# Year In Review: Laws and Policies Affecting Providers and Status Check of the Healthcare Regulatory Environment

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# Today's Program Agenda

- Evolving federal changes impacting healthcare
- Significant changes to reproductive health rights
- Review of various newly passed Connecticut laws impacting healthcare providers
- Compliance reminder: access to care by persons with disabilities
- **Status check on the health data environment**

# Touchbase on the Health Data Environment

- HIPAA recent enforcement actions and focus
- Multiple sets of proposed changes to HIPAA rules
- Artificial Intelligence oversight
- Information Blocking to be strictly enforced
- Big Data's role in health data
- Quick Connie status check

# Evolving Federal Landscape

- Vaccination status and vaccine programs
  - FDA and CDC changes
  - Regional approach starts to take shape
- Public Health oversight and reporting
  - Danger zones
- Changes to regulatory rulemaking process and timelines for notifications of proposed and final rules
  - Too many moving parts at once

# Federal Changes: Ongoing Disruptions

- ACA and Medicaid instability
- Restructure of HHS
  - CDC, FDA, SAMHSA new priorities
- Elimination of various HHS subagencies and programs
  - Work in progress
- Change in Regional Office structure for HHS/OCR

# Federal Changes: Ongoing Disruptions

- Healthcare funding and reimbursement
- Federal agency resources (grants, research, programs)
- FDA approvals and pipeline
- Organ procurement program – 360 degree reassessment
- Research – massive changes

# Lighter Federal Oversight

- Artificial intelligence
- Consumer Data protections and marketing controls
- Big Data and social media
- Rights of disabled persons to access healthcare
- Protecting civil rights related to healthcare access

Lighter federal oversight frequently results in more state-by-state oversight, which is far more difficult to manage

# More Robust Federal Oversight

- Reproductive healthcare
- Gender-affirming care (Bans … and more bans?)
- Immigration status checks and enforcement (Ice raids, Medicaid audit)
- Severe limitations on programs or services promoting aspects of diversity, equity, and inclusion

# Reproductive Health

Landscape changing rapidly

Affects patients and records in most disciplines

Subpoenas must be handled very carefully

# HIPAA Reproductive Health Protection Reversed!!

- A HIPAA rule that had gone into effect on December 23, 2024, which required providers to block government and lawyer requests for reproductive health information unless they first obtained an "attestation" was overturned and "vacated" across the county by a federal court on **June 18, 2025**
- **You should no longer follow that rule**
  - Nuance: the rule was not entirely overturned – a portion survived that requires updates to HIPAA Notice of Privacy Practices for SUD records (this was an unrelated provision)
- There are other rules that might apply – but none that require a provider to obtain an "attestation"

# Connecticut Specific Reproductive Privacy Rights

You will need to comply with Connecticut state laws on reproductive health privacy – the HIPAA rule reversal does not change Connecticut's law

**Section 52-146w** (previously also in 52-146x)

# Connecticut Reproductive Rights, Legal Protection

- Restricts covered entities, as defined in HIPAA (e.g., healthcare providers and health insurers) and their business associates 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
- **Keep in mind there are many records that have this type of information embedded**

# Subpoenas For Health Information

- There are very few circumstances in which you would not challenge a subpoena for patient records (to office, deposition or court); better said -- challenge a subpoena unless you have:
  - Patient written consent to disclose, or
  - An appropriate court order
- Someone else's lawyer telling you it's okay is rarely enough; lawyer should be able to answer:
  - Where's the consent paperwork?
  - Where's the court order?
  - What law requires you to send the records?
  - Does this comply with HIPAA, 42 CFR part 2 and 52-146w?

# Subpoenas For Health Information

- Operational tips: it is rarely safe, if ever, to rely on HIPAA **satisfactory assurances** for subpoenas
  - For SUD records, reproductive or gender affirming care records – DO NOT rely on HIPAA satisfactory assurances
- For SUD records, even a court order must be highly specialized
- DO NOT simply send records to court (or to a lawyer who isn't your lawyer) and hope they handle the situation correctly
- Contrast and compare: many agencies, including licensing agencies like DPH, are allowed to obtain patient records upon request

# A New CT Privacy Step For Providers!

- A covered entity or business associate that receives a subpoena for patient information related to reproductive healthcare services or gender-affirming health care services …that does not fall under any exemption [in the law]… and is not accompanied by the written consent of the patient or the conservator, guardian or other authorized legal representative of the patient **shall provide a copy of the subpoena to the office of the Attorney General not later than seven days after the date of receipt of the subpoena.**
- The Office of the Attorney General is required to post notice of the methods by which a covered entity and business associate may send the copy of the subpoena.

[Section 278 of Public Act 25-168; amending C.G.S. Section 52-146w]

# Other Connecticut Reproductive Rights Legal Protections

- 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.

# Restriction Is Limited To Certain Circumstances

- **Connecticut law expressly states it 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)
- The law affects only the sharing of information when made through a **subpoena** (specific to a legal matter or for other government proceedings)

# Another Major Change to Reproductive Healthcare Rights in Connecticut

- **Minors now control their own reproductive rights**
- Effective June 9, 2025:
  - a minor (under 18 yo) may seek care for **pregnancy and pregnancy prevention** (includes contraception but not sterilization) without parental consent
- This complicates an already complicated online, portal situation
- Similar to pre-existing law: minors already controlled for their own STD and HIV testing (and some treatments)
- You cannot bill in a way that creates an EOB unless minor has agreed to parental/guardian involvement
- Does not change DCF (or any other) reporting obligations

# 2025 New State Laws Affecting Healthcare

## Significant Legal Changes Affecting Healthcare in Connecticut

(the following is NOT an exhaustive list)

# 2025 Legislation – Insurance/Coverage Issues

- Health insurers prohibited from arbitrary restrictions on anesthesia coverage
- CT Medicaid to cover FDA approved therapies for sickle cell (added to an existing list)
- Step therapy by health insurers prohibited for MS and Rheumatoid Arthritis (added to an existing list)
- DSS to study GLP-1 data to inform Medicaid coverage planning
- Facility fee prohibitions and penalties expanded

# 2025 Legislation – Scope of Practice

- CT enters Physician Assistant compact
  - Nurse compact already active – making licensure more flexible
- Lactation consultants have new licensure category (some controversy)
- Marriage and Family Therapists from other states may apply for licensure without exam
- EMS providers have authority to administer nasal epinephrine (in addition to other forms)
- MRI and Radiology techs able to perform added to list of those who can perform certain oxygen patient care services in hospitals
- Retired physicians have easier path to re-licensure

# 2025 Legislation – Maternal, Infant, Child Health

- New maternity care report card will attempt to determine gaps in care, disparities, and suggest improvements
- DPH to study ways to improve perinatal mental health
- DPH, DSS, and OHS to develop strategies for improving birth services (particularly in underserved areas)
- Providers no longer mandated to tell families of newborns about cord and blood banking/donations
- **Vaccines** – dust still settling; likely a regional body will have input that rivals or replaces federal recommendations (more to come)

# 2025 Legislation--  Medical Records & Privacy

- Psychologist records confidentiality privilege changed to mirror psychiatrist privilege
- Minors can make decisions about their own reproductive health records (without parental approval)
- OHS to examine statewide HIE (Connie) certain processes and engagement materials

# 2025 Legislation – New Oversight Laws

- Providers may not require a patient to give electronic payment information if that information will be stored with provider
- Price transparency (including truth in advertising or representations) in effect for all services (most healthcare included)
- Consumers must be allowed to pay in cash (but most healthcare NOT included)
- Interpreting standards oversight boards and agencies for deaf, deafblind and Hard of Hearing (DHOH) will have expanded powers and revised structure

# 2025 Legislation – New Miscellaneous

- Bulk of federal **EMTALA** law principles incorporated into state law, with specific protections for reproductive health crises
- Non-discrimination principles for healthcare services made more robust and more obvious
- Emergency CON processes for hospital ownership changes after a bankruptcy filing
- Palliative marijuana written certification can be 6, 12, 18 or 24 months (previously 12 months only)

# Compliance Reminder: Access For Persons With Disabilities

Connecticut law now requires providers to work toward deploying accessible Medical Diagnostic Equipment

Based on federal regulations – but those federal rules will take longer to 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 (this is not about DME, they just sound the same)
- The law 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 law) and
  - (2) Office practices with **eight or more physicians or APRNs, alone or in combination** (designated as "Practice Locations" under the law)

# What Is Covered In The Law

- 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

# Ongoing Obligations For Provider Groups and Facilities

- 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
- Post contact information on its internet website or otherwise make such information readily available to the public

# Ongoing Obligations For Provider Groups and Facilities

- 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

# Next Steps To Prepare For MDE And Access Updates

- Do not sleep on this – **if you are affected provider**, be sure you have:
  - Completed the MDE inventory
  - Have an up-to-date planning document
  - Trained all staff
- Now: For Connecticut compliance, get a training plan for staff in place
- 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 to manage compliance
- Build awareness with staff

# Implementation Date Approaching

42 CFR PART 2 CHANGES

THIS AFFECTS ALL SUD TREATMENT RECORDS, WHETHER YOU MADE THEM OR JUST HAVE THEM IN A RECORD SET

# 42 CFR part 2: SUD Program Records

- There has been a recent overhaul of "42 CFR part 2" – a set of regulations that protect confidentiality of substance use disorder treatment and referral records; it is a massive reboot of the rule, throwing many things into flux
- **New rule applies to any provider that has or might receive these records**
- Deadline for compliance is **February 16, 2026** (you can adopt anytime you are ready before then)
- Providers that have any protected SUD records **must update their HIPAA Notice of Privacy Practices by February 16, 2026**

# 42 CFR part 2: SUD Program Records

- The changes will impact all data exchanges of SUD records:
  - From a privacy and release POV (e.g., the entire consent process has changed)
  - From a security (technical) POV (e.g., technical data tracking across the continuum appears necessary)
- **Operational tips:**
  - Carefully review all of your documents (e.g., policies, procedures, consents, Notice of Privacy Practices) for any mention of 42 CFR Part 2 or SUD records to see where you need to comply
  - STOP following prior whitepapers or guidance that intertwined HIPAA and SUD record rules – those will be outmoded in places, and completely incorrect in others

# Touchbase On Health Data Environment

HIPAA Enforcement

HIPAA Proposed Changes

Artificial Intelligence Update

Information Blocking and Big Data

# 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

[Note: HHS websites are mostly static\paused for shutdown]

# HIPAA Enforcement Types, Last 12 Months

27 Resolution Agreements over the past year (not counting some since shutdown):

- **Cybersecurity problem or Security Rule failure** [20]
- Patient Access (not timely or denied improperly) [4]
- Sharing information with external entity without permission [3]

- Fines range between a few thousand dollars into the multi-millions
- Most happened years ago
- These episodes are evidence that the HIPAA Security Rule needs updating.
  **In related news: the HIPAA Security Rule may be updated.**

# Security and Cybersecurity

- Penalties for failures of Security and Cybersecurity are frequently based on failure to have correct policies and training, less focused on the technical software and hardware (although important)
  - This exposes a systemic failure of HIPAA Covered Entities and Business Associates to recognize the planning and administrative aspects of **SECURITY**
  - It is **essential** that Security Risk Assessments be conducted, documented and updated frequently and interdisciplinary internal governance and oversight applied

# Security Risk Analysis Must Be A Priority

- HIPAA Security compliance requires a competent security risk analysis or assessment (SRA) that follows the HIPAA Security Rule
- The SRA should be periodically updated or performed again (annually for meaningful use/promoting interoperability compliance)
- Many entities failed to perform and document a risk analysis consistent with the HIPAA Security Rule steps
- The SRA needs to be in writing with all assessments documented; SRA forms the basis of your Security plan
- There are several tools available for SRAs (ONC has a free online tool)

**You could have the best security in the universe, but failure to document your SRA in the manner that the HIPAA Security Rule requires can result in noncompliance**

# Ransomware Fails: Common Corrective Actions

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

# HIPAA Proposed Rule Change

## HIPAA SECURITY RULE PROPOSED CHANGES

# Proposed Changes to HIPAA Security

- Proposed rule released December 27, 2024 (Biden administration)
- **These are not the law – and may never become the law**
- There is an overwhelming emphasis on more sophisticated security measures being needed
- Many of the proposed updates are things that *de facto* happen now as part of good security
- But some is potentially reactive to publicized breaches

# Proposed Changes to HIPAA Security

- Since President Trump took office, there has been substantial industry pushback *about the details* of the proposed Security Rule; arguing that the updates would be overly burdensome (for little benefit)
- Likely to be **years not months** in any event before major changes would become law…. but…**do not ignore**, because:
- **There is universal agreement conceptually that the HIPAA Security Rule is outmoded** and needs fixing
- The current rule is from 1996 – technology has evolved substantially since then
- **There will be an update** – it may look different than the proposal we've seen

An overview of the proposed Security Rule update follows….

# Proposed HIPAA Security Rule Changes: Administrative And Policies

- More specificity required in annual (or sooner) Security Risk Assessments
- Requires a network map and inventory or technology assets
- Policies for change management controls
- Stronger risk management planning

# Proposed HIPAA Security Rule Changes: Administrative And Policies

- Patch management policies required
- Formalized and stricter monitoring and responses to security incidents
- Eliminating or restructuring the Required versus Addressable framing
- New obligations for business associates
  - Expanded reporting of incidents
  - Enhanced compliance with certification thresholds
  - New BAAs needed (with more obligations)

# Proposed HIPAA Security Rule Changes: Technical

- Encryption mandated (at rest and in motion)
- Robust requirements for multi-factor authentication
- Expanded need for technical controls and IT system configuration consistency
- More robust network segmentation

# Proposed HIPAA Security Rule Changes: Technical

- More robust protective software, more aggressive action to reduce software and hardware related threats
- Increased auditing, monitoring and review of system protections
- Vulnerability scanning every 6 months
- Penetration testing every 12 months

- Taken together, these changes will add enormous cost to all levels of providers and health insurers (and their business associates)

# HIPAA Proposed Rule Change

## HIPAA PRIVACY RULE PROPOSED CHANGES

# We Continue to Wait For Privacy Rule Changes

- December 2020 proposed rules are well over 4 years old and still no indication if they will become law
- Other rules have jumped in front
- These 2020 pending rules have been mentioned in *OTHER rules* – as if they will be finalized soon; but still nothing final
- Impossible to tell if the final rule will align with the proposed rule
- At this point, it's hard to see why it's taking so long

# 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

# Proposed HIPAA Rules Changes List

- Expands some “good faith” data uses by covered entities
- 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

# Artificial Intelligence

## Developments For A.I. In Healthcare

# Developments For A.I. In Healthcare

- President Trump cancelled Biden's prior AI executive orders and gave new executive orders
- The Biden plan had been focused on avoiding bias in AI tools and elevating privacy rights
- The Trump plan is radically different, creating both confusion and opportunity in the field
- The new plan applies to all industries; for healthcare the plan is focused on advancing rapid development of AI to assist in healthcare settings (and research)
- The new plan is called "Winning the Race: America's AI Action Plan"

# Developments For A.I. In Healthcare

- **Winning the Race: America's AI Action Plan has 3 pillars:**
  - Accelerate AI innovation
  - Build American AI Infrastructure
  - Lead in International AI Security and Diplomacy
- It's a curious set of ideas because historically, America has not led in cybersecurity or privacy in any way (Europe has)
- And the bulk of the plan is about enhancing private actors' roles (which is in tension with increased government oversight)

# Winning the Race: America's AI Action Plan

*America is in a race to achieve global dominance in artificial intelligence (AI). Winning this race will usher in a new era of human flourishing, economic competitiveness, and national security for the American people. Recognizing this, President Trump directed the creation of an AI Action Plan in the early days of his second term in office. Based on the three pillars of accelerating innovation, building AI infrastructure, and leading in international diplomacy and security, this Action Plan is America's roadmap to win the race.*

# Developments For A.I. In Healthcare

- Immediate impacts for healthcare: directs the National Institute of Standards and Technology (NIST) to "revise the NIST AI Risk Management Framework (RMF) to eliminate references to misinformation, Diversity, Equity, and Inclusion, and climate change"
- It is unclear the extent to which individual states will be allowed to further regulate AI
- There appears to be a direct role for **Big Data** in accelerating AI research and adoption
- FTC, FDA, and CMS all undertaking fresh looks at AI uses and restrictions, with potentially inconsistent outcomes

# Handling AI Operationally (While We Await Clarity)

- Self-governance methods need to be explained and documented, including organizational guidance or frameworks being deployed
- Document the “human in the loop” factors particularly for patient decision-making
- Be sure patients know if they are interacting with AI directly
- Be careful of HR-related AI decisions
- It will not be sufficient to say “the machine did it, don’t blame me”
- Maintain awareness of this topic – **it could develop very quickly**

# Information Blocking Warning

# Information Blocking Renewed Enforcement Plan

Announced federal government agency focus:

(1) Patients should have easy electronic access to their EHI **at no cost**, including via apps of their choice; and that

(2) Healthcare providers should be able to choose the digital tools that allow them to provide the best care, without excessive costs or technical barriers

# Information Blocking Renewed Enforcement Plan

- Consider the government's announcement a direct warning to anyone engaging in information blocking to come into compliance with the rules
- It is also a call to action for patients, providers, payers, local health departments, and health IT companies to report alleged information blocking
- Enforcement threat appears to be signaling increases data access for **Big Data** companies

# Information Blocking Warning: The Devil Is In the Details

- You will need to implement the Information Blocking Rule and all exceptions through written policies that coordinate with your HIPAA written policies
- You will need to reduce most of the Info Blocking exceptions to written policies
- When you draft those policies, you need to pay careful attention to the extensive criteria for each exception – the rule and the interpretive guidance from the federal register
- Your internal analysis might require a more specific review, and multi-disciplinary input (clinical, legal/compliance, HIM, information systems, information security, etc.)

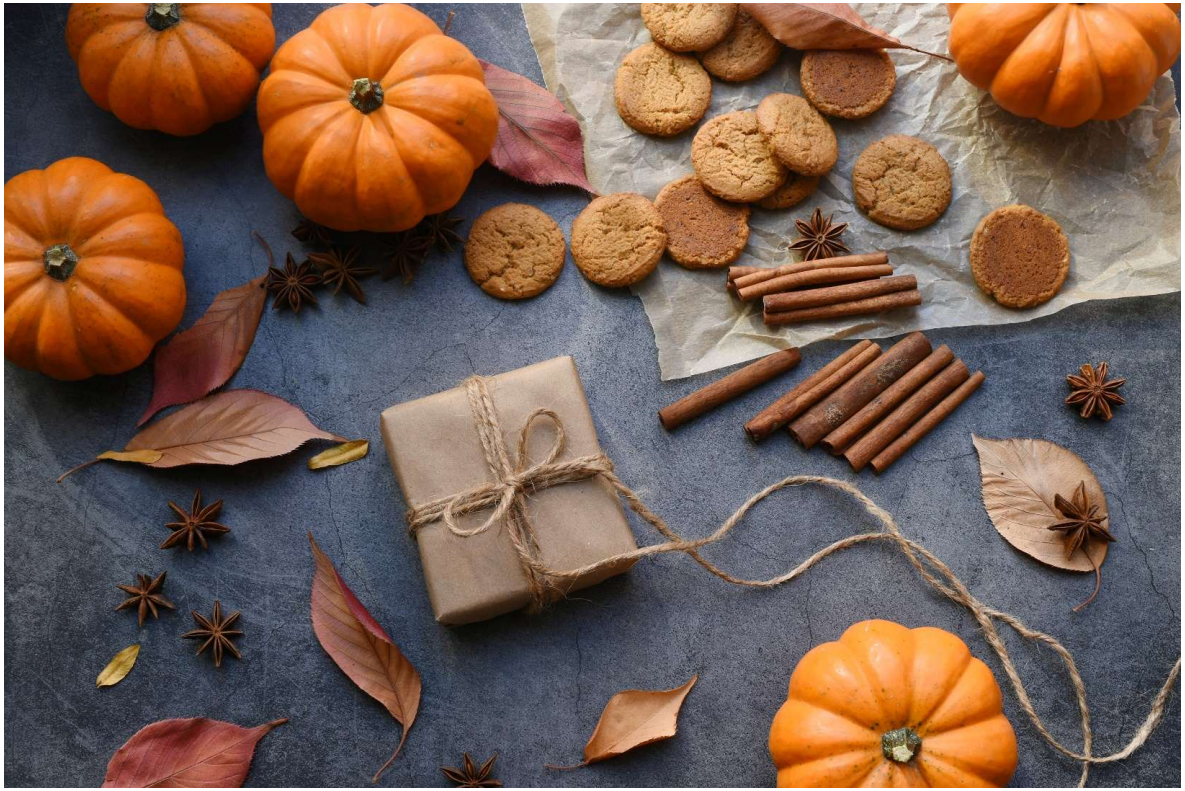
# Operational Tips: Information Blocking

- DO NOT interpret any part of Information Blocking as making it harder for patients to access their own records; do not add fees; do not add paperwork; do not add consent features
- **If you refuse a request for information sharing, you should be prepared to explain why (to a regulator – not always to the requester)**
- Be careful of out-of-state governmental requests
- Prioritize patient requests

# Quick Connecticut Official HIE Status Check

- 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 is expected to 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 (still in process)
- Unclear which providers will be allowed to access or how (still in process)

# 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)

# Resources

- 42 CFR Part 2:

Fact Sheet 42 CFR Part 2 Final Rule | HHS.gov

- Information Blocking notice information:

HHS Announces Crackdown on Health Data Blocking | HHS.gov

Information Blocking | HealthIT.gov