Policy Brief

August 9, 2019

Outpatient Payment Rule Maintains 340B Cuts, Proposes Transparency Model Requiring Published Negotiated Rates

The continuation of steep cuts to 340B drug payments along with rules implementing President Trump's "Price and Quality Transparency" Executive Order have captured industry interest in this year's Outpatient Prospective Payment System proposed rule. If finalized, the rule would require hospitals to publish negotiated rates with insurers. The rule also addresses other key issues, such as changes to the Inpatient Only List and new safety measures for the Outpatient Quality Reporting Program. A detailed outline of the rule can be found here.

Where is CMS going with 340B?

Effective January 1, 2018, CMS reduced the 340B reimbursement rate by nearly 30 percent, a cut which continued into 2019. In December 2018, a coalition of hospitals led by the American Hospital Association, successfully obtained injunctive relief against the reductions. Though the hospital plaintiffs obtained a favorable ruling, the memorandum opinion required CMS to devise its own remedy. The proposed rule reveals CMS' plans, which perpetuate instability for hospitals reliant on the 340B savings. Here's a breakdown:

- As it stands, the rule proposes to keep the ASP-22.5 percent for 340B payment rates in 2020.
- CMS stated its intent to pursue an appeal of the injunction, which determined that the Secretary acted beyond the scope of his authority.
- CMS seeks comments for possible remedies in the event of the Agency losing the appeal but suggests a possible rate of ASP+3 percent for 340B drugs.

What does 'price transparency' look like?

Predicated on the assumption that patients will learn to "shop" for their health care, the President's Executive Order directed CMS to develop a rule that would require hospitals to publicize gross and negotiated prices for 300 items and services. This requirement goes beyond the 2019 final rule requiring hospitals to publish list prices from their chargemasters. Under CMS' proposal, patients would now be able to see the deals hospitals are making with third-party payers, like insurance companies, for individual and packaged items and services. The rule also seeks input on how to assess provider use of price and quality information to aid in consumer decision-making. This request foreshadows a new, unexpected role that providers could play in the health care delivery system as they help patients understand and compare the cost of care. Comments on the proposed rule are due September 27, 2019.

CMS' Final IPPS Rule: Things to Know

This week, CMS also released the final Inpatient Prospective Payment System (IPPS) rule for Fiscal Year (FY) 2020. The top policies finalized include increasing the wage index for hospitals with a wage index value below the 25th percentile and making this change budget-neutral, increasing add-on payments for CAR-T therapy, and adopting a new electronic Clinical Quality Measure (eCQM) for concurrent opioid prescribing. Below are some of the top policies finalized.

Wage Index

- CMS finalized the proposal to increase the wage index for hospitals with a wage index value below the 25th percentile. This policy will be effective for four years.

- In response to provider concerns, CMS retracted from funding the wage index increases with cuts to hospitals with wage indexes above the 75th percentile. Instead, it will cut payments across all IPPS hospitals.
- CMS will limit any hospital's annual wage index decrease to 5% for FY 2020.
- CMS will remove urban to rural hospital reclassifications from the calculation of the rural floor wage index value.

Inpatient Quality Reporting Program (IQR)

- CMS finalized the adoption of the following measures:
  - Mandatory reporting of the hybrid hospital-wide all-cause readmissions, which will replace the existing readmissions claims-based measure. First reporting period will be July 1, 2023 through June 30, 2024.
  - Safe Use of Opioids – Concurrent Prescribing eCQM
- CMS dropped a proposed Hospital Harm — Opioid-Related Adverse Events measure.

Value-based Purchasing (VBP)

- CMS will adopt the same administrative requirements for submitting Hospital Associated Infection (HAI) data that are used on the Hospital Acquired Condition (HAC) program.

Comprehensive Complication or Comorbidity (CC) Adjustments

- CMS had proposed changing the severity level designation for 1,492 ICD-10 codes. However, in response to providers' feedback, the Agency only changed the severity level designations for the 18 diagnosis codes in category Z16- (Resistance to antimicrobial drugs) from a non-CC to a CC (codes listed on page 308 of final rule).
- CMS noted that prior to November 1, 2019, they will seek further feedback on the current severity level designations.

Promoting Interoperability Program

- CMS will adopt a 90-day reporting period for CY 2021.
- The following changes were made to quality reporting:
  - Retain the Query of Prescription Drug Monitoring Programs (PDMP) measure as optional and available for bonus points and change the measure to a yes/no attestation.
  - Beginning in CY 2020, remove the Verify Opioid Treatment Plan measure.

Graduate Medical Education

- Beginning October 1, 2019, a hospital may include residents training in a Critical Access Hospitals (CAHs) in its full-time equivalent count as long as the non-provider setting requirements are met.

Technology Add-On Payments

- CMS will increase the new technology add-on payment for hospitals from 50% to 65%.
- CMS will make *new* technology add-on payments for 18 technologies, including CAR-T therapy used to treat cancer. The maximum add-on for CAR T-cell therapies will increase from $186,500 to $242,450.

Use of Percutaneous (peripheral) Extracorporeal Membrane Oxygenation (ECMO)

- CMS will move cases involving ECMO back to MS-DRG 003. In the FY 2019 final rule, the Agency had reassigned ECMO cases from MS-DRG 003 to several other MS-DRGs.

Democrats Debate Health Care, Round Two

The second iteration of the Democratic party's debates happened last week, with health care once again being a central theme. This round was decidedly more policy-focused than the last, as candidates tried to improve public understanding of their various health care proposals. At times this had confusing results, in part because candidates only had 60 seconds to answer questions. CNN's debate structure is being heavily criticized as incentivizing attacks and one-liners instead of actual policy discussions. Despite the limited time, candidates tried their best to unpack their ideas for America's health care future. Below are health care highlights from both nights of the debate.

What We Heard:

The majority of the health care conversation focused on reducing the financial burden of American families—namely through increasing access to insurance coverage. Major questions were raised on the finer details of "Medicare for All," ranging from how much a single-payer system would cost to the

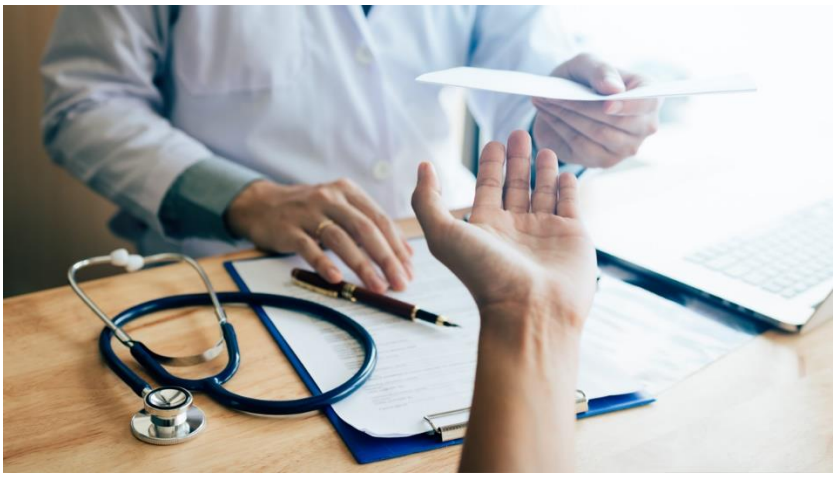
ramifications of eliminating employer-sponsored insurance. Public option proposals, like Joe Biden's, were aggressively criticized for still leaving approximately 10 million people uninsured.

What We Didn't Hear:

Unlike the last round, candidates spent almost no time promoting their ability to unseat President Trump in the 2020 elections. There was little discussion of other health care issues like the opioid crisis or access to reproductive health care, things that came up multiple times in the June debates. Instead, candidates dissected the feasibility of their opponents' health insurance proposals.

What It Means:

It's important to remember that any proposal will go through many evolutions before it can be realized, should the candidate become the President. While we will likely not see any proposal adopted without heavy revisions, we *are* seeing a shift of health policy's "Overton window"—the range of what is politically possible. For the first time, ideas previously considered "unthinkable" like universal coverage or a widespread public option are being seriously debated by both parties. Voters' appetite for increasing access to care shows no signs of abating, regardless of who sits in the Oval Office.



CY2020 Physician Fee Schedule (PFS) Proposed Rule Unveiled

The CY 2020 Physician Fee Schedule (PFS) proposed rule was released. This year, CMS retracts its controversial policy to collapse Evaluation and Management (E/M) billing codes previously finalized due to the large amount of provider push back. The rule also proposes a new structure for the Merit-based Incentive Payment System (MIPS) and expands access to Opioid Use Disorder (OUD) treatment and care management. In the future, it is likely that more policies surrounding home infusion therapies and bundles for physicians will be proposed because the rule seeks comments on these topics. Below is more about the key proposals. Click here for a detailed summary on the entire rule.

E/M Payment Proposals

Due to the significant feedback CMS received last year on their proposal, including AHPA's comments, the Agency established the Joint American Medical Association (AMA) Current Procedural Terminology (CPT) Workgroup on E/M to develop an alternative solution. Instead of a blended payment rate for E/M Levels 2 through 4, CMS proposes to use Medical Decision Making (MDM) and time with the patient in place of histories and exams to determine the level of E/M visit.

MIPS Value Pathway (MVP) Request for Information (RFI)

CMS released an RFI on a proposal to restructure the MIPS program into MVP pathways. These pathways will reorganize measures from the MIPS categories around specific specialties, treatments and other priorities, and physicians would only need to participate in one MVP. If approved, MVPs would eventually replace the current MIPS structure.

Expand Access to OUD Treatment and Care Management

The rule proposes to expand access to OUD services and remove barriers for care management to more effectively provide a continuum of care for patients. As mandated by the SUPPORT Act, CMS proposes to extend coverage for opioid treatment and services to help combat the opioid crisis. CMS also proposes to remove restrictions for certain care management codes and cover payment for "Principle Care Management" services for single, serious chronic conditions.

Future Proposals

CMS seeks comments on two topics: informing patients of alternative treatment options for home infusion therapy and expanding bundled payments. Therefore, CMS is likely to develop proposals in these areas in the future. For home infusion therapy, CMS seeks comments on how physicians should inform their patients of alternative treatment options before initiating home infusion therapy. For bundled payments, CMS seeks comments on opportunities to bundle physician services to improve efficiencies in Medicare payments. There has been an expansion of bundling hospital services under the Bundled Payments for Care Improvement (BPCI) Advanced and this may indicate a future push to bundle payments for physicians.

A Look at the Federal Register

Hospital Inpatient PPS Final Rule for FY 2020.

CMS released the final rule for public inspection on August 2, 2019. The final rule authorizes at net increase in payments of 3.1% along with incentives for electronic health record use and quality data measures. The rule also finalized an increase in the rural wage index.

Biosimilar and Prescription Drug User Fee Rates for FY 2020

FDA published the final rules for both biosimilar fees in connection with product development (84 FR 37888) and prescription drug user fees (84 FR 37882) in connection with the review of products.

OIG Withdraws Fraud and Abuse Proposed Rules

The proposed rules (84 FR 37821) would have expanded a safe harbor provision under the Federal Anti-Kickback Statute and codified Civil Monetary Penalties for unlawful incentive payments to physicians. For more information on this decision, click here.

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