2023 Healthcare Year In Review

CMGMA November 3, 2023

Program Agenda

- COVID-19 response
- New Connecticut laws and requirements
- Update on reproductive healthcare and gender affirming healthcare rights and obligations
- Status check of the statewide HIE operations (CONNIE)
- Cyber security and Health IT update
- HIPAA recent enforcement activity
- Q&A

COVID-19 RESPONSE

FUTURE IMPACT ON PUBLIC HEALTH, DATA, AND TECHNOLOGIES

Public Health Activities And The COVID-19 Pandemic

- The public health infrastructure was insufficient to handle the COVID-19 public health emergency (PHE) including data technologies, analytics staffing, chain of decision-making
- Large scale discussion: How do we prepare better for "next time"?
- These calls to action are eerily similar to the time period immediately following the H1N1 PHE in 2009

Public Health Themes

- Outcomes were disproportionately worse for disadvantaged populations
- States' immunization information systems needed upgrades
- CDC and HHS need more routine data collection
- Ongoing debate on how to limit medical misinformation
- Ongoing debate about privacy of government obtained health information

Reality of Post-COVID PHE

- It is not feasible to operate in constant emergency mode; it's inefficient and extremely expensive
- It's impossible (or highly unlikely) we can guess what the next pandemic will be in a manner that allows for deep preparation
- Data collection is EXTREMELY time-consuming despite advanced EMR technologies; virtually impossible for non-institutional or health systems to participate in sophisticated data collection
- Telehealth will expand (payer driven) but this is complicated by multiple state laws

Other Considerations

- Examination of policies and ethical considerations needed
- Unclear what powers employer has to force vaccination; court cases are making their way through the legal system
- Unclear how long it will take to catch up on delayed and deferred care
- Unclear if more routine vaccination will be required
- Court challenges persist to test limits for government and employer mandates

2023 New Laws and Trends

Significant Legal Changes Affecting Healthcare in Connecticut

(the following is NOT an exhaustive list)

- Change of ownership rules: more red tape for selling, or transferring interest in, a licensed healthcare enterprise
- CON: more regulatory powers, made stricter
- Cytomegalovirus added to newborn screening program
- New protections for "consumer health data"
- Lead poisoning: more reporting, lower testing thresholds (this
 is to align and keep pace with increased federal level
 requirements)

Reimbursement Issues

- Medicaid/DSS to engage in comprehensive program planning
- Study on Medicare Advantage
- Stricter rules for insurer-provider contracts
- State will contract to retire certain medical debt (with ARPA funds)
- Broader facility fee limitations

- Expansion of vaccines pharmacists can administer (and order)
- More ability for pharmacists/pharmacies to provide emergency and hormonal contraception (note federal level issues persist)
- Reciprocal licensure discipline no longer automatic if related to out of state care that is legal in Connecticut (e.g. abortion providers)
- Protections for providers who offer or participate in assisted reproductive healthcare services

- Hospital medical staff appointments can be at 2 or 3-year intervals (prior law was limited to every 2 years)
- Hospital ability to restrict privileges based solely on Board Certification modified (5-year window for initial; full recertification not required)
- Hospitals nurse staffing plans more elaborate; nurse refusal to work more detailed; DPH oversight more involved

- NEW credentialing category for Surgical Technologists
- Study on the scope of practice for podiatrists, CRNAs and others
- APRNs from out of state may be able to practice independently sooner than prior law allowed
- New category of facility "birth centers" for low-risk pregnancies
- Study on access to medical records, fees and ease of use, including in legal cases
- Study of A.I. and controls that should apply

New, SHORTER, Record Release Deadline!! HIPAA's 30-Day Deadline Is Preempted For Transfer Of **Records Between**Institutional Care Settings In Specific

Circumstances

Not applicable to medical offices – only applies to licensed institutions (which is confusing)

Each Licensed Institution Must...

- Pursuant to Public Act 23-97 Section 43
- Upon receipt of a medical records request directed by the patient or the patient's representative
- Provide an electronic copy the patient's medical records to another institution in the following time frame:
 - If URGENT: as soon as feasible, and no longer than six days after request is received
 - NOT URGENT: no later than seven business days after request is received

Patient's Written Consent Not Needed

- "Notwithstanding any other state law" an institution providing an electronic copy pursuant to this law "shall not be required to obtain [the patient's] specific written consent"
- Plain meaning of this is that Connecticut laws that indicate or imply sensitive records that otherwise need written consent to be released can be ignored. [dangerous approach]
- Federal laws protecting SUD information still apply

Exceptions To The New Timeline

Institution is not required to release under this timeline:

- (1) In violation of HIPAA;
- (2) In response to a direct request from another health care provider, unless such provider can validate that such provider has a health provider relationship with the patient whose records are being requested; or
- (3) In response to a third-party request.

For these three instances, nothing changes in record release

Considerations

- Effective January 1, 2024
- Institutional providers: Policies and NOPP may need adjusting
- Portal information may need adjusting
- Looking at exceptions, determine what meets threshold for "unless provider can validate that such provider has a health provider relationship with the patient whose records are being requested"
- Non-institutional providers: be ready for more pressure on record release turn around
- This might be a "coming attraction" for all providers

Provider Testing Mandates

Mandates For Certain Providers To Offer To Test For HIV And Hep-C

Providers Must Offer HIV Tests

[Effective January 1, 2023] Each APRN, PA, and physician that provides primary care (defined in the law as family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics or primary care gynecology, without regard to board certification) is required to offer to provide, arrange for, or order an HIV test to **every patient 13 y.o./older**, unless the primary care provider reasonably believes the patient:

- 1. Is being treated for a life-threatening emergency
- 2. Has previously been offered or has received an HIV-related test
- 3. Lacks the capacity to consent to an HIV-related test
- All HIV testing, consent and privacy laws remain in place
- NEW: Effective January 1, 2024, hospital Emergency Departments will have a similar requirement

Providers Must Offer Hep-C Tests

- Previously, providers had to offer a HEP-C test to every patient born between 1945-1965
- **NEW Effective October 1, 2023:** Each APRN, PA, and physician that provides primary care (defined in the law as family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics or primary care gynecology, without regard to board certification) is required to offer to provide, arrange for, or order for **every patient 18 y.o./older, and all pregnant persons**, a HEP-C test unless the primary care provider reasonably believes the patient:
 - 1. Is being treated for a life-threatening emergency
 - 2. Has previously been offered or has received an HEP-C test
 - 3. Lacks the capacity to consent to an HEP-C test

Considerations HEP-C and HIV Testing

- Determine if your care setting qualifies
- Did you change to all patients 18 yo and up for HEP-C (13yo and up for HIV)
- Have staff been trained to do this routinely
- Who is actually offering when in the encounter process
- How are you documenting compliance
- Assess how to apply HIV privacy requirements
- Do you want to have prepared info on hand for patients

Accessibility of Diagnostic Medical Equipment

- Medical diagnostic equipment (different than DME) includes:
 - an examination table, or an examination chair
 - a weight scale
 - mammography equipment
 - x-ray, imaging and other radiological diagnostic equipment
- Connecticut law requires facilities, BEFORE buying any Medical Diagnostic Equipment [MDE], to first "take into consideration" the federal Access Board standards for MDE accessibility
- Non-facility providers will receive information notices from DPH about accessibility, and links to the Access Board standards
- FEDERAL LAW expected to change to require this almost universally in healthcare as part of Rehab Act (Sect. 504) – similar to ADA

CONSUMER PRIVACY

CONSUMER HEALTH DATA

Consumer Privacy

- Federal efforts to have a comprehensive, nationwide law for online consumer privacy have not been successful
- Since implementation of the California Consumer Privacy Act (CCPA) and California Privacy Rights Act (CPRA) other states have explored making their own consumer privacy laws
- These law usually focus on online services or cyber based data, but affect all data media
- Having cyber services, and the internet, controlled state-bystate will be difficult to manage

Core Purposes Of Consumer Privacy Laws

- To give consumers control over whether their data should be used, including the consumer's ability to:
 - Limit or direct uses
 - Opt out of use entirely
 - Force the holder of the information to destroy data
- To provide consumers with notice about how their data are being used

Consumer Privacy Laws v. HIPAA

- Connecticut's NEW consumer privacy laws have broad exemptions for HIPAA covered information but address HEALTH DATA that is outside of HIPAA
- Theory is that HIPAA already has a well-established privacy framework, but other settings (like retail stores and social media) are not regulated and can exploit peoples' health info
- There is wide-spread scrutiny in consumer rights circles that HIPAA is too weak to deliver effective privacy
- Consumer privacy laws provide an individual more control over data about them than HIPAA does

Healthcare Affected By Consumer Privacy Laws

CAUTION!

- Exemptions for HIPAA data are generally not sufficient to fully exempt a healthcare entity or provider from consumer privacy laws, the line between the two worlds is very thin
- Geofencing, informational apps, social media, public facing websites, bulk data, portals, and data tracking can all result in identifiable data
- Technology can convert what looks like anonymized data into identifiable data (e.g., tracking technology and big data)

Operational Tips: Consumer Privacy

- Identify instances where HIPAA may not cover the entire data set or address all planned uses of the data
- Focus on the source of the data and whether HIPAA controls are applied
- Marketing is a key focus area: consider whether purchased marketing list (or fundraising lists) qualify as consumer data
- Check with community partners (those outside of HIPAA)
 whether their data sharing and handling is affected

Reproductive Healthcare

Adjusting to Significant Legal Changes Affecting Providers and Patients

Dobbs Replaces Roe v. Wade

- Dobbs v. Jackson Women's Health Organization removes previously recognized constitutional right to privacy and bodily autonomy that had controlled U.S. law since 1973's Roe v.
 Wade case
- Reproductive rights no longer have nationwide protection
- Abortion (and related issues) now legislated state-by-state

States Scramble to Revise Laws

- Legal protections in Roe v. Wade were based on privacy rights
- Once those rights were extinguished by Dobbs, the law returned to whatever was "on the books" in each state
- Many states had "old" laws on the books that did not reflect their current position
- Many states had bans or partial bans on the books that were idle

In Anti Abortion States

- Enacting significant limitations and/bans on abortion
- Making it a crime to perform an abortion
- Making it a crime to seek or have an abortion
- Creating "bounty" laws
- Creating laws to punish citizens who seek abortion outside of the state

In Pro-Choice States

- Revising existing laws and regulations to stabilize Roe status quo, removing artifacts of older laws
- Creating "shield" laws for providers
- Addressing records privacy (harder than it sounds)
- Restricting non-essential government access
- Attempting to counterbalance "bounty" laws

Many Areas Of Confusion

- Patients from out of state
- Medication assisted abortions
- Legal risks to licensed professionals
- HIEs, data sharing, patient consent for release of information
- Telehealth and mail order access

Complicating Factors

- Many new laws use the terminology: "Reproductive care"
- Gender affirming care being swept into restrictions and protections
- Federal guidance has been equivocal and sporadic; no clear path to a uniform set of laws at federal level
- "Reproductive care" is a much broader category than abortion (Connecticut law definitions still not completely aligned)

Definition Reproductive Care For Subpoenas

 Connecticut law affecting release of records in legal proceedings defines "Reproductive health care services" as including "all medical, surgical, counseling or referral services relating to the human reproductive system, including, but not limited to, services relating to pregnancy, contraception or the termination of a pregnancy and all medical care relating to treatment of gender dysphoria as set forth in the most recent edition of the American Psychiatric Association's "Diagnostic and Statistical Manual of Mental Disorders" and gender incongruence, as defined in the most recent revision of the "International Statistical Classification of Diseases and Related Health Problems"

Connecticut Consumer Privacy Definition

For consumer privacy laws: "Reproductive or sexual health care" is defined as: "any health care related services or products rendered or provided concerning a consumer's reproductive system or sexual wellbeing, including, but not limited to, any such service or product rendered or provided concerning (A) an individual health condition, status, disease, diagnosis, diagnostic test or treatment, (B) a social, psychological, behavioral or medical intervention, (C) a surgery or procedure, including, but not limited to, an abortion, (D) a use or purchase of a medication, including, but not limited to, a medication used or purchased for the purposes of an abortion, (E) a bodily function, vital sign or symptom, (F) a measurement of a bodily function, vital sign or symptom, or (G) an abortion, including, but not limited to, medical or nonmedical services, products, diagnostics, counseling or follow-up services for an abortion."

Connecticut Reproductive Rights, Legal Protection For Records

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.

Subpoena Access Altered

- Connecticut law with special protection for reproductive health records is **about subpoenas** but is not intended to interfere with or affect the exchange of medical information in the normal course of patient care or for related uses and activities that are otherwise permitted by state and federal law.
- Examples of areas that are NOT impacted:
 - Treatment, payment, healthcare activities
 - Routine public health activities
 - Required reports to DPH, DCF, DSS, or other agencies

Bottom Line: Subpoena

- Do not release reproductive or gender affirming care information in response to a subpoena based on HIPAA satisfactory assurances
 - You need to seek a court order or obtain patient's express consent
 - This means you may need to challenge the subpoena in court or with an agency
- Keep in mind many records contain embedded sensitive information (in history, imported records, prior care, etc.)
- Keep in mind many litigation attorneys do not understand the intricacies of this – and may not realize the legal change

Practical Considerations

- Continue to watch for legal changes in reproductive care
- Review policies relating to:
 - Care delivery (do clinical staff understand the new environment; need training or info?)
 - Credentialing (reciprocal discipline in flux)
- Record releases should be more carefully assessed (always for subpoenas but be more careful with all requests)
 - The scope of records is not limited to abortion
 - Requestor and patient might not know what's in the record

Statewide HIE - Connie

Status Check

Connecticut Official HIE

- State-wide HIE (Connie) continues to evolve
- Currently, all providers are being required to sign up to connect
- Ongoing discussions about:
 - What data needs to be sent
 - What agreements have to be signed
 - What privacy rules apply
- Every provider needs a plan to engage and an understanding of what that entails
- Contact Connie if you have questions

Connecticut Official HIE

- Office for Health Strategy (OHS) and state's Health Information
 Officer (HITO) working on regulations
- There will be temporary "regs" as policies and procedures first
- Unclear what patient access is or will be
- Unclear which providers can access the database (only those that participate?)
- Patient Opt Out rules (and implciations) are complicated

Cyber Happenings

- Tracking Technology (Breaches?)
- Emerging Technologies, Eroding Trust

Big Data Tracking

CAUTION!

- 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)
- Multiple consumer and patient lawsuits pending
- Don't sleep on this: Every provider should assess for this (and consider remediation steps that might be needed)

Data Tracking As Potential HIPAA Violation

- The Office for Civil Rights OCR (OCR) is the lead agency tasked with HIPAA oversight at the federal level
- December 2022, (OCR) released lengthy guidance titled "Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates"
- The guidance contains a high-level discussion outlining HIPAA Privacy Rule issues
 - Not very technical
 - Lacks clear "next steps" guidance
 - Clarifies when business associate agreements must be in place

HIPAA Guidance

The main point of the December 2022 OCR guidance:

- "HIPAA regulated entities are not permitted to use tracking technologies in a manner that would result in impermissible disclosures of PHI to tracking technology vendors or any other violations of the HIPAA Rules."
- The OCR guidance is consistent with OCR's general, prior HIPAA Privacy Rule and Security Rule guidance – but signals a different urgency
- Most healthcare entities will look at this issue through a HIPAA lens
- Disconnect: Facebook and other social media sites often are not acting as HIPAA regulated entities, they may not be thinking in HIPAA terms
- AHA published a scathing response letter outlining weaknesses in OCR's position

Data Tracking: Lessons From FTC Activity

- Federal Trade Commission (FTC) has powers to enforce various consumer protections laws, including various consumer privacy law
- Generally, FTC does not enforce HIPAA, but oversees handling of personal health records and enforces aspects of online data use
- February 2023, GoodRx agreed to accept a \$1.5 million FTC penalty and to stop (or limit) sharing of consumer health data with third party apps or social media [outcome pending court approval]
- An interesting issue the FTC pointed out: GoodRx displayed a seal at the bottom of its telehealth services homepage *falsely* suggesting to consumers that it complied with HIPAA

Related FTC Activity

- March 2, 2023 FTC announced a fine of \$7.8 million and restrictions going forward against "BetterHelp" (an online counseling platform) for leaking or selling sensitive mental health information, to Facebook and other online/social media outlets for targeted advertising
 - BetterHelp used and revealed consumers' email addresses, IP addresses, and health questionnaire information to Facebook, Snapchat, Criteo, and Pinterest for advertising purposes
 - BetterHelp will be required to pay \$7.8 million for deceiving consumers after promising to keep sensitive personal data private

Lawsuits

- Multiple lawsuits being brought in various states and federal courts against hospitals and other healthcare providers (and social media platforms) claiming personal and/or medical information was improperly shared by hospitals and healthcare providers with social media and cyber companies, including Facebook (and then often used in advertising to the patient) through Data Tracking
- The allegations cover similar issues as discussed in the OCR guidance and FTC enforcement actions
- Some of the suits are "class actions," there will be multiple cases spread over several locations
- These cases and investigations are likely to continue for years

HIPAA Specific Considerations

- Organizational awareness of the OCR guidance and for the depth of the evolving situation
- Detection (initial and ongoing), remediation, documentation of response for identifies tracking technologies used in your systems, as discussed in the OCR guidance
- Assess need for external consultants, other resources
- Breach review and assessments
- Security Risk Assessments
- Business associate relationships

Software versus service

Emerging Issues In Health Data

Artificial Intelligence (A.I.) And Increasingly Eroding Trust

Reliance on Technology

- For a variety of valid reasons, providers and health insurers use and analyze data without express consent of patient/enrollee
- Providers and health insurers are encouraged to apply various technologies in innovative ways to:
 - Inform clinical decisions
 - Identify population and community health needs
 - Assist patients in finding resources
 - Avoid duplication of services
 - Create predictive analytics

Bias In Technologies

- Growing focus on whether technologies create, perpetuate, and or worsen bias and/or discrimination
- Not entirely surprising that technology incorporates the biases inherent from programming and in baseline data
- Further struggle between predictive analytics at the individual patient level and generalizations about populations or groups
- False underpinning using race as a major reference point for clinical decisions: race is a social construct not a biological factor and race is a very poor indicator of genetic issues affecting health

Current Examples Of Bias Baked Into Technologies

- Pulse-Oximeters that are more accurate when used on light skin than dark skin
- Embedded racist pseudoscience incorporated into kidney function testing; reliance on social factors instead of biological factors
- Using STONE score for assessing likelihood of kidney stone in ED patient presentations adds 3 points (of 13) if patient is "nonblack"
- Assuming non-white patients are not candidates for VBAC based on hugely flawed original data

Current Examples Of Bias Baked Into Technologies

- Using scoring analytics for organ transplant or crisis care
- Using predominantly male x-rays for training (skewing competency for future reads)
- Using predictive technology tools to make insurance coverage decisions for medical necessity based on an algorithm or software product (failing to assess at patient level)

A.I. and other technologies can be useful in reducing bias, but only if the upfront work is baked in

Considerations: Emerging Technologies

- Connecticut, other states, and federal government considering how to best regulate A.I. (healthcare will be affected)
- Ensure "bias" discussion is ongoing and multidisciplinary
- Do not deploy A.I. (or any new predictive analytics) without some level of human oversight
- Consult bias guidance from FDA, The Joint Commission, other national organizations
- Increase and/or improve diversity and cultural bias training overall

HIPAA ENFORCEMENT

Office For Civil Rights (OCR) Enforcement Activity

HIPAA Enforcement Number 1 Theme: Access

- OCR Resolution Agreements are very rare, but they provide significant insight into the issues that OCR feels are important to pursue
- Recently the most frequent reason (by far) for a Resolution Agreement is failure to provide access to an individual's own record
 - Access rights are essential rights
 - It is very rare a person does not have a right to access their own record
 - Failure to give a patient access can be a HIPAA violation and an Information Blocking Rule violation
- OCR has over 44 access-specific Resolution Agreements (and counting)

Interfering with a valid patient access request for their own records should be rare, only for legitimate and extraordinary circumstances, always carefully reviewed

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

Access Required: 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)

Information Blocking Informs HIPAA Access

- Information blocking rules discuss what parts of an electronic medical record must be disclosed to a patient or other authorized requester
 - Note a printed record from an electronic system is still "electronic" and must meet information blocking rules
- We know from Info Blocking Rules that the designated record set contains the USCDI elements
- USCDI elements include machine readable meta data such as provenance, date of entry, and author

When Can You Refuse To Release To Patient

- The primary legitimate reason a provider might withhold a record from a patient is for safety or to prevent harm
- This occurs more often with:
 - Mental health information
 - Family, personal or intimate violence or abuse situations
- Can be due to recordkeeping errors:
 - You would not want to release a record if realize WRONG patient info
 is stuck in the record
- Minors' records are more complicated

Recent HIPAA Oversight Issues (Non-Access Related)

 Inadequate Security Planning: Failure to have security policies in place, including failure to perform a Security Risk Assessment (SRA) or failing to perform routine security steps (this continues to be a widespread problem)

 Inadequate Security Awareness for staff: the most likely point of intrusion is the result of someone in the workforce clicking on a bad link or interacting with malware in an email; reduce these events by educating staff better

Recent HIPAA Oversight Issues (Non-Access Related)

- Responding to Online Reviews (frequency of failures is trending up)
 - This remains a problem area. Self-inflicted problem.

- Snooping (frequency of failures is trending up)
 - This was a huge focus years ago (breach of celebrity files; e.g.
 Michael Jackson and Farrah Fawcett)
 - It's back with a new focus on everyday patients
 - Enforcement example: Washington state health center security guards with access to medical records (fail)

Other Notable HIPAA Oversight Themes 2022-23

- Improper Disposal: Failure to render paper information, including labels and tags, unreadable before throwing in trash
 - Shred boxes should be the norm
 - Enforcement example: Lab threw out specimen vials with labels in them (fail)
- Ignoring Problems Will Be Punished: Harsher scrutiny of repeat failures for known issues (privacy or security), not remediating gaps, and failing to take OCR technical assistance advice
 - If you find gaps, you need a plan to address
 - If you find significant non-compliance, you need to correct ASAP

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

 Office of National Coordinator (ONC) tools and guidance on Information Blocking and 21st Century Cures Act – includes USCDI description:

www.healthit.gov

Resources Tracking Tools

December 2022 OCR tracking guidance:

- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html
- AHA Response:
- https://www.aha.org/lettercomment/2023-05-22-aha-letter-ocr-hipaa-privacy-rule-online-tracking-guidance

FTC activity posted on www.ftc.gov

- <u>FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising</u>
 | Federal Trade Commission
- FTC to Ban BetterHelp from Revealing Consumers' Data, Including Sensitive Mental Health Information, to Facebook and Others for Targeted Advertising | Federal Trade Commission