December 21, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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

Dear Administrator Verma:

340B Health respectfully submits these comments in response to the Centers for Medicare & Medicaid Service's (CMS) Advanced Notice of Proposed Rulemaking (Advanced Notice) published in the Federal Register on Oct. 30, 2018, regarding the International Pricing Index (IPI) Model for Medicare Part B drugs. 1 340B Health represents more than 1,300 public and nonprofit hospitals that participate in the federal 340B drug pricing program. Our membership spans a broad spectrum of hospitals including academic medical centers, community hospitals, children’s and free-standing cancer hospitals and rural facilities. Enacted in 1992, the 340B program is intended to provide resources to hospitals serving high volumes of low-income and rural patients to enable those hospitals to provide more comprehensive services and treat more patients. 2

340B Health commends CMS for its focus on reducing drug prices. We are concerned, however, that the IPI Model would unintentionally eliminate the 340B program, which would negatively impact the ability of safety-net providers to treat their low-income and vulnerable patients. We have also heard from our hospital members of several operational and patient care concerns relating to the IPI Model, many of which are exacerbated for hospitals that participate in the 340B program. We recommend that CMS consider measures to preserve the 340B program and address the patient care and operational issues that are discussed below.

I. Implications of the IPI Model for the 340B Program

The 340B program requires pharmaceutical manufacturers that participate in Medicaid and Medicare Part B to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of the Department of Health & Human Services (HHS). Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by qualifying providers that meet strict eligibility criteria set out in the 340B statute. Once admitted into the program, 340B hospitals are entitled to discounted prices on all eligible covered outpatient drugs and typically access the discounts by placing drug orders through a wholesaler, unless the manufacturer requires that its drugs be purchased through another channel, such as a specialty distributor. Regardless of how the drug is purchased, a manufacturer may not charge a 340B hospital more than the 340B ceiling price, which is calculated using Average Manufacturer Price (AMP) and Best Price data.

The Advanced Notice describes changes to the drug distribution system that would prevent hospitals selected to participate in the IPI Model from purchasing or holding title to certain Part B drugs, as these hospitals would obtain Part B drugs from commercial entities, or “model vendors,” that would purchase the drugs from pharmaceutical manufacturers and be reimbursed by Medicare for the drugs. Such a change to the buy and bill system would remove the obligation placed on manufacturers to provide 340B discounts on Medicare Part B drugs included in the model, as 340B hospitals would no longer purchase such drugs. While we applaud the Administration’s commitment to addressing the issue of high drug prices, we are concerned that the IPI Model may unintentionally remove an established and proven method of reducing drug prices charged to safety net providers and make it


more difficult for 340B hospitals to treat their low-income and rural patients. We are also concerned about potential risks to patient care and added expense and complication for 340B hospital operations.

Given that the 340B program has been successful in reducing drug prices over the last 26 years, and for the reasons we explain below, 340B Health strongly recommends that CMS preserve the 340B discount and exclude 340B hospitals from the IPI Model. Alternatively, if CMS were to include 340B hospitals in the model, CMS should allow the model vendors to make purchases on behalf of 340B hospitals such that 340B hospitals could maintain title to the drugs and continue to access the 340B discount. Any 340B savings should remain with the safety net hospitals that Congress intended so that they can continue to stretch their resources to provide more services to more patients. CMS should also consider and address hospitals’ concerns that are outlined below regarding the impact of the IPI Model on patient access to care and hospital operations.

II. Preserving the 340B Discount Would Advance CMS’s Goals of Lowering Drug Prices

For more than 25 years, the 340B program has worked to deter manufacturers from raising drug prices generally, and not just to providers that participate in the program. The 340B statute requires manufacturers to pay an “inflationary penalty”, where the 340B discount is higher for drugs that have had their price increased more quickly than the rate of inflation. Researchers with the Pew Charitable Trusts have described the inflationary penalty as an important mechanism that discourages manufacturers from seeking larger price increases and have cautioned that reducing the size of the 340B program could encourage manufacturers to increase drug prices. Given the constraining effect that the inflationary penalty has on drug price increases, it has also likely reduced costs for payers. The researchers note that there may be even more of an impact in the Medicare Part B program, where there are no inflation adjustments or rebates to offset price increases. Maintaining the 340B discount would contribute to CMS’s goal of lowering drug prices.

III. 340B Hospitals Treat High Volumes of Low-Income Patients, and Removing Access to the 340B Discount Could Harm Hospitals’ Ability to Treat These Patients

340B hospitals have a documented record of providing high levels of care to low-income and rural individuals and removing their ability to access 340B discounts under the IPI Model could harm their ability to treat their patients.

Although 340B disproportionate share (DSH) hospitals represent 38 percent of hospitals, they provide 60 percent of all uncompensated care in the U.S. 340B DSH hospitals provide the vast majority of services received by Medicaid and low-income Medicare patients and are much more likely than non-340B hospitals to provide critical health care services that are vital to low-income patients, but are often unreimbursed, including HIV/AIDS services, trauma care, and outpatient alcohol/drug abuse services, including treatment and prevention of opioid dependency. 340B DSH hospitals treat significantly more Medicare Part B beneficiaries who are low-income cancer patients, and are more likely than non-340B hospitals to treat beneficiaries who are dually eligible for Medicaid, or are racial or ethnic minorities.

The 340B program is intended to provide resources to safety net providers so they can use the savings “to improve and expand care in general, benefiting uninsured, indigent, and other patients with the goal of improving and expanding health care in the safety net.” Hospitals use 340B savings to provide free or reduced-cost medicines to patients, to offer vital but often underpaid services critical to low-income patients such as

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4 Id.
5 Id.
7 Id.
IV. Critical Access Hospitals Are Particularly Vulnerable and Should Be Excluded from the IPI Model

CMS has solicited feedback on whether to include critical access hospitals (CAHs) in the IPI Model. We recommend that CMS exclude CAHs from the IPI Model given their current reimbursement structure, financial vulnerabilities, and risk to rural populations if CAHs face increased financial pressure.

CAHs are eligible to participate in the 340B program by virtue of providing safety net services to individuals located in rural or remote areas of the country. CAHs face significant financial challenges and often struggle to remain open. In fact, 90 rural hospitals have closed since 2010. One of the key goals of the IPI Model is to address how Medicare pays for Part B drugs by changing the add-on payment so that it is not directly linked to a drug’s price. CAHs are not paid according to this model, but instead, in recognition of their unique status, are paid by Medicare at cost.

As discussed below, the IPI Model would impose a number of new obligations on hospitals that could be costly. CAHs are least likely to be able to support the expense of the new infrastructure changes that may be required by the IPI Model. Given the financial vulnerability of CAHs, major changes such as participation in the IPI Model could result in additional CAH closures, which would reduce the availability of health care resources in more isolated communities, increasing travel times and potentially putting health care at risk.

V. CMS Should Consider the Impact of the IPI Model on Patient Access to Care and Hospital Operations

a. The IPI Model would alter the drug distribution system in ways that could put patient access to Part B drugs at risk

As described in the Advanced Notice, the IPI Model would make changes to the buy and bill system that could make it more difficult for patients to receive care. Rather than placing a drug order through the hospital’s wholesaler, IPI Model hospitals would need to contract with a third-party model vendor to receive shipments of Part B drugs. 340B Health has heard from many hospitals with concerns about this aspect of the IPI Model. They are concerned that inserting model vendors into the drug distribution process would disrupt a system that currently works well and allows hospitals to maintain control over their drug inventory in ways that help ensure patients have access to needed medications upon arriving at the hospital.

340B hospitals have expressed concerns over not having enough inventory to treat their Part B patients under the IPI Model. Requiring hospitals to rely on model vendors to obtain shipments of Part B drugs could lead to significant access issues and disrupt treatment for patients. For example, model vendors could place restrictions on or dictate how hospitals order drugs, such as by requiring hospitals to submit patient and/or prescription

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11 Id.

information prior to shipping the drugs. Model vendors could also limit which hospital locations are able to receive
drug shipments or limit the amount of inventory hospitals are able to access in advance of patient treatment. Given
the potential restrictions that model vendors could place on the ordering process, 340B hospitals have expressed
concerns over not having enough inventory to treat their Part B patients.

Hospitals are particularly concerned about the ability to access drugs under the IPI Model during drug shortages.
Adding model vendors to the drug procurement system makes the drug distribution system more fractured, which
is particularly problematic when drugs are in short supply and are rationed amongst more entities. If an IPI Model
hospital cannot access a Part B drug from the model vendor, care for Medicare Part B beneficiaries may be
fragmented, as patients may need to receive care from providers that are not participating in the IPI Model and are
able to access Part B drugs through the regular buy and bill system. This impact would be devastating for 340B
hospital patients, given that 340B hospitals treat low-income patients who often have limited or no other options to
receive care or rural patients who must travel significant distances for treatment.

Hospitals have also expressed concerns that drug access issues created by the IPI Model could contribute to
white bagging and/or brown bagging. White bagging occurs when a payer purchases drugs through a specialty
pharmacy, which then ships the medication directly to a hospital pharmacy for administration in a hospital clinic,
while brown bagging occurs when a patient obtains a drug at a specialty pharmacy and physically carries it to the
hospital for administration. Some payers require white bagging and brown bagging because these models can
reduce costs to payers, as drug coverage shifts from the medical benefit to the pharmacy benefit, resulting in the
patient paying a greater portion of the costs. White bagging and brown bagging can also provide payers with
more insight into the drugs they pay for because specialty pharmacies typically provide payers with more
information about the drug than payers would otherwise receive.

If hospitals are unable to access Part B drugs from model vendors under the IPI Model, white bagging and brown
bagging practices may increase as an alternative method for patients to access needed medications while
continuing to be treated by their existing provider. Brown bagging has significant implications for drug safety and
efficacy, particularly for chemotherapy drugs if they are mishandled as the patient transports the drugs to a
provider for administration. Some hospitals will not administer Part B drugs to patients that are brown bagged for
these reasons. In addition, white and brown bagging can lead to excessive waste, as a patient’s treatment may
change prior to the drug being administered. In that case, the drug would be wasted, as the provider could only
administer the drug to the specific patient it was sent for.

The concerns that hospitals have expressed about the IPI Model’s impact on patient access to needed
medications are very similar to issues that arose under CMS’s former Competitive Acquisition Program (CAP) that
operated from 2006 through 2008. Physicians that participated in the CAP placed orders for Part B drugs through
CAP vendors, not unlike how the IPI Model would work, although participation in the CAP was voluntary and did
not include hospitals. An analysis of the CAP revealed that participating physicians often relied on emergency
measures in the CAP to ensure that patients received Part B drugs in a timely and safe fashion. One of the
emergency measures, the “furnish as written” provision, allowed physicians to purchase a drug through the regular
buy and bill system if a dosage form or strength of drug was not available under the CAP. Physicians’ reliance on
emergency measures under the CAP because they could not obtain drugs from the CAP vendor suggest that the
same access issues could arise under the IPI Model. Given the similarities of the CAP to the IPI Model, the issues
that physicians experienced under the CAP would likely resurface under the IPI Model, which CMS should
consider as it moves forward with the IPI Model.

In addition, changes to the drug distribution system under the IPI Model could impact hospitals’ ability to comply
with the Food and Drug Administration’s track-and-trace law, which could impact patient access to Part B drugs
under the IPI Model. Under the Drug Supply Chain Security Act, retail and hospital pharmacies cannot accept
ownership of a product without receiving product tracing information before or at the time of a transaction and must

15 The Advisory Board, The Increasing Role of Specialty Pharmacy in Cancer Care and How Providers Can Respond,
(April 2011). https://www.advisory.com/research/oncology-roundtable/oncology-rounds/2011/04/the-increasing-role-of-
specialty-pharmacy-in-cancer-care-and-how-providers-can-respond
16 Id.
17 CMS, Evaluation of the Competitive Acquisition Program for Part B Drugs, Final Report, (December 2009),
18 Id.
capture and maintain the information.\textsuperscript{19} The law is intended to develop a history of the physical locations of medications as they move through the supply chain and prohibits pharmacies from accepting drug shipments without receiving certain information from the drug’s owner. Under the IPI Model, model vendors would hold title to the drugs distributed to hospitals and though hospitals would not take legal ownership of drugs included in the IPI Model, the intent of the track-and-trace law suggests that model vendors should transmit the information to hospitals required under the law to maintain the purity of the tracing information. Failure to transmit the information to hospitals could preclude IPI Model hospitals from accepting shipments of medications from the model vendors, which could limit patient access to needed medications under the IPI Model.

b. Including 340B hospitals in the IPI Model could create additional costs for 340B hospitals that reduce financial resources and curtail 340B hospitals’ ability to treat their patients

In addition to losing access to 340B discounts and limiting the ability of hospitals to meet the inventory needs of their patients, 340B Health is concerned that 340B hospital participation in the IPI Model would create added operational costs for 340B hospitals that would reduce the level of resources they have available to treat their low-income and rural patients.

As we understand the IPI Model requirements, new hospital obligations would include:

- Enrolling with vendors(s) to obtain included drugs
- Notifying vendors of drug disposition
- Paying model vendors for services
- Tracking use of Part B drugs
- Billing Medicare for the add-on payment
- Collecting co-payments
- Billing supplemental insurers
- Submitting information bills to Medicare

These obligations would impose new, and in some cases, substantial costs on 340B hospitals, which have already invested significant sums into special software and staff to comply with 340B requirements. Inventory management is a good example. To comply with 340B program requirements, 340B hospitals are required to have inventory management safeguards in place, such as systems to track the purchasing and dispensing process. 340B hospitals must use either a virtually separate inventory or a physically separate inventory to segregate 340B drugs from non-340B drugs in areas where both 340B and non-340B drugs are used. Many 340B hospitals use a virtual inventory system where 340B purchases are made using a replenishment process in which the hospital tracks data feeds (e.g., inpatient or outpatient status), and sends the data into split-billing software. This software is complex and uses configurations to virtually separate 340B from non-340B transactions after the drug is administered or dispensed to a 340B-eligible patient. The software, which is connected to the hospital’s electronic medical record system, places a purchase of multiple drugs into the appropriate account. 340B hospitals that are subject to the GPO prohibition must maintain a triple account system that tracks 340B, GPO, and wholesale acquisition or “WAC” inventories, as these hospitals are prohibited from using a GPO to purchase covered outpatient drugs and must instead use a WAC account (i.e., a non-340B/non-GPO account) to purchase drugs in some instances.

Providers that participate in the IPI Model would need to track model drugs given to Medicare Part B patients, which would require the creation of a manual process or investment in software to track model drugs separately from non-model drugs. This would require a fourth account for certain 340B hospitals, adding a significant layer of complexity to an already complex system. The Medicare Payment Advisory Commission (MedPAC) has noted that providers that participated in the former CAP found it burdensome to operate two different drug acquisition systems – one for CAP program beneficiaries and another for payers other than Medicare.\textsuperscript{20} Imposing additional inventory tracking requirements on 340B hospitals would strain their already scarce resources and further limit their ability to treat their low-income and rural patients.

\textsuperscript{19} 21 U.S.C § 360eee-1(d)(1).
\textsuperscript{20} Medicare Payment Advisory Commission Public Meeting, (October 6, 2016), \url{http://www.medpac.gov/docs/default-source/default-document-library/october2016_octobermeetingtranscript-(002).pdf?sfvrsn=0}
In addition, the IPI Model could increase costs for hospitals by affecting access to volume-based discounts that hospitals currently receive from their wholesalers. Wholesalers often offer hospitals pricing incentives that are based on the volume of drugs that hospitals purchase from the wholesalers. Hospitals participating in the IPI Model would obtain certain Part B drugs from the model vendors instead of wholesalers, which could have an impact on hospitals’ ability to meet the volume threshold in their contracts with wholesalers. This could result in increased costs for hospitals for drugs outside of the IPI Model.

Concerns that the IPI Model may negatively impact patient access to treatment and create additional costs for hospitals that would limit their ability to treat their patients further support 340B Health’s request that 340B hospitals be excluded from the IPI Model.

VI. Additional Considerations of the IPI Model’s Impact on the 340B Program

a. 340B ceiling price calculations

We also recommend that CMS consider how the IPI Model may impact the 340B ceiling price and the value of the 340B discount, particularly as CMS considers whether to exclude 340B hospitals from the IPI Model or otherwise preserve their access to the 340B discount. As CMS acknowledges in the Advanced Notice, the IPI Model may impact the 340B ceiling price, which represents the maximum amount that pharmaceutical manufacturers can charge a 340B hospital for a covered outpatient drug. 340B Health supports lowering drug prices and the Administration’s commitment to addressing high drug prices. If CMS determines that including prices under the IPI Model in AMP and Best Price calculations would negatively impact 340B hospitals, we request that CMS consider ways to mitigate that impact.

b. Group purchasing organization limitations

Although we recommend that 340B hospitals be excluded from the IPI Model, if they are included, 340B Health requests that HHS clarify that the model vendors would not constitute group purchasing arrangements for 340B purposes. The 340B statute states that, to participate in the 340B program, DSH, children’s and cancer hospitals must demonstrate that they are an entity that does not purchase or obtain covered outpatient drugs through a group purchasing organization (GPO) or group purchasing arrangement. If these hospitals use a GPO or group purchasing arrangement to purchase covered outpatient drugs, they are no longer eligible to participate in the 340B program. Thus, failing to clarify that the model vendors do not constitute GPOs or group purchasing arrangements could eliminate 340B hospitals’ ability to obtain 340B discounts for any drugs purchased, including drugs outside of the model and outside of Medicare.

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For the above reasons, 340B Health respectfully requests that CMS preserve the 340B discount by excluding 340B hospitals from the IPI Model or in the alternative, by allowing the model vendors to act as agents of 340B hospitals to make Part B drug purchases on their behalf. We also request that CMS consider the impact of the IPI Model on patient access to Part B drugs and hospital operations. Thank you for the opportunity to comment on the Advanced Notice. If you have any questions, please contact Maureen Testoni at maureen.testoni@340bhealth.org.

Sincerely,

Maureen Testoni
Interim President and CEO

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