Health Law Webinar

Frequently Asked Questions

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What is the state of the PHE?

- Renewed for 90 days July 19th.
- Many telehealth and other waivers adopted in fee schedule through the end of 2021 and proposed to continue to 2022.

Can I require someone to wear a mask?

- Is there a reason that this requirement would be discriminatory against a protected class?
- Is there a general rule that requires you to provide services to the person? EMTALA?

Can we force employees to vaccinate?

- Yes. There likely should be religious and medical exceptions.
- There is an “undue hardship” on the employer test.
- https://www.fredlaw.com/news__media/question-of-the-day-mandatory-COVID-vaccinations/

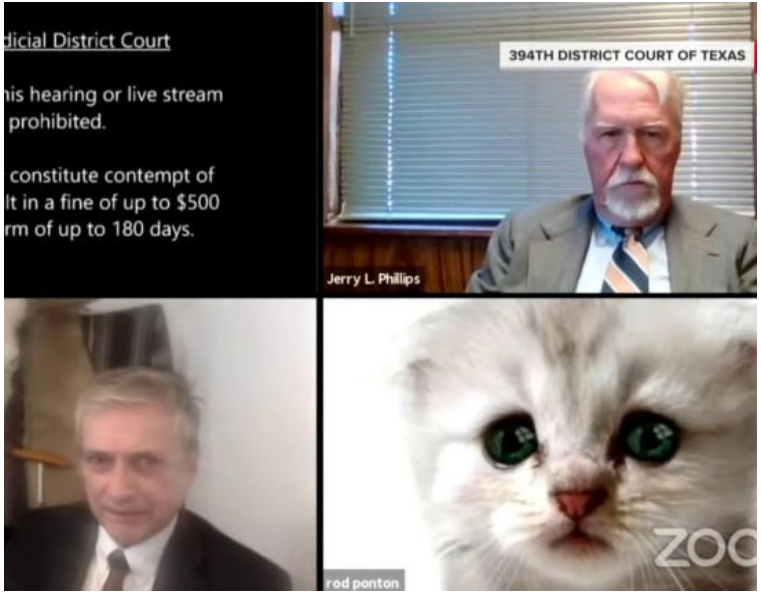
How does OSHA address COVID-19?

- Remember reporting obligations (for example, death of employee or inpatient hospitalization related to a work-related incident)
- OSHA issued an Emergency Temporary Standard (ETS) for the healthcare industry
  - Compliance deadline for the vast majority of the ETS's *sweeping* requirements is July 5, 2021.
- ETS obligates healthcare employers to conduct employee health screenings, make certain notifications re: COVID-19 exposures, and take steps to remove employees from the workplace.
- ETS also contains mandatory pay provisions for situations involving medical removal and vaccine side effects.

OSHA Exception

- Exception for “non-hospital ambulatory care settings” where all non-employees are screened for COVID-19 and denied access if COVID-19 is present or suspected.”
- Clinics, ASCs, etc. can meet this exception.
- https://www.fredlaw.com/news__media/question-of-the-day-new-COVID-19-healthcare-emergency-temporary-standard/?utm_source=fredlawemail&utm_medium=fredlawemail

Is working from home a reasonable accommodation?



Although any inquiry into the reasonableness of a disability accommodation is fact-specific, we do not expect remote work to become the new standard.

What is the future of telehealth?

- Category 1, Category 2, and Category 3. Category 3 is services allowed during the PHE.
- Proposed CY 2022 Medicare Physician Fee Schedule:
  - Category 3 telehealth services remain on the Medicare telehealth list until end of 2023.

What is the future of telehealth?

- Also proposed by CMS for CY 2022:
  - Revise definition of “interactive communications system” to allow for inclusion of audio-only services in certain circumstances:
    - Mental health treatment to patients in their homes;
    - Practitioner must have capability to do two-way audio/video;
    - Patient is not capable of, or does not consent to, the use video technology; and
    - In-person service within 6 months prior to audio-only mental health service and within 6 months after.

What is the future of telehealth?

- Q: Congress recently lifted the telehealth geographic restrictions for mental health services. Do you think the current flexibility that's in place for the PHE will expand outside of behavioral health when the PHE ends?

When the physician does telehealth from home, must we bill with that address?

- During COVID-19 the answer is a clear no.
- Before COVID-19 guidance said infrequently used locations needn't be enrolled.
- Enrolling homes is bad for EVERYONE. Privacy issues, administrative headaches, gaming the system. Let's stop it!!

Incident to/Shared Visits

- Q: Under the proposed rule, if a shared visit is based on time, how much time would the MD need to spend to meet a substantive portion?
  - More than 50%. But it is only proposed! Comment by 9/13!!! For instructions: https://www.govinfo.gov/content/pkg/FR-2021-07-23/pdf/2021-14973.pdf

Incident to/Shared Visits

- Same with documentation using MDM. Would you expect the MD to solely perform the MDM or if both an APP and MD contribute to the plan of care, how much is substantive?
  - As proposed, only time matters.

Incident to/Shared Visits

- Q: With the incident to guidelines currently being pulled down, can you speculate on the changes we might see coming?
  - Note that incident to rules are NOT affected by the proposal.

What is the difference between Medical Decision Making and Medical Necessity?

- Medical Decision Making is a point-based system for evaluating the complexity of a case.
- Medical Necessity is whether care was required.

Must I have certified health IT?

- Office of National Coordinator (ONC) FAQ response: “Again, the information blocking regulations do not require the use of any specific standard or functionality. Instead, the “Content and Manner” exception (45 CFR 171.301) outlines a process by which an actor may prioritize the use of standards in fulfilling a request for EHI in a manner that supports and prioritizes the interoperability of the data. This means that, for the purposes of information blocking, before October 6, 2022, an actor may fulfill a request with the EHI identified by the data elements represented in the USCDI standard, first in the manner requested and, if not, in an alternate manner agreed upon with the requestor, following the order of priority specified in the exception.”

Do I have to have a patient portal?

- No.
- An ONC FAQ makes this clear: “There is no requirement under the information blocking regulations to proactively make available any EHI to patients or others who have not requested the EHI. **We note, however, that a delay in the release or availability of EHI in response to a request for legally permissible access, exchange, or use of EHI may be an interference under the information blocking regulations…**”

How quickly do I actually need to respond to information requests?

- How much time before there is a “delay”?
- Hint: Waiting the full 30 days permitted under the HIPAA Privacy Rule (an outer limit) may very well be a “delay” for information blocking purposes.
- FAQ: “When a state or federal law or regulation… requires release no later than a certain date after the request is made, is it safe to assume that…release within that other required timeframe will never be considered information blocking?”

How quickly do I actually need to respond to information requests?

- Answer: “The information blocking regulations have their own standalone provisions. The fact that an actor…meets its obligations under another law…will not automatically demonstrate that the actor’s practice does not implicate the information blocking definition. If an actor who could more promptly fulfill requests for legally permissible access, exchange, or use of EHI chooses instead to engage in a practice that delays fulfilling those requests, that practice could constitute an interference under the information blocking regulation, even if requests…are fulfilled within a time period specified by a different applicable law.”

May an actor wait to release test results until the physician has seen them?

- ONC FAQ: “It would ***likely*** be considered an interference…if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results.”

May I hold back clinical notes until they are finalized by the practitioner?

- ONC FAQ: “It depends. Draft clinical notes and laboratory results pending confirmation are . . . examples of data points that may not be appropriate to disclose or exchange until they are finalized. However, if such data are used to make health care decisions about an individual then that data would fall within the definition of “designated record set,” and therefore within the definition of EHI. To the extent a data point falls within the definition of EHI, practices likely to interfere with legally permissible access, exchange, or use of that EHI could implicate the information blocking definition. . . .”

What do I do about a call from the BMP?

- Physician gets a call advising that a car in Texas was found with information from the physician and a lot of oxy.
- They are told other members of the group are under investigation and should not be consulted.
- Their license is being suspended.
- An offer to fax a letter with the BMP logo and address. The FBI then joints the call.

What is the Medicare Inpatient Only (IPO) list?

- 1,700 procedures that Medicare will pay for if care takes place in a hospital inpatient setting

Is the IPO still alive?

- 2021 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule.
  - IPO list phased out over 3 years (by CY 2024).

It’s alive!

- CMS proposed in 2022 OPPS and ASC Rule (86 FR 4 2018):
  - Put back the 298 services removed from IPO list in CY 2021.
  - Halt 3-year phase out.
  - Codify in regulation the 5 longstanding criteria used to determine whether a procedure/service should be removed.

Stark and Amendments

- Q: If we amend the payment terms in a contract after the contract has been in place for over 1 year, do those new rates need to remain in place for one year?

Stark and Amendments

- Differentiate between termination and amendment.
- If you terminate during the first year, can't do a new agreement until the anniversary.
- Amendment permitted if PROSPECTIVE and meets the terms of an exception.

What are the new limits on group practice compensation?

- As of 1/1/22:
  - All DHS revenue for the group/subgroup must be aggregated.
  - Subgroups must have at least five physicians.
  - The same allocation methodology must be used for all DHS.
  - This now applies to non-Medicare DHS revenue.
- Stark does NOT require equal division of DHS.

Productivity Bonuses In Group Practice*

- Can credit for services personally performed or incident to if not directly related to volume on the value of referrals (may directly relate for incident to).
- Deemed not to relate to the volume or value if:
  - Personally performed by the physician,
  - Not DHS and not considered DHS if payable by Medicare, or
  - Revenues from DHS are less than 5% of total revenue and each physician's compensation.

* You need to be sure you are a group practice!!!!

Options for DHS Under the Compensation Formula

- Productivity (RVUs, visits etc.).
- Choose an allocation and stick with it.
- Equal division.
- Seniority.
- Any combo of above, provided it is used consistently for all DHS within the group/subgroup of 5. This is a BIG change.
- Anything else unrelated to creating the plan of care.
- Don’t forget state law!

We submitted information to the government but haven’t heard back. Shouldn’t we call them?

How far back must I go when I refund?

- People focus on the 6 years in the 60 day rule.
- That applies when there is an overpayment. There is a 48 month limit on reopening absent “fraud or similar fault.” (Don’t forget SSA § 1870).
- Medicaid and private payors are different.

What is the corporate practice of medicine (CPM) doctrine?

- State law.
- Prohibits corporations/business entities from engaging in the practice of medicine.
- Generally, this means no employment of MDs by unlicensed individuals or corporations not formed and owned by MDs.
  - Different states extend to other practitioners.

Am I practicing medicine?

(1) What state(s) are at issue?

(2) Does the state have a CPM prohibition?

- Not all do! Check: statutes (Medical Practice Act), regulations, court decisions, AG opinions, and state medical licensing board decisions/opinions.

(3) Who does the CPM apply to?

- MDs? RNs? NPs? DMDs/DDSs?
- Business types: Professional corporations, multi-service corporations.

(5) Is there an exception?

HIPAA & State Law

- Generally, HIPAA governs unless state law is stricter.
- HIPAA privacy rules (45 CFR § 164.501 et seq.) and state laws prevent disclosure of PHI unless certain conditions are met.

Step 1 – Who signed the subpoena?

- Court order, warrant, subpoena (signed by a judge or magistrate).
- Subpoena (signed by an attorney or court clerk).
- Administrative subpoena, summons, or investigative demands.
- Health oversight agencies (state licensing boards, CMS, OIG, etc.).

Step 2 – Is it valid?

- Out-of-state requests are often invalid.

Step 3 – Does HIPAA apply here?

- Are you a covered entity?
  - HIPAA does not apply if Provider is not acting in capacity as healthcare provider (e.g. employer).
- Is the requested information PHI?

Step 4 – What is the obligation to comply?

- Court order, warrant, or subpoena signed by a judge or magistrate:
  - Comply with the terms of the request. No more, no less.
  - 45 CFR § 164.512(e)(1)(i) and (f)(1)(ii).

Subpoenas signed by lawyer:

Disclose only if one of the following is satisfied:

1. Provider notifies the patient that the Provider is required to respond unless the patient quashes the subpoena and notifies the Provider before the deadline for responding to the subpoena. (45 CFR § 164.512(e)(1)(vi)).
2. Provider receives a "satisfactory written assurances" from the attorney issuing the subpoena that either: (a) a good faith attempt was made to give the patient written notice of the subpoena, the notice included sufficient information to permit the patient to object to the subpoena, and the time for raising objections has passed or the court ruled against the patient's objections; or (b) the parties have agreed on a protective order or the attorney seeking the information has filed for a protective order. (45 C.F.R. § 164.512(e)(1)(iii)-(iv)).
3. Subpoena is accompanied by valid HIPAA authorization executed by the patient. To be valid, the authorization must contain the elements and statements required by 45 CFR § 164.508.

Step 5 – What other laws apply here?

- Mental health records.
- Drug/alcohol treatment records.
- State laws relating to patient privacy, attorney–client privilege, peer review privilege.

Step 6 – Retain

- The Provider should maintain a copy of the subpoena, order or warrant, and document the facts of the disclosure in the Provider's disclosure log required by 45 CFR § 164.528.

What Is “Direct Supervision”?

- 410.32(b)(3)(ii): “Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.”
- Defined more by what it is NOT, rather than what it IS. Not “in the room.” But where?

Office Suite?

"We are not proposing that there must be any particular configuration of rooms for an office to qualify as an office "suite." However, direct supervision means that a physician must be in the office suite and immediately available to provide assistance and direction. Thus, a group of contiguous rooms should in most cases satisfy this requirement. We have been asked whether it would be possible for a physician to directly supervise a service furnished on a different floor. We think the answer would depend upon individual…

Office Suite?

…circumstances that demonstrate that the physician is close at hand. The question of physician proximity for physician referral purposes, as well as for incident to purposes, is a decision that only the local carrier could make based on the layout of each group of offices. For example, a carrier might decide that in certain circumstances it is appropriate for one room of an office suite to be located on a different floor, such as when a physician practices on two floors of a townhouse."

– 63 Fed. Reg. 1685, Jan. 9, 1998

We want to do diagnostic tests for outside patients. Should we be an IDTF?

- Deleted Manual text said that if a “substantial portion” of an entity’s business was from outside tests, you “may” need to be an IDTF.
- There are icky limits on IDTFs. No direct solicitation of patients, limits on sharing space, etc.

Can we treat out-of-network patients as in-network?

- New Jersey court ruled against Health Net and for the physicians in an ASC dispute where ASC waived co-insurance. State law forbid dentists from waving co-insurance. Garcia v. Health Net of New Jersey, Inc., No. A-2430-07T3, 2009 BL 295398, 2009 WL 3849685 (N.J. Super. Ct. App. Div. Nov. 17, 2009).

Can we treat out-of-network patients as in-network?

- Compare this with North Cypress Medical Center Operating Co., Ltd. v. Cigna Healthcare, 781 F.3d 182 (2015)781 F.3d 182, 197, (5th. Cir. 2015), holding that limiting the patient's liability limited the plan's liability in the same fashion.

Requirements Related to Surprise Billing; Part I

- July 13, 2021, DHS, DOL, USDT, & OPM published interim final rule.
- Related to Title I (the No Surprises Act) of Division BB of the Consolidated Appropriations Act, 2021.

What is surprise medical billing?

- Surprise medical bill = unexpected bill from provider or facility.
- “Balance billing” = out-of-network provider bills individual for difference between the billed charge and the amount paid by plan/insurance.

What does the IFC do?

- No surprise billing for certain items and services.
- Limits cost sharing for out-of-network services.
- Sets out-of-network rates.
- Consumer notices – Health care providers and facilities required to make publicly available, post on website, and provide individuals with a one-page notice about state balance billing limitations/prohibitions, requirements under Public Health Service Act, and how to report violations.

Who does this rule protect?

- Individuals with coverage through employers (including federal, state, or local government).
- Federal Marketplaces, state-based Marketplaces, or directly through an individual market health insurance issuer.
- It does not apply to people with coverage though Medicare, Medicaid, Indian Health Services, Veterans Affairs Health Care, or TRICARE (already prohibit balance billing).

Next Steps

- Effective January 1, 2022.
- More to come during our November webinar.

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