Health Law Webinar

Health Law FAQ: COVID-19 and More

August 12, 2020

Fredrikson & BYRON, P.A.

What is the status of the public health emergency?

- While extended 7/25 for 90 days, that does NOT guarantee another 90 days of emergency!
- “It’s over when I say it’s over…”
- The fee schedule may be an attempt to help with SOME of the issues.


Perfection
SNACKS
Snack Mix
A Gluten-free Snack Mix of Cheddar
Chips, Pretzel Twists and Cheese Curls
UD

What is the state of telehealth?

- There are many layers.
  - Medicare.
  - Medicaid.
  - State licensure requirements.
  - Prescribing controlled substances.
- Tune in September 16, 2020.

May I perform a telehealth visit for a patient in a state where I am not licensed?

- The answer has always been, and still is, “It depends.”
- Look to the licensing laws of the state where the patient is located.
- State licensure waivers may have ended, may be extended, and may now be permanent.

If the answer is not clear, what factors mitigate the risk?

- Insurance coverage – yours and the patient's.
- Established patient versus new.
- Prescribing versus no prescription.
- Frequent versus occasional.
- Temporarily in the state versus permanently.
- Patient's condition – acuity, safety of remote treatment.

What is the state of audits and appeals?

- It’s all informal.
- CMS is encouraging flexibility, but you have no right to extension.
- Be sure to have proof of any extension.
- Try to keep records of instructions.

Our lawyer told us to self-disclose an issue. Should we?

- There is nothing wrong with getting a second opinion!!!!
- Better to check first, but you can appeal from a voluntary refund!
- You can't "appeal" after entering the self-disclosure protocol.

Should we document that the visit is mid-PHE?

- The date of service does much of this.
- Did COVID-19 impact the encounter?
- Patient-specific info may save you.
- Is a missing exam treated like a missing history?

Our documentation is crummy. Are we toast?

- Documentation is generally not REQUIRED.
- Take any chance to improve it.
- Clearly identify edits/changes.

Do I need a CLIA certificate to do on-site testing at an employer?

- If it is COVID-19 testing, during the PHE they are exercising discretion to allow testing under current CLIA certificates.

What's going on with CMS's 340B payment cuts?

- In 2017, CMS proposed to cut drug payments to 340B hospital departments paid under the OPPS by 28.5%; the cuts began in 2018.
- In May 2019, the lower court said the cuts were illegal.
- On July 31, 2020, the D.C. Circuit upheld CMS's payment policy, which purported "to avoid reimbursing these hospitals at much higher levels than their actual costs to acquire the drugs."

What's going on with the site-neutral payment policy?

- As of January 2019, CMS paid off-campus outpatient clinic visits the same as (no longer more than) freestanding physician clinic visits.
- Lower court ruled the policy was unlawful.
- In July 2020, D.C. Circuit panel reversed the lower court, ruling that the site-neutral payment policy was lawful.

Do I need a positive test to bill with a COVID-19 modifier?

- The short answer is no.

A Medicare patient presents at the ED with COVID-19 symptoms. Can the CS modifier be applied?

- Maybe, if a COVID-19 test is ordered or administered.
- Services can be provided via telehealth.
- What if a test is ordered but not administered?

Can the CS modifier apply to a diagnostic test (i.e. chest x-ray)?

- E&M codes for Medicare beneficiaries.
- Potential for different cost-sharing requirements between private insurance and Medicare.

My hospital is investigating a claim of potential fraud. My communications with our coding consultant are privileged, aren't they?

- Privilege applies to communications with an attorney for the purpose of obtaining legal advice.
- Privilege may apply to consultants who (1) assist in understanding/interpreting complex principles or (2) are the functional equivalent of an employee.
- Work-product doctrine may apply to materials prepared in anticipation of litigation.

Should we have an investigations policy?

- When do policies help and when do they hurt?
- Policies make the most sense for counterintuitive rules, and situations where people will actually look for a policy. FAQs with standard answers are also good subjects.

Do I need to worry about the price transparency rule?

- Are you a hospital?

Do I need to worry about the price transparency rule?

- Are you a hospital? YES!!!!!
  - At least the penalties aren't bad to start.
- Are you a clinic, HHA, SNF or any other non-hospital? No, but…

A hospital underbilled a physician clinic. Do you need to do a Stark Self-report?

- You want to study the 10/17/19 Federal Register, 84 FR 55766, 55808.

For purposes of this illustration, assume that a hospital pays a physician $150 per hour for medical director services when the written agreement between the parties identifies $140 per hour as the physician's rate of pay. If the $150 per hour payment is due to an administrative or other operational error—that is, the discrepancy was unintended—the parties may, while the arrangement is ongoing during the term initially anticipated (in this example, during the year of the arrangement), correct the error by collecting the overage (or making up the underpayment, if that is the case). We expect entities and the physicians who refer designated health services to them to operate effective compliance programs that identify these types of errors and rectify them promptly. However, if the parties fail to identify the error during the term of the arrangement as anticipated (that is, the ''live'' or ongoing arrangement), they cannot simply ''unring the bell'' by correcting it at some date after the termination of the arrangement. Rather, the failure to timely identify and rectify the error through an effective compliance program would expose the parties to the referral and billing prohibitions of the physician self-referral law during the entirety of the arrangement.

We are missing a physician order for an inpatient admission. We can't bill it, right?

- Wrong!
- We acknowledged that in the extremely rare circumstance the order to admit is missing or defective, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record, (sic) medical review contractors are provided with discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record.
- 83 FR 41700, 41506-41507 Aug. 17, 2018

The physician who admitted the patient didn't have privileges. We can't bill the stay, right?

- Not necessarily!
- The Medicare regulations require the ordering physician have admitting privileges. Whether the physician has the other requisite privileges is a matter of Conditions of Participation.
- This is helpful when there are credentialing paperwork errors.

Is an LCD binding?

- "The district court correctly stated in its instructions to the jury that LCDs are 'eligibility guidelines' that are not binding and should not be considered "the exact criteria used for determining" terminal illness."
  - *United States v. Aseracare, Inc.*, et al., 938 F.3d 1278, 1288 (11th Circ. 2019)

What can you say about the Payment Protection Program (PPP)?

- Margy Ahmann can help!!!

  612.492.7495

  mahmann@fredlaw.com

A doctor delivered a baby 25 years after delivering his mom in the same hospital

By Alaa Elassar

Updated 6:09 PM EDT, Mon August 10, 2020

What is the status of billing for outpatient services provided in the patient's home?

- Same policy as in the Interim Final Rule published April 30, 2020…with some clarifications.

Relocating PBDs

- “PBD” = Provider-based Department
- Background: Services provided at off-campus provider-based departments established on or after November 2, 2015, are paid at Physician Fee Schedule rate. On-campus and “excepted” off-campus PBDs are paid under the OPPS.

Temporary "Extraordinary Circumstances" Relocation Policy

- During the PHE, on-campus PBDs (or "excepted" off-campus PBDs) that temporarily relocate off-campus—**including to the patient's home**—during the PHE for purposes of addressing COVID-19 will still be "excepted" – i.e., paid under the OPPS – if the relocation is not inconsistent with the state pandemic plan.

Process for Temporary Relocation

- No enrollment update required (if PBD services are billed under the main hospital);
- May begin furnishing and billing under the OPPS in the new location prior to notifying the Regional Office (RO);
- Use modifier “PO” for OPPS claims; and
- Notify the RO by email of the relocation.

Notification to the Regional Office

- Email notification should include (i) hospital CCN; (ii) addresses of current and relocated PBD; (iii) start date of services at relocated PBD; (iv) brief justification for relocation and role of relocation in hospital's response to COVID-19; (v) why the location is appropriate for outpatient services; and (vi) attestation the relocation is not inconsistent with state emergency/pandemic plan.

Relocation of PBD to the Patient's Home

- During the PHE, a hospital may relocate to an off-campus PBD that is otherwise the patient's home: i.e., it may register and treat outpatients at their homes (for some services).
- CMS has clarified that hospitals must submit the address of each patient to whose home the PBD is relocated.
  - Bummer.

Question: Under the new process to seek an extraordinary circumstances relocation exception that is in place during the COVID-19 PHE, do hospitals need to submit a relocation request for *every* location to which its PBD relocates, including in circumstances where the excepted PBD relocates to several different patients' homes?

Answer: Hospitals have 120 days from the date on which they begin furnishing services at a relocated PBD to submit a temporary extraordinary circumstances relocation exception request (85 FR 27561). As part of a relocation exception request, hospitals should notify their CMS Regional Office by email of the addresses of the locations to which its PBD relocates. Hospitals are not required to submit a separate email for every relocation site. Hospitals can send a request that includes all of the addresses to which the PBD relocated over a period of weeks or months, rather than a single request for each location. The hospital should also notify the Regional Office of the addresses of any patients' homes to which the PBD relocates if the hospital intends to be paid under the OPPS for these services. If a hospital chooses not to submit a patient's home address for an extraordinary circumstances relocation request, the hospital can simply bill for services provided at such relocation site with the "PN" modifier and receive payment at the PFS-equivalent rate for those services.

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

So what about outpatient telehealth visits?

- Do you bill Q3014 or as if it is an in-person visit at a hospital outpatient department?
- Where is the professional located?
- If the physician and the patient are both “in the hospital” then bill is as an in-person visit.

Question: For services furnished to patients in a provider-based department of the hospital (which may include the patient's home during the COVID-19 PHE), when can a hospital bill for the clinic visit code (G0463, "Hospital outpatient clinic visit") and when can a hospital bill for the originating site facility fee (Q3014)?

Answer: We remind readers that the provider should bill using the HCPCS code that describes the service(s) that were furnished. The following information may help hospitals determine appropriate billing.

- If a distant site practitioner furnishes a telehealth service to a registered hospital outpatient, and hospital staff provide administrative and clinical support, the hospital may bill for the originating site facility fee (Q3014). It would not be appropriate for the hospital to bill HCPCS code G0463 in this situation.
- HCPCS code G0463 describes a clinic visit furnished in the hospital outpatient setting when the practitioner and the patient are both located within the hospital. Typically, the hospital would bill G0463 when a professional is located in the hospital and furnishes an evaluation and management outpatient service to a hospital outpatient who is also in the hospital. If a physician is practicing from a hospital that has registered the patient as a hospital outpatient in the patient's home, which is serving as a provider-based department of the hospital, we consider the physician and patient to be "in the hospital" and usual hospital outpatient billing rules would apply in terms of billing for the service(s) furnished. In this situation, there is no distant site practitioner and no telehealth service being furnished.

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

Can I bill for home pulmonary rehab through Medicare?

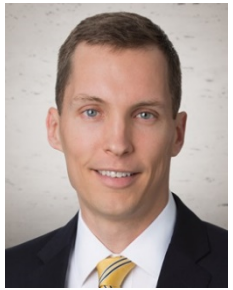
- Is the patient's home registered as a PBD?
- CMS hinted guidance will be forthcoming.
- What about private insurers?

My hospital got a letter from a drug manufacturer asking for 340B claims data. What do we do?

- Eli Lilly, Merck, and Sanofi are sending letters.
- Unless there is reasonable cause to believe a covered entity has violated 340B, the manufacturer cannot conduct an audit.
- Any manufacturer audit work plan must be reviewed by HRSA (Health Resources Services Administration of HHS).

Presenters

David Glaser
612.492.7143
dglaser@fredlaw.com



Andrew Holm
612.492.7221
aholm@fredlaw.com

Katherine Ilten
612.492.7428
kilten@fredlaw.com