Health Law Webinar

The 2022 Regulatory Update: Vaccines, Shared Visits, Co-Mingled Space and More

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Fredrikson & BYRON, P.A.

Agenda

- Welcome to Marielos Cabrera!
- 2022 Physician Fee Schedule
- Co-Mingled Space Policy
- CMS COVID-19 Vaccine Mandate
- 2022 OPPS
- 2022 IPPS


U.S. Bank Stadium
WELLS FARGO

E/M Visits

Shared Visits: 42 CFR § 415.140

- Replaces guidance with a regulation.
- Applies where “incident to” billing is prohibited.
- Requires a modifier on the claim.
- Only the professional doing the “substantive portion” may bill.

Shared Visits: Substantive Portion

- 2022 more flexible than 2023 for all but Critical Care.
- In 2022, “substantive portion” of the visit means one of the three key components (history, exam or medical decision-making) or more than 50 percent of the time.
- In 2023, time time controls.

Shared Visits: General Principles

- 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.

MCPM Ch. 12, Section 30.6.1

"When a hospital inpatient/hospital outpatient or emergency department E/M is shared between a physician and an NPP from the same group practice and the physician provides any face-to-face portion of the E/M encounter with the patient, the service may be billed under either the physician's or the NPP's UPIN/PIN number. However, if there was no face-to-face encounter between the patient and the physician (e.g., even if the physician participated in the service only by reviewing the patient's medical record than the service may only be billed under the NPP's UPIN/PIN."

Critical Care: 99291 / 99292

- Adopts CPTs listing of bundled services (codes 93561-2, 71045-6, 94760-62, 43752-3, 92953, 94002-94004, 94660, 94662 and vascular excess procedures.)

Critical Care: 99291 / 99292

- 99291 for the first 30-74 minutes.
- 99292 for each additional 30 minutes. Time need not be continuous.
- Split and shared critical care is allowed. When two professionals provide care, only one of their time counts.

Critical Care: 99291 / 99292

- When critical care is billed, no other E/M may be billed by the same specialty in the same group on that date unless the E/M service before the patient required critical care.
- Documentation must include the total time spent, but need not have start and stop times.

Teaching Physician Rules

- As of 2021, teaching physicians code on time or MDM.
- Clarifies that only the physician's time counts. And only teaching specific to the patient. "General" instruction isn't billable.
- Declines to make remote supervision permanent.
- Claims NPPs can't be "teaching physicians."

Did CMS Goof?*

"Under the respective Medicare statutory benefit categories for the services of PAs, nurse practitioners (NPs), and clinical nurse specialists (CNSs), these nonphysician practitioners (NPPs) are authorized to furnish services that would be physicians' services if they were furnished by a physician, and which they are legally authorized to perform by the State in which the services are furnished; and such services that are provided incident to these NPPs' professional services (but only if no facility or other provider charges or is paid any amount for the services)."

86 FR 65167

*Hint: Sure looks like it!

Primary Care Exception

- The ability to do 4s and 5s will expire with the PHE.
- The resident must use MDM to choose the level of service. Time is not an option.

Telehealth – Category 3 Codes

- Finalized “Category 3” PHE additions to the Medicare Telehealth List through December 31, 2023 (plus 4 new outpatient cardiac rehabilitation codes).
- Timeline is intended to (1) provide certainty and (2) allow for further evaluation regarding whether these additions should be permanent.
- https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

Telehealth – Mental Health

- Patient's home = valid originating site for the purpose of diagnosis, evaluation, or treatment of a mental health disorder. “Home” includes temporary accommodations.
- In-person service must be furnished:
  - 6 months prior to the initial telehealth service; and
  - At least once within 12 months of each subsequent telehealth service (with exceptions based on beneficiary circumstances).
  - Another physician/practitioner of the same specialty and in the same group can provide in-person visit.
- Audio-only is permitted.

Extended Virtual Check-In

- Permanent adoption of HCPCS Code G2252:

Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion.

Remote Therapeutic Monitoring

- Finalized five new RTM codes: 98975-98977, 98980-98981
- RTM codes are meant to monitor health conditions, including musculoskeletal status, respiratory system status, (medication) therapy adherence and response.
- Data may be self-reported as well as digitally uploaded.
- Therapists and other qualified health care professionals may bill RTM codes. The items and services described by the RTM codes must be furnished directly by the billing practitioner or a therapy assistant under the physical therapist's or occupational therapist's supervision.

CCM Services

- Finalized five new CPT codes: 99437, 99424-99427
- Updated values for Chronic Care Management (CCM), Complex Chronic Care Management (CCCM) and Principal Care Management (PCM)
- CMS will consider supervision necessary to obtain beneficiary consent based on comments

Outpatient Therapy Services

- Reduced payment for services furnished by PTA/OTA (85%)
- Use of CQ/CO Modifiers
- If PTA/OTA working with PT/OT in tandem, no modifier required
- If PT/OT provides over 8 minutes of timed service, no modifier required
- If PTA/OTA provides 10% of service, independently from PT/OT, and PT/OT does not provide over 8 minutes, modifier required

PA Direct Billing

- Effective Jan. 1, 2022, PAs can directly bill Medicare for their professional services
- PAs can also reassign payment and incorporate with other PAs

Vaccine Administration Services

Administration of Preventative Vaccines

- $30 per dose for the administration of the flu, pneumococcal, and hepatitis B vaccines
- $40 per dose for the administration of the COVID-19 vaccine

In-Home Administration of COVID-19 Vaccines

- Additional $35.50 through the year PHE ends
- Not billable when another preventative vaccine is being administered at home

COVID-19 Monoclonal Antibodies

- Pay at 95% of avg wholesale price through the year PHE ends
- After year in which PHE ends it will be paid as a biological product

OTP Payment Policy

- Counseling and therapy services may be furnished via audio-only interaction where audio/video communication is “not available to the beneficiary.”
- Must use a service-level modifier for audio-only services in order to facilitate program integrity activities.

Electronic Prescribing of Controlled Substances

- Delayed compliance start date to 1/1/2023 (Part D long-term care beneficiary prescriptions delayed until 1/1/2025)
- Compliance threshold = 70%
- Exceptions to the EPCS requirements:
  - Prescriber and dispensing pharmacy are the same entity;
  - Prescriber issues ≤ 100 controlled substance prescriptions for Part D drugs per calendar year;
  - Prescriber is in the geographic area of an emergency or disaster declared by a federal, state or local government entity; or
  - The prescriber has been granted a CMS-approved waiver based on extraordinary circumstances.

Clinical Laboratory Fee Schedule

- Solicited comments on specimen collection and travel allowance

Open Payments

- CMS is disallowing deletions without a substantiated reason
- CMS is disallowing delayed publication for general payment records
- Defining physician owned distributorship and updating the definition of ownership interest

Provider Enrollment Changes

- Designed to provide CMS with greater flexibility to kick providers/suppliers out of the Medicare program.
- Be wary of outsourcing.

Other Updates

- Appropriate Use Criteria (AUC) Program delayed, again
  - Payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the COVID-19 PHE
- No permanent policy on remote direct supervision
- Modification to “indirect compensation arrangement”

Co-Located Hospitals

- 11/12/21 CMS finalized memo QSQ-19-13.
- Replaces the May 3, 2019 version which emphasized the perils of shared staff/space.
- Final version retracts the troubling language.
- If shared space is deficient, both facilities may face penalties.

CMS COVID-19 Vaccine Mandate

- One of Several Federal Vaccine Mandates
- On September 9, 2021, President Biden announced that the Centers for Medicare & Medicaid Services (CMS) would be taking action to require COVID-19 vaccinations for workers in most health care settings that receive Medicare or Medicaid reimbursement.
  - *"If you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated. Simple. Straightforward. Period."*
- President Biden also announced that the Department of Labor's Occupational Safety and Health Administration (OSHA) was developing a rule requiring all employers with 100+ employees to ensure their workers are vaccinated or tested weekly.
- President Biden also announced that he would be signing executive orders requiring vaccination of:
  - All federal employees; and
  - Employees of federal contractors and subcontractors.

CMS COVID-19 Vaccine Mandate – The Regulation

- On November 5, 2021, CMS issued an interim final rule requiring vaccination of staff at certain facilities subject to health and safety standards known as Conditions of Participation (CoPs) and Conditions for Coverage (CfCs).
  - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555

CMS COVID-19 Vaccine Mandate – The Highlights

- The mandate is expected to apply to over 17 million staff members at over 76,000 health care facilities across the country.
- The original implementation deadline was December 6, 2021, with full vaccination of all staff required by January 4, 2022.
- As of November 30, 2021, federal courts have temporarily halted enforcement of the mandate in all 50 states.

What Facilities Are Covered?

- The CMS mandate does not apply to all entities that participate in Medicare and Medicaid.
- The CMS mandate only applies to certain Medicare- and Medicaid-certified providers and suppliers who are subject to CoPs or CfCs.

Covered Medicare/Medicaid Providers and Suppliers

- Hospitals
- Ambulatory surgical centers
- Long-term care facilities (including skilled nursing facilities and nursing facilities, generally referred to as nursing homes)
- Home health agencies
- Hospices
- Intermediate care facilities for individuals with intellectual disabilities
- Comprehensive outpatient rehabilitation facilities

Covered Medicare/Medicaid Providers and Suppliers, Cont.

- Specialized clinics, rehabilitation agencies, and public health agencies that are certified providers of outpatient physical therapy and speech-language pathology services certified under 42 CFR Part 485
- Community mental health centers
- Home infusion therapy suppliers
- Rural health clinics
- Federally qualified health centers
- End-stage renal disease facilities
- Psychiatric residential treatment facilities
- Programs of all-inclusive care for the elderly

Notable Exclusions

- Freestanding physician offices
- Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers
- Many state-licensed Medicaid service providers

Requirements for Covered Facilities

- Establish written policies and procedures to ensure that all "staff" are vaccinated with their first dose by December 6, 2021, and fully vaccinated by January 4, 2022
  - CMS considers staff to be "fully vaccinated" if it has been two weeks or more since they completed a primary vaccination series (boosters not required).
  - However, CMS will consider completion of a primary vaccination series (without the 14-day waiting period) as sufficient for purposes of the January 4 deadline.

Requirements for Covered Facilities, Cont.

- Medical and religious exemptions from vaccination are permitted to the extent required by Federal law.
  - On December 16, 2021, our Employment & Labor Group will be hosting a webinar titled “Vaccines in the Workplace” that will include tips for navigating the exemption process. Register here.
- Testing is not an alternative to vaccination.

Definition of “Staff”

- The term “staff” is **very broad**.
- Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the covered facility and/or its patients:
  - Facility employees;
  - Licensed practitioners;
  - Students, trainees, and volunteers; and
  - Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

Definition of “Staff,” cont.

- Staff subject to the mandate include: administrative staff, board members, housekeeping and food services, etc.
- Excluded:
  - Fully remote staff who do not have any direct contact with patients or other facility staff
  - “One off” vendors, volunteers, and professionals who infrequently provide ad hoc non-health care services

Required Policies and Procedures

- A process for ensuring all staff (except for who have pending requests for, or who have been granted, exemptions) have received [by December 6, 2021], at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;
- A process for ensuring that all staff are fully vaccinated for COVID-19 [by January 4, 2022], except for those staff who have been granted exemptions
- A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19

Required Policies and Procedures, Cont.

- A process for tracking and securely documenting the COVID-19 vaccination status of all staff
- A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses (though boosters are not required)
- A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law
- A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption

Required Policies and Procedures, Cont.

- A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner and contains information specifying which vaccines are clinically contraindicated and the recognized clinical reasons for the contraindications and a statement by the signing practitioner recommending the exemption based on the contraindications
- A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom the vaccination may be delayed due to clinical precautions
- Contingency plans for staff who are not fully vaccinated for COVID-19

Consequences of Noncompliance

- CMS's stated goal is to bring health care facilities into compliance. CMS has said that it will not hesitate to use its "full enforcement authority" if a facility does not comply:
  - Civil monetary penalties
  - Denial of payment for Medicare or Medicaid services
  - Termination from the Medicare and Medicaid program

Status of Legal Challenges

- On November 29, 2021, the U.S. District Court for the Eastern District of Missouri issued a preliminary injunction enjoining the federal government from implementing and enforcing the CMS Vaccine Mandate in ten states.
  - On December 1, the district court denied the Biden administration's request for a stay on the preliminary injunction pending an appeal to the 8th Circuit.
- On November 30, 2021, the U.S. District Court for the Western District of Louisiana issued a similar preliminary injunction that applies to the rest of the country.
  - On December 1, the district court denied the Biden administration's request for a stay on the preliminary injunction pending an appeal to the 5th Circuit.

The Latest from CMS

"While CMS remains confident in its authority to protect the health and safety of patients in facilities funded by the Medicare and Medicaid programs, it has suspended activities related to the implementation and enforcement of this rule pending future developments in the litigation."

IPPS Final Rule

- Published August 13, 2021, at 86 FR 44774.
- Estimated increase in payments of $2.3 billion.
- New COVID-19 Treatments Add-On Payments continued.
- Continued increased wage index for low-wage hospitals.
- Repealed MS-DRG cost reporting and 2024 shift to relative weight methodology.

OPPS Final Rule

- Published November 16, 2021, at 86 FR 63458.
- Estimated increase in payments of $5.9 billion.

Inpatient Only (IPO) List

- In the 2021 OPPS final rule, CMS announced elimination of IPO list over 3 years.
- CMS is now:
  - Halting elimination of the IPO list;
  - Codifying criteria for removing a procedure from IPO list;
  - Reinstating 2-year exemption from 2-midnight review for procedures removed from the IPO list; and
  - Halting expansion of the ASC covered procedure list.

Hospital Price Transparency

- Current penalty of up to $300/day for noncompliance.
- CMS concerned about hospital noncompliance.
- New scalable penalty of $10 per bed per day for hospitals with more than 30 beds (up to $5,500/day).

Hospital Price Transparency

TABLE 76: Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 - $5,500 per hospital (number of beds times $10)	$113,150 - $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

340B Pricing

- CMS is continuing payment for certain 340B drugs at average sales price (ASP) minus 22.5%.
- The Supreme Court accepted review of a challenge by the American Hospital Association and heard oral arguments on November 30, 2021.

Service Categories for OPD Prior Authorizations

- In 2020, CMS established a prior authorization process for certain procedures.
- It is primarily cosmetic.
- Two high-growth procedures were added in 2021.
- No new procedures were added for 2022.

Presenters

Marguerite Ahmann
612.492.7495
mahmann@fredlaw.com

Marielos Cabrera
612.492.7462
mcabrera@fredlaw.com

David Glaser
612.492.7143
dglaser@fredlaw.com

Andrew Holm
612.492.7221
aholm@fredlaw.com

Sean Nagle
612.492.7386
snagle@fedlaw.com