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December 31, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Advance Notice of Proposed Rulemaking, Medicare Program; International Pricing Index Model for Medicare Part B Drugs, (CMS-5528-ANPRM)

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the advance notice of proposed rulemaking (ANPRM) with comment entitled "Medicare Program; International Pricing Index Model for Medicare Part B Drugs," 83 *Fed. Reg*. 54546 (October 30, 2018), issued by the Centers for Medicare and Medicaid Services (CMS or the Agency).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 152 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

As drug prices continue to take a larger share of the health care dollar, the AAMC supports efforts to limit skyrocketing costs. Prescription drug prices continue to rise every year. Each year, there are more high-cost, brand-name drugs (including specialty drugs) entering the market. Drug manufacturers set the price of their drugs upon entry into the market. Subsequent price increases also contribute to the unsustainable rise in costs for prescription medicines. These prices put needed medication out of reach for many Americans. Patients should not have to choose not to undergo a needed treatment simply because it is too expensive. Oftentimes, not following prescribed drug regimens results in patients requiring high-cost treatment in hospitals.

The AAMC appreciates CMS's efforts to address high drug prices and its acknowledgement that drug prices are unsustainable. We agree that more must be done to stem the rising prices of existing prescription drugs and ensure that new drugs entering the market are not priced by manufacturers at a rate that puts them out of reach of many patients. The ANPRM would create an additional drug distribution channel that we are concerned would impose significant cost and burden on our member hospitals, jeopardize beneficiaries' access to needed medications, and have a negative impact on the 340B Drug Pricing Program (340B Program). This is a program which, at no cost to taxpayers, expands vital programs to vulnerable populations. This important program must be preserved to ensure that safety-net

hospitals can continue to garner savings that benefit their most vulnerable populations. Restricting safety net hospitals' ability to acquire drugs through the 340B Program could potentially leave vulnerable patients and communities without access to needed care. Therefore, if CMS decides to move forward with further rulemaking, the 340B Program must not be impacted by reimbursement changes to Part B drugs, and disproportionate share hospitals participating in the 340B Program should be excluded from the IPI Model.

The AAMC is concerned that, as outlined, the ANPRM will create a new drug acquisition and reimbursement channel that will impose significant burden on hospitals. Before publishing a proposed rule, we ask that the Agency work with hospital and physician stakeholders to identify ways that achieve the goal of reducing drug prices without regulatory and financial burden to hospitals that we fear could jeopardize beneficiaries' access to needed medications.

Overview

The AAMC urges CMS not to restrict hospitals' ability to continue to acquire through the 340B Program those Part B drugs that would be included in the Model, thus preserving the critical savings safety net hospitals derive from the Program. Eliminating hospitals' participation in the 340B Program could leave vulnerable patients and communities without access to needed care.

CMS believes that the proposal would reduce drug prices, but the AAMC questions whether replacing Medicare's existing reimbursement structure with a proposal that would change how hospitals procure a small number of Part B drugs, as well as introducing an additional intermediary with whom a hospital will have to contract, will achieve that result. In light of the complexity of the Model and limited details in the ANPRM, we are concerned that the IPI Model would disrupt the current Part B drug acquisition process without achieving the projected savings.

In addition, unfortunately, CMS continues to claim in the ANPRM that the current reimbursement structure for Part B drugs incentivizes the overutilization of expensive drugs, particularly in hospital outpatient departments (HOPDs). The AAMC strongly disagrees with this premise. Our data analysis shows that HOPDs and associated off-campus provider-based departments (PBDs) disproportionately treat higher acuity patients with more advanced disease progression requiring treatments that are usually more expensive than first-line treatments that often are obtained elsewhere. Providers in HOPDs and PBDs use drug treatments that best suit the needs of their patients' medical conditions.

The IPI Model also is structured as a mandatory model in selected geographic regions of the country. As we interpret the ANRPM, this would add significant administrative burden to those providers and disrupt the current drug acquisition system. Providers in the mandated geographic areas would have to secure additional contracts with multiple new vendors to acquire the Part B drugs included in the Model. This is in addition to changing or modifying contracts that currently secure these drugs. In addition, the timeline to implement the IPI Model is ambitious and has the potential to cause delays in the availability of drugs that are required for some beneficiaries. We do not believe drug distribution and reimbursement arrangements would be in place in time to guarantee that there are no disruptions to the acquisition of drugs. CMS must also consider the negative impact on beneficiaries' access to needed drugs this timeline would impose.

The AAMC offers the following comments and recommendations in response to the ANPRM.

Under the current system Part B drug reimbursement system, providers purchase drugs and then bill Medicare after administration, also referred to as "buy and bill." (83 FR 54548). However, some providers claim that rising prescription drug prices has made the buy-and-bill system more challenging. To mediate the potential negative impacts of buy and bill on a few select providers and with the hope of decreasing drug prices, CMS is proposing to change how a small subset of Part B drugs will be acquired and reimbursed. CMS believes that changing to the IPI Model will alleviate some of these challenges and in conjunction with calculating a new Medicare payment for Part B drugs based on international prices will decrease drug prices.

Under the IPI Model, beginning in 2020, newly created vendors would purchase drugs from manufacturers, supply the drugs to contracted providers and then bill Medicare. Vendors would negotiate drug purchases from manufacturers and, in turn, supply the drugs to hospitals and providers in geographic regions mandated to participate in the program. Providers would no longer be required to purchase the Part B drugs included in the IPI Model. While vendors would bill Medicare for the drug, providers would still be required to submit a "no pay" claim to Medicare. Adding a new drug distribution channel will increase regulatory burden and financial obligations which is in direct contrast to what this Administration has been trying to correct in Medicare.

Interactions with the 340B Drug Pricing Program

Exclude DSH Hospitals Participating in the 340B Drug Pricing Program from the IPI Model

While the AAMC supports efforts to lower drug prices, we could not support any proposal that jeopardizes the 340B Program. We believe that, as currently structured, the IPI Model could jeopardize the 340B Program, a program that is essential for safety net hospitals' ability to serve vulnerable populations. We strongly urge CMS to exclude 340B disproportionate share hospitals (DSH) from the IPI Model to preserve the ability of safety net hospitals to acquire certain Part B drugs through the 340B Program.

If CMS moves forward with this proposal, it will mean that drugs currently purchased under the 340B Program would be included in the IPI and therefore will no longer be part of the 340B Program, thus significantly reducing the amount of 340B savings to support programs for vulnerable populations. Additionally, the IPI Model could affect 340B ceiling prices and trigger the group purchasing prohibition. If CMS moves forward with the IPI Model, it must ensure that the Model does not negatively impact the 340B Program.

Congress created the 340B Drug Pricing Program in 1992 under the Public Health Service Act to support certain safety net hospitals and other providers that serve low-income, vulnerable patients. At no cost to taxpayers, the program allows these "covered entities" to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

[1] H.R. Rept. No. 102-384(II), at 12 (1992)

The 340B Program has been unfairly targeted as a driver of high drug costs.[2] Proposals to undermine this important program are counterproductive to ensuring access to affordable drugs. The 340B Program is not driving drug prices but rather provides vital support and access to vulnerable patients and communities. The Program allows safety net hospitals that treat large numbers of uninsured and underinsured patients to generate savings from discounts that are then used to expand health care services and provide access to needed drugs for these vulnerable populations. Hospitals operate a variety of programs and provide services that otherwise may not be financially viable without support from the 340B Program.

According to Health Resources and Services Administration (HRSA), which administers the program, 340B sales represents just 3.6 percent of the total $457 billion U.S. drug sales.[3] The net reduction to drug manufacturer revenue is even less - estimated to be approximately 1.9 percent.[4] This is a negligible impact on drug manufacturers, whose worldwide estimated sales revenue increased to $775 billion in 2015 with the largest 25 drug companies reporting annual profit margins between 15 and 20 percent.[5] Such a small percentage of total drug sales cannot be driving skyrocketing drug prices. The responsibility for high drug costs rests with the high prices set by the manufacturers, not by the small sales associated with the 340B Program. Shrinking the 340B Program will only harm patients who rely on the services provided by covered entities – it will not affect drug prices.

Waive 340B Prohibition on Group Purchasing Organization Participation

DSH hospitals that acquire drugs under the 340B Program are prohibited from obtaining covered outpatient drugs through a group purchasing organization (GPO). According to HRSA, compliance with the 340B prohibition is an eligibility requirement for certain categories of eligible covered entities.[6] If a DSH hospital participating in the 340B Program also purchases drugs through a GPO, that hospital will no long be able to purchase covered outpatient drugs under the 340B Program. If CMS chooses to proceed with future rulemaking, the AAMC asks that CMS clarify that GPOs that participate as vendors in the IPI Model would not trigger the 340B GPO prohibition.

Consider Ways to Mitigate IPI Model's Impact on the 340B Ceiling Price

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 DSH hospitals from the IPI Model or otherwise preserve their access to the 340B discount. As CMS acknowledges in the ANPRM, 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. AAMC supports lowering drug prices and the Administration's commitment to addressing high drug prices. However, if CMS determines that including prices under the IPI Model in average manufacturer's price (AMP) and

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[2] AAMC Comment Letter in Response to HHS Drug Blueprint. July 16, 2018.
https://www.aamc.org/download/490210/data/aamccommentsonthehhsblueprinttolowerdrugpricesrfi.pdf
[3] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. "Observations on Trends in Prescription Drug Spending." March 8, 2016. https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending
[4] Coukell, Allan and Dickson, Sean. "Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenues." JAMA Internal Medicine. Published online May 21, 2018.
[5] U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." https://www.gao.gov/assets/690/688472.pdf
[6] Health Resources and Services Administration. Statutory prohibition on group purchasing organization participation. Release No. 2013-1. February 7, 2013.
https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

Medicaid's Best Price calculations would negatively impact 340B DSH hospitals, we request that CMS consider ways to mitigate that impact.

Model Concept Design

Participation in the IPI Model Should Be Voluntary to Be Consistent with Other CMMI Demonstrations

Under the ANPRM, CMS would mandate participation from all physician practices and hospital outpatient departments ("providers" or "participants") within geographic regions that furnish the drugs included in the Model. Historically, demonstrations to test new payment models under the authority of the Center for Medicare and Medicaid Innovation (CMMI) have been based on voluntary participation, particularly in recent years. We believe that principle should apply to the IPI Model in that participation should *not* be mandatory. Many AAMC member institutions are committed to ensuring high-quality care in a cost-efficient manner, as evidenced by their voluntary participation in many CMMI-sponsored demonstrations. Because of this commitment and to best meet the needs of their communities, hospitals have chosen the CMMI demonstrations they wish to participate in. **Therefore, we strongly recommend that CMS and CMMI continue this practice and not require mandatory participation in the IPI Model.**

Implementation Timeline is too Ambitious

The ANPRM suggests that CMS would implement the IPI Model in the Spring of 2020. We believe this timeline does not consider the time needed to ensure systems will be in place to guarantee a smooth transition between the current Medicare Part B drug procurement process to the new Model. **The AAMC is concerned that the proposed timeline for implementation is too ambitious and would not allow for adequate stakeholder engagement nor prudent execution of the complex proposal. We urge CMS to develop a more realistic timeline.**

To keep to the timeline suggested, CMS would be required to release both a proposed rule and a final rule in calendar year 2019. We do not think the proposed start date would provide adequate time for CMS to thoughtfully review and respond to stakeholder comments on the proposed rule. CMS may also be required to release subregulatory guidance to assist Model participants' compliance with the new requirements. All this must be completed within what appears to be less than a 12-month timeframe to meet the proposed start date of Spring 2020.

In addition, the IPI Model would require multiple levels of new contract negotiations between hospitals and distributors that currently supply the affected drugs, in addition to new contracts with the vendors that would be supplying the drugs under the Model. Even before this occurs, CMS would have to develop and issue a Scope of Work for these new entities, collect and evaluate bids, and award contracts. In turn, selected IPI vendors would be required to participate on a national level and may be required to obtain state licensure. They would also be required to secure and negotiate contracts with both drug manufacturers and providers.

Providers mandated to participate in the IPI Model would also be required to negotiate new contracts with vendors, potentially more than one vendor, to implement a new procurement avenue for a small subset of Part B drugs included in the Model. Additionally, providers would be required to renegotiate current contracts with other distributors to exclude the drugs included in the IPI Model. This will not only be

overly burdensome but also costly for providers. **This additional burden, complexity, and expense must be worked into any implementation timeline and included in any projected savings to truly understand the cost of implementing the IPI Model. If CMS mandates participation in the IPI Model, then CMMI should be allowed to exercise its authority to compensate participants for the added costs of meeting the requirements of the IPI Model.**

Put in Place Safeguards to Ensure Timely Access to Drugs Included in the Model

The ANPRM would require participants to acquire Part B drugs included in the IPI Model from vendors chosen by CMS. CMS expects to select at least three vendors to participate on a national basis and potentially serve all selected geographic regions and include all drugs within the Model. To increase vendor competition within the Model, CMS is open to allowing entities currently involved in drug distribution channels to be vendors.

True competition in the marketplace is intended to reduce drug prices but additional safeguards also are needed. CMS should require that each geographic region include *at least three* vendors that should supply *all* drugs included in the IPI Model. Even this requirement, however, may not ensure competition in the selected markets. AAMC is concerned that even with multiple vendors in the marketplace so called "shadow-pricing" may occur.[7] As recently reported in the Washington Post, generic drug companies conspired to manipulate the market to "ensure that each company reaped" profits and went after competitors that "ignored these unwritten rules and sold drugs for less than agreed-upon prices."[8] CMS must put in place safeguards to ensure that vendors do not manipulate the market to their benefit.

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 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. It is incumbent upon CMS to design a model that adequately addresses this concern.

Provide Exceptions When Drugs Are in Shortage

The ANPRM states that CMS is considering whether to exclude from the IPI Model drugs that are identified by the Food and Drug Administration to be in short supply. Drug shortages are an unfortunate reality for hospitals and the AAMC agrees that hospitals must have additional flexibility to acquire these drugs in order to ensure beneficiary access to needed medications. Under the current system, when there is a drug shortage, hospital pharmacies make considerable efforts to source supplies "off-contract," often at higher prices. Under the Model, if a vendor is unable to deliver the needed drugs, hospitals would have no choice but to directly purchase them outside of the structure of the model. CMS should provide an

[7] U.S. House of Representative Committee on Oversight. Cummings and Welch Launch Investigation of Drug Companies' Skyrocketing Prices for MS drugs. August 17, 2017. https://democrats-oversight.house.gov/news/press-releases/cummings-and-welch-launch-investigation-of-drug-companies-skyrocketing-prices

[8] The Washington Post. Investigation of generic "cartel" expands to 300 drugs. Published December 9, 2018. https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7_story.html?noredirect=on&utm_term=.bc610a4f942e

exception allowing hospitals to bill directly for a drug at non-model rates in such an event to ensure beneficiary access.

Hospitals That Are Part of Health Systems in Multiple Geographic Regions Should Be Excluded from the Model

The IPI Model would identify geographic regions that would include 50 percent of Medicare Part B spending on separately payable Part B drugs. CMS has not identified how these geographic regions would be determined but is considering using Core Based Statistical Areas (CBSAs) "as the primary unit of analysis in the Model." (p. 54553) CMS would mandate participation from all physician practices and hospital outpatient departments within these geographic regions that furnish the drugs included in the Model. Not all Medicare fee-for-service (FFS) beneficiaries would be included in the geographic regions and those not included would continue to "receive drugs that were obtained by their health care provider using the buy and bill approach." (p. 54552)

The AAMC is concerned that, depending on how the geographic regions are determined, some health systems located in diverse geographic regions will have some hospitals included in the Model and others excluded. Hospitals serving diverse areas should not be penalized because they have facilities in areas different than those in the geographic regions defined by CMS. Therefore, hospitals that have some sites outside of the geographic regions should be excluded from the IPI Model.

Utilization Management Techniques Should Not Be Overly Restrictive

Hospitals are concerned that vendors could impose overly restrictive drug utilization management (UM) tools such as tiering and prior authorization, as a means to limit access to high-cost drugs. These tools are often used to reduce utilization and spending on high-cost prescription drugs, and often impose unnecessary administrative burdens on prescribers and access delays on patients. These methods require providers treating patients enrolled in a variety of health plans, each with their own formularies and UM requirements, to sift through myriad information in order to ensure patients receive the drugs that best treat their conditions. Similar to quality measure requirements, physicians and hospitals receive no compensation for the administrative time required to address the burdens health insurance plans often have in place to access these medications. If CMS chooses to allow Model vendors to apply UM tools as a means of value-based design, these tools should not be overly burdensome or restrict beneficiary access to needed medications based solely on price. Lastly, CMS notes that "Medicare does not mandate the use of or encourage white bagging or brown bagging," and we urge CMS to maintain this policy. (p. 54549) "Bagging" could result in delays in obtaining essential drugs for some beneficiaries; instead, hospitals should have drugs in their inventory, so they can administer them immediately.

Add-on and Bonus Payments

Calculation of the Add-on Payment Should Not Negatively Impact Hospitals

Currently, Medicare reimburses providers for separately payable Part B drugs at the average sales price (ASP) plus 6 percent.[9] This 6 percent add-on payment is to help cover the costs of drug ordering, storage and handling, and to help offset deficiencies in cases where the drug is acquired at a higher price than

[9] With sequestration, the actual payment allowance is ASP +4.3 percent.

ASP. As is noted in the ANPRM, hospitals will continue to have fixed pharmacy costs – *e.g.*, storage, handling, compounding, track and trace – that will likely not be reduced due to the IPI Model.

Under the IPI Model, CMS would replace the current ASP plus 6 percent add-on structure for providers with a fixed dollar amount per encounter, or per month, for an administered drug, and not vary based on the price of the drug itself. The new add-on payment would be based on the current percent add-on to ASP.

We are concerned that this change from a 6 percent add-on to a flat fee per drug could significantly reduce payments to HOPDs, depending on how the add-on is calculated and redistributed. Because HOPDs tend to treat sicker patients and use higher cost drugs, they could be unfairly penalized. We cannot support a potential option that would further reduce payments to HOPDs.

Current ASP Add-on Structure Does Not Incentivize the Use of Higher Cost Drugs

The AAMC disagrees with the assertion that the current ASP add-on structure incentivizes the use of higher cost drugs. Providers select treatments, including the choice of a drug, based on the needs of the patient, not the cost of the drug. HOPDs have been unfairly targeted as utilizers of higher cost drugs. However, differences in patient mix (including sociodemographic status), severity of illness, quality of care, and patient outcomes are much different in HOPDs that in private physician offices. Often, patients seen in teaching HOPDs have higher disease burden requiring newer drugs – many of which have no competition – that come with a high price tag. If CMS moves forward to an alternative to the current ASP plus 6 percent system, the change must reflect the differences in utilization based on the differences just mentioned. For example, hospitals that utilize higher cost drugs, for the reasons mentioned above, should not be harmed by this proposal.

Beneficiary Cost Sharing Should Not be Part of the Calculation of the Alternative Add-on Proposal

As we outline later in this letter, providers should not be required to collect beneficiary cost sharing because any cost-sharing obligation will be generated by the claim the vendor submits to Medicare, not by the "no pay" claim submitted by the provider. CMS notes that "beneficiary cost-sharing would apply to the model specific alternative compensation payments and for model payments for included drugs." (p.54553) Is this to mean that CMS will deduct the beneficiary cost-sharing obligation from the drug add-on payment? Will providers be required to submit to Medicare and/or the vendor whether or not it received a coinsurance payment from the beneficiary and how much they received?

Additionally, CMS must also clarify who bears the financial risk of uncollected beneficiary cost sharing. If the responsibility to collect the cost sharing would ultimately rest with the provider, then presumably this would count as Medicare bad debt. If the collection of cost sharing resides with the vendor, it is unclear how the provider would coordinate with the vendors on the uncollected amount. Given the complexity of this arrangement, particularly for beneficiaries with a Medicare supplemental plan, providers should not be required to collect beneficiary cost sharing and thus this cost sharing should not be included in the add-on payment.

Drug Utilization Should be Based on Clinical Decision-making, Not Incentivized by Bonus Payments

CMS is considering the creation of a bonus pool that would provide additional payment to providers that prescribe lower-cost drugs or practice evidenced-based utilization. The AAMC believes that drug choice should be based on a patient's needs, not whether the provider will receive a financial reward. Often, patients receive initial, lower-cost cancer care in physicians' offices and are referred to hospital outpatient

departments for more advanced treatments that are costlier. In recent years, HOPDs and off-campus PBDs have seen a spike in patients requiring treatment – particularly cancer treatments – for advanced stages of disease.[10,11] In this scenario, HOPDs and off-campus PBDs may not receive a bonus payment because they are treating a patient with a more expensive drug, whereas, a physician may benefit. Any incentive structure should be based on quality of care and clinical outcomes, not on using a cheaper drug. If CMS chooses to create a bonus pool, consideration must be given to how it will be funded and to ensure that it does not negatively impact other payments hospitals receive, such as add-on payments.

Collection of Beneficiary Cost Sharing

Vendors that Bill Medicare Should be Required to Collect Beneficiary Cost Sharing, Not Providers

The Model would require participating providers to collect any cost-sharing liability from beneficiaries for the drugs included in the Model. The AAMC believes that the responsibility to collect any beneficiary cost-sharing obligation should rest with the vendor, not the provider. Since the vendors in the Model would be responsible for billing Medicare for reimbursement of the drug, they should also be responsible for collecting any required cost sharing from the beneficiary, including billing beneficiaries' Medicare supplemental plans (*e.g.*, Medigap), retiree plans, or Medicaid.

Beneficiaries' with a Medigap policy can assign payment for services which allows the practitioner to file a claim to Medicare on the beneficiaries' behalf. In these case, Medicare must transfer Medicare claims information to Medigap insurers, also known as a crossover claim. The Medigap insurer will then pay the provider directly. Crossover claims can also be generated for Medicaid agencies and other commercial payers. The "no pay" claims that providers would be required to submit under the Model do not generate a crossover claim. Therefore, it should be incumbent upon the vendor to handle all Medicare billing requirements including collecting beneficiary cost sharing and billing Medicare supplemental plans.

Finally, providers will likely not know what a beneficiary's exact cost sharing will be at the time of drug administration. Vendors would be required to provide that information to the providers at the time of the patients' visits. **Given the increased complexity of requiring a provider to collect beneficiary cost sharing at the time of service, CMS should not include this policy**.

Impact on the Medicare Hospital Payment Systems

The ANPRM requests feedback on how the IPI Model may impact other payment systems. The AAMC wants to ensure that the IPI Model does not negatively impact other hospital prospective payment systems. In the attached addendum, we outline concerns we ask CMS to consider as it addresses changing how Medicare would pay for Part B drugs.

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[10] MedPAC. Report to Congress, March 2018. Chapter 3: Hospital Inpatient and Outpatient Services. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch3_sec.pdf?sfvrsn=0

[11] Nelson, Roxanne. Oncology practices have lost $78 million, many closing. September 4, 2018. https://www.medscape.com/viewarticle/901521

Interaction with the Oncology Care Model

Drugs Administered as Part of the Oncology Care Model Should Not be Included in the IPI Model

The Oncology Care Model (OCM), which began July 1, 2016, is a 5-year voluntary pilot project aimed at improving the quality and effectiveness of cancer care for Medicare beneficiaries and reducing Medicare costs. Payments for OCM participating providers are based on total costs of care for a 6-month episode triggered by a Medicare Part B or Part D chemotherapy claim. Drugs are included in the calculation of the target price and, on average, represent greater than 40 percent of the total cost of care per episode (including both Part B and Part D chemotherapy claims).

Removing chemotherapy drugs paid under Part B will disrupt the OCM demonstration and negate any advances in understanding how the OCM improved quality of care and health care outcomes for beneficiaries with cancer. It may also change provider participation in the OCM given the added complexity of removing the drugs from the target price. Under the IPI Model, only certain geographic areas would require mandatory participation, which means some OCM participants would be impacted by the changes while others are not. If these changes were to occur within the OCM, how would OCM participants in the IPI Model areas be evaluated when compared to their peers outside of those areas? How would this impact the target prices of the OCM for these different groups? How would this impact the quality of care for beneficiaries? **The AAMC believes that including OCM in the IPI Model would be disruptive. We urge CMS to keep OCM intact by excluding current OCM participants from the IPI Model.**

Quality Measures

Limit Administrative Burden to Model Participants When Incorporating Quality Measures into the Potential IPI Model

The AAMC thanks CMS for acknowledging concerns regarding adding administrative burden to Model participants due to quality measures that require the submission of additional data by providers and suppliers outside of the data submitted through claims. We urge the Agency to remain mindful of operational and cost burdens for providers and suppliers when considering quality measures for the Model.

Ensure All Measures Considered be NQF-Endorsed as Reliable and Valid for Measuring Performance of Model Participants

The AAMC strongly recommends that all measures incorporated in the Model be NQF-endorsed to ensure that the measure is scientifically valid, reliable, and feasible, and determine whether the measure is appropriate for review in the NQF Socioeconomic Status (SES) trial period to allow for risk-adjustment of SES and other demographic factors. In making this recommendation, the AAMC requests that CMS only implement quality measures in the manner that they are NQF-endorsed.

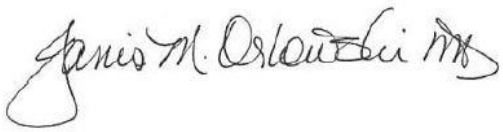
The request for feedback specifically refers to the quality measures utilized by the Bundled Payments for Care Improved Advanced (BPCIA) model, which does not meet this principle for measure endorsement. Under the BPCIA model the Innovation Center has chosen to modify specifications of NQF-endorsed measures for implementation in the Model, though those modifications have not been reviewed for validity and reliability, calling into question the appropriateness of such measurement for Model

participants. For example, the Patient Safety and Adverse Events composite measure (PSI-90) is NQF-endorsed (NQF # 0531) to measure hospitals at the facility level of observed-to-expected ratios across 10 common patient safety component indicators to monitor performance over time or across regions and populations. Instead of implementing the measure as specified, CMMI is implementing a modified version to measure at the episode-level (90 days), rather than across a calendar year or more of data (for CMS's Value-Based Purchasing Program, the reporting period is 3 years). The sample size at the episode level is likely to be incredibly small for very rare events and thus extremely sensitive. The AAMC has asked the Innovation Center to provide timely, detailed specifications on how it will modify the measure to apply at the episode level, without which stakeholders cannot know whether the measure is valid or reliable, defeating the purpose of NQF-endorsement.

Conclusion

Thank you for the opportunity to comment on this ANPRM. We share CMS's desire to find ways to reduce drug prices but believe that the current proposal contains significant flaws. The AAMC would very much like to work with CMS to find ways for the Agency to address unsustainable drug prices and also address the concerns we mention in this comment letter, which we believe ultimately could affect patients access to care and needed medications. We look forward to future opportunities to engage with CMS to achieve the goals of reducing cost, improving care, and preserving the essential role of teaching hospitals and health systems in our nation's health care system. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P
Chief, Health Care Affairs

cc: Ivy Baer

Addendum: Potential impacts of the IPI Model on other Medicare payment systems

CMS should also consider the potential impact of the Model on the rate setting process of the Outpatient Prospective Payment System (OPPS) and Inpatient Prospective Payment System (IPPS), which may also affect the design and evaluation of the IPI Model ("demonstration"). Below are some potential scenarios that CMS should take into consideration.

Part B drug payments for hospitals outside of the demonstration regions

Reducing ASP would affect Part B drug payments for providers that are not part of the Model. Providers in regions not included in the Model may not be able to obtain drugs at or below ASP and, as a result, suffer financial loss. This "spill-over effect" may impact the evaluation of the Model as the providers outside of the Model's geographic regions will also be affected by the change in drug prices.

Comprehensive Ambulatory Payment Classifications (C-APCs)

CMS is proposing that the Model applies to separately payable drugs (status indicator K under OPPS) among others. These drugs, however, are not separately payable in Comprehensive APCs, rather they are packaged in. The ANPRM is not clear in terms of how to handle drugs included in the Model in the rate setting process of C-APCs. Below are three methods to potentially address this issue noting drawbacks for each.

- Include the claims submitted by hospitals in demonstration regions as is but exclude their drug lines from rate setting. The weights of C-APCs will reflect that only half of the drug costs are included in the rate setting. As the costs of drugs are not fully reflected in C-APC weights, the approach would underpay providers in regions not included in the Model.
- Exclude the claims submitted by providers in regions included in the Model from the rate setting of C-APCs. This could have the drawback of setting rates on less data leading to more variability each year.
- Create two separate C-APC weights, one for providers in the Model regions and one for those outside of the Model regions. This could lead to significant complexity and confusion.

ASP, status indicator and APC weights

If the price of certain drugs selected for the Model falls below the packaging threshold for drugs under OPPS, it may affect APC rate setting and cause financial harm to providers in regions not included in the Model. Hospitals in the non-demonstration regions would not continue to receive separate payment for the packaged drugs. The cost of these drugs would be packaged to other APCs and reflected in the weights of these APCs. Depending upon how CMS decides to handle the issue in the rate setting process as mentioned in the three approaches above, if drug costs in the Model are not fully factored in the rate setting process, it will result in underpayment for hospitals in regions not included in the Model.

Cost-to-charge ratio of pharmacy cost center

Depending upon how CMS decides to handle reporting of drug costs in Medicare cost report, the Model may affect the computation of the cost-to-charge ratio of the pharmacy cost center, which would affect not only OPPS and IPPS rate setting processes, but also calculation of certain Medicare payments like the Uncompensated Care Payment.