

December 27, 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; Advance Notice of Proposed Rulemaking with Comment (Vol. 83, No. 210), October 30, 2018.***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) advance notice of proposed rulemaking (ANPRM) on the International Pricing Index (IPI) model for Medicare Part B drugs.

The AHA shares CMS's concern about the skyrocketing cost of drugs and commends the agency for its willingness to address the issue. Indeed, we frequently reiterate that an unaffordable drug is not a lifesaving drug. America's hospitals rely on innovative drug therapies to save lives every day. However, high and rising drug prices are putting access and quality of care at risk by straining providers' ability to get the drug therapies they need to care for their patients. **We appreciate that CMS has heard, and is attempting to address, the AHA's frequently voiced concerns that the responsibility for unsustainable drug pricing, ultimately, lies with drug manufacturers.**

As we and our members have analyzed the proposed IPI model, many policy questions, considerations and concerns have arisen about how the demonstration project would be operationalized. **Our specific comments and concerns about the model fall into four categories, as described below.** In addition, given the amount of model specifics



still to be determined, the anticipated operational burdens, as well as other logistical concerns, **the AHA urges CMS to consider narrowing the scope of the program to a more targeted intervention than that described in the ANPRM.** For example, if the model included a more limited set of drugs or a more limited number of geographic areas, it would be more manageable for providers, vendors and CMS alike.

Impact on 340B Hospitals. The AHA's primary concern with the IPI model is its interaction with the 340B Drug Pricing Program. The discount that 340B hospitals receive allows them to stretch their resources to provide more comprehensive services to more patients, as Congress intended. However, the IPI model could undermine the intent of the program because hospital participants would no longer be able to achieve 340B savings and use them to improve access and services. **It will be impossible for the IPI model to be successful unless the issues surrounding 340B drug discounts can be resolved. Specifically, we ask that CMS hold 340B hospitals harmless and allow them to continue to benefit from the discounts they obtain.**

Regulatory and Operational Burden. This model would create a brand new supply line and payment mechanism for Part B drugs, which has the potential to cause increases in regulatory and operational burden. **We ask that you take steps to minimize burden to the greatest extent possible and also provide hospitals with more time for implementation beyond the 2020 date mentioned in the notice. Doing so would make it much easier for hospitals to be successful in the model.**

Payment Reductions. Changing the add-on payment for drugs from percent of the average sales price (ASP) to a flat fee per drug has the potential to redistribute payments away from and/or among hospitals. **We ask CMS to ensure that payments to the hospital field as a whole, as well as to individual providers, are not reduced as a result of the proposed change to a flat fee.** Doing so would help ensure that the responsibility for fixing unsustainable drug pricing ultimately lies with drug manufacturers, not with providers.

Model Vendors' Fees and Policies. We are concerned that, to create a sustainable business model, vendors could assess additional distribution and other fees on hospitals, effectively raising the cost of drugs for providers. They also could impose unilaterally-defined, retroactive arrangements and onerous utilization management tools that could restrict access to the right drug at the right time for beneficiaries. **We would feel much more comfortable with the model if either the vendors billed Medicare directly for their fees or if, at a minimum, there were some guardrails established to protect hospitals from high fees. Such guardrails should, for example, prohibit the imposition of contrived arrangements and restrictive utilization management policies.**

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Our detailed comments are attached. Once again, we appreciate and commend the agency's efforts to reduce excessive growth in drug prices. We look forward to working with you to improve the IPI model.

If you have any questions concerning our comments, please feel free to contact Roslyne Schulman, AHA director of policy, at 202-626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President

## AMERICAN HOSPITAL ASSOCIATION'S DETAILED COMMENTS

### LIMITING THE SCOPE OF THE MODEL

As described in the ANPRM, the IPI model would require the participation of hospital outpatient departments (HOPDs) and physician practices in selected geographic areas across the U.S., which would encompass 50 percent of Medicare Part B spending on separately payable drugs. **Given our concerns described above, the AHA urges CMS to consider narrowing the scope of the program to a more targeted intervention than that described in the ANPRM. Specifically, the AHA recommends that CMS consider limiting further the number of Part B drugs included in the IPI model or the number of geographic areas included.** This would make the model more manageable for providers, vendors and CMS alike, which would result in more accurate results.

For example, limiting further the number of Part B drugs included in the model would make it more manageable but still provide a reasonable test and achieve significant savings for the program. In our analysis of Medicare Part B drug data, we found that the top 10 separately payable Part B drugs account for nearly half (48 percent) of the total Medicare Part B drug expenditures for separately payable drugs. The top 20 drugs account for nearly 63 percent. **As such, we recommend that, if CMS moves forward with the IPI model, it limit the number of drugs included to the top 10 separately payable Part B drugs.**

In addition, CMS solicits comments on whether certain non-subsection (d) hospitals should be included in the IPI model. **The AHA recommends that the model exclude prospective payment system (PPS)-exempt dedicated cancer centers, children's hospitals and critical access hospitals (CAHs).** These hospitals are subject to distinct reimbursement methodologies and should not be part of the model. For example, CAHs receive cost-based reimbursement for Medicare services in order to reduce their financial vulnerability and improve access to health care by keeping essential services in rural communities so they also should be excluded from the model. The PPS-exempt dedicated cancer centers and children's hospitals were granted permanent hold-harmless status by Congress. In addition, the cancer centers are not impacted uniformly by the application of this model. Including these hospitals in the IPI only would add burden without benefit.

### IMPACT ON THE 340B DRUG PRICING PROGRAM

**The AHA's primary concern with the IPI model is its interaction with the 340B program.** Congress, more than 25 years ago, established the 340B program in response to the pressure high drug costs were putting on providers serving vulnerable

communities. As such, it requires drug manufacturers participating in the Medicaid program to sell outpatient drugs at discounted prices to eligible hospitals and clinics that care for many uninsured and low-income patients. **The discount that 340B hospitals receive allows them to stretch their resources to provide more comprehensive services to more patients, as Congress intended.** Through this program, 340B hospitals have been able to expand access to lifesaving prescription drugs and comprehensive health care services in vulnerable communities across the country, including to low-income and uninsured individuals.

However, the IPI model would disrupt this proven model to reduce drug prices for 340B hospitals. Specifically, under the IPI model, 340B hospitals would no longer buy and bill for many Medicare Part B drugs. As such, it would undermine the intent of the 340B program because hospitals participating in the model would no longer be able to achieve 340B savings and use them to improve access and services. **This is of such paramount importance to the AHA and our member hospitals that we believe this model cannot be successful unless the issues surrounding 340B drug discounts can be resolved. Specifically, we ask that CMS hold 340B hospitals harmless and allow them to continue to benefit from the discounts they obtain.**

To address this concern, we have identified a few ways the agency could hold these hospitals harmless. Under the first option, the basic structure of the 340B program would be maintained and the IPI model vendor would become an agent of the 340B hospitals participating in the demonstration project. This vendor-agent relationship only would apply to the purchase of 340B drugs. This approach preserves the 340B drug manufacturer discount. In the current 340B program, there are examples of third-party entities, such as wholesalers, that negotiate with drug manufacturers on behalf of the hospital – thus, serving as an “agent” of the hospital.

A second option would be to hold 340B hospitals harmless by requiring the manufacturer to give hospitals a backend “rebate” equal to the difference between the IPI model price and the 340B price. This approach attempts to recognize that in many cases the 340B program may achieve a bigger discount than the IPI model. If no rebate were given, Medicare and providers would effectively be giving money back to drug manufacturers to mitigate their losses under the model. This option is less preferred, however, because it would lead to the erosion of the 340B program by creating a backend “rebate” that merely resembles the 340B discount.

In addition, we are concerned that the IPI vendors may effectively meet the legal definition of a group purchasing organization (GPO). This presents an issue for certain 340B hospitals – disproportionate share hospitals (DSH), children's hospitals and free-standing cancer hospitals – because they are prohibited by statute from purchasing covered outpatient drugs from GPOs. Thus, if vendors are effectively GPOs, 340B hospitals participating in the IPI model would not be able to access 340B discounts for *any* drug. **To address this concern, we strongly urge CMS to work with the Health**

**Resources and Services Administration (HRSA) to ensure that the GPO prohibition would not apply to any 340B hospitals that may participate in the IPI model.**

## **INCREASED REGULATORY AND OPERATIONAL BURDEN**

CMS states that one of its goals in proposing the IPI model is to reduce participating health care providers' burden and financial risk associated with furnishing included drugs by using private-sector vendors to purchase and take title to these drugs. However, hospitals are concerned that the IPI model could greatly increase their regulatory and operational burden and costs. This would be due to, for example, the introduction of new vendors into an already complex supply chain process, new billing requirements contemplated in the demo, and the need to resolve many complex regulatory and operational challenges that would be created under the model. **As such, the AHA urges CMS to extend its commitment to reducing regulatory burden to also encompass the IPI model. That is, if the agency moves forward with the IPI model, we urge it do everything in its power to minimize the regulatory and operational burden that would be imposed on hospitals. Doing so would make it much easier for hospitals to be successful in the model.**

This increased burden primarily arises out of the fact that the model would layer an entirely new set of vendors onto the existing array of supply chain partners and arrangements. This is further complicated since the new vendors only would be furnishing *some* of the Part B drugs needed to care for Medicare beneficiaries. That is, in addition to all the changes needed under the new IPI model, hospitals still would need to maintain their contracts and relationships with their current GPOs, wholesalers and distributors, both for purchasing Part B and other Medicare drugs that are not covered under the model as well as all drugs needed to care for non-Medicare patients. These new vendors could be disruptive to current operations, and potentially could impose new regulatory and operational burdens, as we describe more specifically below.

Our members also have identified logistical challenges and raised questions about billing and inventory management under the model. For example, even though hospitals would not be purchasing model drugs, they would still be responsible for submitting "informational" drug claims to the Medicare Administrative Contractor (MAC), along with claims for drug administration services and the model add-on payments after model drugs are administered. Presumably, the hospitals also would have to notify the vendor that the drugs were administered so the vendor actually could bill Medicare and receive payment. In addition, the hospitals also would bill for and collect beneficiary cost-sharing amounts, including billing supplemental insurers. But, once they do, they would be responsible for then tracking and transmitting these remaining payments to the

vendors. These new claims and obligations would add complexity and additional administrative costs to the current claims processing systems.

Among the biggest operational concerns raised by hospitals is the model's impact on inventory management. Hospitals would need to, at best, significantly modify or, at worst, create new drug inventory management systems in order to track model drugs separately from non-model drugs. This would be particularly challenging for large health systems that could have some of their hospitals included in the model and not others. These large health systems, which often utilize centralized purchasing and inventory management systems, would have to create a new and costly process to separately track specific drugs for specific patients and be able to report this to CMS and vendors.

**Due to these and other concerns described below, we also recommend that CMS delay implementation of the model by at least one year beyond the potential 2020 implementation date mentioned in the ANPRM.** Many of our members have noted that the timeframe described in the ANPRM, which would implement the model by the spring of 2020, would be impossible to meet. The complexity of the model, the need to establish contracts with the new vendors and re-work contracts with their existing supply chain, as well as to make systems changes necessary for inventory management and the billing elements of the model, would require far more lead time.

Other regulatory and operational questions and concerns have been raised by hospitals and would need to be fully addressed before the model is finalized and implemented. Among these are the following.

- *How would excess drug inventory and drug wastage be handled by vendors?* In order to ensure adequate access to drugs for a patient population whose needs are, of course, not predictable in advance, hospitals have to store more doses of drugs in their inventory than are ultimately administered, which can result in wastage. This wastage may be a result of drugs expiring, vials being opened but not used due to a cancelled appointment, or a last-minute change in the patient's plan of care. This is a normal and necessary cost of doing business, and one for which hospitals bear the financial risk under the current "buy and bill" structure. However if vendors would be purchasing and billing for drugs under the IPI, they should bear this financial risk; we ask that CMS address this issue in its proposed rule.
- *How will drug shortages be handled?* New and ongoing drug shortages are an unfortunate reality for hospitals and health systems. 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. We ask that, to

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

- *How will drug claim denials be handled?* CMS needs to address situations in which a claim for an administered model drug is denied by the MAC due to, for example, not being medically necessary or conflicting with a coverage decision or Medically Unlikely Edit. We believe that the vendor should continue to be at financial risk in these cases. They also should be responsible for submitting an appeal to the MAC. However, since the vendor would not have access to the patient's medical record, would the participating hospital be obligated to provide the vendor with the patient's record and medical justification for such an appeal?
- *How would model drugs packaged into Comprehensive Ambulatory Payment Classifications (C-APCs) be handled?* CMS proposes that only separately payable drugs be included in the IPI model. However, under the outpatient PPS, even drugs that would otherwise be separately payable are packaged if they are on a claim with a primary procedure that is part of a C-APC. Since hospitals won't necessarily be aware of whether an administered drug would be swept into a C-APC, CMS should address how the Medicare payment and the beneficiary copay would be reconciled between the agency, the vendor and the hospital in these circumstances.
- *How would conflicts between Medicare Parts A and B be handled?* Under current Medicare regulations for hospitals, it is not always known whether a drug will be covered under Part A or Part B at the time the drug is administered. How would CMS reconcile payment in the situation in which an inpatient (normally billed and paid under Part A) became an outpatient through a Condition Code 44 process? How would CMS reconcile payment in the situation in which a model drug was administered to a hospital outpatient, but that under current regulations would be bundled into a Part A inpatient stay due to the 3-day/1-day window?
- *How would bad debt be handled?* Although CMS expects that hospitals would collect beneficiary cost-sharing, it does not state who would bear the financial risk of uncollected coinsurance. If it is the responsibility of the provider, presumably they still would be able to receive Medicare bad debt reimbursement. If it is the responsibility of the vendor, how would the provider coordinate with them on the uncollected amount?

## **PAYMENT REDUCTIONS: CONSIDERATIONS FOR THE DRUG ADD-ON PAYMENT**

Under the IPI model, vendors would be both purchasing and billing for drugs; hospital participants would no longer do so for any included Part B drugs administered to Medicare beneficiaries. However, hospitals would continue to bill for drug administration

as well as a “drug add-on amount.” The add-on would be based on the current percent add-on to ASP. Under sequestration, it is 4.3 percent, but would be increased back to pre-sequestration levels (6 percent) and converted to a fixed dollar amount per encounter, or per month (based on beneficiary panel size), for an administered drug, and would not vary based on the price of the drug itself. As with the current percentage add-on, CMS states that it intends the fixed dollar add-on in the model to help cover the costs of drug ordering, storage and handling as well as other costs borne by hospitals and physicians. Specifically, CMS reports that the total drug add-on amount would be calculated based on the expected add-on amount for included drugs that would have been paid in the absence of the model, before sequestration. CMS is considering translating that amount into a unique payment amount per administered drug based on: (1) which class of drugs the administered drug belongs to; (2) the physician’s specialty; or (3) the physician’s practice<sup>1</sup>.

**In the notice, CMS states that one of its goals for the model add-on payments would be to “hold health care providers harmless to current revenue to the greatest extent possible.” The AHA supports this goal.** However, we are concerned that this change from a 6 percent add-on to a flat fee per drug could be redistributive across Part B, with the potential to significantly reduce payment to HOPDs. This is because hospitals tend to treat sicker patients and, therefore, use higher-priced drugs than other settings. We could not support options that would impose further cuts to HOPDs, either in total or to individual HOPDs, which already have significantly negative margins<sup>2</sup>.

**Specifically, we would be very concerned if the flat fee was calculated and redistributed evenly across either the entirety of Medicare Part B or by class of drug, because this would likely reduce payments to hospitals.** It is difficult to determine the impact of the second option presented in the notice – to calculate/redistribute the fee by physician specialty – because hospitals do not have specialties. **Finally, we believe that the option of calculating the add-on payment by individual physician practice and individual HOPD would involve little redistribution and make it workable for hospitals.**

Whatever mechanism is ultimately used to calculate and distribute the add-on payment amount, the AHA believes that the total amount in each separate pool of add-on dollars should be updated annually, not only to adjust for changes in ASP, but also to adjust for changes in drug volume, mix and utilization. Furthermore, given that the model would impact ASPs for included drugs, we urge CMS to consider instituting a stop-loss policy

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<sup>1</sup> For hospitals, we assume that “physician practice” equates to hospital outpatient department.

<sup>2</sup> Based on an AHA analysis of FY 2016 Medicare cost report data, Medicare margins for outpatient services were a record low of negative 14.8 percent in 2016. According to the Medicare Payment Advisory Commission, overall Medicare margins were a record low of negative 9.6 percent in 2016, with a new record low of negative 11.0 percent projected for 2018. Of note, MedPAC also reported that for the first time ever, even “efficient” hospitals had a negative margin in 2016.

to ensure that if the ASPs for included drugs fall, the decline would not reduce the add-on payment amount by more than a certain percent per year. Doing so would help promote predictability and stability in hospital payments.

Further, in the ANPRM, CMS also states that to incentivize reduced utilization where appropriate, it is considering creating a bonus pool, under which model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization. **The AHA is concerned that such a bonus pool could inappropriately impact beneficiary access to the most clinically effective drugs.** Hospitals have little control over which drugs physicians prescribe in hospital-based settings, yet the notion of a bonus pool would hold them accountable for such decisions to an inappropriate degree. Moreover, there is a dearth of lower-cost, clinically meaningful alternatives available for many of the common conditions treated in HOPDs. Further, there is no convincing evidence that physicians who practice in HOPD settings consider profitability over clinical effectiveness when deciding which drugs to prescribe or order. **However, if the agency believes it is necessary to move forward with a bonus pool approach, we strongly recommend that it establish safeguards to ensure that beneficiary access to drugs is not compromised.**

## **MODEL VENDOR CONSIDERATIONS: FEES AND POLICIES**

Hospitals have many questions and concerns about their relationship with the model vendors. Specifically, this model would not directly address the actual price of the included drugs; rather it changes Medicare reimbursement. This puts vendors at financial risk for negotiating enough of a discount from the drug manufacturers to sustain a business model.

If a manufacturer declines to reduce the cost of the drug below the IPI model payment level, we would expect that the vendor would look to make up the financial loss. Providers are the likely targets of these efforts, which could take the form of additional/unnecessary distribution and other high administrative fees. It also could be, as we have seen in the pharmacy benefit manager (PBM) space, unilateral, retroactive arrangements that have resulted in providers rebating money back to the PBM without a mutually-agreed upon basis. **Any and all of these arrangements have the same effect – providers paying more to obtain drugs while manufacturers continue to extract high prices.**

Hospitals also are concerned that vendors could impose overly restrictive utilization management tools, such as formulary tiering, step therapy and prior authorization, which could both interfere with Medicare beneficiaries' timely access to necessary treatment and dramatically increase provider burden and costs. In addition, although we are encouraged that in the ANPRM, CMS states that "Medicare does not mandate use

of or encourage white bagging or brown bagging<sup>3</sup>,” we remain concerned that, similar to the previous Competitive Acquisition Program (CAP), vendors could still impose “white-bagging” type of delivery. Doing so could result in delays in obtaining necessary drugs for particular beneficiaries, creating access and safety issues; instead, hospitals need to have drugs in their inventory so they can obtain and administer them immediately.

Further, the AHA understands that CMS expects that there will be enough model vendors to ensure that they would compete for business based on low fees and customer service. However, given the financial risk vendors would take on, if there were too few vendors approved, such competition would be impossible. Hospitals fear that limited distribution channels would provide them with little recourse but to be subjected to whatever the vendor charges in fees or imposes in restrictive policies. **Therefore, the AHA would be much more comfortable with this model if the vendors billed Medicare directly for their fees, or if, at a minimum, there were some guardrails enacted to protect hospitals from high fees. Vendors also should be prohibited from imposing unilateral, retroactive arrangements and inappropriate utilization management tools on hospitals that could disrupt access to care for beneficiaries.**

## **MODEL PAYMENT METHODOLOGY FOR VENDOR-SUPPLIED DRUGS**

In the ANPRM, CMS states: “Manufacturer sales through the IPI model would be included in current ASP reporting.” **However, the AHA recommends that CMS exclude IPI sales from the calculation of ASP.** Including these sales in ASP would be contradictory to the notion of a true demonstration project, where an experimental intervention is applied to the intervention group, but not to the comparison group. That is, including IPI model sales in ASP calculations would have an impact on ASP-based payment rates in geographic areas that are not included in the model (the comparison group). This would make the determination of whether the model intervention was successful unclear. In addition, if model prices are included in ASP, it would impact future rate-setting in non-model geographic areas. For instance, if the model affects ASP enough, it could shift drugs from being separately payable to packaged under the outpatient PPS cost-based packaging thresholds.

## **INTERACTION WITH OTHER FEDERAL PROGRAMS**

The IPI model potentially could interact with several other federal drug pricing programs and policies, including the Medicaid “Best Price” drug rebate program, Average

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<sup>3</sup> “Brown bagging” is a term used when the patient obtains the drug at a pharmacy and then brings it to the physician for administration. “White bagging” is a term used when the specialty pharmacy ships directly to the physician office or hospital outpatient department for administration to a specific patient.

Manufacturing Price (AMP) and the 340B ceiling price. It is imperative that CMS fully consider the potential ramifications the IPI model could have on these programs and policies.

- *Medicaid Drug Rebate Program.* Under the Medicaid Drug Rebate program, a drug manufacturer must offer state Medicaid programs the “best price” given to any other purchaser (with a few exceptions), with a mandatory rebate of 23.1 percent off the list price. As such, the Medicaid “Best Price” is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity. CMS needs to consider whether the drug manufacturer lowering prices to model vendors would reset the manufacturer’s best price. If so, it would have implications for the Medicaid rebate program and, potential state budgets.
- *AMP.* AMP is generally determined based on the average price paid to the manufacturer by wholesalers and retail community pharmacies, with certain exclusions. It is one of three factors in the Medicaid rebate formula. One consideration for CMS is whether drug manufacturers’ sales to IPI model vendors could lower the AMP. If so, it also could affect the Medicaid drug rebate program by lowering the rebate, again affecting state budgets.
- *340B Ceiling Price.* As discussed above, the 340B program requires drug manufacturers to provide discounts to eligible hospitals and clinics. The 340B ceiling price is the maximum price a manufacturer can charge a 340B entity for a drug and is calculated based on a drug’s AMP, net of the Medicaid unit rebate amount. As with Medicaid Best Price and AMP, the IPI model has the potential to lower the 340B drug ceiling prices because the Medicaid unit rebate amount is based partly on AMP minus best price. This raises the question as to how lower 340B ceiling prices would affect 340B covered entities, including hospitals and clinics.

## **QUALITY MEASURES**

**The AHA strongly agrees that improving – or at least maintaining – the quality of care must be a foundational policy goal for any new value-based payment model.** Quality measures and data are important tools to assessing the extent to which models are achieving this goal. The measure topics that CMS has identified for data collection – patient experience, as well as medication adherence, access and management – would be important to understanding the model’s effects on quality. Moreover, we greatly appreciate CMS’s stated goal of using judiciously selected, targeted quality measures that minimize provider data collection burden.

**The AHA urges extreme caution, however, in using a “pay-for-performance” approach to assessing quality in this model. At a minimum, we urge CMS to adopt a “pay-for-reporting” approach in early program years.** As with other innovative value-oriented approaches, the field as a whole is learning what measures and measurement approaches are the most appropriate for particular models. For example, at this point, the extent to which differences in patient risk factors (e.g., severity of underlying illness, co-morbid conditions, social risk factors) drive differences in performance on particular measures is unknown. Such differences may require the use of risk adjustment in either the underlying measures or use of peer groupings or other stratification approaches in the model as a whole. Yet, it would be challenging to know what approach might be necessary without collecting some baseline data. In part, that is why past CMS programs (e.g., the Medicare Shared Savings Program) have used pay-for-reporting approaches in their initial years, and have not tied payment to the level of performance until later years.

**Finally, we urge CMS to ensure it conducts a “big picture” assessment of the project’s impact on both cost and quality.** This type of analysis goes beyond any pay-for-reporting or performance approach, and looks at the whole care of patients to see if CMS’s design and execution of the program is successful in achieving these overarching goals. CMS should focus this analysis on questions such as:

- Did the providers in this experimental program outperform other providers nationally?
- Were there changes in the types of patients receiving particular drugs?
- Were different types or therapies used instead of the drugs included in the model?
- Were these changes medically appropriate?
- Were there changes in the nature or types of services provided to these patients?
- Did these changes have an impact on patient outcomes?

## **OTHER OPTIONS FOR ADDRESSING INCREASING DRUG PRICES**

While the AHA appreciates CMS’s focus on high and rising drug prices, we recognize that there is no single solution to this challenge and that the Department of Health and Human Services (HHS) is evaluating multiple approaches. We have worked with our members to document the challenges hospitals and health systems face with drug prices and to develop policy solutions that protect access to critical therapies while encouraging and supporting much-needed innovation. The full set of recommendations are outlined in [Attachment B of our July letter to HHS](#). In addition, the AHA, in collaboration with the Federation of America’s Hospitals, will be releasing an independent report by the NORC at the University of Chicago in mid-January 2019 that details the specific experience of hospitals and health systems with drug purchasing

and drug shortages. While outside of the comment period for this ANPRM, we will share the report when it is available, as the data may help inform CMS's consideration of drug pricing solutions.

The AHA is particularly encouraged by the work of the Food and Drug Administration (FDA) in speeding more generic drugs and biosimilar products to the market, and we believe that more can be done to support these efforts. We also are concerned about other anti-competitive behaviors on the part of drug companies, like pay-for-delay<sup>4</sup>, the ever-greening of patents<sup>5</sup> and price collusion.<sup>6</sup> We encourage HHS to more closely evaluate these issues, as addressing these will likely have a far greater impact on drug pricing than any reimbursement levers. We recognize that the FDA may need additional legislative authority to fully prevent and address these issues, and the AHA is eager to work on specific solutions with Congress and the Administration. Finally, while we are encouraged by the FDA's efforts to fast-track generic applications when no or limited generic competition exists, we also recognize that the FDA could benefit from clearer statutory authority. This is another area where America's hospitals and health systems are eager to work with Congress and the Administration.

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<sup>4</sup> <https://www.communitycatalyst.org/doc-store/publications/top-20-pay-for-delay-drugs.pdf>

<sup>5</sup> Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: <https://ssrn.com/abstract=3061567> or <http://dx.doi.org/10.2139/ssrn.3061567>

<sup>6</sup> [https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7\\_story.html?utm\\_term=.abe5ab6362d2](https://www.washingtonpost.com/business/economy/investigation-of-generic-cartel-expands-to-300-drugs/2018/12/09/fb900e80-f708-11e8-863c-9e2f864d47e7_story.html?utm_term=.abe5ab6362d2)