



AMERICA'S ESSENTIAL HOSPITALS

December 21, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: CMS-5528-ANPRM: Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the advance notice of proposed rulemaking (ANPRM) on the international pricing index (IPI) model for Medicare Part B drugs. America's Essential Hospitals appreciates the Center for Medicare & Medicaid Services' (CMS) efforts to counter the problem of skyrocketing drug prices. Rising drug prices are unsustainable for patients, hospitals, and taxpayers and underscore the urgent need for programs that expand patients' access to lifesaving drugs and treatment. Essential hospitals are committed to expanding access to affordable, high-quality care for their patients. As CMS works to address costly prescription drugs, we encourage the agency to consider the interplay of new policies with existing government programs, such as the 340B Drug Pricing Program, one of the only remaining buffers between patients and high-cost drugs. These programs allow essential hospitals to continue to fulfill their missions to treat vulnerable patients in underserved communities.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 320 member hospitals provide a disproportionate share of the nation's uncompensated care and devote more than 75 percent of their inpatient care and nearly 70 percent of their outpatient care to the uninsured and to patients receiving insurance through public programs. Our members provide state-of-the-art, patient-centered care while operating on margins substantially lower than other

hospitals—4 percent on average compared with 7.8 percent for all hospitals nationwide.¹ In comparison, the average drug manufacturer operates on a 20 percent margin.

Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care, including trauma care, outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services. Our members also offer specialized inpatient and emergency services not available elsewhere in their communities. The high cost of providing complex care to struggling Americans leaves our hospitals with limited resources, driving them to find increasingly innovative strategies for high-quality care.

CMS' plan for a potential mandatory five-year payment model, under the authority of the Center for Medicare and Medicaid Innovation, would constitute a sweeping overhaul of the current drug purchasing system for Medicare providers. The ANPRM is a stark departure from the existing buy-and-bill system under Part B and leaves many details unclear, raising questions about how the model would operate. For example, the ANPRM does not anticipate problems such a model would create for hospitals, particularly for those participating in the 340B program. We echo the comments of Health and Human Services Secretary Alex Azar who, in the context of the IPI model, stressed the importance of ensuring "these reforms will help, and never harm, our most vulnerable populations."² Below, we highlight areas that CMS must further evaluate and address before moving a proposal of this magnitude through the rulemaking process.

1. CMS must preserve the 340B program, as defined in statute, by reconsidering the proposal to place purchasing power in the hands of vendors; otherwise, the IPI model would eliminate the benefit of the 340B program to hospitals and conflict with the program's intended design.

CMS' IPI model would disrupt existing drug distribution and reimbursement practices, with inevitable implications for patients' access to lifesaving drugs. CMS currently reimburses providers for separately payable Part B drugs, which are primarily administered in hospital outpatient departments and physician offices, at average sales price (ASP) plus 6 percent. Providers purchase these drugs from drug wholesalers or manufacturers, administer or dispense them to the patient, and then bill Medicare for the drug. The types of drugs reimbursed under Part B include lifesaving injectable drugs, intravenous cancer drugs, immunosuppressive drugs, and hemophilia blood clotting factors.

For providers in the mandatory model, CMS would shift the responsibility for purchasing Part B drugs to model vendors. The concept is based on the now-defunct Competitive Acquisition Program (CAP) for physicians, which ran from 2006 to 2008. After piloting the program for two years, CMS ultimately suspended the CAP because of

¹ Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. www.essentialdata.info/. Accessed December 7, 2018.

² Azar A. Remarks to America's Essential Hospitals. Washington, D.C. December 11, 2018. <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-americas-essential-hospitals.html>. Accessed December 12, 2018.

a lack of physician and vendor participation. The IPI model would be even broader in scope, covering not just physicians but also hospital outpatient departments. Further, CMS would require providers in certain geographic areas to participate in the model.

CMS intends for the private-sector vendors in the model to negotiate prices with manufacturers, take title to drugs, and then supply the drugs to providers. Medicare then would reimburse vendors directly instead of reimbursing providers, as is currently the practice under the buy-and-bill system. Providers would continue to receive a separate add-on payment to cover administrative costs, such as drug storage and handling, although CMS also is considering changing the methodology for determining the add-on payment.

Most concerning is the introduction of vendors into the process; this would deprive 340B hospitals of the ability to receive discounts and realize savings as intended by the 340B statute. The program, codified in section 340B of the Public Health Service Act (PHSA), was created by Congress to allow covered entities to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³ Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings that are critical to the operations of hospitals that fill a safety-net role. The 340B program is structured by statute to provide hospitals discounts for covered outpatient drugs provided to patients, regardless of the patient’s insurance status. Congress expected that various public and private payers would reimburse hospitals at higher rates than the discounts they received from drug manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services.

By allowing vendors to take title to Part B drugs, CMS would remove hospitals’ ability to purchase and receive reimbursement for Part B drugs, thus depriving them of savings on 340B drugs. Hospitals participating in the IPI model would no longer purchase drugs directly; instead, vendors would purchase and take title to these drugs. Because these vendors are not 340B covered entities, they would not purchase these drugs at 340B discounts. Thus, the model would negate the benefit of the 340B program to hospitals and, ultimately, to patients that benefit from hospitals’ use of related savings.

Essential hospitals provide lifesaving drugs and services through programs made possible by their 340B savings. Specifically, savings from the 340B program have enabled essential hospitals to reduce emergency department use, increase access to coordinated care, reduce readmissions, and increase availability of lifesaving prescription drugs to low-income patients. CMS shares the goals of these initiatives, which benefit the health care system more broadly. **By preserving access to 340B discounts, CMS will ensure that hospitals can continue to use their limited resources to develop programs that achieve their shared goals.**

³ H.R. Rep. No. 102-384, pt. 2 (1992).

2. CMS must consider how provider-vendor arrangements could conflict with the group purchasing organization (GPO) prohibition for 340B hospitals.

As a condition of eligibility, the 340B statute restricts disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals in the program from purchasing covered outpatient drugs through a GPO. GPOs use their collective purchasing power to negotiate lower prices on drugs and supplies for hospitals. Failure to comply with the GPO prohibition can result in severe sanctions, including repayment and removal from the 340B program. Participating hospitals invest substantial resources in inventory management systems and internal processes to ensure they comply with the GPO prohibition.

Without further clarification from CMS, hospitals in the IPI model could run afoul of the GPO prohibition. In requiring hospitals to purchase drugs from model vendors instead of directly from manufacturers, CMS would put hospitals in the position of potentially purchasing covered outpatient drugs through a GPO. The vendors, as described by CMS, are essentially entities that would negotiate lower drug prices on behalf of providers—in fact, CMS explicitly mentions GPOs as a type of entity that could participate as a vendor under the IPI model. If CMS deems hospitals participating in the IPI model are obtaining drugs from a GPO (in this case, a model vendor), the hospital could become ineligible to participate in the 340B program for violating the GPO prohibition. Hospitals would be unable to purchase drugs with 340B discounts, thus removing the benefit of the program. **CMS should consider this potential conflict with the GPO prohibition and clarify which types of entities can participate as model vendors, and whether they would be deemed a GPO. The agency also should collaborate with the Health Resources and Services Administration (HRSA) to ensure that 340B hospitals are not violating the GPO prohibition by participating in the IPI model.**

3. The IPI model could cause changes in manufacturer drug prices, affecting 340B ceiling prices and possibly resulting in a change in 340B discounts.

The IPI model, as described by CMS in the ANPRM, would affect manufacturer drug prices and, in turn, could drive up the prices providers pay for 340B drugs. The purpose of the model is to enable vendors to negotiate with drug manufacturers, thereby reducing prices on drugs reimbursed under Medicare Part B. As manufacturer drug prices change, 340B discounts could change and even become smaller. Under the 340B program, manufacturers cannot charge 340B providers more than a ceiling price. HRSA calculates the ceiling price for a given drug as the difference between the average manufacturer price (AMP) for that drug and the unit rebate amount (URA). The URA for a given drug is determined by a statutory formula that uses a drug's AMP and best price, which is the lowest price offered by the manufacturer to a provider, wholesaler, or other entity. If the lower prices manufacturers charge vendors for Part B drugs decrease and are included in the calculation of AMP, this would bring down AMP. It could also change the best price for these drugs if the price negotiated between a manufacturer and vendors ends up being the lowest price offered by the manufacturer in the market. Because the URA is either a percentage of AMP or the difference between AMP and best price, a lower AMP would result in a lower URA, which would increase the 340B

ceiling price. In this way, 340B hospitals could end up paying more for these drugs, both reducing their savings and affecting vulnerable patients' access to the drugs.

4. The model would impose excessive burden on providers' drug purchasing and inventory management practices.

340B hospitals use complex inventory management systems to separate 340B drugs from non-340B drugs. Due to the GPO prohibition, hospitals must have an inventory for GPO-purchased drugs and a separate one for 340B drugs. They also generally maintain a third inventory, for other drugs priced at wholesale acquisition cost (WAC). Hospitals have invested in costly special technology and staffing to maintain these distinct inventories. The introduction of an additional category of drugs—Part B drugs purchased by a vendor and then supplied to the hospital—could require operational changes, including adjustments to existing inventory management systems and split billing software.

Further, introducing a third party into the drug purchasing process could make it more difficult for hospitals to provide patients with needed drugs in a timely manner. As large organizations, hospitals are accustomed to ordering drugs to keep in their inventory based on the needs of their patients. These drugs are kept in the hospital or the hospital pharmacy, thus providing easy access. Hospitals can quickly replenish their inventories when they realize they are short on a given drug. Adding the vendor to the process would increase the time it takes to acquire critical drugs. Additionally, such a move could add unnecessary complexity to the existing drug distribution process.

CMS has listed relieving administrative and regulatory burden from providers as an agency priority. As part of the Patients over Paperwork initiative, the agency has sought feedback on ways to reduce regulatory burden on providers. We applaud the administration's efforts to allow hospitals to focus more of their time and resources on patient care instead of onerous, administratively burdensome actions. The potential changes in the IPI model, however, would undoubtedly place additional unnecessary burden on providers and be a step backward from the agency's goal of reducing provider burden. **We urge CMS to consider this and other consequences of a potential IPI model on providers treating the nation's vulnerable patients.**

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

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