The Annual Regulatory Update

Health Law Webinar

December 11, 2024

Questions from the Health Law 101 Webinar

- Are you obligated by Medicare/Medicaid to bill a facility fee for a pharmacist's visits in a community benefit program such as Hep C treatment? Can the pharmacist's visit be "no charge" if that is your standard practice?

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Understanding Free Visits

- Completely free is better than a co-payment waiver.
- Is the free service linked to another service?
- Congress passed an exception to the beneficiary inducement limitations under the Civil Monetary Penalty Provision. SSA §1128A(i)(6)(F), 42 U.S.C. 1320a–7a(i)(6)(F), excludes from remuneration "**any** other remuneration which **promotes access to care** and poses a **low risk of harm to patients and Federal health care programs** (as defined in section 1128B(f) and designated by the Secretary under regulations);"
- The government claims this exception doesn't extend to antikickback statute.

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Are You Saying That if a Healthcare System Refers a Patient to Another Healthcare System, Stark Isn't Involved?

- People often conflate Stark and the Antikickback statute.
- Stark only applies to compensation relationships with physicians. Action by non-profit healthcare organizations, or non-physicians, may implicate the antikickback statute, but they aren't governed by Stark when physicians are not involved.

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Are There Prohibitions Against a Competitor Being in Charge Of Peer Reviews?

- Prohibition? No. But it has major implications.
- It can obligate certain federal protections, and it makes for an easy basis for challenge.
- Some things are “only” ill-advised, not illegal.

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No Surprises Act / Price Transparency

- No major regulatory update yet.
- IDR litigation continues.
- Price transparency enforcement has escalated.
- Still awaiting good faith estimate expansion.

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Is the False Claims Act Dead?

- Absolutely not.
- U.S. Exrel. vs. Zafirovv Florida Medical Assocs. found it unconstitutional for the relator to continue with a case.
- Perhaps private action will be stopped, but that does not eliminate the FCA generally.

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HIPAA Privacy Rule to Support Reproductive Health Care Privacy

- Published: April 26, 2024.
- Effective Date: June 25, 2024.
- Compliance Date: December 23, 2024, except for the Notice of Privacy Practices (NPP) requirements.
- NPP Compliance Date: February 16, 2026.
- Applies to all covered entities and business associates.

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Prohibited Disclosures

- Prohibits the use or disclosure of protected health information (PHI) for the following activities:
  - To conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided.
  - The identification of any person for the purpose of conducting such investigation or imposing such liability.

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Prohibited Disclosures (Cont.)

- The prohibition applies:
  - Where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care; and
  - The covered entity/business associate that received the request for PHI has reasonably determined that one or more of the following conditions exists:
    - The reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided.
    - The reproductive health care is protected, required, or authorized by Federal law, including the U.S. Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.
    - If the care was provided by another person, its presumed lawful unless there's actual knowledge or requestor supplies substantial factual basis that it was not lawful.

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Attestation Obligations

- When a HIPAA covered entity or business associate receives a request for PHI potentially related to reproductive health care, it must obtain a signed attestation that clearly states the requested use or disclosure is not for a prohibited purposes described below, where the request is for PHI for any of the following purposes:
  - Health oversight activities;
  - Judicial or administrative proceedings;
  - Law enforcement; or
  - Regarding decedents, disclosures to coroners and medical examiners.

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HHS Model Attestation

Model Attestation Regarding a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care

The entire form must be completed for the attestation to be valid.

Name of person(s) or specific identification of the class of persons to receive the requested PHI.
e.g., name of investigator and/or agency making the request
Name or other specific identification of the person or class of persons from whom you are requesting the use or disclosure.
e.g., name of covered entity or business associate that maintains the PHI and/or name of their workforce member who handles requests for PHI
Description of specific PHI requested, including name(s) of individual(s), if practicable, or a description of the class of individuals, whose protected health information you are requesting.
e.g., visit summary for [name of individual] on [date]; list of individuals who obtained [name of prescription medication] between [date range]

I attest that the use or disclosure of PHI that I am requesting is not for a purpose prohibited by the HIPAA Privacy Rule at 45 CFR 164.502(a)(5)(iii) because of one of the following (check one box):

☐ The purpose of the use or disclosure of protected health information is **not** to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for such purposes.

☐ The purpose of the use or disclosure of protected health information **is** to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for such purposes, but the reproductive health care at issue was **not lawful** under the circumstances in which it was provided.

I understand that I may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if I knowingly and in violation of HIPAA obtain individually identifiable health information relating to an individual or disclose individually identifiable health information to another person.

Signature of the person requesting the PHI

____________________ Date ______________

If you have signed as a representative of the person requesting PHI, provide a description of your authority to act for that person.

____

This attestation document may be provided in electronic format, and electronically signed by the person requesting protected health information when the electronic signature is valid under applicable Federal and state law.

https://www.hhs.gov/sites/default/files/model-attestation.pdf

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What Do I Need to Do?

- By December 23, 2024:
  - Update HIPAA policies and procedures.
  - Update training programs, especially for those who respond to requests for data.
  - Review BAAs and update if necessary.
- By February 16, 2026:
  - Updated NPP requirements (45 C.F.R. § 164.520).

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Telehealth Generally

- Several telehealth flexibilities enacted during the PHE are scheduled to expire after December 31, 2024, including:
  - Originating (i.e., Patient) Site Flexibilities – urban or rural, including at home.
  - Distant (i.e., Provider) Site Flexibilities – Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs); provider's home.
  - Provider Type Flexibilities – e.g., Physical Therapists, Occupational Therapists, Speech Language Pathologists and Audiologists.
  - Audio-Only Services.
  - Mental Health Flexibilities – Moratorium on requirement for in-person visit within six months of patient starting mental health telehealth services.

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Telehealth Generally (Cont.)

- Bipartisan Legislative Efforts to Extend Flexibilities.
  - Telehealth Modernization Act of 2024 (H.R. 7623).
    - Unanimously approved by House Energy and Commerce Committee in September 2024.
  - Preserving Telehealth, Hospital and Ambulance Access Act (H.R. 8261).
    - Unanimously approved by House Ways and Means Committee in May 2024.
  - Reports of competing Republican and Democratic proposals just last week for inclusion in year-end funding package (funding deadline to avoid a government shutdown is December 20, 2024).
- 2025 Physician Fee Schedule includes preservation and expansion of telehealth flexibilities that do not require congressional action.

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Additions to Medicare Telehealth Services List

- Caregiver Training Services (see next slide for non-telehealth updates re: Caregiver Training Services).
  - CPT codes 97550, 97551, 97552, 96202, 96203 and HCPCS codes G0541-G0543 (GCTD1-3) and G0539-G0540 (GCTB1-2).
- HIV Pre-Exposure Prophylaxis (PrEP) Counseling.
  - HCPCS codes G0011 and G0013.
- Safety Planning Interventions.
  - HCPCS code G0560.

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More on Caregiver Training Services

- New coding and payment for caregiver training for direct care services and supports.
  - Potential topics for trainings: techniques to prevent decubitus ulcer formation, wound care and infection control.
  - HCPCS codes G0541, G0542 and G0543.
- New coding and payment for caregiver behavior management and modification training that can be furnished to the caregiver(s) of an individual patient.
  - Previously, these services could only be furnished in a group setting with multiple sets of caregivers of multiple patients.
  - HCPCS codes G0539 and G0540.

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Continued Suspension of Telehealth Frequency Limitations for CY2025

- Subsequent Inpatient Visits.
  - CPT codes 99231, 99232 and 99233.
- Subsequent Nursing Facility Visits.
  - CPT codes 99307, 99307, 99308 and 99307.
- Critical Care Consultation Services.
  - HCPCS codes G0508 and G0509.

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Audio-Only Permitted for any Medicare Telehealth Service, with Limitations

- Permanent amendment to definition of "interactive telecommunications system" at 42 CFR 410.78(a)(3) to include audio-only technology <u>for any Medicare telehealth service</u>, subject to the following limitations:
  - Must be two-way, real-time, audio-only communication technology.
  - Patient must be in their home.
  - Distant site physician or practitioner must be technically capable of using video technology.
  - Patient must not be capable of, or must not consent to, the use of video technology.

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Continued Telehealth “Location” Flexibility for CY2025

- 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, 2025.

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"Direct Supervision" via Virtual Presence

- Pre-PHE, direct supervision generally required the supervising physician or practitioner to be physically present.
- During the PHE, direct supervision was expanded to include "virtual presence through audio/video real-time communications technology (excluding audio-only)".
  - Requires supervisor's ability to be "immediately available" via such technology, <u>not</u> continuous real-time presence/monitoring via such technology.
- Extended through December 31, 2025 (but see the following slide for a related permanent extension).

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“Direct Supervision” via Virtual Presence (Cont.)

- For a certain subset of services, the definition of “direct supervision” at 42 CFR 410.26(a)(2) was amended to <u>permanently</u> include “virtual presence through audio/video real-time communications technology (excluding audio-only)”.
- Applies to the following services:
  - Services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of “5”.
  - Services described by CPT code 99211 (office and other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

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Virtual Presence Permitted for Teaching Physicians, with Limitations

- Pre-PHE, teaching physicians were generally required to be physically present during services provided by residents.
- During the PHE, teaching physicians were permitted to be virtually present.
- After the PHE, CMS announced an intent to reinstate requirement of physical presence, but this was previously delayed through CY 2024.
- Extended through December 31, 2025.
- Applies residents in all teaching settings, but only with respect to services furnished virtually (e.g., a three-way telehealth visit, with the patient, resident, and teaching physician in separate locations).

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Telehealth in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- Extended payment for telehealth services furnished by practitioners located in these facilities through December 31, 2025.
  - Continued use of HCPCS code G2025 for non-behavioral health services.
- Extended delay of the in-person visit requirement for mental health services furnished via telehealth by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.
- Direct supervision will continue to include a virtual presence through December 31, 2025.

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Telehealth for Opioid Treatment Programs (OTPs)

- CMS made permanent the current flexibilities for periodic assessments via audio-only telecommunications.
- Revised the definition of "opioid use disorder treatment service" at 42 CFR 410.67(b) to allow the OTP intake add-on code (HCPCS code G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone.
- Both of the above are subject to (1) compliance with Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) requirements, and (2) the OTP's determination that services can be adequately provided via telehealth.

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

- Background:
  - Ryan Haight Act of 2008 generally requires an in-person medical evaluation of a patient before prescribing a controlled substance.
  - Suspended during PHE.
  - DEA and HHS jointly proposed new rules in March 2023, making permanent certain of the PHE flexibilities and rolling back others.
  - Proposed rules generated over 38,0000 public comments and multiple DEA listening sessions.
  - PHE flexibilities were previously extended through December 31, 2024.
- Extended again through December 31, 2025, but watch for future rule-making.

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Behavioral Health – Suicide Prevention

- CMS goal: increase access to behavioral health.
- Focusing on safety planning: safety planning “interventions involve a patient working with a clinician to develop a personalized list of coping and response strategies and sources of support that the person can use in the event of experiencing thoughts of harm to themselves or others”.
- Code (HCPCS G0560) can be billed in 20 minute increments when personally perform by billing practitioner.

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Behavioral Health – Psychotherapy Access

- Finalized payment for digital mental health treatment.
- Finalizing new HCPCS codes to monitor how digital mental health is being used.
- Six new G-codes.

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Opioid Treatment

- Payment increase for social determinants of health (SDOH) risk assessments as part of the intake process to identify unmet health-related social needs (HRSNs).
- Help identify needs for harm reduction intervention or recovery support services.
- Avoid having patients leave opioid use disorder treatment too early.
- Finalizing add on codes for use of coordinate care referral services, patient navigational services and peer recovery support services.
- New opioid medications.
- Don’t forget to add the OUD diagnosis code on claims for OUD treatment services.

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Evaluation and Management Visits

- Adding on complexity code G2211.
- Bill when E/M service is performed on the same day as an:
  - Annual wellness visit.
  - Vaccine administration.
  - Medicare part B preventative service.

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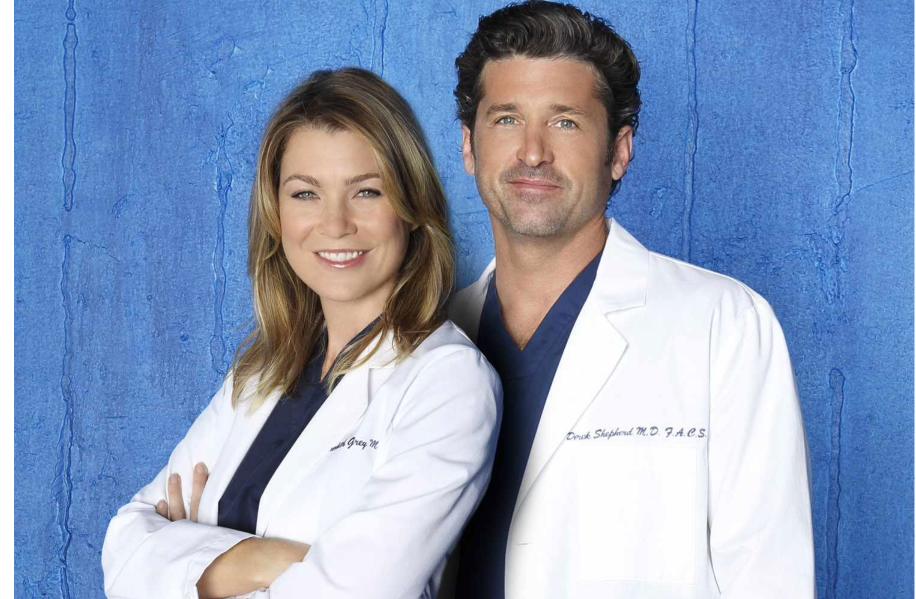
Advanced Primary Care Management Services

- CMS is adding 3 new G codes for monthly APCM services.
- No time based thresholds.
- Code levels are based on patients' chronic conditions and complexities.
    - Chronic condition.
    - Two or more chronic conditions.
    - Two or more chronic conditions and qualified Medicare beneficiary.
-



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Cardiovascular Risk Assessment and Management

- Coding and payment for an Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment service and risk management services.
- Risk assessment will be performed with an E/M visit when a provider identifies a patient at risk for cardiovascular disease who does not already have a diagnosis of CVD.
- CMS is also including coding and payment for ASCVD risk management services such as (aspirin, blood pressure management, cholesterol management, smoking cessation) for those at risk of CVD in the next ten years.
- Coding and payment for risk management services.

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Hospital Inpatient or Observation for Infectious Disease

- New HCPCS add on code to describe service elements.
  - Disease transmission risk.
  - Public health investigation.
  - Complex antimicrobial counseling.

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Supervision for PT/OT

- CMS is allowing general supervision of physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) by PTs in private practice (PTPPs) and OTs in private practice (OTPPs) for all applicable physical and occupational therapy services.

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Certification of Therapy Plans of Treatment

- Finalizing amendments to certification regulations.
- The signature will not be required on the treatment plan if:
  - Written order or referral from patient's physician is on file.
  - Therapist has evidence that treatment plan was transmitted to doc within 30 days of the initial evaluation.

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Rural Health Clinics and Federally Qualified Health Centers

- Care coordination.
  - Report individual CPT codes to describe care coordination services.
  - Have six months to update billing systems.
- Payment for preventative vaccine costs.
- Removing RHC productivity standards.
- Conditions for certification.
  - Provide primary care services.

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Medicare Part B – Preventative Services

- Expanding hepatitis B Vaccinations.
- No physicians order required for hepatitis B vaccine.
- Payment for hepatitis B at 100% reasonable cost in RHCs and FQHCs.
- CMS will begin paying for pre-exposure prophylaxis (PrEP) for HIV infection prevention.

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Colorectal Cancer Screening

- Expanding coverage to include computed tomography colonography.
- Adding Medicare covered blood-based biomarker CRC screening tests.
- CRC frequency do not apply to follow-on screeding colonoscopies in the context of complete CRC screenings.

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Global Surgery Payment Accuracy

- For 90-day global surgical packages, CMS finalized its proposal to require the use of modifier -54 when a physician plans to furnish only the surgical procedure portion of the global package.
- CMS is finalizing a new add-on code, HCPCS code G0559, for post-op care furnished by a practitioner other than the one who performed the surgical procedure (or another practitioner in the same group practice).

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OPPS and ASC Payment System

- (CMS 1809-FC).
- CMS increased payment rates by 2.9%.
- Hospitals and ASCs that fail to meet their quality reporting program requirements will be subject to a 2 percent reduction in the fee schedule increase factor.
- Non-opioid pain management policy allows for temporary separate payments.
- New standard within emergency services.
- Health equity measures across quality programs.

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IPPS Final Rule

- Finalized August 28, 2024, at 89 FR 68986. Updated October 3, 2024, at 89 FR 80405.
- Estimated increase in hospital payments of $2.9 billion.
  - Includes approximately $200 million decrease in uncompensated care payments to disproportionate share hospitals.
- Update: Eliminated the increased wage index for low-wage hospitals but with a transition period.
- Add-on payments for access to essential medicines.
  - Separate payment for small, independent hospitals.
- New residency positions with at least half to psychiatry and related subspecialties.
- Increased severity designation for inadequate or instable housing.
- New, modified, and removed inpatient clinical quality measures.

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Pixels and Other Online Tracking Technologies

- Plaintiffs' Attorneys, HHS's Office of Civil Rights, and the FTC have targeted online tracking technologies on health related websites.
- HHS's Office of Civil Rights Guidance.
  - Issued December 2022.
  - Revised March 2024.
  - Partially vacated June 2024. *See American Hospital Ass'n v. Becerra*.
- Evaluate your exposure, goals, facts, and uses.
  - *See* November 2023 webinar.
- Check your insurance.

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2024 Administrative Law Case Recap

- *CFPB v. Community Financial Services Ass'n of America, Ltd.*
  - Upheld CFPB funding structure.
  - Suggests no constitutional issue with Medicare, Medicaid, and ACA subsidy funding structures.
- *SEC v. Jarkesy*
  - Limited SEC's power to seek civil monetary penalties through ALJ proceedings.
  - Could affect HHS's ability to seek CMPs through agency adjudication.
  - Avoided certain other questions that could have affected the agency adjudication structure.
- *Loper Bright Enterprises v. Raimondo*
  - Overruled *Chevron*.

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2025 Health Administrative Law Cases to Watch

- *Advocate Christ Medical v. Becerra.*
    - Supreme Court.
    - Challenge to how HHS calculates disproportionate share hospital payments.
    - Estimated effect of about $1 billion per year in DSH payments.
- *Texas v. HHS.*
    - Northern District of Texas.
    - Challenge to HIPAA's Privacy Rule:
        - 2024 Rule to Support Reproductive Health Care Privacy.
        - Original Privacy Rule as it relates to subpoenas.

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