2023 Regulatory Update

Health Law Webinar

December 14, 2022

Fredrikson

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Agenda

- Physician Fee Schedule Final Rule.
- Medical Device Audits.
- Interesting Points.
- IPPS/OPPS/ASC Final Rule.

Physician Fee Schedule Final Rule

Physician Fee Schedule Final Rule

- Published November 18, 2022, at 87 FR 69404.
- Reduces CY 2023 payment levels by almost 4.5% compared to CY 2022.

Shared Visits: How Did We Get Here?

42 CFR § 411.15 Particular services excluded from coverage

(m) ***Services to hospital patients*** -

(1) ***Basic rule.*** Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in § 410.2 of this chapter) during an encounter (as defined in § 410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term "hospital" includes a CAH.

(2) ***Scope of exclusion.*** Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

42 CFR 410.26(b)

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(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.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic o a physician (or other practitioner).

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services

Former 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).
- Was used January 2021:

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

- The Manual was withdrawn in May 2020.

Shared Visits: 42 CFR § 415.~~140~~ 150

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

42 CFR 415.~~140~~ 150

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~~ 150

Substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit, except as otherwise provided in this paragraph. For visits other than critical care visits furnished in calendar year 2022 ***and 2023***, *substantive portion* means one of the three key components (history, exam or medical decision-making) or more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit.

42 CFR 415.~~140~~ 150

(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.

Shared Visits: Substantive Portion

- 2023 remains more flexible for all but Critical Care.
- In 2023, “substantive portion” of the visit means the professional performed any one of the three key components (history, exam or medical decision-making) or more than 50 percent of the time.
- In 2024, absent another change, only whoever does the most time may bill. (CMS has indicated informally that if both professionals are there, they may decide which gets the time.)

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.
- Historically signatures have NOT been a condition of payment. Is that changing?

Shared Visit Critical Care Technical Correction

- The preamble said that you could bill 99292 with 75 minutes of critical care. They meant to say 104, because you need a full 30 minutes of additional time.
- Note that CMS differs from CPT.

Behavioral Health Services

- Added exception to direct supervision requirement under “incident to” regulation at 42 CFR 410.26(b)(5).
- Key definitions:
  - Auxiliary personnel.
  - Direct supervision.
  - General supervision.
- Behavioral health services include any service furnished primarily for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders.

42 CFR 410.26(b)(5)

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). Behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

42 CFR 410.26(a)(1)

(1) ***Auxiliary personnel*** means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

Includes behavioral health practitioners such as Licensed Professional Counselors (LPCs) and Licensed Marriage and Family Therapists (LMFTs).

42 CFR 410.26(a)(2), (3)

(2) ***Direct supervision*** means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii).

42 CFR 410.32(b)(3)(ii): ***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...

(3) ***General supervision*** means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service.

Behavioral Health Services, Cont.

- Created a new G-code to allow Clinical Psychologists (CPs) and Clinical Social Workers (CSWs) to bill for general behavioral health integration (BHI).
- GBHI1 was placeholder code; final code is G0323.
- *Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month. (These services include the following required elements: Initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.)*

Audiology Services

- Provided a limited exception to the physician/NPP order requirement for diagnostic hearing testing services furnished by audiologists for non-acute hearing conditions in order to broaden patient access to these services. See new 42 CFR 410.32(a)(4).
- New modifier (AB); not a new G-code as originally proposed.
- See Table 36: Codes for Tests that Audiologists can Bill with the AB Modifier for Nonacute Hearing Conditions without a Physician or NPP Order/Referral. 87 FR 69662.

42 CFR 410.32(a)

(a) ***Ordering diagnostic tests.*** Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary…

42 CFR 410.32(a)(4)

(4) *Application to audiologists.* Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed using a modifier CMS designates for this purpose.

Table 36 – 36 Codes Covered by Audiology Direct Access Policy

TABLE 36: Codes for Tests that Audiologists can Bill with the AB Modifier for Nonacute Hearing Conditions without a Physician or NPP Order/Referral

CPT Code	Short Descriptor
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92562	Loudness balance test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92571	Filtered speech hearing test
92572	Staggered spondaic word test
92575	Sensorineural acuity test
92576	Synthetic sentence test
92577	Stenger test speech
92579	Visual audiometry (vra)
92582	Conditioning play audiometry
92583	Select picture audiometry
92584	Electrocochleography
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92602	Reprogram cochlear implt <7
92603	Cochlear implt f/up exam 7/>
92604	Reprogram cochlear implt 7/>
92620	Auditory function 60 min
92621	Auditory function + 15 min
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
92640	Aud brainstem implt programg
92651	Aep hearing status deter i&r
92652	Aep thrshld est mlt freq i&r
92653	Aep neurodiagnostic i&r

Colorectal Cancer Screening

- Reduced the minimum age payment limitation for colorectal cancer screening from 50 to 45 years, citing recently revised policy recommendations by the U.S. Preventive Services Task Force. See amendments to 42 CFR 410.37(c), (e), and (i).
- Added new paragraph (k) to 42 CFR 410.37: *A complete colorectal cancer screening.* Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. The frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

Requiring Manufacturers of Certain Drugs to Provide Refunds with Respect to Discarded Amounts

- Section 90004 of the Infrastructure Investment and Jobs Act, also known as the Bipartisan Infrastructure Bill (Public Law 117-48, Nov. 15, 2021), amended Section 1847A of the Social Security Act (42 U.S.C. 1395w– 3a) to redesignate subsection (h) as subsection (i) and insert a new subsection (h) titled "Refund for Certain Discarded Single-Dose Container or Single-Use Package Drugs".
- First introduced by Senators Dick Durbin (D-Ill.) and Rob Portman (R-Ohio) as the "Recovering Excessive Funds for Unused and Needless Drugs Act of 2021" or the "REFUND Act of 2021" (S. 1287, April 21, 2021).
- Amended 42 CFR 414.902 to add the definition of "Refundable single-dose container or single-use package drug" and added new § 414.940 to implement Section 90004.

42 CFR 414.902

Refundable single-dose container or single-use package drug means a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information. The term "refundable single-dose container or single-use package drug" excludes—

(1) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(2) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(3) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

42 CFR 414.940 – Highlights

(a) *Provision of information to manufacturers.*

- CMS will send annual reports to manufacturers detailing their refund obligations, but the timing of the first report will be the subject of future rulemaking.
- CMS plans to issue preliminary reports on estimated discarded amounts based on available claims data from the first two quarters of CY 2023 no later than December 31, 2023.
- Note operational implications of requirements for the use of the existing JW modifier, for reporting discarded amounts of drugs, and the new JZ modifier, for attesting that there were no discarded amounts.

(c) *Refund amount.*

- Manufacturers will be required to reimburse CMS for the charges associated with the amount of discarded drug that exceeds an applicable percentage (10% unless increased under (d), below) of total charges for the drug in a calendar quarter.

(d) *Treatment of drugs that have unique circumstances.*

- Higher "applicable percentage" of 35% for drugs that are reconstituted with a hydrogel and have variable dosing based on patient-specific characteristics (CMS has identified only one applicable drug - Jelmyto®).
- Other drugs with unique circumstances will be the subject of future rulemaking.

Skin Substitutes

- Opted not to finalize proposed changes to terminology (“wound care management products”) and payment methodology.
- Instead, CMS will host a townhall session in early 2023 to discuss any changes to its policies for skin substitute products ahead of 2024 rulemaking.

Telehealth

- Adding Category 3 services and extending them through 2023.
- Temporary telehealth codes extended for 151 days after the PHE ends.
- Postponing Telemental Six Month Rule for 151 days after the PHE ends.
- Discontinuing virtual direct supervision.
- Audio-Visual Communications will be the appropriate standard of care.
- Bill with the place of service indicator that would have been reported if the service was furnished in person.
- Originating site facility fee/list of services: List of Telehealth Services | CMS

Remote Therapeutic Monitoring Services

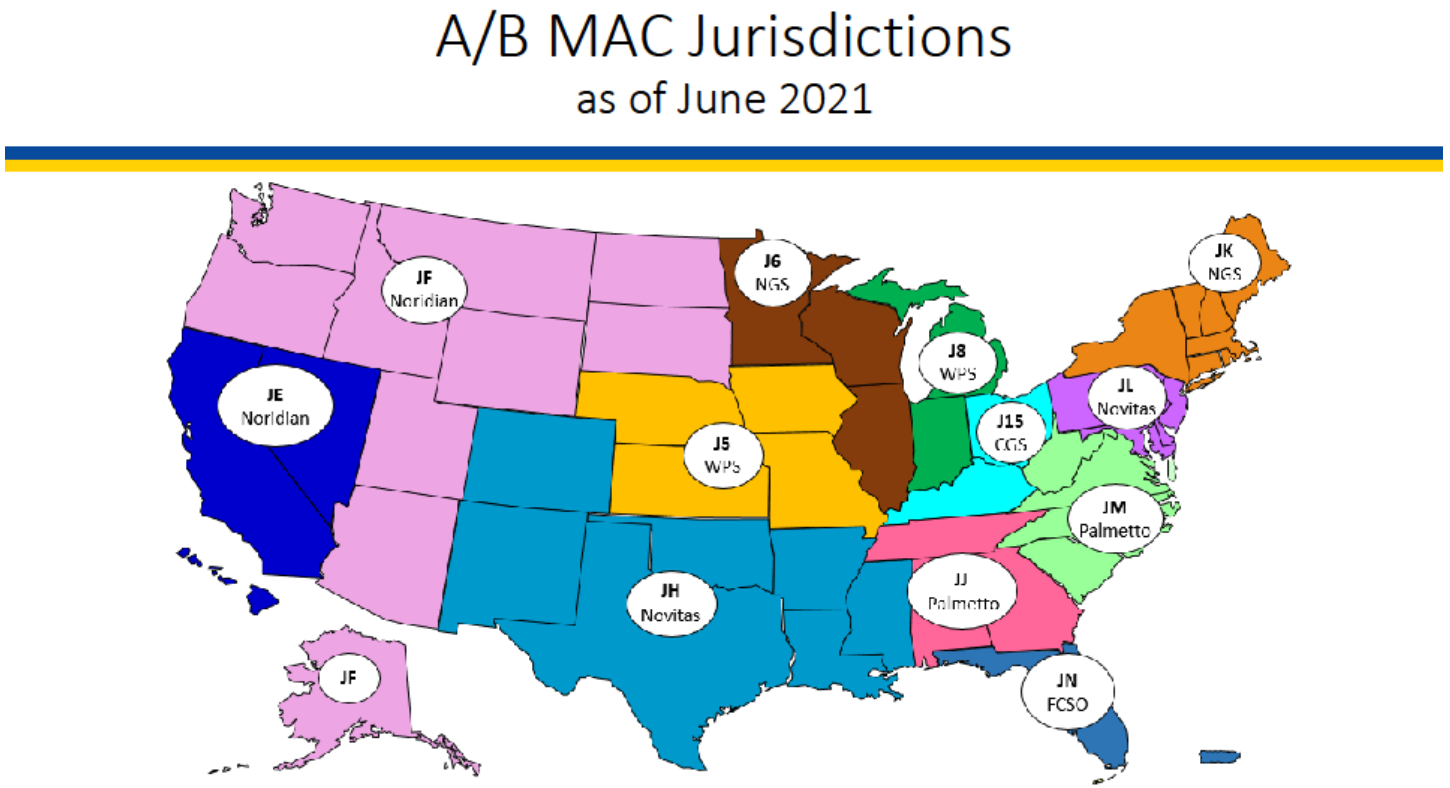
- CMS did not adopt the four new G-codes.
  - *Meant to increase patient access and reducing supervisory burden.*
- Allowing for RTM services to be provided under general supervision requirements.

Opioid Use Disorder Treatment Services/Opioid Treatment Programs

- CMS is revising the methodology for pricing methadone.
- Will use the amount used in 2021 and update annually to account for inflation.
- Update the rate for individual therapy (30 min – 45 min).
- Allow two-way audio-video communications for the initiation of buprenorphine.
- In some cases, where all other requirements are met, CMS will allow audio only communications to initiate treatment with buprenorphine.
- OTPs can bill for services furnished via mobile units.

Removal of NCD

- CMS will remove NCD 160.22 (Ambulatory EEG Monitoring).
- MACs will make these determinations moving forward.



Payment for Preventive Vaccine Administration

- CMS will continue to provide additional payment for at-home COVID-19 vaccinations.
- Annually update based on the MEI increase and will adjust based on the geographic adjustment factor for the location of administration.
- Rules on administration of COVID-19 vaccine and monoclonal antibody products will end in the year in which EUA declaration is terminated.
- CMS will permanently cover monoclonal antibody products for prevention of COVID-19.

DMEPOS Conditions of Payment

- DMEPOS Suppliers must comply with Conditions of Payment (42 C.F.R. § 424.57 (b)).
- DMEPOS Suppliers must comply with application certification requirements (42 C.F.R. § 424.57(c)(1)(ii)(A)).
- DMEPOS Suppliers must comply with state licensure requirements.

Medical Device Credit Audits

Defective Devices

42 CFR §§ 412.89 and 419.45 require reductions in Medicare payments for the replacement of implanted devices that are due to recalls or failures.

The DRG is reduced for certain replacement devices if the hospital gets the device for free/discount ≥ 50% of the cost of the device, and when the assigned MS-DRG is noted in the IPPS rule. See also MCPM Ch. 3 § 100.8.

Must use condition code 49 or 50, along with value code FD.

Defective Drafting

The regulation indicates you reduce the APC by “the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under §419.66.”

That is defined as: (h) *Amount of pass-through payment.* Subject to any reduction determined under §419.62(b), the pass-through payment for a device is the hospital's charge for the device, **adjusted to the actual cost for the device**, minus the amount included in the APC payment amount for the device.”

What does it mean to “adjust” the charge to the cost. Wouldn’t you just say “the cost?” Why does charge matter at all if you are “adjusting’ it to the cost? This is incomprehensible.

Since it calls for a “lesser of” you can ignore it.

Interesting Points

Rare Opportunity To Solve Stark Problems?

Rare Opportunity To Solve Stark Problems?

- The Stark Covid waivers are still in place.
- Created to permit hospitals to help physicians during this rough patch, they allow opportunity for creativity.
- The window may be closing. Seize it!

EKRA: Commission Payments

- EKRA prohibits “kickbacks” in recovery, but applies to labs broadly. Can a lab pay its sales force on a commission basis?
- The law penalizes anyone who: pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
  - “(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

EKRA: Commission Payments

- It exempts:
- a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—
- "(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
- "(B) the number of tests or procedures performed; or
- "(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

EKRA: Commission Payments

- Can we rely on S&G Labs Hawaii v. Darren Graves? Judge Kobiyashi ruled that EKRA does not prohibit commission-based payments when the recipient of the commission is not interacting directly with patients.

EKRA: Commission Payments

- Can we rely on Hawaii, S&G Labs Hawaii v. Darren Graves? Judge Kobiyashi ruled that EKRA does not prohibit commission-based payments when the recipient of the commission is not interacting directly with patients.
- USA v. Schena comes out the other way.

IPPS/OPPS/ASC Final Rule

IPPS Final Rule

- Published August 1, 2022, at 87 FR 48780.
- Estimated increase in payments of $1.4 billion.
- Direct GME payment formula updated.
- Continued increased wage index for low-wage hospitals and implemented a 5% cap on year-over-year decreases in a hospital's wage index.
- Solicited feedback regarding climate change.

OPPS Final Rule

- Released November 1, 2022, published at 87 FR 71748.
- Estimated increase in payments of $6.5 billion (OPPS) and $230 million (ASCs).

Service Categories for OPD Prior Authorizations

- In 2020, CMS established a prior authorization process for certain procedures.
- New service category added for 2023 (facet joint interventions).
- CPT codes 64490-64495 and 64633-64636.

Hospital Inpatient Only List

- In the 2021 OPPS final rule, CMS announced elimination of IPO list over 3 years.
- CMS reversed course in 2022.
- 11 codes removed in 2023; 8 new codes added.
- Listed on Table 65 of the final rule.

Table 65

- CPT Codes Removed from IPO List.
  - 22632, 47550, 21141-21143, 21194, 21196, 21255, 21347, 21366, 21422.
- CPT Codes added to IPO List.
  - 15778, 22860, 49596, 49616-49618, 49621-49622.

ASC Covered Procedure List

- 4 out of 64 suggested codes added to ASC CPL.
  - CPT codes 19307, 37193, 38531, and 43774.
- New process for suggesting codes for inclusion starts in 2024 (not 2023 as originally planned).
  - Can be submitted January 1 to March 1.
  - Additional codes can always be submitted during the comment period.

Rural Emergency Hospitals (REHs)

- New provider type established by Section 125 of the Consolidated Appropriations Act of 2021.
- Critical access hospitals and certain rural hospitals can convert.
- CMS allows submitting a Form CMS-855A rather than an initial application.

REH Conditions of Participation

- Must have a physician or other practitioner on-call at all times and available onsite within 30 or 60 minutes, depending on whether the facility is located in a frontier area.
- ED must be staffed at all times by an individual competent in the skills needed to address emergency medical care.
- The annual per-patient average length of stay cannot exceed 24 hours.
- Must have a facility-wide infection prevention and control and antibiotic stewardship program.

REH Services

- Payment for REH Services is 105% of the OPPS fee schedule plus a monthly facility fee.
- REHs may elect to provide outpatient services not paid under the OPPS.
- REHs may not provide inpatient care…
- But may be able to provide post-hospital extend care services.

REH Stark Updates

- REHs required to provide certain DHS as a CoP.
- Certain provider-specific exceptions for compensation arrangements updated to include REHs:
  - 42 CFR 411.357(e), (r), (t), (v), (x) and (y).
- Ownership/investment exception not finalized, though rural provider exception may apply.

340B Pricing

- CMS is discontinuing payment for certain 340B drugs at average sales price (ASP) minus 22.5%.
- New payments will be ASP plus 6%, which was used prior to 2018.
- Change due to SCOTUS decision holding prior reimbursement was unlawful.
- Unclear how CMS will resolve underpayments from 2018 to 2022.

NPP Supervision

- CMS allowed NPPs (NPs, PAs, CNSs, CRNAs, and midwives) to supervise diagnostic tests paid under the PFS.
- Change made permanent in 2021 PFS final rule.
- For 2023 OPPS final rule, CMS is extending this change so these NPPs can supervise OPD diagnostic services.
- Must be allowed under scope of practice and state law.

PPE Reimbursement

- Due to shortage of N95 respirators during pandemic, CMS will increase reimbursement for wholly domestically produced N95s.
- All respirator components are grown, reprocessed, reused or produced in the US.
- Hospital can rely on written statement of manufacturer…
- If it's from CEO or COO (or their designee).

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Thank you!

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