2024 Healthcare Year In Review

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Today's Program Agenda

- Debrief of 2024 Connecticut legislative session (healthcare related)
- NEW!! Medical Diagnostic Equipment – significant new provider obligations under state and federal law
- HIPAA recent enforcement activity
- **HIPAA Hot Topic**: Update on reproductive healthcare and gender affirming healthcare rights and obligations
- Emerging and Developing Healthcare technologies
- Preview SUD Records Privacy changes to 42 CFR Part 2; compliance deadline February 2026

2024 New Laws and Trends

Significant Legal Changes Affecting Healthcare in Connecticut

(the following is NOT an exhaustive list)

2024 Legislation Affecting Healthcare

- Mandatory Paid Sick Leave expanded (to reach almost all employers by 2027)
- Lower maximum civil penalty that DPH may impose against an individual healthcare provider, now $10,000 (was $25,000)
- Adds the American Medical Certification Association (AMCA) to the list of organizations from which a clinical medical assistant may be certified for purposes of qualifying to administer vaccines in non-hospital settings

2024 Legislation Affecting Healthcare

- Expansion of podiatrist scope of practice to independently perform Chopart joint-level (i.e., forefoot and midfoot) amputations after meeting criteria
- DPH must create a proposed “universal intake form” eventually to be used by providers treating pediatric behavioral health patients
- Protections for physicians who do not maintain Board Certification

2024 Legislation Affecting Healthcare

- Elaborate requirements to disclose home care patient's background (screening for violence) to protect workforce; training for staff
- Expansion of pharmacists' role in routine vaccinations (allowing them to order in certain cases)
- DPH will create a new data registry for Parkinson's Disease reporting and tracking (like the current tumor registry)
- DPH required to study whether naturopaths should be allowed to prescribe

2024 Legislation Affecting Healthcare

- Various studies and groups required to assess and report on how to alleviate ED Crowding
- 2025-2028 Hospitals must perform toxicology screens on non-fatal opioid overdose patients (with patient consent) and report types of drugs to DPH
- Hospitals have new cybersecurity planning responsibilities
- Clarifies patient rights under Connecticut law for service animals

2024 Legislation Affecting Healthcare

- Telehealth flexibilities reworked
- DSS must provide medically necessary Medicaid coverage for rapid whole genome sequencing for critically ill infants ages 0 to 12 months treated in a neonatal intensive care or pediatric intensive care unit
- DSS must study its own Medicaid eligibility processes including phone wait times and efficiencies
- DSS required to bolster home care and skilled nursing access

2024 Legislation Affecting Healthcare

- Health insurance policies must cover coronary calcium scans
- Interstate nurse compact, and social workers compact, take steps toward finalization (essentially increasing ease of reciprocal licensure)
- Various mandatory studies to combat drug shortages
- Significant updates to provider relationship with the state-wide HIE (Connie)

Connecticut Official HIE

- State-wide HIE (Connie) continues to evolve
- State law extended the provider sign up deadline
- Provider agreements are being reworked by OHS and Connie
- Before community providers are required to join Connie, the State will clarify through policies and procedures:
  - What data needs to be sent
  - What agreements have to be signed
  - What privacy rules apply
- Unclear what patient access rules will be
- Unclear which providers will be allowed to access or how

New Access To Care Rules Specific to Persons With Disabilities

New Connecticut law that affects providers immediately specific to Medical Diagnostic Equipment

Updated federal regulations that affect providers, with longer roll out

Who Must Comply With MDE law

- New Connecticut law expands providers' obligations under Section 19a-490dd of the general statutes (the MDE access law)
- The Act is designed to make healthcare more accessible to persons with disabilities and applies to the following types of providers:
  - (1) hospitals, outpatient clinics, long term care facilities, and hospice (designated as "Health care facilities" under the Act) and
  - (2) Office practices with **eight or more physicians or APRNs, alone or in combination** (designated as "Practice Locations" under the Act)

What Is Covered In The Law

- **Not about DME** (they just sound the same)
- MDE is a defined subgroup of equipment that need special attention for access planning. The equipment included in the law are:
  - Examination tables
  - Examination chairs
  - Weight scales
  - Mammography equipment, x-ray, imaging, and other radiological diagnostic equipment
- Appropriate equipment in these categories must meet federal “Access Board” technical standards

By January 1, 2025, affected providers must…

- Train all staff with direct patient care responsibilities regarding the provider's policies and procedures for addressing patients' access to care
- Designate a contact phone number and provide the steps patients may take to contact the health care facility or practice location for assistance with patient access needs and post such information on its internet website or otherwise make such information readily available to the public
- Take an inventory and document "all medical diagnostic equipment that meets the standards for accessibility and all medical diagnostic equipment that does not meet such standards," including but not limited to documenting an action plan for addressing gaps in such inventory and making such documentation available to the DPH upon request
- Identify and document the steps necessary to comply with the requirements that begin January 1, 2026 and make such documentation available to the DPH upon request

By January 1, 2026, affected providers with **three** or more exam rooms must…

- When purchasing, leasing, replacing, or otherwise obtaining MDE, independently verify or obtain assurances from the seller or source of such equipment that the equipment complies with the Access Board's standards for accessibility and maintain documentation of such verification or assurances
- Have available either an examination table or examination chair that meets the Access Board's standards for accessibility in at least one examination room that is capable of allowing a patient using an assistive device, including, but not limited to, a wheelchair to easily enter, exit, and maneuver in such examination room
- Have available at least one weight scale that meets the standards for accessibility (if a weight scale is used for patients generally)

Regulatory Flexibility For Connecticut MDE Law

- It is not a violation if a provider is unable to comply with a provision of the 2026 requirements if the provider is:
  - Unable to obtain medical diagnostic equipment that is commercially available at a commercially reasonable price
  - In the process of obtaining a necessary approval from a municipal or state agency, including, but not limited to, an approval relating to the building code, a building inspection, a site plan review, or a Certificate of Need (CON)
- Additionally, if a provider would be exempt from an obligation under federal rules, they are likely exempt from the Connecticut law

Federal Health Care Access Rules Update

- ADA and REHAB Act (aka Section 504) are being updated
- These updates include similar provisions to Connecticut's MDE law, but are much broader in other areas and have a longer glide path
- The ADA and REHAB Act changes go well beyond MDE requirements, and will require providers to undertake substantial process and space changes over the next several years to better accommodate persons with disabilities who are seeking care
- **These changes are in addition to Section 1557 – another civil rights law that applies to providers**

Next Steps To Prepare For MDE And Access Updates

- Do not sleep on this – if you are an affected provider, get started on the January 2025 Connecticut obligations for the MDE inventory and planning document **immediately**
- Now: For Connecticut compliance, get a training plan in place to meet (short) deadlines
- In coming months: Look for programs focused on the federal law changes
  - Many complex details on exemptions, building specs, etc., need to be understood (federal rules are constantly being clarified)
- Assign a point person
- Build awareness with staff, management and practice owners

HIPAA ENFORCEMENT

Office For Civil Rights (OCR) Enforcement Activity

OCR HIPAA Resolution Agreements

- OCR posts HIPAA settlements and imposed fines
- This can be used as an early warning system for everyone
- Make it part of your HIPAA compliance routine to check it periodically
- Compliance tip: Routinely study the OCR Resolution Agreements

https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html

HIPAA Enforcement Types, Last 12 Months

10 Resolution Agreements in last year's time:

- **Cybersecurity** [7]; Four of which are RANSOMWARE!
- Patient Access (not timely or denied improperly) [2]
- Sharing information with a reporter without prior patient authorization (this was a COVID-19 public relations mistake)

- 5 in NY/NJ; 1 in Massachusetts (Mass. is same OCR region as CT)
- 1 each in mid-Atlantic, California, Washington state, Penn-Ohio
- On Ransomware, the government's criticisms of the covered entities points back to gaps in basic HIPAA Privacy and HIPAA Security policies and training – but the recommendations for avoiding events are not robust

Common OCR Elements After Ransomware Fail

Entities must:

- Conduct an accurate and thorough Security Risk Analysis (SRA)
- Implement a risk management plan to address and mitigate security risks and vulnerabilities identified in the SRA
- Be able to identify, track, log, and audit users; track security incidents (with policies detailing the processes)
- Develop policies and procedures in preparation for emergencies or other contingencies if systems with PHI go offline
- Have up-to-date, written HIPAA Privacy and Security Rules policies and procedures

Filming and Promotions

- General rules:
  - You **may not film or photograph patients** without their **PRIOR** permission
  - **You may not allow media to use PHI (or film, or interview, or hang out) without prior patient permission ("blue dot" or later edited materials will not suffice)**
  - You may not use patient's identity in your promotional materials without consent
  - You may not post photos or identifying information about patients on your social media sites/pages without their consent
- Operational Tip: Work to control what is within your control
  - You should remove inappropriate posts on your own social media pages
  - You are not required to stop all friends and family from their personal Facebook use

Reminder Access Required For Entire Designated Record Set

Individuals have a **right to access** PHI in a "designated record set," which is defined (at 45 CFR 164.501) as a group of records maintained by or for a covered entity that comprises the:

- Medical records and billing records about individuals maintained by or for a covered health care provider
- Enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan
- Other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals
- "Record" means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity
- **Ensure Designated record set includes USCDI elements!! (to avoid information blocking)**

Invalid Reasons For Access Denial Of Patient's Own Record

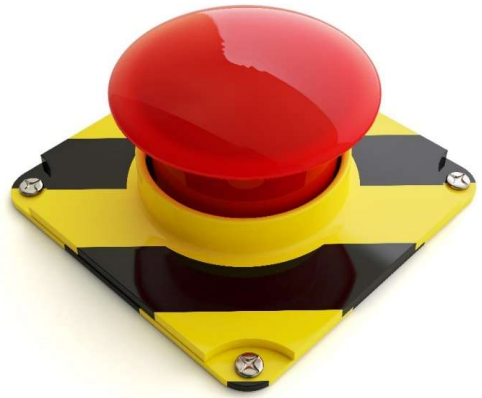
- Request is for electronic records
- Patient lives in Sri Lanka
- We had staff out sick
- Patient is mean and insulting
- Case is in litigation
- This isn't our patient anymore
- Physician does not think the patient needs the record (not a safety issue)
- Patient has an outstanding bill
- We had more requests than usual
- Patient refuses to pay the copy fee
- Patient just got a copy last month, and has submitted a new request
- Patient refuses to sign practice's full authorization form

Red Alert!!

Significant Changes To HIPAA To Improve Privacy of **Reproductive Health Information**

(All reproductive health information, not just abortion)

Compliance deadline is **December 23, 2024**



Specific Situations Where Authorization Not Required For Release, Patient Opt-Out Not Required (45 CFR 164.512)

- Each of these categories has significant detail; policies should show how the provider intends to handle the situation operationally; five sections directly affected by new REPRODUCTIVE HEALTH rules
  - Required by law
  - **Public health activities**
  - Abuse or neglect reporting
  - FDA related data collection and reporting
  - **Health oversight activity**
  - **Law enforcement**
  - **Judicial and administrative proceedings (covered in-depth next week)**
  - **Decedents**
  - Organ and tissue donation
  - Research
  - Averting a serious threat to health or safety
  - Specialized governmental function
  - Workers' compensation

Reproductive Health Records: Now Highly Sensitive

- Roe v. Wade stopped being law June 2022 (controlling US Supreme Court case is called Dobbs)
- Each state now has flexibility to restrict or protect access to abortion (and other reproductive health care) because Dobbs indicates it is no longer a Constitutionally protected right
- Various changes to EMTALA and HIPAA have been proposed or have been implemented by HHS to counteract the patient access concerns that go along with Roe v. Wade being overturned
- Lawsuits challenging those changes are in process now (with varied results); rapidly changing landscape causes additional confusion

NEW HIPAA Rules: Reproductive Health Information

- Significant Update to HIPAA Privacy Rule released April 26, 2024
- The new rule alters how specific requests for access and use of PHI must be handled
- Be advised that this new HIPAA rule (and the new EMTALA rules) are **being challenged in federal court** (by states with stricter abortion laws than Connecticut); so far **with reasonable success** in raising questions about the legality and enforceability of the new rules
- We do not know if those legal challenges will affect if/how Connecticut providers must comply with the new HIPAA rule
- For now, in Connecticut, assume the new rules are the ones you must follow: compliance deadline is **December 23, 2024**

Scope Of The Rule

- Reproductive health care includes all health care that affects the health of an individual **in all matters relating to the reproductive system and to its functions and processes. That could include:**
  - Abortion and pregnancy-related care
  - Birth control, including emergency contraception
  - Fertility or infertility
  - Anything relating to care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system
- The definition is for this rule only, and is not intended to set any standard of care or affect clinical choices

New HIPAA Reproductive Health Rule Basic Premise

Basic premise is a new PROHIBITION on use or disclosure of PHI in specific situations relating to otherwise legal reproductive healthcare: A CE or BA **may not use or disclosure** PHI for either of the following activities:

1. To conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided
2. The identification of any person for the purpose of conducting such investigation or imposing such liability

Specifics Of New HIPAA Rule: Reproductive Health

PROHIBITION basic rule applies if a CE or BA has "reasonably determined" one or more of the following conditions exists:

1. The reproductive health care provided was lawful in the state where the care occurred. This would include, for example, an out-of-state resident who travels to Connecticut for a legal abortion
2. The reproductive health care is protected, required, or authorized by Federal law, including the U.S. Constitution, regardless of where the care was provided. For example, use of contraception is (currently) protected by the Constitution
3. The reproductive health care was provided by someone other than the CE or BA that received the request and the **PRESUMPTION** that the care was lawful (as described on the next slide) is met

Presumption In Place: That Care Was Lawful

PRESUMPTION: Reproductive health care **is presumed to be lawful** under the circumstances in which it was provided *unless* either:

1. CE or BA has actual knowledge that the care was not lawful.
   - For example, patient reports to their doctor that they obtained an illegal abortion from an unlicensed person
2. CE or BA receives factual information from the requester that demonstrates a substantial factual basis that the reproductive health care was not lawful
   - For example, a law enforcement official provides a health plan with evidence that the information being requested is reproductive health care that was provided by an unlicensed person where the law requires that such health care be provided by a licensed health care provider

Outside Of The Prohibition

HIPAA permits CE or BA to use or disclose PHI if the purpose is otherwise permitted under the Privacy Rule **and** the PHI **will not** be used to investigate or impose liability on any person **for the mere act of seeking, obtaining, providing, or facilitating reproductive health care**. HHS examples:

- CE or BA is not prohibited from using PHI to defend themselves in an investigation or proceeding related to professional misconduct or negligence involving reproductive health care
- CE or BA is not prohibited from using or disclosing PHI to defend any person in a criminal, civil, or administrative proceeding where liability could be imposed on that person for providing reproductive health care
- CE or BA is not prohibited from disclosing PHI to an Inspector General where the PHI is sought to conduct an audit for health oversight purposes

Attestations

- If the Request for reproductive health information is in any the following four identified categories, the updated rule requires the CE or BA to first obtain a specific **ATTESTATION** from the requester before disclosing:

1. Health oversight activities -- 45 CFR 164.512(d)
2. Judicial and administrative proceedings -- 45 CFR 164.512(e)
3. Law enforcement purposes -- 45 CFR 164.512(f)
4. Disclosures to coroners and medical examiners -- 45 CFR 164.512(g)(1)

(A Template ATTESTATION form is available on HHS website)

Disclosures To Law Enforcement Clarification

- The Privacy Rule **permits** certain, limited disclosures to law enforcement subject to specific conditions (but *does not mandate* such disclosure)
- Under the NEW RULE: CEs and BAs are only permitted to disclose PHI for law enforcement purposes where they suspect ***an individual*** of obtaining reproductive health care (lawful or otherwise) if the CE or BA is **required by law** to disclose – and all applicable conditions are met for that portion of the privacy rule.
- Specifically, that all three of the following conditions are met:
  - The disclosure is not subject to the PROHIBITION
  - The disclosure is required by law
  - The disclosure meets all applicable conditions of the Privacy Rule permission to use or disclose PHI as required by law

Connecticut Specific Reproductive Rights

- You will need to consider Connecticut state laws on reproductive health privacy while planning for compliance with HIPAA changes
- Connecticut law is similar but not identical to HIPAA
  - CGS Sections 52-146w and 52-146x
- Connecticut law expressly includes gender-affirming care records along with reproductive health

HIPAA and Connecticut Law Must Be Considered – not easily aligned

Connecticut Specific Reproductive Rights

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Sections 52-146w and 52-146x

Connecticut Reproductive Rights, Legal Protection

- **Restricts covered entities, as defined in HIPAA (e.g., healthcare providers and health insurers) from disclosing records in response to a subpoena, if the subpoena seeks to access or obtain records about abortions or reproductive health or gender-affirming healthcare services, in connection with a legal, administrative, or other official governmental proceeding, without express patient consent for the release of the records.**

- **Clarifies that the Act does not interfere with or affect the exchange of medical information in the normal course of patient care or for related uses and activities, as permitted by state and federal law** (e.g., payment, routine public health activities, required reports to DPH, DCF, DSS, or other agencies), and affects only the sharing of information when made **through a subpoena** (specific to a legal matter or for other government proceedings). In those instances, covered entities must follow the strict requirements of the new law (i.e., obtain patient consent or a seek a court order from a court with jurisdiction).

Other Connecticut Reproductive Rights, Legal Protection

- Connecticut law prohibits state agencies, employees, and their agents from participating in, or assisting with, interstate investigations or proceedings that seek to punish a person for activities relating to abortion or other reproductive healthcare services, or gender-affirming healthcare services, to the extent that those activities are legal in Connecticut.

- Laws restrict the State of Connecticut's power to extradite an individual to another state for criminal proceedings relating to abortion or other reproductive healthcare services, or gender-affirming healthcare services, to the extent that the alleged criminal actions are legal in Connecticut.

In A Nutshell…

Assume Subpoena not enough until proven otherwise

DO NOT use HIPAA satisfactory assurances when releasing records in response to a subpoena if the records contain REPRODUCTIVE HEALTH or GENDER AFFIRMING CARE

Follow the federal law new HIPAA prohibitions and obtain attestation for the four listed categories

Challenges And Considerations For Achieving Compliance

For any medical record that might have reproductive health information:

- CE or BA has to do a lot of leg work, review, legal processing and guesswork about the motivations of the requester
- Puts CE or BA in a precarious posture with regulators, health oversight, law enforcement, and others
- Makes satisfactory assurances unreliable for any records that might have reproductive health information in the PHI
- Patient authorizations need to be honored – but can place providers in jeopardy
- **What to do with court orders that might be missing the point?**
- NOPP changes required in early 2026

Practical Planning Questions

- Will vendors who handle ROI requests on your behalf be ready? (What's your cross check on their compliance?)
- How will other BAs handle?
- What about HIEs/HIOs, including medical record sharing through EMR vendors or wheel and spoke situations?
- Should you update BAAs?
- From which agencies or entities will you seek ATTESTATIONS?
- Does this alter your Information Blocking plans and policies?
- How do state law protections for reproductive health information affect this?

Touchbase: Emerging And Developing Healthcare Technologies

- Artificial Intelligence
- Data Tracking

A.I. Is The Next Big Thing

Artificial Intelligence Is The New HOT Topic In Health Information Technology

Common Rules Of The Road Are Sparse – Government Wants to Fill That Void

Examples Of Healthcare Deployment of A.I.

- Assisting in clinical diagnosis
  - Imaging cross check and review
  - Ability to detect disease or anomalies earlier
  - Enhance clinical decision support
  - Assist in precision medicine

- Automating administrative tasks
  - Enhance recordkeeping, identify gaps and continuity issues
  - Streamline EMR utility
  - Improve scheduling
  - Improve patient interaction and education
  - Reimbursement tasks (including prior authorization**, UR, QI/QA)

****Good example of a double-edged sword**

Examples Of Healthcare Deployment of A.I.

- Contributing to drug and device development
- Augmenting and streamlining research
  - Quicker, large data pool analysis
  - Ability to enhance rare disease and targeted disease research
  - Generating synthetic medical data (e.g., to help solve for issues in low population diseases and conditions)
- Facilitating medical training and simulation

Examples Of A.I. That Support Healthcare

Areas where A.I. can advance efforts in healthcare:

- Study and address healthcare inequities
- Community health and population health
- Public health

- Workforce planning and retention
  - Recruiting and onboarding
  - Analyze employee feedback, performance, behaviors
  - Increase workforce diversity
  - Improve workforce scheduling and coverage

Executive Order on A.I.

Focuses in Executive Order On A.I. with direct application for healthcare:

- Safety and real-world performance monitoring of AI-enabled technologies
- Non-discrimination and anti-bias protections
- Added safety, privacy, and security standards for software development
- Transparency and open documentation to help deployers and end users determine appropriate and safe uses of AI in local settings
  - Including open-source solutions and mandatory red teaming
- Coordination with state, local and tribal agencies to promote best practices
- Identification of uses of AI to promote workplace efficiency and satisfaction

Executive Order on A.I.

HHS must develop specific strategies for quality, non-discrimination, and drug development, including:

- Promote federal nondiscrimination laws
- Develop a quality strategy, including premarket assessment and post-market oversight of AI-enabled health care technology performance against real-world data
- Develop a strategy for regulating the use of AI in drug development

Office Of National Coordinator (ONC)

- ONC is the federal subagency of HHS in charge of certification standards for CEHRT
- ONC is one of the agencies that enforced interoperability and information blocking rules
- ONC is on of the two primary leads within HHS to address A.I. in healthcare (the other is FDA, which has a separate set of rules for A.I.)

ONC Final Rule: HTI-1

- Final Rule: The Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing
- **Short name**: **HTI-1**
- This is a HUGE new rule with tons of requirements for A.I., interoperability, sharing, and EMR development
- With a VERY short timeframe (similar to other rule implementation that had ambitious timeframes)

HTI-1 Algorithm Transparency

- Algorithm Transparency: Establishes first of its kind transparency requirements for the artificial intelligence (AI) and other predictive algorithms that are part of certified health IT
- ONC-certified health IT supports the care delivered by more than 96% of hospitals and 78% of office-based physicians around the country
- Framework promotes responsible, making it possible for clinical users to access a consistent, baseline set of information about the algorithms used to support their decision-making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety

HTI-1: Many Moving Parts

- Requires United States Core Data for Interoperability Version 3 by January 1, 2026
- Requires certified health IT developers to provide extensive feedback on how their products are working, including metrics on CEHRT performance and deployment in patient care settings
- The ONC website has massive amount of information to review, including a link to the actual rule, and numerous guidance materials sorted by topic

What's Next For A.I. In Healthcare?

- Healthcare will need to do better at identifying and addressing bias in technologies for A.I. and other technologies
  - Human systems obviously have bias (sometimes unchecked bias)
- Federal rules and guidance will accelerate in the next several years
- Outcome of Connecticut and other state-based legislation to regulate A.I. will set the stage for locally based work
- Eventually federal agency powers (and state powers) will be tested in courts to determine the extent of their regulatory power

Data Tracking As Potential HIPAA Violation

Office for Civil Rights OCR (OCR) anti-tracking guidance from December 2022 titled "**Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates:**

has been CANCELED

HIPAA and Data Tracking Legal Challenge

- American Hospital Association (along with the Texas Hospital Association and others) sued HHS/OCR challenging the guidance as **beyond HHS power**
- Federal courts agreed with AHA and vacated a portion of the guidance
- HHS:
  - Posted that the enforceability of the guidance is in question
  - Not appealing the court decision
  - Left the guidance available online (although it is not likely they will enforce all of it after the lawsuit)

Pixel Problem Is Not Over

- The guidance being canceled does not solve the “pixel” problem
- It is not clear how Big Data and the HIPAA de-identification rules can co-exist
- Technologies embedded in software that many healthcare providers utilize can convert what looks like anonymized data into identifiable data (e.g., Meta Pixel tool; Google Analytics), or use actual patient data for commercial reasons (e.g., assessing web traffic or ad clicks)
- That can be a HIPAA violation in some circumstances
- There are still numerous private lawsuits and class actions still pending across the country claiming providers should be liable for damages for violating patient privacy
- The court vacating parts of the guidance is helpful, but will not in itself stop those lawsuits
- FTC has similar guidance (unresolved)

SUD Record Privacy: Significant Update

42 CFR Part 2 has been reworked

Compliance deadline: February 16, 2026

42 CFR Part 2 Basics

- 42 CFR Part 2 is a federal regulation governing substance use disorder program patient records ("SUD Records")
- Originated in 1975 and implemented in the current form in 1983 (in a paper records world that no longer exist)
- Revised somewhat in 2017-18
- Overall – few meaningful revisions throughout its lifecycle
- Called "Part 2" for short

Part 2 Versus HIPAA

- HIPAA Privacy began in 2003
- HIPAA and Part 2 are not coordinated (even though they often both apply to the same records)
- Part 2 rules require much stricter privacy handling than HIPAA and it can be difficult to blend them operationally
- The new rule assumes too much about providers and insurers understanding of HIPAA and SUD Records rules
- Added confusion: Not all SUD Program providers are governed by HIPAA (today's program focuses mostly on entities that are governed by HIPAA)

Efforts To Align HIPAA and Part 2

- During the COVID-19 pandemic Congress passed the CARES Act
- CARES Act includes requirements for HHS to better align HIPAA and Part 2
- NEW rules published in the federal register February 16, 2024: very detailed and very long (160 pages of tiny type in three column format)
- Deadline for compliance: **February 16, 2026**
  - Many necessary details still need to be filled in!!
  - "Accounting Rule" change on hold, awaiting compliance date

Alignment With HIPAA

- Part 2 will be more like HIPAA -- but ultimately still too different to unify operationally
- Policies, procedures, and new forms will be necessary to comply (whatever you are doing now will need to change)
- Part 2 records will still need to be "tracked" in most circumstances because different or additional rules often apply
- There are different nuances and procedures for non-HIPAA entities for most parts of the rule

Major Updates For Part 2 Privacy

- **Consents**: Disclosures and types of consent
- **Prohibitions**: expansion and clarification of limits of use and disclosures (generally by or to government authorities)
- **Breach and de-identification** rule clarification
- HIPAA **Notice of Privacy Practices** (aka “NPP” or “NOPP”) mandatory changes
- **Restrictions and patient control** clarified
- **Accounting** of disclosures (from HIPAA 45 CFR 164.528)
  - This portion of the rule is on hold awaiting a change to HIPAA

Penalties

- Prior rule had enforcement penalties but were rarely used
- New rule aligns penalties with HIPAA sanction rules
- Range is vast:
  - $25,000 to $1,500,000
  - Criminal sanctions fines ($50-250k) and jail time of 1-10 years in prison
- The inference is the government is more serious about enforcement

Consent Updates

- This is the most complex and lengthy area of changes in the new rule
- Conceptual shift from needing a consent for each purpose and recipient to a consent that can be for all HIPAA “TPO”
- TPO incudes the HIPAA designation for Treatment, Payment and Operations
- A single patient consent can be used for multiple, future (some unknown as of yet) purposes

Single Consent For TPO

- Can be a single form for all TPO
- The type and scope of data being release per the consent should be identified in a "specific and meaningful" way (prior rule needed to be exact)
- Covers future uses and disclosures (within TPO)
- Expiration date can be "none"
- Recipients or downstream users identified in the consent can be by class or type
  - E.g.: a health plan or third-party payer; all of my providers

HIPAA Rules On TPO

- A HIPAA covered entity or business associate may use or disclose SUD Records for TPO unless and until patient revokes the single consent
- This does not extend to legal proceedings which would require the patient's specific and separate consent (or a specialized court order)
- Non-HIPAA SUD Programs are confined to the scope of the consent

Segregation Of Records No Longer Required

- Part 2 programs, and HIPAA covered entities or their business associates that receive records through a single consent for treatment, payment or operations (TPO) are not required to segment or segregate the SUD Records from other records
- That sounds a lot better than it is
- Harder to manage in practice because re-release will always need to track the original as SUD Records to ward off inappropriate use in legal proceedings

Prohibited Through Single Consent

- Single consent not allowed for use in a civil, criminal, administrative or legislative proceeding against the patient (needs court order or patient's specific written consent with more details than a single TPO consent)
- This is not a new concept, more a clarification
- It is designed to reduce hesitance to seek treatment due to stigma or fear of reprisal
- This prohibition substantially aligns conceptually with similar changes to the HIPAA Privacy Rule relating to reproductive health privacy that go into effect December 23, 2024

Prohibited Through Single Consent (continued)

- Single consent may not be used for “SUD Counseling Notes” (a new category of protected records similar to HIPAA Psychotherapy note protections)
- This is going to be confusing to implement
- Government assumed providers already understand HIPAA Psychotherapy notes rule
- Very few use the HIPAA psychotherapy notes rule now; that framework is not as illuminating as the SUD Rule makes it sound

Single Consent For TPO & Disclosure Process

- Consent must contain certain “magic words” with various warnings and disclosures to ensure the consent process is transparent for the patient
- Disclosure must be done with a warning to the downstream recipient
- Not clear if the same wording is required for HIPAA covered entities or business associates – but some indication would be needed
- **Intermediaries** have different sharing rules; these are entities that are not subject to HIPAA but access SUD Records (examples: for research or care coordination – but only when **not** a HIPAA covered entity or business associate)

Breach & Deidentification

- HIPAA level deidentification rules apply
- Prior rule had a similar but less clear standard
- Deidentification is very specific under HIPAA – and should be followed carefully
- HIPAA Breach rules apply

Notice Of Privacy Practices

- HIPAA Notice of Privacy Practices ("NPP" or "NOPP") has more details than the prior Part 2 privacy notice
- Under new rule, HIPAA NOPP can be used for Part 2 compliance
  - **NOTE: HHS still working on examples and clarifications**
- Revised language required to be implemented by providers and others by February 16, 2026
- This is a great opportunity for HIPAA covered entities to revise other NOPP issues that may be lingering
- Specific language is needed in the revised NOPP for Part 2 patients and fundraising (nuanced detail from HIPAA's current NOPP obligation)

Legal Proceedings

- Prior rule already blocked most uses by authorities for prosecution of the patient or when used against the patient (absent patient's specific consent)
- New rule clarifies and expands those blocking rules to all legal proceedings to include use or disclosure in any civil, criminal, administrative, or legislative proceedings
- Similar in theory to new reproductive health rules for HIPAA privacy
- As with prior rule, effective court orders mandating disclosure are more complicated than under HIPAA; required by law disclosures per HIPAA are **not applicable** to Part 2
- HHS still working on examples and clarifications

Restrictions & Patient Control

- As with prior rule, SUD Records accessed for program oversight or audit cannot be repurposed for proceedings against a patient
- Patient can request restrictions – new rule follows HIPAA restrictions rule (see 45 CFR 164.522 for specific on restrictions to health insurers)
- That should be what HIPAA entities are already doing
- As with prior rule, Part 2 programs have more power to condition treatment on patient consents than a HIPAA entity that is not Part 2 program can require

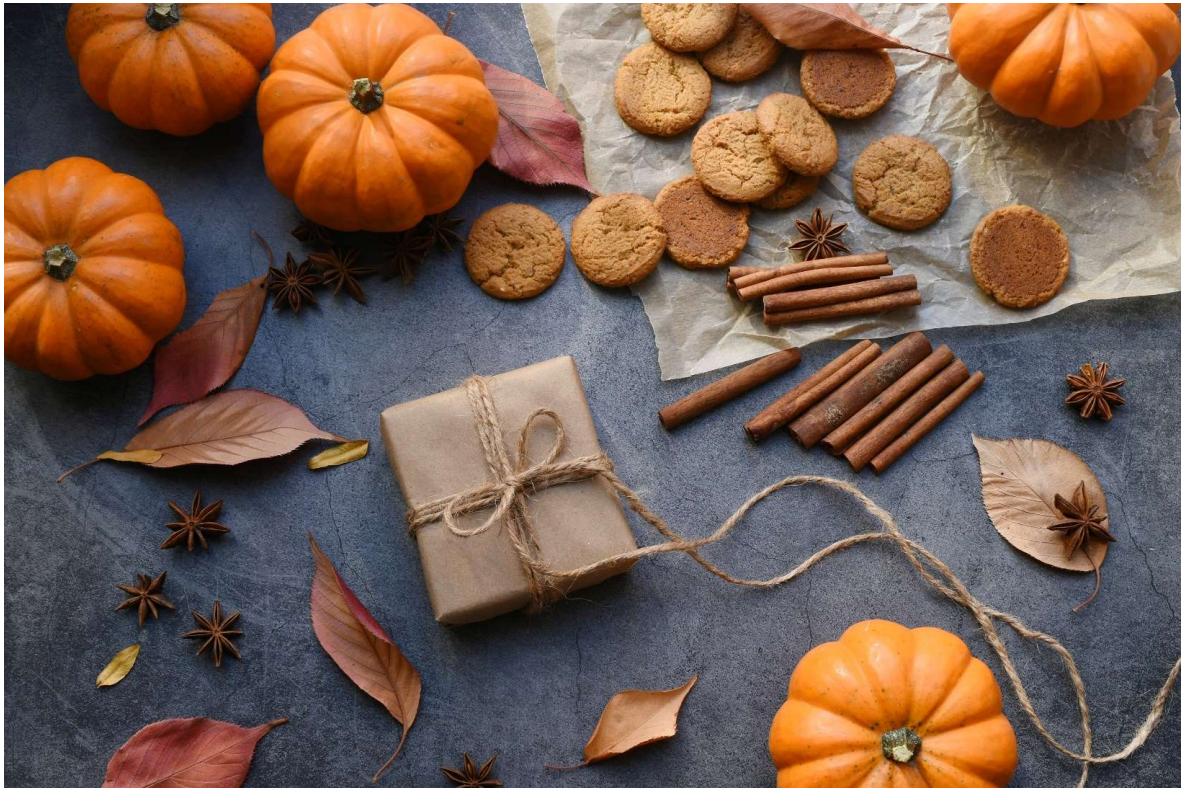
Accounting – 45 CFR 164.528

- In the last 10 years, there have been multiple (soft) attempts to rework HIPAA's "Accounting of Disclosures" rule to remove most of the exception categories to create a true audit log of users available for patient review
- Those efforts have never been finalized (providers and health insurers generally oppose the proposed changes)
- Another attempt to modify this rule is pending
- If those pending changes become law, they will also apply to SUD Records

Next Steps

- Identify policies and procedures relating to use, disclosure, and handling of SUD Records and related forms
- Review all consent forms
- Pencil in changes that will be needed
  - Assess whether HHS owes guidance information on those topics before finalizing your changes
- Update breach policies and procedures
- Plan staff training po new rule and policy and forms updates
- Create schedule for completion by February 2026

Q & A



Resources

- Connecticut legislation (searchable database):

  www.CGA.ct.gov

- HIPAA tools and guidance from OCR:

  www.hhs.gov/hipaa/for-professionals/index.html

- Access Board landing age for MDE:

  About MDE (access-board.gov)

More Resources

HIPAA Reproductive health privacy landing page (includes a link to attestation template):

HIPAA and Reproductive Health | HHS.gov

ONC's HTI-1 landing page:

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule | HealthIT.gov

Key Resources SUD Records

- HHS resources fact sheet and landing page:
  Fact Sheet 42 CFR Part 2 Final Rule | HHS.gov

- Final rule text in federal register on February 16, 2024:
  2024-02544.pdf

Appendix

- List of proposed HIPAA Privacy changes pending since 2020
- Chart of USCDI v.3 elements for illustration

Proposed Changes to HIPAA

The following are pending disposition – **do not follow them yet**, hopefully these will be resolved or finalized early to mid 2025

Proposed/Pending HIPAA Rules Changes List

- 30 days **to 15 days for maximum** time to fulfill request (paper and electronic)
- Free copies for direct patient requests
- Posting of copy fees schedule in advance
- Estimate of actual fees on demand
- Clarifies patient rights to direct release to HIPAA entities and other third parties
- New NOPP rights must be listed, including rights to copies and to direct disclosures

Proposed HIPAA Rules Changes List

- Patients must be allowed to take notes or photographs of their records
- Patients must be allowed in-person records inspection
- Clarifies health insurer obligations to allow record access and process disclosure requests
- Eliminates NOPP acknowledgment requirement
- Clarifies use of existing rule on disclosures made to avert a serious health threat
- Expands some “good faith” data uses by covered entities

Proposed HIPAA Rules Changes List

- Revises the minimum necessary standard and definition of healthcare operations to allow for expanded uses of care coordination and case management
- Clarifies and expands existing military services uses
- Prohibits unreasonable verification practices before release of records

We Continue to Wait For The Final Rule

- Proposed Rule was in January 2021
- We've been waiting with no word on when to expect final rule
- Other rules have jumped in front
- These pending rules have been mentioned in *OTHER rules* – as if they will be finalized soon; but that's not a sure thing
- Impossible to tell if the final rule will align with the proposed rule
- But if there were only a few changes, it's hard to see why it's taking so long

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Goals
- Patient Goals
- SDOH Goals

Health Insurance Information
- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Number
- Payer Identifier

Health Status/Assessments
- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Smoking Status

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results
- Specimen Type
- Result Status

Medications
- Medications
- Dose
- Dose Unit of Measure
- Indication
- Fill Status

Patient Demographics/ Information
- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Related Person's Relationship
- Occupation
- Occupation Industry

Problems
- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- SDOH Interventions
- Reason for Referral

Provenance
- Author Organization
- Author Time Stamp

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic Blood Pressure
- Diastolic Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)