CAPITOL STREET

July 13, 2023

Hospital Outpatient Pay +3.4% In 2024

Rural Hospitals +4%, Stricter Price Transparency & Device Pass-Through

Relevant Companies



On July 13, CMS released the proposed CY 2024 Hospital Outpatient & Ambulatory Surgery Center (ASC) rule. The regulation can be found <u>here</u>. The proposed policies will affect 3,500 hospitals and 6,000 ASCs, along with impacts to some Medtech and Biopharma manufacturers. Final rates and policies will be released on or about Nov 1, 2023.

>>> Our Take & Next Up

Positive for acute-care hospitals with mixed news for some MedTech & Biopharma manufacturers.

Comments are due by Sept. 11, 2023, and the final rule is due on or around Nov 1, with new payments and policies that start Jan 1, 2024. Rural hospital rates (+4.4%) are stronger than urban ones (+2.8%) for CY24. Price transparency requirements are stricter for hospitals starting in 2024. Part B drug payment remains at ASP+6%, but 340B hospitals will get dollars back per a recent court decision (link to hospitals and payment amounts is below) per CMS repayment rules released last Friday July 7. Medical device (6) pass through coverage applications are being reviewed by CMS with decisions in the final rule. CMS will not expedite non-opioid coverage into 2024 (No Pain Act, 2025), while lithotripsy pass-through ends June 30, 2024. In person visit rules will remain relaxed for remote mental health services through the end of 2024.

>>> Key Points

HOPD 2024

Hospital outpatient departments will see an update of +3% in 2024, a positive for hospitals, though facilities would have wanted higher rates (due to inflation, clinical labor, etc). Urban hospital outpatient departments

would see a +2.8% increase, but rural hospital departments will see an even greater update of +4.4%. Final rates will be posted by Nov 1.

Proprietary hospitals would see a +3.4% update in 2024 (UHS, THC, HCA, Others). Voluntary hospitals would see a +3.0% increase, and government hospitals would see a +2.8% increase in 2024.

AMBULATORY SURGERY CENTERS

Surgery centers (ASC) would see a proposed update of +3.0% in 2024. The range of pay updates is -6% to +6%. On the higher range Eye (+6%) and Genitourinary (+6%) surgeries and on the much lower end Nervous System surgeries would be -6%.

Positives for dental (surgical) services in CY 2024, CMS is proposing to add 26 dental surgical procedures to the ASC covered procedures list, and 78 ancillary dental services to the covered ancillary services list.

HOSPITAL PRICE TRANSPARENCY

CMS calls for more hospital price transparency enforcement, attestation. CMS will revise enforcement process by updating methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance.

CMS wants hospital affirmation of price transparency data submitted. CMS wants to (1) add definitions for "CMS template", "consumer-friendly expected allowed charges", "encode", and "machine-readable file" (MRF); (2) require hospitals to affirm the accuracy and completeness of data in their MRF; (3) revise and expand the data elements hospitals must include in the MRF; (4) require hospitals to conform to a CMS template layout and other technical specifications for encoding standard charge information in the MRF; (5) require hospitals to establish and maintain a txt file and footer as specified by CMS

MENTAL HEALTH

CMS is proposing to establish Intensive Outpatient Programs (IOP) under Medicare. An IOP is an organized outpatient program of psychiatric services for individuals with acute mental illness. IOP services can be furnished in hospital outpatient departments, community mental health centers (CMHCs), federally qualified health centers (FQHCs), and rural health clinics (RHCs). CMS is also proposing to extend IOP coverage to Opioid Treatment Programs (OTPs).

Other (positive) mental health policies (telehealth). CMS proposes to delay the periodic in-person visit requirement for patients' remote mental health services to remain covered, until the end of CY 2024.

DRUGS & 340B PAYMENT UPDATE

For non-opioid treatments (Pacira) CMS seeks comments for 2025 implementation (not 2024). CMS seeks comment on any drug, biological, or medical device that a commenter believes would meet the definition of a non-

opioid treatment for pain relief under the Act." Scenario 1: Payment Limitation Based on the Top Five Services by Volume with Known Claims Data Scenario 2: Payment Limit Without Claims Data.

On July 7, CMS released a rule detailing \$9 B pay allocation to 340B hospitals that received reduced Medicare payments under a Trump-era rule. See hospital-specific payments owed to every 340B entity in the US <u>here</u>. CMS is proposing to make one-time lump sum payment to affected 340B entities. However, the proposed ruling also comes with a –0.5% reduction to the OPPS conversion factor for non-drug item and service payments for 16 years starting CY 2025.

CMS will continue to pay the statutory default rate, which is generally ASP plus 6%, for 340B acquired drugs and biologicals. The payment for 340B acquired drugs and biologicals would not differ from the payment rate for drugs and biologicals not acquired through the 340B program.

INPATIENT ONLY (IPO) LIST & DEVICES FOR PASS THROUGH

CMS received 6 complete applications for device pass-through payments. CMS is soliciting public comments on all 6 of these devices. They are:

- Alternative Pathway Device Pass-Through Applications -- 2 FDA breakthrough (1) CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath (Philips) and (2) CERAMENT G (BONESUPPORT)
- Traditional Device Pass-Through Applications (3) Ambu aScopeTM 5 Broncho HD (Ambu USA) (4) Praxis Medical CytoCore (Praxis Medical Devices) (5) EchoTip (Cook Medical) (6) FLEX Vessel Prep System (VentureMed)

Shockwave (lithotripsy) pass-through expiration date is June 30, 2024. Lithotripsy's HCPCS code is C1761 and CMS says it will cost \$19.6 M in pass through expenditures in CY 2024. For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2024 CMS proposes an estimate for the first group of devices of \$93.7 M.

For 2024, CMS is proposing to add 9 services to the IPO list. CMS is not proposing to remove any services from the IPO list for 2024.

The added procedures include: (1) X114T Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering (2) 2X002 Anterior thoracic vertebral body tethering (3) 2X003 Anterior thoracic vertebral body tethering (4) 2X004 Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering (5) 619X1 Insertion of skull-mounted cranial neurostimulator pulse generator or receiver (6) 7X000 Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic (7) 7X001 Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic (8) 7X002 placement, manipulation of transducer, and image acquisition only (9) 7X003 interpretation and report only 0646T Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, percutaneous approach

Ipsita Smolinski

Managing Director | Capitol Street

900 19th Street, NW 6th Fl Washington DC 20006

202.250.3741

ipsita@capitol-street.com

www.capitol-street.com

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