Frequently Asked Questions

Health Law Webinar

August 14, 2024

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What Is All Of This Talk About Chevron?

- At least three big decisions this term.
- Loper involves deference to an agency. Chevron required deference. Loper permits courts to exercise independent judgment.
- Corner Post says the APA's six-year statute of limitations only runs once the injured party is affected.
- Jarkesy says juries, not ALJs must impose fines unless the case meets the "public rights" exception.

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What's Up With Telehealth? Proposals:

- Delay frequency limits for subsequent nursing facility in inpatient visits for another year.
- Permit audio-only communication or services to a beneficiary's home.
- Everything else expires unless Congress acts.
- Permit the distant site practitioner to use enrolled practice location instead of home address when doing telehealth from home.*

*Not really a "proposal!"

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Where Is A Service Provided?

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Where Is A Service Provided?

- Remarkably little guidance. MLN MM 7631, page 9 says that “If the professional interpretation was furnished at an unusual and infrequent location for example, a hotel, the locality of the professional interpretation is determined based on the Medicare enrolled location where the interpreting physician most commonly practices.”
- Regulations are silent.
- Shouldn’t the government worry about arbitrage? The patient’s location should not control.

Are You Required To Document Why A Visit Was Audio Only?

- Does CMS still intend to stop coverage for audio only 1/1/25? Is this final?
  - The proposal would extend coverage. Requirements are to be determined.

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Can I Offer Free Transportation Within A System?

- Free transportation gets a bad rap.
- No one questions bringing a service to the patient.
- Why is bringing the patient to the service different?
- Free transportation to a medical site is more complicated.

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Asking For A Friend: A RAC Unexpectedly Had No Findings. Is This Related To Chevron?

- Sometimes audits surprise you.
- Unlikely it is Chevron related.

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Who Can Do Transitional Care Management (TCM) Calls?

- Clinical staff under direction may perform the follow up call within two days of discharge.
- Clinical staff means someone who is supervised by a physician or other qualified healthcare professional and is allowed by law, regulation, and facility policy to perform or assist in a specialized professional service, but does not individually report that professional service.
- Sometimes ambiguity is your friend.

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Who Can Supervise Annual Wellness Visits (AWV)? Can An NP Supervise?

- 42 CFR § 410.15(b) states that Medicare Part B covers first and subsequent AWVs if they are furnished by a "health professional" to an eligible beneficiary. In this context, "health professional" is defined to include the following:

  (i) A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or

  (ii) A physician assistant, ***nurse practitioner***, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); or

  (iii) A ***medical professional*** (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, ***working under the direct supervision (as defined in § 410.32(b)(3)(ii)) of a physician*** as defined in paragraph (i) of this definition.

- What does it mean to furnish? What about delegating common sense components of the AWV?

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AWVs, Continued…

- Guidance:
  - March 2012 CMS FAQs: **"Does the supervising physician have to be in the same room with the patient to meet the requirements for Direct Supervision for the Initial Preventive Physical Exam and Annual Wellness Visit?** To meet the Direct Supervision requirement, the physician or non-physician practitioner who is billing Medicare for the service must be present in the office suite and immediately available to provide assistance and direction throughout the time the service is being provided, but they do not have to be in the room where the services are being furnished." (Emphasis added.) https://www.cms.gov/outreach-and-education/outreach/npc/downloads/ippe-awv-faqs.pdf
  - April 2024 NGS FAQs: "**(9) If a "medical professional" (e.g., RN) is performing an AWV, does this require physician supervision? Or can supervision be provided by a PA or NP? Answer:** When an RN performs any element of an AWV, supervision by a physician, NP, or PA is required. The supervising provider must be physically present in the office suite and immediately available to the RN." https://www.ngsmedicare.com/hu/evaluation-and-management?selectedArticleId=828074&lob=96664&state=97178&rgion=93623

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Are You SURE New Problems Can Be Considered Incident To??

- The conventional wisdom is that “new problems” can’t be done incident to.
- While nearly everyone accepts this as a given, it is absolutely clearly wrong. There is no regulatory ambiguity at all!

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42 C.F.R. § 410.26(b)

- Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner)…..
- (2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of **diagnosis** or treatment of an injury or illness.

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MBPM Chapter 15 § 60.1.B

- Thus, where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician.

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“Course of Treatment*” MBPM Chapter 15 § 60.1.B

- This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment*.

*What happened to diagnosis???

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What Is A “Course of [Diagnosis or] Treatment”?

- Patient receiving chemo, develops an infection.
- A derm patient comes for their annual mole check.
- Child has a series of ear infections. What if they now get strep throat?
- Is the course of diagnosis broader?
- **NEITHER THE REGS OF THE MANUAL MENTION “NEW PROBLEM.”**

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What Is Direct Supervision?

- Through the end of 2024 (likely 2025!) availability via smartphone!
- ***Direct supervision*** in the office setting means the physician (or other supervising practitioner) 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 (or other supervising practitioner) must be present in the room when the procedure is performed. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

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Must We Give A GFE To An Out-Of-Network Patient Who Is Pre-Paying?

- GFE currently only required for patients who are not using insurance to pay for a claim.
- Note that final rules for insured patients may be forthcoming.
- If the patient isn't going to USE their insurance, GFE is necessary.
- When in doubt, GFE it!

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Can We Find Out What Our Competitors Are Paid?

- If you aren’t using price transparency data, you are missing out.
- It has always been legal to KNOW what others charge. The antitrust issue is AGREEMENT.
- Price transparency makes hospital data readily available.
- The insurers are mining this data. You should too.

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Can We Do A Cash Only Service?

- Of course. But can Medicare patients use it?
- Social Security Act Section 1848(g)(4) requires the submission of claims for all services provided to Medicare beneficiaries.
- 45 CFR § 164.522(a)(1)(vi) provides that:
  - A covered entity must agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:
  - (A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and
  - (B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full. (underlining added).

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One Provider In Our Group Practice Wants To Opt-Out, Can They?

- Yes. Opting out of Medicare happens at the individual and not group level.
- It's a commitment of 2 years (with a 90-day window to change your mind during your first opt-out cycle).
- Must enter private contracts with any Medicare beneficiaries.
- What about Medicare Advantage? Private contracts are required there, too.
    - "Except as provided in § 405.440, no payment may be made directly by Medicare or by any Medicare Advantage plan to the [opted out] physician or practitioner or to any entity to which the physician or practitioner reassigns his right to receive payment for services." 42 C.F.R. 405.425.

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Is This Consistent With The "Mandatory Claims Submission" Statutory Language?

(4) PHYSICIAN SUBMISSION OF CLAIMS.—

(A) IN GENERAL.—For services furnished on or after September 1, 1990, within 1 year after the date of providing a service for which payment is made under this part on a reasonable charge or fee schedule basis, a physician, supplier, or other person (or an employer or facility in the cases described in section 1842(b)(6)(A))—

(i) shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of a beneficiary, and

(ii) may not impose any charge relating to completing and submitting such a form.

(B) PENALTY.—

(i) With respect to an assigned claim wherever a physician, provider, supplier or other person (or an employer or facility in the cases described in section 1842(b)(6)(A)) fails to submit such a claim as required in subparagraph (A), the Secretary shall reduce by 10 percent the amount that would otherwise be paid for such claim under this part.

(ii) If a physician, supplier, or other person (or an employer or facility in the cases described in section 1842(b)(6)(A)) fails to submit a claim required to be submitted under subparagraph (A) or imposes a charge in violation of such subparagraph, the Secretary shall apply the sanction with respect to such a violation in the same manner as a sanction may be imposed under section 1842(p)(3) for a violation of section 1842(p)(1).

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I Work At Multiple Clinics, Can I Accept Medicare At One And Not The Other?

- Enrollment in Medicare is at the individual provider level. If you enroll as a participating provider, you agree to accept assignment for all Medicare patients you see, regardless of where you see them.
  - If you are participating and you see Medicare patients at both clinics, you must accept Medicare at both clinics.
  - You can, however, choose not to see Medicare patients.
- Similarly, a Medicare Opt-Out is at the individual provider level. When you opt-out of Medicare, you are not allowed to bill Medicare for any services (with the exception of emergency services).
  - If you opt out, that applies at every clinic or facility at which you provide services.

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How Long Do We Need To Retain Patient Records? How Long Should We?

- Contrary to popular belief, HIPAA does not set a record retention requirement.
- State laws may set a clear rule or imply patient ownership:
  - Laws governing patient rights to access and receive records.
  - Regulated providers may have licensing requirements.
- Medicare enrolled providers and suppliers must keep the following for 7 years after the date of service:
  - Written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.
- Consider your potential legal liability (False Claims Act = 10 years).
- When in doubt, no less than 10 years.

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Poll: How Far Back Must You Go When Refunding Medicare?

- Forever.
- 10 Years.
- 6 years.
- 5 years after the year in which payment was made.
- 4 years.
- 3 years.
- 1 year.

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What Does The Baylor Settlement Mean?

- Government declares it is the “largest teaching physician settlement” at $15 million.
- Involved some certifications that the physician was present for the entire procedure for two simultaneous cases.
- Lessons include:
    - Mind the template.
    - Sometimes relators/enforcers take aggressive, but incorrect positions. We must push back.

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The Teaching Physician Rule

- Medicare pays hospitals for training residents. When there is Graduate Medical Education (GME) payment, pretend the resident didn't exist.
- When the resident is "off" the GME clock, if they are licensed, they are just a physician.
- Most other payors don't pay for GME, so there isn't an equivalent limit on billing.
- For Medicare, there is a documentation requirement!

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42 CFR § 415.172(b)

- The medical records must document that the teaching physician was present at the time the service (including a Medicare telehealth service) is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

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Doctors Must Personally Document Right? Can We Use A Scribe?

42 § 410.20 Physicians' Services

- Medical record documentation. The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

Can An NPP Supervise A Resident?

- If we're talking billing, this is the wrong question.
- Remember Fruit Loops! Can we DO it and can we BILL for it are different.
- Billing is about the billing professional's WORK, not supervision.

Medical Students

- Like a medical assistant or other unlicensed individual.
- They can document. Their exam doesn’t count.
- Functionally, they are a scribe.
- Various purported limits on scribes are baseless.

What Must The Doctor Document In A Split/Shared Visit?

- People often make things up.
- There are few times where a specific person must document a specific thing.
- While split/shared is one of those rare situations, the requirement is much narrower than many insist.

Split Shared

- Background: Merely “policy” (subregulatory guidance) in the Manuals until that was withdrawn in May 2021.
- Shared visit reg in 2022 PFS final rule (86 FR 65150-65159), 42 CFR § 415.140.
- Don’t get lost in semantics. Co-visits are totally fine in the clinic! As CMS says, “In the non-facility (for example, office) setting, the rules for “incident to” billing apply under this circumstance.” (See 88 FR 78818, 78982). Functionally the same as shared visits, with different lingo and fewer requirements!

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42 CFR 415.140

- *Facility setting* for purposes of this section means institutional settings in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under§ 410.26(b)(1) of this subchapter.
- *Split (or shared) visit* means an evaluation and management (E/M) visit **in the facility setting** that is performed in part by both a physician and a nonphysician practitioner who are in the same group, in accordance with applicable law and regulations such that the service could be billed by either the physician or nonphysician practitioner if furnished independently by only one of them.

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42 CFR 415.140

- *Substantive portion* means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit, **or** a substantive part of the medical decision making except as otherwise provided in this paragraph. For critical care visits, substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit.

42 CFR 415.140

(b) *Conditions of payment.* For purposes of this section, the following conditions of payment apply:

(1) *Substantive portion of split (or shared) visit.* In general, payment is made to the physician or nonphysician practitioner who performs the substantive portion of the split (or shared) visit.

(2) *Medical record documentation.* Documentation in the medical record must identify the physician and nonphysician practitioner who performed the visit. The individual who performed the substantive portion of the visit (and therefore bills for the visit) must sign and date the medical record.

(3) *Claim modifier.* The designated modifier must be included on the claim to identify that the service was a split (or shared) visit.*

*The FS modifier is used.

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CMS Inserted A Landmine In Preamble

- “Although we continue to believe there can be instances where MDM is not easily attributed to a single physician or NPP when the work is shared, we expect that whoever performs the MDM and subsequently bills the visit would appropriately document the MDM in the medical record to support billing of the visit.” 88 FR 78985
- Nothing in the regulation requires a particular person to document any more than a signature and date. This sentence is rogue, and will cause trouble. I am going to ignore it.

My Vendor Experienced A Breach – Whose Job Is It To Notify Patients?

- Covered entities are responsible for ensuring that HHS, affected individuals, and, where applicable, the media, are timely notified of the breach of unsecured PHI.
- A covered entity may **delegate** to its business associate the tasks of providing the required breach notifications on the covered entity's behalf.
- Only one entity—which could be the covered entity itself or its business associate—needs to complete notifications to affected individuals, the HHS Secretary, and where applicable the media.
- What does your BAA say?

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I Hear I Need To Update Our NPP – When?

- Assess whether you need to update your Notice of Privacy Practices (NPP) for the Reproductive Health Rule, the new Part 2 Final Rule, or both.
- By **February 16, 2026:**
  - All HIPAA covered entities must update their NPP to: (i) state that the covered entity will not use or disclose PHI for the Prohibited Activities and include one example of the type of use or disclosure that is prohibited; and (ii) include a description and example of the types of activities that require an attestation.
  - All Part 2 Programs must update their "Patient Notice" to mirror elements pf the HIPAA NPP, including the header, a description of patient rights, Part 2 Program duties, and process for filing complaints.
- Model forms from HHS are anticipated…

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Part 2: Can Our General Consent For TPO Be Included In Our Standard Consent Intake Forms?

- Yes.
  - Other Part 2 consents cannot be combined (e.g., SUD Counseling Notes and or disclosures related to a civil, criminal, administrative, or legislative investigation or proceeding).
- Make reasonable effort to comply with requested restrictions:
  - We draw attention to the Sense of Congress expressed in the CARES Act that “[c]overed entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding such use or disclosure,” and we encourage part 2 programs to do so as well. We believe that this language makes it clear that reasonable effort is expected and that it may be balanced by what is feasible. We believe that a program should not condition treatment on a TPO consent unless it has some capacity to fulfill patients' requests for restrictions on uses and disclosures for TPO such that “every reasonable effort” has some meaning. We are finalizing as proposed in § 2.22 a requirement to include in the Patient Notice a statement that the patient has the right to request restrictions on disclosures for TPO and in § 2.26 a patient's right to request restrictions.

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What About Fundraising Communications?

- When obtaining a patient's TPO consent, the Part 2 Program must provide the patient the opportunity to elect not to receive fundraising communications.
  - “A part 2 program may use or disclose records to fundraise for the benefit of the part 2 program only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications.”
- HIPAA requires fundraising communications to include the opportunity to opt-out of any further fundraising communications.
- For Part 2, health care operations is defined by cross-referencing HIPAA, but the above caveat essentially carves out fundraising for Part 2.

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Do I Need To Update My BAAs?

- For Part 2 Programs:
  - It's a good time to confirm your BAAs qualify as QSOAs, and vice versa.
- For Covered Entities:
  - Certain requirements apply directly to business associates (e.g., the attestation requirements).
  - Consider allocating respective responsibilities when either party receives requests for disclosures of PHI regarding an individual's reproductive health care.
  - "The modifications in this final rule may require regulated entities to revise existing business associate agreements where such agreements permit regulated entities to engage in activities that are no longer permitted under the revised Privacy Rule. Regulated entities must be in compliance with the provisions of this rule by December 23, 2024."

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What Else Should We Be Doing?

- Update your HIPAA privacy compliance policies and procedures
- Retrain staff to understand, as applicable:
  - When information regarding reproductive health care may and may not be provided to law enforcement entities and other officials (soon); and
  - The more expansive Part 2 changes (by February 2026).
- Update release of information/authorization and consent forms to conform with new requirements.
- Part 2 providers who are not covered entities may have more work to do.

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