows through, and leaves the organization's information systems.
- Integrate risk analysis and risk management into the organization's business processes.
- Ensure that audit controls are in place to record and examine information system activity.
- Implement regular reviews of information system activity.
- Utilize mechanisms to authenticate information to ensure only authorized users are accessing ePHI.
- Encrypt ePHI in transit and at rest to guard against unauthorized access to ePHI when appropriate.
- Incorporate lessons learned from incidents into the organization's overall security management process.
- Provide workforce members with regular HIPAA training that is specific to the organization and to the workforce members' respective job duties.”

# <https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>

In September 2025, HHS published updated Security Assessment Tool



TOPICS ▾ BLOG NEWS ▾ DATA

HealthIT.gov > Topics > Privacy, Security, and HIPAA > Security Risk Assessment Tool

## Privacy, Security, and HIPAA ▾

Educational Videos

### Security Risk Assessment Tool ▾

Security Risk Assessment Videos

Top 10 Myths of Security Risk Analysis

HIPAA Basics >

Privacy & Security Resources & Tools >

Model Privacy Notice (MPN)

How APIs in Health Care can Support Access to Health Information: Learning Module

Patient Consent and Interoperability

## Security Risk Assessment Tool

The [Health Insurance Portability and Accountability Act \(HIPAA\) Security Rule](#) requires that [covered entities](#) and its business associates conduct a risk assessment of their healthcare organization. A risk assessment helps your organization ensure it is compliant with HIPAA's [administrative, physical, and technical safeguards](#). A risk assessment also helps reveal areas where your organization's protected health information (PHI) could be at risk. To learn more about the assessment process and how it benefits your organization, visit the [Office for Civil Rights' official guidance](#).

### What is the Security Risk Assessment Tool (SRA Tool)?

The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with the HHS Office for Civil Rights (OCR), developed a downloadable Security Risk Assessment (SRA) Tool to help guide you through the process. The tool is designed to help healthcare providers conduct a security risk assessment as required by the HIPAA Security Rule. The target audience of this tool is medium and small providers; thus, use of this tool may not be appropriate for larger organizations.

### SRA Tool for Windows

The SRA Tool is a desktop application that walks users through the security risk assessment process using a simple, wizard-based approach. Users are guided through multiple-choice

### Need Help?

Please leave any questions, comments, or feedback about the SRA Tool using our [Health IT Feedback Form](#). This includes any trouble in using the tool or problems/bugs with the application itself. Also, please feel free to leave any suggestions on how we could improve the tool in the future.

You may also leave a message with our Help Desk by contacting [734-302-4717](tel:734-302-4717) or sending email to [SRAHelpDesk@Altarum.org](mailto:SRAHelpDesk@Altarum.org).

[Submit Questions Or Feedback](#)

SRA Webinars

<https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html>

## Health Information Privacy



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HIPAA for Professionals

Regulatory Initiatives

Privacy +

Security +

Breach Notification +

Compliance & Enforcement +

Special Topics +

Patient Safety



## Guidance on Risk Analysis

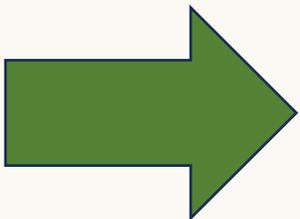
The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with the HHS Office for Civil Rights (OCR), developed the [HIPAA Security Risk Assessment \(SRA\) Tool](#). The tool's features make it useful in assisting small and medium-sized health care practices and business associates in complying with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule.

# OCR Cybersecurity Guidance

<https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>

The screenshot shows the U.S. Department of Health and Human Services website. The header includes the HHS logo and the tagline "Enhancing the health and well-being of all Americans". A search bar is located in the top right. Below the header is a navigation bar with links for "About HHS", "Programs & Services", "Grants & Contracts", and "Laws & Regulations". The main content area is titled "Health Information Privacy" and features four buttons: "HIPAA for Individuals", "Filing a Complaint", "HIPAA for Professionals", and "Newsroom". Below this is a breadcrumb trail: "HHS > HIPAA Home > For Professionals > The Security Rule > Security Rule Guidance Material > Cyber Security Guidance Material". A left sidebar menu lists "HIPAA for Professionals", "Regulatory Initiatives", "Privacy", "Security", "Summary of the Security Rule", "Security Guidance", and "Cyber Security Guidance". The main content area is titled "Cyber Security Guidance Material" and includes a sub-header "Cyber Security Guidance Material" and a paragraph: "In this section, you will find educational materials specifically designed to give HIPAA covered entities and business associates insight into how to respond to a cyber-related security incidents." Social media icons for text, print, Facebook, and email are also visible.

- Cybersecurity Resources
- Cybersecurity Newsletters
  - Sanction policies (10/23)
  - Authentication (6/23)
  - Security rule incident procedures (10/22)
  - Defending against common cyber attacks (3/22)
  - Others
- Cyber incident response checklist



Sign up for OCR listserv at  
<https://www.hhs.gov/hipaa/for-professionals/list-serve/index.html?language=es>

# OCR Cybersecurity Resources

<https://www.hhs.gov/about/news/2024/03/13/hhs-office-civil-rights-issues-letter-opens-investigation-change-healthcare-cyberattack.html>

- [OCR HIPAA Security Rule Guidance Material](#) – This webpage provides educational materials to learn more about the HIPAA Security Rule and other sources of standards for safeguarding electronic protected health information. Materials include a Recognized Security Practices Video, Security Rule Education Paper Series, HIPAA Security Rule Guidance, OCR Cybersecurity Newsletters, and more.
- [OCR Video on How the HIPAA Security Rule Protects Against Cyberattacks](#)  – This video discusses how the HIPAA Security Rule can help covered entities and business associates defend against cyberattacks. Topics include breach trends, common attack vectors, and findings from OCR investigations.
- [OCR Webinar on HIPAA Security Rule Risk Analysis Requirement](#)  – This webinar discusses the HIPAA Security Rule requirements for conducting an accurate and thorough assessment of potential risks and vulnerabilities to electronic protect health information and reviews common risk analysis deficiencies OCR has identified in its investigations.
- [HHS Security Risk Assessment Tool](#) – This tool is designed to assist small- to medium-sized entities in conducting an internal security risk assessment to aid in meeting the security risk analysis requirements of the HIPAA Security Rule.
- [Factsheet: Ransomware and HIPAA](#) – This resource provides information on what is ransomware, what covered entities and business associates should do if their information systems are infected, and HIPAA breach reporting requirements.
- [Healthcare and Public Health \(HPH\) Cybersecurity Performance Goals](#) – These voluntary, health care specific cybersecurity performance goals can help health care organizations strengthen cyber preparedness, improve cyber resiliency, and protect patient health information and safety.

# HIPAA and Online Tracking

<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html>



About HHS Programs & Services Grants & Contracts Laws & Regulation

## Health Information Privacy

HIPAA for Individuals

Filing a Complaint

HHS > HIPAA Home > For Professionals > Privacy > Guidance Materials > U

HIPAA for Professionals	
Regulatory Initiatives	
Privacy	+
Security	+
Breach Notification	+
Compliance & Enforcement	+
Special Topics	+
Patient Safety	+

## Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates

On March 18, 2024, OCR updated this guidance to increase clarity for regulated entities and the public.

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) is issuing this Bulletin to

Use of tracking technologies on websites and mobile apps may violate HIPAA, e.g.,

- Cookies
- Web beacons
- Tracking pixels
- Session replay scripts
- Fingerprint scripts
- IP addresses
- Geolocations

1. Does the data contain individually identifiable info that relates to past, present, or future health, healthcare or payment?
2. If so, does HIPAA permit the use or disclosure without patient authorization?

# Online Tracking



**ROB BONTA**

*Attorney General*

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## Attorney General Bonta Announces Largest CCPA Settlement to Date, Secures \$1.55 Million from Healthline.com

Press Release / [Attorney General Bonta Announces Largest CCPA Settlement to ...](#)



Tuesday, July 1, 2025

Contact: (916) 210-6000, [agpressooffice@doj.ca.gov](mailto:agpressooffice@doj.ca.gov)

*Action represents fourth settlement, continued enforcement priority under the California Consumer Privacy Act*

**OAKLAND** — California Attorney General Rob Bonta today announced a settlement with website publisher Healthline Media LLC (Healthline),

**Beware state enforcement!**

**Holland & Hart**

# HIPAA Proposed Security Rule Changes



Proposed rule published 1/6/25.

- Significantly revamps and strengthens cybersecurity requirements.
  - Administrative safeguards
  - Physical safeguards
  - Technical safeguards.
- All standards are required; no addressable standards.
- On annual basis, covered entities and business associates must review and update inventory, risk analysis, plans, policies, etc.
- In addition to usual BAA requirements, business associates must report activation of contingency plan.

(90 FR 901).

# FTC Enforcement of Privacy and Security

FTC is using FTCA § 5 to go after entities for data security breaches.

- Bars unfair and deceptive trade practices, e.g.,
  - Mislead consumers re security practices.
  - Misusing info or causing harm to consumers.

(<https://www.ftc.gov/news-events/topics/protecting-consumer-privacy-security/privacy-security-enforcement> )

- [Apitor](#) (October 1, 2025 )
- [Iconic Hearts Holdings, Inc., U.S. v.](#) (September 29, 2025 )
- [Disney](#) (September 5, 2025 )
- [Pornhub/Mindgeek/Aylo](#) (September 3, 2025 )
- [Support King, LLC \(SpyFone.com\), In the Matter of](#) (July 18, 2025 )
- [Roca Labs, Inc.](#) (July 9, 2025 )
- [GoDaddy Inc., et al., In the Matter of](#) (May 21, 2025 )
- [Facebook, Inc., In the Matter of](#) (May 2, 2025 )
- [Avast](#) (February 24, 2025 )
- [Aqua Finance](#) (February 19, 2025 )
- [Cognosphere, LLC, U.S. v.](#) (January 17, 2025 )
- [General Motors LLC., et al., In the Matter of](#) (January 16, 2025 )
- [Snap, Inc., U.S. v.](#) (January 16, 2025 )
- [Mobilewalla, Inc., In the Matter of](#) (January 14, 2025 )
- [Intellivision, In the Matter of](#) (January 13, 2025 )
- [Vivint Smart Home, Inc.](#) (December 5, 2024 )
- [Gravy Analytics, Inc., In the Matter of](#) (December 3, 2024 )
- [Marriott International, Inc. and Starwood Hotels & Resorts Worldwide, LLC, In the Matter of](#) (October 9, 2024 )
- [1Health.io/Vitagene, In the Matter of](#) (September 9, 2024 )
- [Verkada Inc., U.S. v.](#) (August 30, 2024 )

# Information Blocking Rule



# Ino Blocking Rule: Increased Enforcement?



U.S. DEPARTMENT OF  
HEALTH AND HUMAN SERVICES

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[Home](#) > [Press Room](#) > [HHS Announces Crackdown on Health Data Blocking](#)

“HHS will take an active enforcement stance against health care entities that restrict patients’ engagement in their care by blocking the access, exchange, and use of electronic health information.”



**FOR IMMEDIATE RELEASE**  
**September 3, 2025**

**Contact: HHS Press Office**

202-690-6343

[Submit a Request for Comment](#)

## HHS Announces Crackdown on Health Data Blocking

WASHINGTON--Today, the U.S. Department of Health and Human Services (HHS) announced that Secretary Robert F. Kennedy, Jr. has directed HHS to increase resources dedicated to curbing the harmful practice of information blocking. HHS will take an active enforcement stance against health care entities that restrict patients’ engagement in their care by blocking the access, exchange, and use of electronic health information.

The 21st Century Cures Act of 2016 authorized the Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (ASTP/ONC) and HHS Office of Inspector General (OIG) to take enforcement actions to hold those who block patient information accountable and to prevent future violations. As a result, ASTP/ONC, the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information

# Info Blocking Rule

- Applies to “actors”
  - Healthcare providers.
  - Developers or offerors of certified health IT.
    - Not providers who develop their own IT.
  - Health info network/exchange.

(45 CFR 171.101)

- Prohibits info blocking, i.e., practice that is likely to interfere with access, exchange, or use of electronic health info unless
  - Action is required by law, or
  - Exception applies, and
- Provider: knows practice is unreasonable and likely to interfere, or
- Developer/HIN/HIE: knows or should know practice is likely to interfere.

(45 CFR 171.103)

# Info Blocking Rule Penalties

## DEVELOPERS, HIN, HIE

- Complaints to OIG
  - <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6>
  - OIG Hotline
- Civil monetary penalties of up to \$1,000,000 per violation  
(42 CFR 1003.1420)

## HEALTHCARE PROVIDERS

- Hospitals: loss of status as meaningful user of EHR
- Providers: loss of status as meaningful user under MIPS
- ACOs: ineligible to participate.  
(42 CFR 1003.700-.720)
- Loss of federal payments.

# <https://www.healthit.gov/topic/information-blocking>

 Official Website of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT



[TOPICS](#) ▾ [BLOG](#) [NEWS](#) ▾ [DATA](#) [ABOUT ASTP](#) ▾



[HealthIT.gov](#) > [Topics](#) > [Information Blocking](#)

## Information Blocking

Most clinical information is digitized, accessible, and shareable thanks to several technology and policy advances making interoperable, electronic health record systems widely available. In 2016, the 21st Century Cures Act (Cures Act) made sharing electronic health information the expected norm in health care and authorized the Secretary of Health and Human Services (HHS) to identify "reasonable and necessary activities that do not constitute information blocking." Information blocking exceptions are identified in 45 CFR Part 171. [Learn more](#) about laws, regulations, and policies related to information blocking.



# Telephone Consumer Protection Act (TCPA)



# Telephone Consumer Protection Act (TCPA)

## Generally prohibits:

- Using automatic phone dialing system (“robo-call”) to call a hospital emergency line or guest room, cell phone, or other line if recipient is charged for call.
- Robo-calling or using pre-recorded voice to deliver message unless:
  - Emergency,
  - Have prior written consent,
  - Have consent if made by tax-exempt nonprofit organization, or
  - “health care” message by HIPAA-covered entity or business associate.

(47 USC 227; 47 CFR 64.1200)

## Penalties

- Recipient of more than 1 call within prior 12-month period may sue for:
  - Actual damages or \$500 per call, whichever is greater.
- State AGs may sue.

(47 USC 227)

# TCPA: Healthcare Message Exception

- Exception only applies to three types of calls by a healthcare provider or its business associates without a patient's prior authorization:
  - calls to describe a health-related product or service that is provided by the covered entity making the communication;
  - calls for treatment of the individual (e.g., appointment reminder; prescription refill reminders; etc.); and
  - calls for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.
- **For healthcare calls, must limit to no more than 1 call per day up to 3 calls per week.**  
(47 CFR 64.1200; <https://www.ftc.gov/business-guidance/resources/complying-telemarketing-sales-rule#healthcare>)

# Telephone Consumer Protection Act (TCPA)

Effective **4/11/26** (delayed from 4/11/25):

- Consumers may revoke consent to robocalls and robotexts “in any reasonable manner”, including:
  - Through text message, email, phone calls, conversation, social media, etc.
  - Using words such as stop, quit, end, revoke, opt out, cancel, or unsubscribe.
- Callers must honor do-not-call and revocation requests “as soon as practicable”
  - No later than 10 business days after the request.
- Text-senders may send one text message in response to a revocation request confirming or clarifying the scope of the request within five minutes.

(47 CFR 64.1200; <https://public-inspection.federalregister.gov/2024-23605.pdf>; 89 FR 15756)

# Telehealth



# Telehealth: Medicare Coverage

- Coverage for certain telehealth services were set to expire after 9/30/25, but...
- Budget law signed 11/12/25 extends such telehealth services to **1/30/26**, e.g.,
  - Beneficiaries may continue to receive telehealth services in any location.
  - Audio-only services.
  - Physical and occupational therapy, speech pathology, and audiology services.
  - FQHC and RHC services.
  - Mental health visits without need for in-person item or service.
  - Hospice recertifications via telehealth.
- Some services are set to expire **12/31/25**, e.g.,
  - Prescription of controlled substances

(See <https://www.cms.gov/medicare/coverage/telehealth> and <https://www.cms.gov/files/document/mln901705-telehealth-services.pdf>)

- **Check your telehealth services and billing for services.**
- **States and private payers may have other requirements.**

# Telehealth: Risk Areas

Beware—

- Laws governing provision of telehealth, e.g.,
  - Law of state in which provider is located.
  - Law of state in which patient is located.
- Licensure and scope of practice rules.
- Prescribing.
- Corporate practice of medicine.
- Billing.
- HIPAA and patient privacy.
- Malpractice insurance coverage.
- Others?



# Non-Discrimination Rules

They are still in effect...



# Anti-Discrimination Laws

## LAWS

- Civil Rights Act Title VI
- Americans with Disability Act
- Age Discrimination Act
- **Affordable Care Act § 1557**
  - **HHS issued new rules on 5/6/24.**  
(45 CFR part 92; 89 FR 37522 )
- **Rehabilitation Act § 504**
  - **HHS issued new rules on 5/9/24.**  
(45 CFR part 84; 89 FR 40066)
- State discrimination laws

## RISKS

- Persons with disabilities
- Persons with limited English proficiency
- Sex discrimination
- Physical access to facilities and equipment
- Websites and mobile apps
- Service animals
  - Dogs and mini-horses
  - Not emotional support animals

# Anti-Discrimination Laws

## DISABILITIES

- Must provide reasonable accommodation to ensure effective communication and accessibility.
  - **Accessibility**
  - **Auxiliary aids**
  - **Modifications to policies or processes**
- Includes person with patient.
- May not charge patient.
- May not rely on person accompanying patient.

## LIMITED ENGLISH

- Must provide meaningful access
  - **Interpreter**
  - **Translate key documents**
- Includes person with patient.
- May not charge patient.
- May not require patient to bring own interpreter.
- May not rely on person accompanying patient.

# New 1557 Rule

- Recipients of federal financial assistance (HHS money) may not discriminate on the basis of race, color, national origin, sex\*, age and disability.

(45 CFR part 92)

\* Federal court stayed rules re gender identity and sexual orientation.

(*Tennessee v. Bercerra*, No. 6:24-cv-211-JDK (E.D. Tex 2024))

Specific requirements re:

- Coordinator and grievance procedure
- Policies and procedures
- Training employees
- Notice of nondiscrimination
- Notice of availability of language assistance
- Persons with limited English proficiency
- Persons with disabilities
- Equal access on the basis of sex\*
- Facility accessibility
- Info and communication technology access
- Patient care decision support tools

# New Rehab Act Rule

- Recipients of federal financial assistance (HHS money) may not discriminate on the basis of disability.
- “Disability” construed very broadly.  
(45 CFR part 92)

Specific requirements re:

- Notice and signage requirements.
- Communication (e.g., auxiliary aids, interpreters)
- Facility accessibility
- Service animals
- **Medical treatment (e.g., devaluing worth of disabled persons)**
- **Mobility devices**
- **Medical diagnostic equipment**
- **Kiosks**
- **Web and mobile apps**

# New Rehab Act Rule

## By 7/8/24

- Cannot discriminate based on disability, i.e., must provide meaningful access to persons with disability, e.g., facility accessibility, interpreters, auxiliary aids, service animals, etc.
- Newly purchased or leased medical diagnostic equipment (MDE) must meet accessibility standards.
- At least 10% but no less than one (1) MDE must meet Standards for Accessible MDE.

## By 5/11/26

- If have 15+ employees, must ensure web content and mobile apps comply with Web Content Accessibility Guidelines (WCAG) unless fundamental alteration or undue burden.

## By 7/8/26

- At least one exam table and weight scale must meet Standards for Accessible MDE.

## By 5/10/27.

- All recipients must ensure web content and mobile apps comply with WCAG.

(45 CFR part 92)

# Discrimination Statutes: Olmstead Initiative



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[Home](#) > [Press Room](#) > HHS' Office for Civil Rights, Idaho Reach Agreement to Transition Teen from State Facility to Community



“Section 504 of the Rehabilitation Act (Section 504), Section 1557 of the Affordable Care Act, and Title II of the Americans with Disabilities Act ... require services to be provided in the most integrated setting appropriate to an individual’s needs [and avoid institutionalization], consistent with the Supreme Court’s decision in *Olmstead v. L.C.*”

**FOR IMMEDIATE RELEASE**  
**September 23, 2025**

**Contact: HHS Press Office**  
202-690-6343  
[Submit a Request for Comment](#)

## HHS’ Office for Civil Rights, Idaho Reach Agreement to Transition Teen from State Facility to Community

*Collaborative Plan Advances Idaho’s Olmstead Compliance by Ensuring Successful Community Placement for Teenager with Autism*

The U.S. Department of Health and Human Services, Office for Civil Rights (OCR) has reached a resolution agreement with the Idaho Department of Health and Welfare (IDHW) to resolve a civil rights complaint alleging unnecessary institutionalization of a teenager with autism and behavioral health needs. This is the seventh voluntary resolution in OCR’s Olmstead Initiative to support integration of persons with disabilities into community life. Through OCR’s Expedited Complaint Resolution process,

# Conscience Rights

## Conscience and Religious Freedom

[Conscience and Religious Freedom Protections](#)

[Filing a Complaint](#)

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[HHS](#) > [Conscience and Religious Freedom Home](#) > [Your Protections Against Discrimination Based on Conscience and Religion](#)

### Conscience and Religious Freedom —

#### Conscience and Religious Freedom Protections

[Filing a Complaint](#) +

[Newsroom](#)

[Office for Civil Rights Speaker Request](#)

## Your Protections Against Discrimination Based on Conscience and Religion

- Federal laws protecting conscience objections, e.g.,
- 45 CFR part 87 and 88
  - Affordable Care Act § 1553
  - Church Amendments (abortion and sterilization)
  - Coates-Snowe Amendment (abortion training)
  - Others

# Conscience Rights



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HHS Investigates State Health Department to Protect Conscience Rights and Ensure Equal Treatment of Faith-Based Org...



**FOR IMMEDIATE RELEASE**  
December 9, 2025

**Contact: HHS Press Office**

202-690-6343

[Submit a Request for Comment](#)

## HHS Investigates State Health Department to Protect Conscience Rights and Ensure Equal Treatment of Faith-Based Organizations

*HHS' Office for Civil Rights Examines Whether State Licensing Practices Comply with Federal Conscience and Equal Treatment Laws and Regulations*

Today, the U.S. Department of Health and Human Services, Office for Civil Rights (OCR) launched a major investigation into a State health department to assess whether its licensing policies, interpretations, or enforcement practices for behavioral health residential facilities and licensed behavioral health personnel violate Federal law by:

“This marks the fifth announced investigation during the second term of President Trump’s Administration examining compliance with Federal laws that safeguard conscience rights for health care professionals. Today’s announcement also demonstrates continued efforts across HHS to preserve the fundamental rights of conscience and religious exercise.”

# Conscience Rights



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[Home](#) > [Press Room](#) > HHS Reinforces Religious and Conscience Exemptions from Childhood Vaccine Mandates



Press Room

HHS Live

**FOR IMMEDIATE RELEASE**  
**September 4, 2025**

**Contact: HHS Press Office**

202-690-6343

[Submit a Request for Comment](#)

## HHS Reinforces Religious and Conscience Exemptions from Childhood Vaccine Mandates

The U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) today issued a letter notifying state awardees of the Vaccines for Children Program (VCP) that participating immunization programs and program-registered providers must respect state religious and conscience exemptions from vaccine mandates.

"Today's letter makes clear that providers must respect state laws protecting religious and conscience-based exemptions to vaccine mandates," **said HHS Secretary Robert F. Kennedy, Jr.** "States have the authority to balance public health goals with individual freedom, and honoring those decisions builds trust. Protecting both public health and personal liberty is how we restore faith in our institutions and Make America Healthy Again."

"[P]roviders must respect state laws protecting religious and conscience-based exemptions to vaccine mandates."

# Artificial Intelligence (AI)



# Artificial Intelligence in Healthcare

Rapidly developing area of the law; watch for federal and state regulation.

## Common uses in healthcare

- Imaging
- Clinical decision support tools
- Research
- Virtual assistant for transcription, administration, or practice management
- Others?

## Concerns

- Bias or discrimination
- “Garbage in, garbage out” → incorrect results
- Lack of transparency in algorithms, i.e., “black box” results
- Data privacy
- Others?

# AI in Healthcare

**Know and continue to monitor state law developments.**

- State laws, e.g.,
  - Consents for use of ambient or other AI.
  - Disclose use of AI in interactions.
  - Prohibit misleading consumers about involvement of providers, e.g., info suggesting human providers involved..
  - Limit use of AI in mental or behavior health care.
  - Authorize licensing boards to act on inappropriate use of AI.
  - Use of AI by payers in claims decisions.
  - Others.
- Standard of care, e.g.,
  - Consents and disclosures in use of ambient AI.
- Joint Commission, *Guidance on Responsible Use of AI in Healthcare* (9/17/25)

# AI in Healthcare

The screenshot shows the NPR News website header with navigation links for NEWS, CULTURE, MUSIC, PODCASTS & SHOWS, and SEARCH. The article is categorized under TECHNOLOGY and is titled "Class-action suit claims Otter AI secretly records private work conversations". It is dated August 15, 2025, at 8:44 PM ET and is written by Bobby Allyn. The article features a video player showing a meeting with three participants and an Otter AI logo.

npr CPR News

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NEWS CULTURE MUSIC PODCASTS & SHOWS SEARCH

TECHNOLOGY

## Class-action suit claims Otter AI secretly records private work conversations

AUGUST 15, 2025 · 8:44 PM ET

Bobby Allyn

Otter Meeting Agent

The video player shows a meeting with three participants: a woman in the top left, a man in the bottom left, and a woman in the bottom right. A blue circular logo with the text "Otter AI" is visible in the top right corner of the video frame.

- Alleges recording and use of private conversations to train AI without consent. (*Brewer v. Otter.ai*, (N.D. Cal. 2025))
- Beware use of PHI for purposes not permitted by HIPAA. (see, e.g., <https://www.hollandhart.com/us-e-of-phi-for-non-patient-purposes>)

# Hospital Price Transparency Rules



PRESIDENT DONALD J. TRUMP

The WHITE HOUSE



PRESIDENTIAL ACTIONS

## Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information

The White House | February 25, 2025

- Pres. Trump issued Executive Order 14221 (2/25/25)
- CMS has issued an RFI for improving transparency.

# Hospital Price Transparency

- Hospital must publish list of the hospital's "standard charges".
  - See regulations for specifics.
- Must be posted through hospital's website.
- Must update at least annually.

(45 CFR 180.70)

## Penalties

- Written warning, corrective action plan, fines
- Increased penalties
  - Small hospitals ( $\leq 30$  beds)
    - Maximum of \$300 per day
  - Large hospitals ( $> 30$  beds)
    - Minimum of \$10 per bed per day, and
    - Maximum of \$5,500 per day.
  - Range of \$109,500 to \$2,007,500 per year

(45 CFR 180.70-.90; CMS Fact Sheet,

<https://www.cms.gov/newsroom/press-releases/cms-oppasc-final-rule-increases-price-transparency-patient-safety-and-access-quality-care>)

# Employee v. Contractor



# Employee v. Contractor

## Some potential ramifications

- Federal and state wage claims.
- IRS tax liability
- Workers compensation
- Liability for person's misconduct
- Stark, Anti-Kickback and EKRA compliance
  - Rules differ for employee v. contractor
- HIPAA obligations
- Other?

## Ensure personnel are properly classified as employees v. contractors

- State common law standards
- DOL standards
- IRS standards
- HIPAA “common law of agency”
- Other?

# Employee v. Independent Contractor

## DEPT OF LABOR

- Effective **3/11/24**, new rules for evaluating employees v. contractors for purposes of FLSA. (29 CFR part 795; 89 FR 1638)

U.S. DEPARTMENT OF LABOR

Wage and Hour Division

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WHD > Wages and the Fair Labor Standards Act > Misclassification of Employees as Independent Contractors Under the Fair Labor Standards Act > Final Rule: Employee or Independent Contractor Classification Under the Fair Labor Standards Act, RIN 1235-AA43

### Final Rule: Employee or Independent Contractor Classification Under the Fair Labor Standards Act, RIN 1235-AA43

On January 10, 2024, the U.S. Department of Labor published a final rule, effective March 11, 2024, revising the Department's guidance on how to analyze who is an employee or independent contractor under the Fair Labor Standards Act (FLSA). This final rule rescinds the Independent Contractor Status Under the Fair Labor Standards Act

## IRS

- Existing rules for evaluating employees v. contractors for purposes of taxes.

(<https://www.irs.gov/businesses/small-businesses-self-employed/independent-contractor-self-employed-or-employee>)

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### Independent contractor (self-employed) or employee?

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**Individuals**

It is critical that business owners correctly determine whether the individuals providing services are employees or independent contractors.

**Businesses and self-employed**

Generally, you must withhold and deposit income taxes, social security taxes and

**Related**

- [Businesses with employees](#)

# Are You An Employee Or An Independent Contractor?



## Indicators of an Employee

Working for someone else's business

Generally, can only earn more by working additional hours

Typically uses the employer's materials, tools and equipment

Typically works for one employer or may be prohibited from working for others

Continuing or indefinite relationship with the employer

Employer decides how and when the work will be performed

Employer assigns the work to be performed

-OR-

## Indicators of an Independent Contractor

In business for themself

Can increase profit through business decisions

Typically provides their own materials, tools and equipment and uses them to extend market reach

Often works with multiple clients

Temporary relationship until project completed

Decides how and when they will perform the work

Decides what work or projects they will take on



*These are general concepts. All relevant facts about the work relationship should be considered as a whole, and the existence or absence of any particular fact does not require a particular outcome.*

# Non-Competition Clauses



# Noncompetition Clauses

- ~~FTC rule: effective 9/4/24~~
  - ~~It is unfair method of competition to enter or enforce a post-termination non-compete against workers or senior executives.~~
    - ~~Subject to limitations.~~
  - ~~Employer must provide notice to workers otherwise covered by non-compete that it will not be enforced.~~

~~(16 CFR 910)~~

- **On 8/20/24, federal court in Texas struck down the rule and enjoined the FTC from enforcing it.** (*Ryan LLC v. FTC*, CV 3:24-CV-00986E (N.D. Tex. 2024))

# FTC Warning Letter



FEDERAL TRADE COMMISSION  
PROTECTING AMERICA'S CONSUMERS

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For Release

## FTC Chairman Ferguson Issues Noncompete Warning Letters to Healthcare Employers and Staffing Companies

September 10, 2025 | [f](#) [X](#) [in](#)

Tags: [Competition](#) | [Bureau of Competition](#) | [Nonmerger](#) | [Health Care](#) | [Noncompete](#)

[Warning Letters](#)

“The FTC is focusing resources on enforcing Section 5 of the FTC Act against unlawful noncompetes, particularly in the healthcare sector. Accordingly, I encourage you to conduct a comprehensive review of your employment agreements—including any noncompetes or other restrictive covenants—to ensure that they comply with applicable laws and are appropriately tailored to the circumstances. If your company is currently using noncompetes that are unfair or anticompetitive under the FTC Act, I strongly encourage you to discontinue them immediately and to notify relevant employees of the discontinuance.”

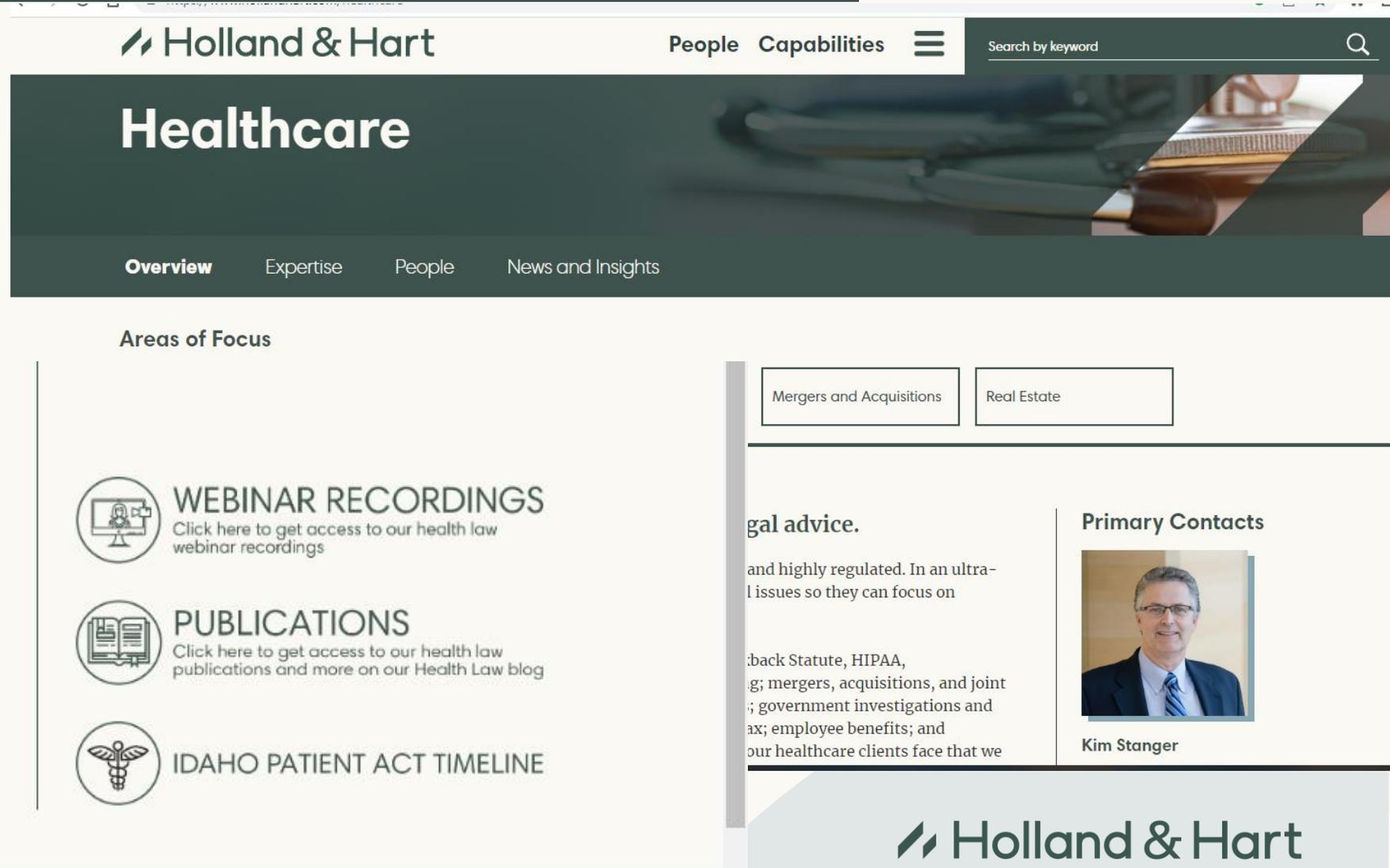
# Additional Resources



# HTTPS://WWW.HOLLAND HART.COM/HEALTHCARE

## Free content:

- Recorded webinars
- Client alerts
- White papers
- Other



The screenshot shows the Holland & Hart website's Healthcare section. The header includes the firm's logo, navigation links for 'People' and 'Capabilities', and a search bar. The main heading is 'Healthcare'. Below this are navigation tabs for 'Overview', 'Expertise', 'People', and 'News and Insights'. The 'Areas of Focus' section features three icons: a monitor for 'WEBINAR RECORDINGS', an open book for 'PUBLICATIONS', and a caduceus for 'IDAHO PATIENT ACT TIMELINE'. On the right, there are buttons for 'Mergers and Acquisitions' and 'Real Estate'. A 'Primary Contacts' section includes a photo of Kim Stanger and a list of services such as 'legal advice', 'and highly regulated. In an ultra-issues so they can focus on', 'back Statute, HIPAA,', 'g; mergers, acquisitions, and joint', 'government investigations and', 'ax; employee benefits; and', and 'our healthcare clients face that we'. The footer features the Holland & Hart logo.

Holland & Hart

People Capabilities

Search by keyword

## Healthcare

Overview Expertise People News and Insights

### Areas of Focus

Mergers and Acquisitions Real Estate

 **WEBINAR RECORDINGS**  
Click here to get access to our health law webinar recordings

 **PUBLICATIONS**  
Click here to get access to our health law publications and more on our Health Law blog

 **IDAHO PATIENT ACT TIMELINE**

legal advice.

and highly regulated. In an ultra-issues so they can focus on

back Statute, HIPAA,  
g; mergers, acquisitions, and joint  
; government investigations and  
ax; employee benefits; and  
our healthcare clients face that we

### Primary Contacts



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Holland & Hart

# Questions?



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