April 10, 2023

CMS ‘24 Hospital Inpatient Rule Preview

340B, DSH, TCET (Med Tech), Cell & Gene Therapy, Hospital Sentiment

Relevant Companies

HCA Healthcare, Tenet Health, UHS Universal Health Services, Inc., AstraZeneca, Gilead, Amgen, Edwards, Medtronic, Novartis, Stryker, Sage Products, Recordati, Bristol Myers Squibb, CSL Behring Biotherapies for Life™, bluebirdbio, Boston Scientific

See Key Points for our hospital payment regulation preview. We expect that the IPPS could be released any day given the early release of IRF, Psych and Hospice. The IPPS/LTCH proposal cleared OMB on April 4 (for FY24) could be out this week, any day now.

Our Take & Next Up

The proposed LTCH/IPPS ‘24 is likely to be released over the next few days. The rule cleared OMB, with a final rule being released ahead of August recess. The payments and proposals would be for FY24, which starts Oct 1, 2023.

Key Points

MARKET BASKET UPDATE & 340B PAY RECOUPMENT

The market basket (MB) update is likely to be in line with other providers (approx. +3%). The IRF regulation, which was released on Apr 3, 2023 (here), proposes to adopt a 2021-based IRF market basket for FY24 of 3.0%. The hospice PPS proposal, released on Mar 31, 2023 (here) would to apply the 2018-based IPPS MB update for FY24 of 3%. The Psych PPS, released April, proposed a MB of 3%, as well.

340B payments to hospitals are unlikely to be addressed in the ‘24 IPPS proposal. On June 15, 2022, the US Supreme Court unanimously ruled in favor of hospitals to overturn a 2020 decision to uphold the authority of the HHS to significantly cut payments to certain hospitals participating in the 340B Drug Pricing Program. 340B hospitals received a reimbursement rate based on “an estimate

from MedPAC that 340B hospitals obtained prescription drugs at an average discount of at least 22.5% below the average sales price charged by manufacturers." (here).

We could see site neutral payment (limited) proposal discussed by CMS, but Congress eventually has its eye on that $100B+ prize. While Congress eyes $100 B+ in hospital savings, CMS would not have the authority to regulate on this topic. So-called site-neutral payment reforms could save Medicare upward of $100 B over a decade, according to CBO and other projections, and those with private health insurance could see savings. Medicare lets hospital-owned clinics be designated as outpatient departments and net a higher payment for certain services than if they were owned by clinicians or independent. As a reminder, MedPAC and BCBSA recently (2023) discussed reforms, providing recommendations to Congress, along with mentions at recent House & Senate hearings on costs in the healthcare system.

Hospitals want more on DSH and CMS could opine on quality measures in the rule. We could see CMS provide color on disproportionate share hospital (DSH) payments as well as quality measures. Recall that CMS has provided alternative formulas for calculating DSH payments. CMS uses 2018 and 2019 data to determine the distribution of 2023 DSH uncompensated care payments. CMS also will use a three-year average of data for FY 2024 and beyond. The 2023 rules (issued in 2022) would cut DSH payments by about $800 M, due partially to a decrease in the uninsured population.

MED TECH – TCET UNLIKELY IN IPPS BUT OUR TAKE

Transitional Coverage for Emerging Technologies (TCET) impacting novel MedTech could be announced with the IPPS but it's unlikely. CMS is slated to release TCET guidelines this Spring, but we think a separate rule is more likely. Bipartisan House Reps Eshoo (D-CA), Guthrie (R-KY) and DelBene (D-WA) all have asked CMS to release a rule by the end of 2022, and CMS has publicly stated that it intends to do so in April.

As a reminder, CMS repealed the Medicare Coverage of Innovative Technology (MCIT) program in November 2021 without a replacement on hand. MCIT would have established automatic national Medicare coverage for all Breakthrough Devices that fit into benefit categories starting on the day of FDA approval.

On breakthrough medical technologies, our take. We predict the new TCET rule will not be as generous as automatic Medicare coverage for innovative technologies and is likely to have additional reporting/data generation requirements for manufacturers compared to the notion of definite Medicare coverage, as envisioned previously.

RARE DISEASES, CELL & GENE THERAPIES

Rare disease, cell & gene therapy coverage could be addressed in the FY24 rule. In the 2023 IPPS final rule, CMS solicited comments on how to address inpatient payment issues for rare diseases, including ways to address hospital formulary challenges for high-cost, low volume therapies. For FY 2024, CMS may release a change in MS-DRG classification for an inpatient orphan drug specific proposal to improve reimbursement for rare disease treatment.

Specifically, CMS noted that there is a challenge in formulary coverage for potentially high-cost therapeutics for rare diseases. Hospitals utilize formularies for inpatient drugs as a cost-management tool that strongly incentivizes physicians to use on-formulary drugs over off-formulary drugs, whenever clinically appropriate to do so. High-cost drugs are not accessible in hospital formularies and stakeholders petitioned that it create a disincentive in addressing rare diseases.

3 specific cases of low-volume, high-cost drugs brought to CMS were described for comments

- Treatment of patients with Porphyria (a group of rare disorders that interfere with the production of hemoglobin). Stakeholders reported difficulty in receiving Panhematin (Recordati)
- Treatment of patients with uncontrolled bleeding. Difficulty in access for Andexxa (AZN), a recombinant decoy protein that rapidly reverses the anticoagulant effects of oral anticoagulants, apixaban and rivaroxaban.
- Treatment of patients with postpartum depression. Stakeholders wanted to know how the administration of Zulresso (SAGE) is recognized for payment under the ICD-10 MS-DRG.

Solutions sought by CMS could include creating a new DRG, a new NTAP-like pathway, novel hospital reimbursement for ASP (Hospital Outpatient System) as well as other methodologies described here.

- Creating a “permanent” payment methodology approach which combines the MS-DRG “fixed price” with continued partial payment for the actual cost of treatment per stay.
- Creating new MS-DRGs for certain low-volume therapies or for orphan conditions with more flexible cost outlier funding.
- Creating new MS-DRG categories to ensure access to rapidly expanding transformative therapies like cell and gene therapies,
- Creating a new enhanced new technology add-on payment-like pathway that establishes separate payment for low volume high-cost drugs.
- Reimbursing hospitals for orphan drugs based on the Average Sales Price (ASP) as published in the HOPD Addendum B file using the same authority that the Agency relied on to make the recent COVID-19 payment adjustments.
- Establishing a central formulary to provide high-cost drugs for rare conditions instead of utilizing individual hospital pharmacy formularies to ease burdens of carrying high-cost drugs on rural and smaller hospitals, as drug transport can potentially be cheaper than patient transport.

HOSPITAL SENTIMENT

Hospital sentiment is not great in Washington these days. The bloom is off the rose – hospitals saved the day during COVID, but they are now largely viewed as a large cost burden to the system. The view is held by many Democrats and Republicans alike.

Congress held two healthcare cost hearings in key House committees (March). Both the Ways & Means and House Energy & Commerce Committees are diving into the reason for high healthcare costs facing Americans.

FTC hospital deal opposition likely caused NY hospital merger to collapse. SUNY Upstate Medical University dropped the acquisition of Crouse Health, announced in April 2022 (here). The deal was abandoned amidst FTC opposition of the proposed merger (see FTC letter New York State Health Department here). The agency expressed concerns of consumers experiencing higher healthcare costs and reduced services. Last year, HCA Healthcare and Steward Health Care abandoned their deal involving five Utah hospitals only 13 days after the FTC challenged the transaction (see FTC statement here). On February 15, CommonSpirit Health announced that it will acquire Steward Health Care's sites of care in Utah (to be managed by Centura Health), Steward’s second stab at selling off the 5 hospitals in Utah.

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