Meeting on Pending Final Rule Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022

October 20, 2023

Key Provisions of the Proposed Rule

- In a July 2023 Proposed Rule to remedy the 340B-acquired drug payment policy, CMS solicited comment on how to structure a potential remedy for CYs 2018-2022 following the Supreme Court's decision in *American Hospital Association v. Becerra* invalidating certain OPPS payment reductions for 340B drugs

- CMS is proposing a one-time lump-sum payment to each 340B-covered hospital that was paid a reduced amount under the 340B policy during the years at issue, and ***a budget neutral recoupment of $7.8 billion received by all hospitals from the base payment increase over the five years the policy was in effect***

- ***CMS proposes to recoup that $7.8 billion through a one-time 0.5 percent reduction to the base rate either in 2025 or 2026, which would remain in effect for an estimated 16 years***

Why are we here?

- While we appreciate CMS' attempt to minimize the impact of the budget neutral recoupment through the 16-year window, we strongly oppose recovery of these funds through any mechanism due to ***two fundamental constraints***

- First, a budget neutral approach **is *not legally defensible***
  - The statute does not permit recoupment

- Second, a budget neutral approach ***is not fair or sound policy***
  - Hospitals and their patients would suffer considerable harm due to CMS' unlawful action

A budget neutral recoupment would harm hospitals and patients

- Hospitals relied on OPPS reimbursement rates over the past five years to:
  - Provide the ***full range of outpatient items and services***, including emergency services, treatment of life-threatening and debilitating conditions, and preventive care
  - Continue operations in ***rural and urban areas***, often with razor-thin margins amid a chronically underfunded system, emerging from COVID, and facing record inflation
  - Attract and ***hire employees***, while facing workforce shortages
- FAH hospitals provide care for some of the country's most at-risk populations
  - For example, many FAH members meet or exceed the ***low-income threshold*** applicable to 340B hospitals
  - On average, our members spend a larger proportion on ***uncompensated care*** than 340B hospitals—accounting for 5.5% of total operating costs for our members (versus 3.5% for 340B hospitals)

A budget neutral recoupment would harm hospitals and patients – especially in rural areas

- The financial health of many hospitals—especially rural hospitals—is extremely fragile
- ***A budget neutral remedy could force some hospitals to reduce or suspend services—or even close their doors***
  - Forty-five percent of rural hospitals already have a ***negative operating margin***
  - National average operating margin for rural hospitals is ***1.8%***
  - Over 150 ***rural hospitals*** have closed since 2010, majority were PPS hospitals
- Rural hospitals uniquely situated to be harmed by this budget neutral remedy more deeply than others
  - Medicare is a predominant payer for rural hospitals
  - Rural hospitals already lose money providing care to Medicare beneficiaries
  - Low patient volumes, inadequate Medicare and Medicaid payment rates, sequestration are already harming rural hospitals

Compounding factors of CMS policies harm hospitals and patients

- Recent historic challenges have exacerbated hospitals' financial hardships
  - Hospitals were, and remain, on the front lines of the ***COVID-10 pandemic,*** which significantly strained an ***already fragile health care workforce***
  - Hospitals hit by record inflation in two ways – hospitals' costs of labor, products and services going up at accelerating rates, while CMS' under-estimates of market basket inflation have led to additional Medicare shortfalls from forecast error of $10.8 billion in 2021-2025
- ***Rapidly growing MA penetration will precipitate unanticipated and excessive harm to hospitals subject to the recoupment***
  - Hospital losses for MA payments that are based on FFS rates are not accounted for in CMS' aggregate recoupment target and projected rate reductions, yet they will inevitably produce significant and unnecessary additional harms for participating hospitals

Retrospective recoupment is unlawful

- ***The OPPS is a <u>prospective</u> payment system***
  - The notion that reimbursement will be made at a ***pre-determined*** rate is the foundation of a prospective payment system
  - Once reimbursement rates are set ***in advance*** based on ***estimated*** budget neutrality, there is no retrospective true-up ***after the fact*** that ensures ***actual*** budget neutrality
  - It would contravene the text and purpose of the OPPS if CMS were to retrospectively recoup amounts in the name of budget neutrality
- ***The statute does not permit retrospective recoupment***
  - Past payments were lawfully made for **non-drug** items and services
  - Nothing in the statute authorizes CMS to claw back these proper payment amounts in the name of budget neutrality

Retrospective recoupment is unlawful

- ***In particular, the budget neutrality provision neither requires nor permits retrospective recoupment***
  - The budget neutrality provision requires only that ***estimated*** savings that the agency ***projects*** for the upcoming calendar year be offset by ***estimated*** costs that the agency ***projects*** for the upcoming calendar year
  - Once reimbursement rates are set ***in advance*** based on ***estimated*** budget neutrality, the budget neutrality provision is inapplicable by its own terms to ***actual*** savings and ***actual*** costs
- ***Statutory and regulatory history reinforces that CMS lacks authority to retrospectively recoup amounts in the name of budget neutrality***
  - CMS has never identified ***any*** instance where the agency has retroactively recouped amounts in the name of budget neutrality, absent a specific Congressional authorization to do so
  - To the contrary, CMS has a long history of implementing non-budget neutral relief, without disruption to prospective payment systems
  - For example, in wage index appeals, CMS has long allowed for non-budget neutral relief for hospitals that prevail on appeal—without adjusting the wage indices of hospitals that are not parties to the appeal

A future adjustment to indirectly effectuate retrospective recoupment is unlawful

- CMS may not make a future adjustment to indirectly effectuate retrospective recoupment
- By the terms of the budget neutrality provision, any estimated adjustment to offset any estimated cost must concern the ***coming year***, not a past year
- The final rule should not—and must not—directly or indirectly effectuate retrospective recoupment

Thank You

Participants

- Ken Choe, Partner, Hogan Lovells
- Don May, SVP, Federation of American Hospitals
- Alexa McKinley, Regulatory Affairs Manager, National Rural Health Association
- Steve Speil, EVP, Federation of American Hospitals
- Katie Tenoever, SVP and General Council, Federation of American Hospitals