The Annual Regulatory Update

Health Law Webinar

December 13, 2023

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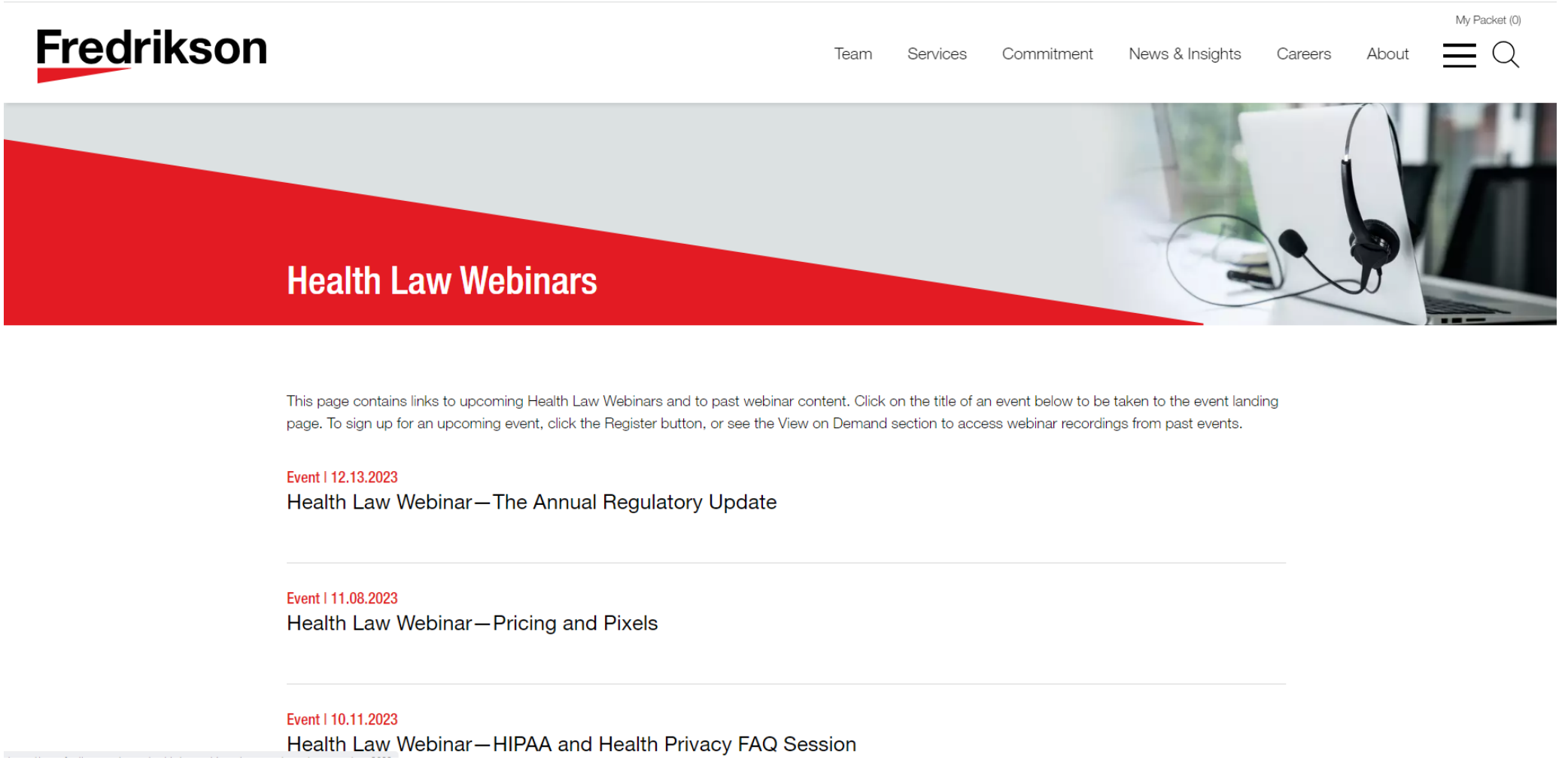

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Agenda

1. E/M: G2211
2. Split Shared
3. Telehealth
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Key Acronyms

- CAA = Consolidated Appropriations Act
- CHI = Community Health Integration
- CPT = Current Procedural Terminology
- DSMT = Diabetic Self-Management Training
- FQHC = Federally Qualified Health Centers
- HCPCS = Healthcare Common Procedure Coding System
- MIPS = Merit-Based Incentive Program System
- MHC = Mental Health Counselor
- MFT = Marriage Family
- MRF = Machine-readable File
- PFS = Physician Fee Schedule
- PHE = Public Health Emergency
- PIN = Principal Illness Navigation
- QPP = Quality Payment Program
- REH = Rural Emergency Hospitals
- RHC = Rural Health Clinic
- SDOH = Social Determinants of Health

Evaluation and Management

- Major changes over time (including, in some cases, TO times!).
- Declining emphasis on history and exam.
- CMS is worried about undervalued primary care/quarterbacking. Feel RUC undervalues office visits.
- Did you know? E/M is 40% of Physician Fee Schedule payment, split evenly between clinic and hospital.
- They use O/O for “office/outpatient.” Contrasted with facility E/M visits.

G2211

- Code for visit complexity inherent to evaluation and management services add-on.
- Included in 2021 Physician Fee Schedule (PFS).
- Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020, prohibited CMS from implementing it before 1/1/24.

G2211

- “This code should be used when furnishing O/O E/M visit associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious condition or a complex condition.”
- Used examples of sinus congestion and HIV drug treatment, and the need to build/maintain trust with the patient.
- Not specialty dependent.

G2211 In One Paragraph:

- “We thank the commenter for providing these clinical scenarios. However, the most important information used to determine whether or not the add-on code could be billed is missing: the relationship between the practitioner and the patient. If the practitioner is the focal point for all needed services, such as a primary care practitioner, this add-on code could be billed in these examples. Or, if the practitioner is part of ongoing care for sickle cell disease (a single, serious and complex condition) then the add-on code could be billed. Otherwise, this add-on code could not be billed.”

SPLIT SHARED

- Background: Merely “policy” (subregulatory guidance) in the Manuals until that was withdrawn in May 2021.

A Process To Challenge Manuals?!?!

- HHS Good Guidance Practices Regulation, 85 Fed. Reg. 78,770 (Dec. 7, 2020)/45 C.F.R. § 1.5(a)(1).
- CMS withdrew it! 87 Fed. Reg. 44002 (July 25, 2022).
- The complaint about shared visits was submitted in January 2021:

  https://www.cms.gov/files/document/enf-instruction-split-shared-critical-care-052521-final.pdf.

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!

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.

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

Shared Visits: Keep in Mind

- Must be a physician and an NPP in the same group.
- New medical record documentation requirements including identifying both the physician and NPP, and signature and date from the professional performing the substantive portion.

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.

Telehealth Generally

- New codes to Medicare telehealth services.
- Originating site includes any site in U.S. where patient is located at the time the telehealth service is being furnished.
- Expanding the definition of telehealth practitioners.
- Payment for telehealth services furnished by RHC and FQHC.
- Delaying in person requirement for in person visit within six months prior starting mental health telehealth services.
- Direct supervision = permit supervising practitioner through real-time audio and video.

Telehealth Services Furnished In Teaching Settings

- 2021 policy said after PHE teaching physicians must have physical presence to bill for services.
- But for 2024, virtual presence is enough.

Telehealth for Diabetes Self-Management Training

- DSMT training can be furnished via telehealth.
- Allowing billing on behalf of others who are part of the DSMT entity.

Telehealth Payment for Outpatient Therapy

• Institutional providers are able to continue to bill for PT, OT, SLP, DSMT and MNT services provided remotely in the same way they could during the PHE with some modifications, as follows:

- For outpatient hospitals, patients' homes no longer need to be registered as provider-based entities to allow for hospitals to bill.
- Except for Critical Access Hospitals (CAHs) electing Method II, the 95 modifier is required on claims from all providers, as soon as hospitals needing to do so can update their systems.

Telehealth “Location” – Extended Flexibility

- During the PHE, CMS allowed telehealth practitioners to provide telehealth services from their homes while billing from their enrolled practice locations instead of their home addresses.
- Extended through December 31, 2024.

Prescribing Controlled Substances Via Telehealth to Patients That Have Not Been Evaluated in Person

- Background:
  - Ryan Haight Act generally requires one in-person medical evaluation of a patient before prescribing a controlled substance.
  - Suspended during PHE.
  - DEA proposed new rules in February 2023.
- Generally permitted through December 31, 2024.
  - Extended (and simplified) in October 2023.
  - 88 FR 69,879; 21 C.F.R. § 1307.41; 42 C.F.R. § 12.1.
- Watch for new rules in 2024.

Updates for Rural Health Clinics and Federally Qualified Health Centers

- CMS is extending payment for telehealth services furnished in these facilities through December 31, 2024 (delaying in person requirements).
- Addiction, drug and alcohol counselors who meet requirements of MHC's will also apply for RHCs and FQHCs.
- Extend definition of direct supervision to include virtual.
- Supervision for "incident to" will be general supervision.
- Changes to general care management code. (HCPCS Code G0511).

Preventive Vaccine Administration Services

- In 2021 CMS announced additional payment for in home COVID vaccine administration – we will keep it.
- Extend in home payment for other vaccines provided in the home.
- Every vaccine dose administered during home visit will receive its own vaccine administration payment.

Opioid Treatment Programs

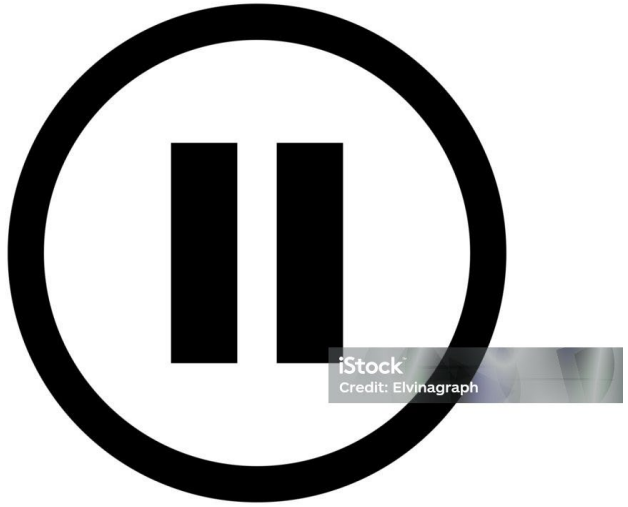
- CMS will extend current flexibilities for assessments via audio-only telecommunications through 2024.
- So long as comply with SAMHSA and DEA requirements at the time the service is furnished.
- Finalizing increase in bundled episode payments for office-based opioid use disorder treatment.

Supervision for Physical and Occupational Therapists in Private Practice

- Switch from direct supervision to general supervision for therapy assistants by PTPPs and OTPPs.

AUC Diagnostic Imaging Program

- CMS is pausing efforts to implement Appropriate Use Criteria Program.



Caregiver Training Services

- Practitioners can bill to train caregivers to support patients with certain diseases without patient present.
- New CPT Codes: 96202, 96202, 97550, 97551, and 97552.

CHI and PIN

- Finalizing to pay separately CHI and PIN services to account for resources when clinicians involve certain types of health care support staff (historically called “auxiliary personnel”):
  - Community health workers (CHWs).
  - Care navigators.
  - Peer support specialists.

CHI and PIN

- CHI = For patients with an unmet SDOH need that affects the diagnosis and treatment of a medical problem. By auxiliary personnel (including CHWs).
- PIN = For patients with a serious, high-risk condition. By auxiliary personnel (including care navigators).
- PIN-Peer Support = For patients with a serious high risk behavioral health condition. By auxiliary personnel, including peer support workers.

CHI and PIN

- Must start with “initiating visit”.
  - *E/M visit performed by billing practitioner.*
  - *Can be annual wellness visit if the practitioner is also the supervisor going forward.*
- Patient consent is required for services.
- Finalized that billing practitioner can arrange to have CHI services provided by auxiliary personnel who are external to (or under contract with) the practitioner or their practice (such as community-based organization).

SDOH Risk Assessment Codes

- Finalized coding and payment for practitioners to furnish risk assessment that assesses for housing, utilities, transportation, food insecurity, and others social determinants in effort to understand diagnosis/treatment of medical problem.
- Provide during E/M, annual wellness visit, hospital discharge visit, and certain psychiatric codes and health behavior assessment and intervention changes.
- HCPSC Code G0136 (once every 6 months).

MFTs and MHCs

- First time MHCs and MFTs can enroll in Medicare and bill Medicare for services.
- Addiction/drug and alcohol counselors that meet all applicable requirements to be an MHC may enroll in Medicare as MHCs.
- Clinical social workers, MFTs, and MHCs can bill for Health Behavior Assessment and Intervention services.
  - Described by CPT codes: 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes.

Dental and Oral Health

- Payment for certain dental services inextricably linked to other covered services used to treat cancer, prior to, or contemporaneously with:
  - Chemotherapy services;
  - Chimeric Antigen Receptor T- (CAR-T) Cell therapy; and,
  - The use of high-dose bone modifying agents (antiresorptive therapy).
- Codified policies for payments on treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these (whether primary or metastatic).

Medicare Enrollment Revocation/Denial Reason Changes

- 42 C.F.R. § 424.535(a)
- Expanded the definition of enrollment requirements under the noncompliance provision.
- Added False Claims Act judgment in previous 10 years.
  - *Does not include settlement agreements.*
- Changed scope of "debt referred" to the Treasury.
- Expanded the list of regulations that may be grounds for revocation.
- One major non-change: misdemeanor convictions.

New “Stay of Enrollment” Provision

- CMS may deactivate an entity’s enrollment.
    - Different from revoking/denying enrollment.
- CMS added a “stay of enrollment” provision that is between non-action and deactivation.
- When it may be used:
    1. Non-compliant with enrollment requirement.
    2. Can be remedied by submitting a form.
- During stay, cannot receive payment but can submit claims for services provided during stay once it is lifted (if meet various requirements).

High Level QPP/MIPS Developments

- Maintained 75-point performance threshold.
- MIPS Value Pathways
  - Created 5 new MVPs.
  - Modified existing MVPs.
  - Consolidated two into “Value in Primary Care.”
- Improvement Activities
  - Adding 5.
  - Modifying 1.
  - Removing 3.

IPPS Final Rule

- Finalized August 1, 2023, at 88 FR 58640.
- Estimated increase in payments of $2.2 billion.
    - Includes $957 million decrease in disproportionate share hospital payments and uncompensated care payments.
- Continued increased wage index for low-wage hospitals.
- Hospitals reclassifying from urban to rural to be treated as geographically rural for the wage index calculation.
- Change to GME payments at REHs.
- Health equity changes.
- Increase the severity designation for homelessness code.
- New Covid-19 Treatments Add-On Payment allowed to expire.

OPPS and ASC Payment System

- 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule (Reg. No. CMS-1786-FC).
- CMS increased payments rate by a productivity-adjusted market basket factor of 3.1%.
- Estimated total payments to providers: OPPS ($88.9 bil.) and ASC ($7.2 bil.).

Price Transparency

- Information on a hospital's standard charges must be available to the public (45 CFR Part 180).
- CMS finalized changes:
  - Increased standardization of MRFs.
  - Must use CMS template layout, data specifications, and data dictionary.
  - Required MRF linked footer and .txt file in root folder of hospital website.
  - Required affirmation statement (data in MRF is true).

No Surprises Act

- *Texas Medical Association* litigation (and others).
- Limited information on State Attorneys General enforcement.
- Center for Consumer Information and Insurance Oversight investigating provider compliance at Federal level.
- Outstanding rulemaking:
  - *Civil monetary penalties for noncompliant providers.*
  - *Co-convenor requirements for good faith estimates.*
  - *Good faith estimate for patients using insurance.*

Looking Ahead to 2024(?)

- Office of Civil Rights at HHS proposed changes to the HIPAA Privacy Rule.
    - Main focus: Reproductive health care data.
- Prescribing by telehealth regulations.
- Enrolled practice location.

Looking Ahead to 2024: Supreme Court Administrative Law Cases

- *CFPB v. Community Financial Services Ass'n of America, Ltd.*
    - Challenge to CFPB funding structure.
    - May affect or eliminate funding for Medicare, Medicaid, ACA subsidies, and more
- *SEC v. Jarkesy.*
    - Challenge to administrative law judge and agency adjudication structure.
- *Loper Bright Enterprises v. Raimondo*
    - Challenge to *Chevron* deference.

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Thank you!

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