

LEGAL UPDATE



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Southwest Idaho AHEC
(12.24)



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Overview



- Idaho Minor Consent Law
- Fraud and Abuse Issues
- HIPAA and Data Privacy
 - Reproductive Rights Rule
 - Online Tracking Guidance
 - Substance Use Disorder Rule
- Data Security
- Info Blocking Rule Penalties
- TCPA
- Artificial Intelligence (AI)
- Telehealth
- Anti-Discrimination Rules
 - 1557
 - Rehab Act
- Employment issues
 - Contractor v. employee
 - Noncompetes
- IPACT and Idaho liens



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Who knows what's in store under new administration?



CAUTION

EVERYTHING I AM GOING TO TALK ABOUT MAY CHANGE AT ANYTIME

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Who knows how the Supreme Court and other federal decisions may affect health law?



- In *Loper*, the Supreme Court rejected prior precedent giving deference to government agency interpretation.
 - Limits subregulatory guidance.
 - Leaves agency rules subject to attack.
- The Supreme Court has been willing to vary from precedent, e.g., reproductive rights.
- Federal courts have limited various regulations.

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IDAHO PATIENT ACT TIMELINE

Mergers and Acquisitions

Real Estate

gal advice.

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

Back Statute, HIPAA,
ig: mergers, regulations, and joint
government investigations and
no employee benefits, and
our healthcare clients face that we

Primary Contacts



Kim Stranger

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Minor Consent Law



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Parent's Rights in Medical Decision-Making Act

Effective July 1, 2024:

- Must obtain parental consent to treat unemancipated minor with limited exceptions.
- Must allow parents to access unemancipated minor's records with limited exceptions.
- Parents may sue provider for violations and recover damages, costs and attorneys' fees.

(IC 32-1015)

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Parental Consent Law (effective 7/1/24)

- "An individual shall not furnish a health care service ... to a minor child without obtaining the prior consent of the minor child's parent."
 - "Health care service" = service for the diagnosis, screening, examination, prevention, treatment, cure, care, or relief of any physical or mental health condition, injury, illness, defect, disease.
 - "Minor child" = unemancipated person < 18.
 - "Parent" = biological or adoptive parent or an individual who has been granted exclusive right and authority over the welfare of a child under state law.
- Violation: parent may sue for damages, costs and fees.

(IC 32-1015)

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Parental Consent Law: Effect on Prior State Laws?

PRIOR STATE LAWS

Minors may consent to own care:

- Sufficiently mature: contraceptives
- Family planning under Title X programs
- Age 14: communicable diseases
- Age 14: admission to mental health facility
- Age 16: treatment or rehab by physician for drug abuse



PARENTAL CONSENT LAW

Must have parent consent to treat unemancipated minor with limited exceptions.

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Parental Consent Law: Effect on Prior State Laws?

- IC 32-1015: "This section shall be construed in favor of a broad protection of parents' fundamental right to make decisions concerning the furnishing of health care services to minor children." (IC 32-1015(7))
- SB1329 Statement of Purpose: "[C]onsent for the furnishing of health care services to any person who is an unemancipated minor must be given or refused by the parent of such person.... [T]he Act is intended to supersede any current provisions of Idaho law that may otherwise conflict with the Act." (<https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2024/legislation/S1329SOP.pdf>)
- Idaho courts often look to Statement of Purpose to determine legislative intent. (*Farmers Nat'l Bank v. Green River Dairy, LLC*, 155 Idaho 853, 860 at n.4 (2014))
- General principle: if there is conflict, later law preempts earlier conflicting law v. specific law preempts conflicting general law.
- ✓ **Conservative approach: assume parental consent is needed unless exception applies or we receive further authoritative guidance.**

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Parental Consent Law: Exceptions

- Minor is emancipated,
- “[A]s otherwise provided by court order.”
(IC 32-1015(3))
- “[A] health care provider may authorize or furnish a health care service without obtaining the informed consent of the minor child’s parent, if:
 - (a) A parent of the minor child has given blanket consent authorizing the health care provider to furnish the health care service; or
 - (b) The health care provider reasonably determines that a medical emergency exists and:
 - (i) Furnishing the health care service is necessary in order to prevent death or imminent, irreparable physical injury to the minor child; or
 - (ii) After a reasonably diligent effort, the health care provider cannot locate or contact a parent of the minor child and the minor child’s life or health would be seriously endangered by further delay in the furnishing of health care services.”
(IC 32-1015(4))

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Parental Consent Law: Exceptions

If federal law authorizes minors to consent and preempts Idaho law, e.g.,

- EMTALA?
 - “A minor (child) can request an exam or treatment for an [emergency medical condition]. Hospital personnel should not delay the MSE by waiting for parental consent. If after screening the minor, it is determined that no EMC is present, the staff can wait for parental consent before proceeding with further examination and treatment.” (CMS SOM App. V, EMTALA Interpretive Guidelines).
- Title X programs?
 - “Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.” (42 CFR 59.10(b)).
 - *But see Deandra v. Becerra*, No. 23-10159 (5th Cir. 2024) (holding that Title X regs do not preempt Texas parental consent laws).
- Other?

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Parent’s Right to Access Minor’s Records



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Confidentiality of Minor Records (before 7/1/24)

HIPAA

- If minor may consent to their own healthcare under state law, then...
 - Parent is not “personal representative.”
 - Parent has no right to access info.
 - Generally need minor’s consent or authorization to disclose.
 - May deny access to avert serious threat of harm.
(45 CFR 164.502(g))

OTHER LAWS

- If minor aged 16+ seeks drug treatment or rehab, may not disclose to parent without minor’s consent. (IC 37-3102)
- If minor seeks care for substance use disorder, may not disclose the request for care to parents. (42 CFR 2.14(b)(2))
- If minor seeks family planning services under Title X, may not disclose to parents. (42 CFR 59.10(b))
- Others?

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Parental Consent Law (effective 7/1/24)

- “No health care provider or governmental entity shall deny a minor child’s parent access to health information that is ... in such health care provider’s ... control.”
 - “Health info” = info or data, collected or recorded in any form or medium, and personal facts about events or relationships that relates to:
 - (i) Past, present, or future physical, mental, or behavioral health or condition of individual or member of individual’s family;
 - (ii) Provision of health care services to an individual; or
 - (iii) Payment for the provision of health care services to an individual.
- Violation: parent may sue for damages, costs and fees.
(IC 32-1015)

✓ Likely applies to records created or info relating to treatment before 7/1/24.



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Parent’s Access to Minor’s Records: Exceptions

May deny parent access if:

- “Minor is emancipated.
(See IC 32-1015(5))
- “Parent’s access to the requested health info is prohibited by a court order”; or
- “The parent is a subject of an investigation related to a crime committed against the child, and a law enforcement officer requests that the information not be released to the parent.”
(IC 32-1015(6))



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Parent’s Access to Minor’s Records: Exceptions

- HIPAA
 - “Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal rep ... if:
 - (i) The covered entity has a reasonable belief that:
 - (A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or
 - (B) Treating such person as the personal rep could endanger the individual; and
 - (ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual’s personal rep.”
(45 CFR 164.502(g))



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Parent’s Access to Minor’s Records: Exceptions

- Substance use disorder programs?
 - “Where state law requires parental consent to treatment, the fact of a minor’s application for treatment may be communicated to the minor’s parent, guardian, or other person authorized under state law to act on the minor’s behalf only if: (i) The minor has given written consent to the disclosure ...; or (ii) The minor lacks the capacity to make a rational choice regarding such consent ...” (42 CFR 2.14(b)(2))
- Title X programs?
 - “Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.” (42 CFR 59.10(b)).
 - But see *Deandra v. Becerra*, No. 23-10159 (5th Cir. 2024) (holding that Title X regs do not preempt Texas parental consent laws).
- Others?



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Fraud and Abuse



- False Claims Act (FCA)
 - Includes repayment obligation
 - **Maybe qui tam litigation.**
- Anti-Kickback Statute (AKS)
- Eliminating Kickbacks in Recovery Act (EKRA)
- Civil Monetary Penalties Law (CMPL)
 - Inducements to program beneficiaries
 - Excluded Entities
- Idaho Fraud and Abuse Laws

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CMS Report and Repay Rule

- A person who has received an overpayment must report and return the overpayment by the later of:
 - The date which is 60 days after the date on which the overpayment was identified; or
 - The date any corresponding cost report is due, if applicable.
- **60-day reporting period suspended for up to 180 days during timely, good faith investigation.**

(42 CFR 401.305(1))

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HIPAA and Patient Privacy



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Recent HIPAA Resolutions

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

Top HIPAA Risks

1. Cyberattacks
2. Security rule violations
3. Right of access violations



Date	Conduct	
10/31/24	Ambulance services hit with ransomware attack.	
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
2/6/24	Montefiore Medical Center failed to protect against malicious insider selling info.	\$4,750,000
11/20/23	St. Joseph's Medical Center disclosed PHI to news reporter.	\$80,000
10/31/23	Doctor's Management Services hit by ransomware affecting 206,695 persons.	\$100,000
9/11/23	L.A. Care Plan failed to secure patient portal, perform risk analysis, and mailed ID cards to wrong patients. Affected 2500+ persons.	\$1,300,000
8/24/23	UnitedHealthcare failed to timely provide copy of records.	\$80,000

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HIPAA Reproductive Rights Rule



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HIPAA Reproductive Rights Rule

- Must comply by **12/23/24**.
- Applies to PHI re “reproductive health care”, i.e., “healthcare that that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.”
(45 CFR 160.103)
- **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)

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Reproductive Rights Rule: Required Attestation

Valid attestation =

- Description of info requested, including name of patient whose info was sought or description of class of such persons.
- Name or description of class of persons requested to make the disclosure.
- Statement that the use or disclosure is not for purpose prohibited by the rule, i.e., criminal, civil or administrative liability.
- Statement that person may be criminally liable under 42 USC 1320d-6 for improperly obtaining or disclosing info in violation of HIPAA.
- Signature of person requesting disclosure.
- Does not contain additional elements.
- Generally, cannot be combined with other documents.

(45 CFR 164.509(b)-(c))

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Reproductive Rights Rule: OCR Model Attestation

Model Attestation for a Requested Use or Disclosure of Protected Health Information (PHI)
Health Information Potentially Related to Reproductive Health Care

When a HIPAA covered entity or business associate receives a request for protected health information (PHI) potentially related to reproductive health care, it must obtain a signed attestation that clearly states the requested use or disclosure is not for the prohibited purposes described below, where the request is for PHI for any of the following purposes:

- Health oversight activities⁽¹⁾
- Judicial or administrative proceedings⁽²⁾
- Law enforcement⁽³⁾
- Research, development, disclosures to consumers and medical examinations⁽⁴⁾

Prohibited Purposes. Covered entities and their business associates may not use or disclose PHI for the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.

(3) To identify any person for any purpose described in (1) or (2).

The prohibition applies when the reproductive health care at issue (1) is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided, (2) is protected, required, or authorized by federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided, or (3) is provided by another person and presumed lawful.⁽⁵⁾

Model Instructions

Information for the Person Requesting the PHI

- By signing this attestation, you are verifying that you are not requesting PHI for a prohibited purpose and acknowledging that criminal penalties may apply if untrue.⁽⁶⁾
- You may not add content that is not required or combine this form with another document except where another document is needed to support your statement that the requested disclosure is not for a prohibited purpose.⁽⁷⁾ For example, if the requested PHI is potentially related to reproductive health care that was provided by someone other than the covered entity or business associate from whom you are requesting the PHI, you may submit a document that supplies information that demonstrates a

- Available at
<https://www.hhs.gov/sites/default/files/model-attestation.pdf>.

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Reproductive Rights Rule: Texas Lawsuit

Stay tuned...

Case 5:24-cv-00204-H Document 1 Filed 09/04/24 Page 1 of 16 PageID 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS,
Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
XAVIER BECERRA, in his official capacity
as Secretary of the United States
Department of Health and Human Services;
MELANIE FONTES RAINER, in her
official capacity as Director of the
Department of Health and Human Services
Office for Civil Rights,
Defendants.

CIVIL ACTION No. _____

TEXAS'S ORIGINAL COMPLAINT

1. Texas brings this action seeking declaratory and injunctive relief against enforcement of two final rules issued by the United States Department of Health and Human Services.

2. The first is entitled "Standards for Privacy of Individually Identifiable Health Information."

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HIPAA and Administrative Requests



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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.

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HIPAA and Online Tracking Technologies



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HIPAA and Online Tracking

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

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?

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.

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HIPAA and Online Tracking

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

“On June 20, 2024, [a district court] issued an order declaring unlawful and vacating ... the guidance to the extent it provides that HIPAA obligations are triggered in ‘circumstances where an online technology connects (1) an individual’s IP address with (2) a visit to a[n] [unauthenticated public webpage] addressing specific health conditions or healthcare providers.’”
See *Am. Hosp. Ass’n v. Becerra*, 2024 WL 3075865 (N.D. Tex. June 20, 2024).

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Online Tracking Lawsuits

NC Health System Agrees to Pay \$6.6M in Web Tracking Case

Novant Health Is Among Latest Organizations Opting to Settle Patient Privacy Claims

Marianne Kolbasuk McGee • HealthInfoSec • January 16, 2024

Possible Theories

- Negligence per se based on violation of statute
- Unfair or deceptive trade practices acts
- Federal and state wire-tapping laws
- Negligent misrepresentation
- Invasion of privacy
- Breach of contract
- Others?

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HIPAA Proposed Privacy Rule Changes

COMING SOON

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))

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42 CFR Part 2 Rules



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Substance Use Disorder Records

New rule:

- Issued 2/8/24.
- Effective 4/16/24.
- **Enforced 2/16/26.**
(89 FR 12472)

Applies to:

- Federally assisted SUD programs.
- Recipients of SUD records from such a program.

Aligns 42 CFR part 2 with HIPAA.

- HIPAA enforcement applies to Part 2 violations.
- Allows single consent for uses or disclosures for treatment, payment or healthcare operations.
- HIPAA-covered entities and business associates receiving SUD info under consent may use or disclose consistent with HIPAA.
- Must provide HIPAA-like notice of privacy practices (NPP) and update HIPAA NPP.

(42 CFR part 2)

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HIPAA and SUD Rules: Notice of Privacy Practices



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HIPAA and SUD Rules: Notice of Privacy Practices

- Reproductive Rights Rule: modified NPP requirements to accommodate SUD Rule changes.
- 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 regulations when drafting updated NPP.**
- ✓ **Watch for new NPP requirements when final HIPAA revisions are published.**
- ✓ **OCR plans to publish model NPP.**

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Data Security



Data Protection

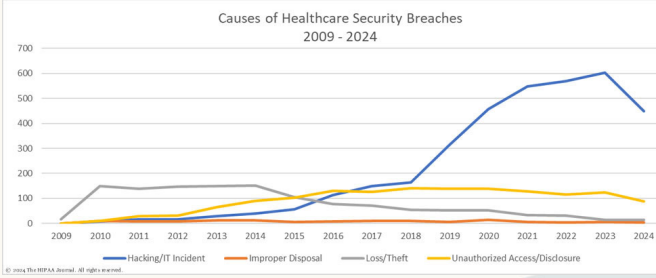


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Cybersecurity

According to HHS:

- 2018-22: 93% increase in large breaches
- 2018-22: 278% increase in large breaches from ransomware.
- 2023: 77% of large breaches resulted from hacking.
- 2023: Persons affected by large breaches increased 60% to 80,000,000.



Source: The HIPAA Journal
<https://www.hipaajournal.com/healthcare-data-breach-statistics/>



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Change Cyberbreach

<https://www.hhs.gov/hipaa/for-professionals/special-topics/change-healthcare-cybersecurity-incident-frequently-asked-questions/index.html>

Change Healthcare Cybersecurity Incident Frequently Asked Questions

Updated as of October 24, 2024

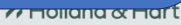
1. Why did OCR issue the Dear Colleague letter about the Change Healthcare cybersecurity incident?

A: Given the unprecedented magnitude of this cyberattack, its widespread impact on patients and health care providers nationwide, and in the interest of patients and health care providers, OCR issued the [Dear Colleague letter](#) addressing the following:

- OCR confirmed that it prioritized and opened investigations of Change Healthcare and UnitedHealth Group focused on whether a breach of protected health information (PHI) occurred and on the entities' compliance with the [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\) Rules](#). OCR did this because of the cyber incident's unprecedented impact on patient care and privacy.
- OCR's investigation interests in other entities that partnered with Change Healthcare and UHG is secondary. OCR would include those [covered entities](#) that have [business associate](#) relationships with Change Healthcare and UHG, and those organizations that are business associates to Change Healthcare and UHG.

FAQs address items such as:


- Covered entities' obligation to report the breach.
- Delegating breach reporting to its business associate (e.g., Change).
- Resolving breach notification with Change.



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HHS Strategy Paper

<https://aspr.hhs.gov/cyber/Documents/Health-Care-Sector-Cybersecurity-Dec2023-508.pdf>



On 12/6/23, HHS published strategy for strengthening cybersecurity for healthcare industry.

1. Establish voluntary cybersecurity performance goals.
2. Provide resources to incentivize and implement cybersecurity practices.
3. **Greater enforcement and accountability.**
 - Cybersecurity requirements for hospitals through Medicare/Medicaid.
 - Update HIPAA Security Rule to include new cybersecurity rule requirements.
 - Increase civil penalties.
 - Increase resources for audits and investigation.
4. HHS to provide one-stop shop for healthcare cybersecurity resources.



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Recent HIPAA Resolutions https://www.hhs.gov/hipaa/newsroom/index.html		
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10/31/23	Doctor's Management Services hit by ransomware affecting 206,695 persons.	\$100,000
9/11/23	L.A. Care Plan failed to secure patient portal and mailed ID cards to wrong patients.	\$1,300,000
8/24/23	UnitedHealthcare failed to timely provide copy of records.	\$80,000
6/28/23	iHealth Solutions' PHI of 267 persons was exfiltrated by unauthorized persons.	\$75,000

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HPH Cybersecurity Gateway

<https://hphcyber.hhs.gov/>

Welcome to Health & Human Services

HPH Cybersecurity Gateway

Connecting the Healthcare and Public Health (HPH) Sector with specialized healthcare specific cybersecurity information & resources from across the U.S. Department of Health and Human Services and other federal agencies.

A NOTE TO HHS

HPH Cybersecurity Performance Goals

Questions? Contact Us!

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Proposed Legislation: HISAA

Health Infrastructure Security and Accountability Act

HISAA: New Federal Law Introduced That Would Create Significant New Cybersecurity Requirements for HIPAA Covered Entities and Business Associates

by: Allen R. Killworth of Epstein Becker & Green, P.C. - Health Law Advisor

HISAA would provide:

- Mandatory minimum cybersecurity standards for healthcare providers.
- Annual independent cybersecurity audits.
- HHS security audits.
- Top executives certify compliance annually.
- Eliminate statutory caps on HHS fines.
- Funded by user fees.

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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>)

- Facebook, Inc., In the Matter of (November 7, 2024)
- Marriott International, Inc. and Starwood Hotels & Resorts Worldwide, LLC, In the Matter of (October 9, 2024)
- Verkada Inc., U.S. v. (August 30, 2024)
- FTC v Kochava, Inc. (July 15, 2024)
- NGL (July 9, 2024)
- Avast (June 26, 2024)
- Monument, Inc., U.S. v. (June 7, 2024)
- Cerebral, Inc. and Kyle Robertson, U.S. v. (May 31, 2024)
- Blackbaud, Inc. (May 20, 2024)
- BetterHelp, Inc., In the Matter of (May 6, 2024)
- Aqua Finance (May 1, 2024)
- InMarket Media, LLC (May 1, 2024)
- Ring, LLC (April 23, 2024)
- X-Mode Social, Inc. (April 11, 2024)
- Rite Aid Corporation, FTC v. (March 8, 2024)
- Global Tel Link Corporation (February 23, 2024)
- Epic Games, In the Matter of (January 10, 2024)
- CafePress, In the Matter of (January 10, 2024)
- TransUnion Rental Screening Solutions, Inc. and Trans Union, LLC., FTC and CFPB v. (October 20, 2023)
- TruthFinder, LLC, FTC v. (October 11, 2023)

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Information Blocking Rule



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

(45 CFR 171.101)

(45 CFR 171.103)

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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

- Final rule issued 6/24/24:
 - **Hospitals: loss of status as meaningful user of EHR**
 - **Providers: loss of status as meaningful user under MIPS**
 - **ACOs: ineligible to participate.**
- **Loss of federal payments.**

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Telephone Consumer Protection Act (TCPA)



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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)

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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>)

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Telephone Consumer Protection Act (TCPA)

Effective 4/11/25:

- Consumers may revoke consent to robocalls and robotexts “in any reasonable manner” — including use of the words: 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)

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Artificial Intelligence (AI)



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Artificial Intelligence in Healthcare

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

Common uses in healthcare

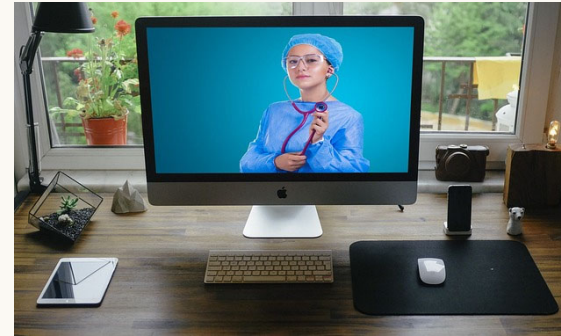
- Imaging
- Clinical decision support tools
- Research
- Virtual assistant for transcription, administration, or practice management
- Others?

Concerns

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

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Telehealth



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Telehealth



- Many of the **Medicare** COVID-19 waivers are currently due to **expire 12/31/24**
 - Covered telehealth services.
 - Originating site requirements.
 - Eligible distant site telehealth providers.
 - Coverage of audio-only services.
 - In-person visit requirements.
 - Prescription of controlled substances*
 - Others?

Check your telehealth services to ensure that you comply.

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

- **States and private payers may have other requirements.**

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Non-Discrimination Rules



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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.**
 - **Effective 7/5/24.**
- **Rehabilitation Act § 504**
 - **HHS issued new rules on 5/9/24.**
 - **Effective 7/8/24.**
- State discrimination laws

Apply if receive federal money, e.g., participate in Medicare/Medicaid

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

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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.

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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)
- 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 accessibility**
 - **Patient care decision support tools**

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New 1557 Rule: Legal Challenges

- In *Tennessee v. Becerra*, No. 1:24-cv-161-LG-BWR (S.D. Miss.), the court stayed nationwide the specific 1557 regulations to the extent they “extend discrimination on the basis of sex to include discrimination on the basis of gender identity”... and enjoined HHS from enforcing the 2024 Final Rule “to the extent that the final rule provides that ‘sex’ discrimination encompasses gender identity.”
- In *Texas v. Becerra*, No. 6:24-cv-211-JDK (E.D. Tex.), the court stayed nationwide the 1557 regulations that would otherwise obligate providers to follow those rules related to gender identity and sexual orientation. (<https://www.hhs.gov/civil-rights/for-providers/resources-covered-entities/index.html>)

- *And remember that first Trump administration eviscerated prior 1557 Rules...*



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New 1557 Rule

By 7/5/24

- Provide meaningful access, e.g., interpreters and translators; auxiliary aids, facility accessibility, information technology, telehealth.
- Provide equal access on basis of sex (subject to litigation).

By 11/2/24

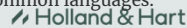
- If have 15+ employees, designate 1557 Coordinator.
- Publish Notice of Nondiscrimination on website, in physical location, and upon request.

By 5/1/25

- Don't discriminate in decision support tools (e.g., AI).
- Train employees re 1557 policies and procedures and document training.

By 7/5/25

- Implement written 1557 policies and procedures.
- Publish Notice of Availability of Services in English + at least 15 most common languages. (45 CFR part 92)



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1557 Rule Resources

<https://www.hhs.gov/civil-rights/for-providers/resources-covered-entities/index.html>

Civil Rights

[Information for Individuals](#)
[Filing a Complaint](#)
[Information for Providers](#)

[HHS](#) > [Civil Rights Home](#) > [For Providers](#) > Resources for Covered Entities

Civil Rights for Providers of Health Care and Human Services

[Provider Obligations](#)
[Civil Rights Clearance for Medicare Provider Applicants](#)
[Compliance & Enforcement](#)
[Training](#)

Resources for Covered Entities

Pursuant to decisions by various district courts regarding the 2024 Final Rule implementing Section 1557, entitled Nondiscrimination in Health

- Sample policies and procedures
 - *Effective communication*
 - *Grievance*
 - *Language access*
 - *Nondiscrimination policy*
 - *Reasonable modification*
- Sample notices
 - *Availability of language assistance and auxiliary aids*
 - *Notice of nondiscrimination*

[Feedback](#)

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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**



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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)



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Anti-Discrimination Laws: Recent OCR Enforcement

Date	Alleged Conduct	Resolution
10/10/24	Maryland failed to accommodate persons with disability in programs	Policy and training
9/12/24	Psych hospital failed to provide sign language interpreter.	Policy and training
8/5/24	Imaging network denied mammography patient who used wheelchair.	Policy and training
6/21/24	Puerto Rico agency failed to provide sign language interpreters.	Policy and training
6/4/24	ENT practice failed to provide aids to persons with hearing challenges.	Policy and training
11/13/23	SNF allegedly denied admission to individuals because they were taking Suboxone or methodone to treat opioid use disorder.	Policy and training
8/30/23	Home Health agency denied home health care services based on HIV status	Policy and training
8/8/23	Pa DHS denied application as foster parent because she receives SUD medication	Policy and training
6/16/23	CVS and Walgreens failed to fill prescriptions for methotrexate and misoprostol unrelated to abortion	Policy and training
5/15/23	MCR Health failed to provide auxiliary aid to deaf wife who accompanied patient.	Policy and training
3/23/23	Dearborn OBGYN refused request for sign language interpreter, cancelled appointment and terminated her as patient	Policies, training \$7,500 in damages

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Compliance Programs



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OIG General Compliance Program Guidance

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

Watch for industry-specific 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

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Employment Issues



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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

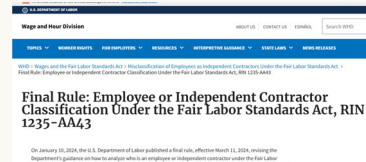
- State common law standards
- DOL standards
- IRS standards
- HIPAA "common law of agency"
- Other?

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Employee v. Independent Contractor

DEPT OF LABOR

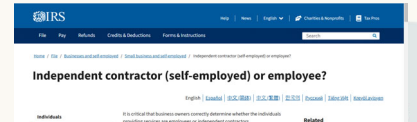
- Effective **3/11/24**, new rules for evaluating employees v. contractors for purposes of FLSA. (29 CFR part 795; 89 FR 1638)



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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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.

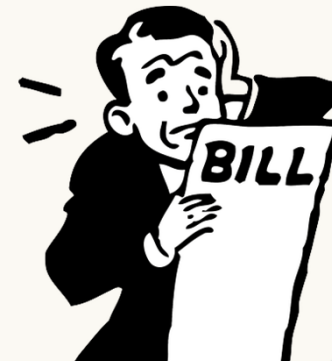
(16 CFR 910)

- On 7/23/24, federal court in Pennsylvania upheld the FTC rule. (*ATS Tree Services, LLC v. FTC*, No. 24-1743 (E.D. Pa. 2024))
- 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))

✓ Stay tuned....

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Idaho Patient Act and Liens



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Idaho Patient Act v. Liens (before 3/28/24)

IDAHO MEDICAL LIEN LAW	IDAHO PATIENT ACT
<ul style="list-style-type: none"> Allows healthcare provider to file a lien against recovery by tortfeasor. To perfect lien, must file within 90 days of discharge or last date of service or discharge. (IC 45-701 et seq.) 	<ul style="list-style-type: none"> Cannot engage in extraordinary collection actions (including filing a lien) until 60 days after: <ul style="list-style-type: none"> Submitting claims to payers. Providing consolidated statement of services. Providing final notice.

v.

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Idaho Patient Act v. Liens (effective 3/28/24)

IDAHO LIEN LAW	IDAHO PATIENT ACT
<ul style="list-style-type: none"> If patient has no third-party payor: file lien w/in 90 days of discharge or last service. If patient has third party-payor: file lien within 30 days after the payor pays. (IC 45-702) 	<ul style="list-style-type: none"> IPACT does not prohibit provider from filing a lien within the timelines permitted by IC 45-701 et seq. (IC 48-303)

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Additional Resources

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HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE

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Questions?



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