AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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

Re: Advance Notice of Proposed Rulemaking: Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comment regarding the Advance Notice of Proposed Rulemaking (ANPRM) on an International Pricing Index Model (IPI model) for Medicare Part B Drugs. The AMA strongly supports efforts to address the ongoing challenges patients and their physicians face accessing affordable and timely medication treatment covered under Medicare Part B. Medicare beneficiaries receiving Part B drugs are often medically fragile and rapid access to treatment by their established health care team is essential to driving improved health outcomes and improved value in the health care system. The AMA has already expressed our pronounced concern that Medicare beneficiaries who seek care in community practices along with their treating physicians struggle to find affordable treatments options under the average sale price (ASP) reimbursement formula.[1] We are strongly committed to working with you to address overall cost growth and to fashion viable, modern programs to improve patient access to needed medication by addressing barriers associated with cost as well as administrative and paperwork burdens. Administrative and paperwork burdens continue to divert scarce clinical resources and can delay or prevent necessary care, thereby degrading patient health outcomes while fueling health care team burn-out. We welcome discussing significant reforms to the Medicare Part B competitive acquisition program (CAP) and the IPI model to ensure that beneficiaries have timely access to necessary treatments.

The AMA continues to urge policymakers to consider some key parameters when implementing new programs and policies to lower drug costs and improve patient access. The high price of medication not only negatively impacts the patient who requires them and their physician who has difficulty obtaining them, but the cost is also passed on to other patients when physicians and the extended heath care team are consumed with repetitive administrative minutiae required to comply with expanding insurer

[1] Part B drugs are generally reimbursed at ASP plus six percent, a rate set by the Medicare Modernization Act of 2003 (MMA). However, the Budget Control Act of 2011 put a 2 percent sequestration on the federal budget, effective April 1, 2013, and extended numerous times after, most recently in the Bipartisan Budget Act of 2018. This has the effect of lowering Part B drug reimbursement to ASP plus 4.3 percent.

medication utilization management policies. As a result, we have previously urged Congress and the Administration that new policies and programs to address the high cost of drugs and reduced patient access should:

- Increase transparency along the pharmaceutical supply chain;
- Result in increased competition and production capacity in all segments of the pharmaceutical and biological markets;
- Not shift costs from one set of patients to another set of patients through increased premiums for all, nor shift the patient's care and treatment from the prescription drug benefit to coverage of emergency department services and in-patient care because they could not afford their medication;
- Decrease the administrative and red tape burdens to obtain medically necessary treatments faced by patients, physicians, pharmacists, and other members of the health care team; and
- Not financially penalize physicians and pharmacists as an indirect mechanism to lower prescription medication prices nor favor a site of service.

The above parameters are equally pertinent when specifically applied to reform options under Medicare Part B drugs. Medicare is accounting for a larger percentage of domestic prescription drug spending. The increase in Part B drug costs and current payment methods have driven the delivery of medical care to higher cost sites of care. Community-based physician practices have struggled to recover their costs for obtaining, storing, and preparing Part B drugs while hospital outpatient departments (HOPDs) have leveraged volume discounts and other economy of scale benefits along with, in some cases, the 340B discount program. **Fundamentally, however, our goal is to ensure broader access to affordable treatment options, and we have concern that certain policies to address perverse incentives will limit access even more.**

As a threshold matter, we urge CMS to use caution when considering the application of utilization management programs to a Part B vendor program. Commercial health plans respond to high prescription medication costs by imposing administrative barriers, such as frequently changing formularies, step therapy requirements, and prior authorization requirements. Physicians and their staff then must undertake multiple steps before their patient is able to receive their medically necessary medication, including: finding clinically appropriate but more affordable alternatives; identifying and applying for discounts or patient assistance programs; and filing appeals or exception requests. These are compounded by antiquated insurer communication methods to process utilization requirements and appeals/exception requests including faxes, non-standardized forms, and understaffed telephone call lines that can include limits on the number of requests. Physicians around the nation now spend days responding to prior authorization and exception request rejections even for common medications. **A recent AMA survey showed that every week, a medical practice completes an average of 29 prior authorization requests per physician, taking physicians and their staff an average of 14.6 hours to process.** The growing maze of insurer utilization management requirements delays treatment for patients, consumes time physicians could be spending with other patients, and adds costs to the health care system as a whole. As a result, finite resources are diverted away from direct patient clinical care to a large volume of paperwork, emails, facsimiles, and phone calls. Administrative burdens have led to increasing delays in medically necessary care.

Instead of relying on strategies to limit or control access, we urge CMS to instead consider testing a limited, voluntary Part B vendor model that focuses on selecting an optimized number of vendors to provide the latter with adequate economies of scale while selecting among those with demonstrated technological capabilities and distribution and delivery experience to structure a program that starts and finishes with high quality customer service. Technologically and logistically capable vendors will simplify and streamline the drug acquisition process while enhancing choice and increasing speed and flexibility, continuity of care, and coordination. CMS provider participation mandates and additional paperwork requirements will diminish the vendor impetus to provide a superior customer experience that is needed to support improved patient health outcomes and will substitute a physician's clinical decision-making with bureaucratic utilization controls that harm patients.

The AMA's House of Delegates has specifically considered the issue of a new Part B vendor program given the compelling need for Part B drug payment reform. AMA policy provides that any such program (including by extension the IPI model) should meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- Must be genuinely voluntary and not penalize practices that choose not to participate.
- Should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs.
- Must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate health care inflation rate.
- Should permit flexibility such as allowing for variation in orders that may occur on the day of treatment and allow for the use of vendor-acquired drugs at multiple office locations.
- Should allow practices to choose from multiple vendors to ensure competition and ensure that vendors meet appropriate safety and quality standards.
- Should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician.
- Should not allow vendors to restrict patient access using utilization management policies such as step therapy.
- Should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

We applaud the decision of CMS to issue the ANPRM for the IPI model to allow stakeholders to solicit expert opinion and focused feedback. We urge CMS to rely on the comments provided above as well as specific comments on the IPI model below and the comments and recommendations provided by other physician organizations that similarly have experience and insight gained from the prior Part B vendor program. In sum, a successful redesign will need to provide physicians with a true choice of whether to participate or not; ensure that patient access to necessary drugs is not harmed; and avoid the temptation to add burdensome new administrative procedures aimed at enhancing vendors' negotiating power and cost-constraints.

Proposed IPI Model and Key Questions. CMS seeks comment on a reprised Medicare Part B drug vendor program, the IPI model, that would allow the vendors to negotiate for Part B drugs but align the Medicare payment to the vendors more closely with international reference prices that are partly based on an

average of prices paid by other countries. CMS has outlined that the Center for Medicare and Medicaid Innovation (CMMI) would initiate the IPI model under waiver authority. To that end, CMS indicates it is proposing to design the IPI model to achieve the following:

- Reduce expenditures while preserving or enhancing the quality of care for beneficiaries;
- Ensure the United States is paying comparable prices for Part B drugs relative to other countries by phasing in reduced Medicare payment for selected drugs based on a composite of international prices;
- Reduce out-of-pocket costs for included drugs for Medicare beneficiaries, and thereby increase access and adherence due to decreased drug costs;
- Maintain relative stability in provider revenue through an alternative drug add-on payment for furnishing drugs that removes the current percentage-based drug add-on payments, which CMS states would create incentives for higher list prices and to prescribe higher cost drugs;
- 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 included drugs; and
- Introduce greater competition into the acquisition process for separately payable Part B drugs.

The AMA strongly supports efforts to reduce costs while enhancing the quality of care, reducing beneficiary out-of-pocket costs, reducing provider burden and financial risk, and increasing competition.[2] However, the AMA is concerned with the potential impact of the proposed transition over five years of the model to using target prices for Part B drugs that are heavily based on the international pricing index. By moving away from Part B drug pricing that is more reflective of domestic market forces, we are concerned that vendors may have difficulty obtaining Part B drugs and biologicals at the indexed price, even though it will be phased in over time. If vendors are not able to obtain Part B drugs and biologicals, patient access to necessary treatments can be adversely impacted, raising the potential for patient harm.

Provider and Supplier Participation. CMS has indicated that the IPI model participants would include physician practices, HOPDs, and potentially other suppliers or providers, that furnish the selected Part B drugs in the specified geographic areas. CMS has noted that IPI model participation would be mandatory. **The AMA strongly opposes mandatory participation in the IPI model. Participation must be premised on the superior performance and capability of the vendor to meet patient clinical need including availability of the clinically indicated medication, responsiveness and flexibility to changing patient status, timeliness as measured in hours (as opposed to days), and continuity of care even when patient co-payment is not current.** Vendors that excel in these four areas will not need a mandate to drive participation. If the IPI model were to be voluntary, the AMA would recommend that CMS allow all interested providers and suppliers in a specified, but limited, geographic region to participate. The potential for patient harm would be substantially reduced as long as providers and suppliers were allowed to opt-out if they found the vendor was not able to provide covered Part B drugs under conditions to optimize patient access and clinical outcomes.

[2] The AMA also supports efforts to maintain the relative stability in provider revenue, but the AMA strongly disputes the assertion implicit in the ANPRM that physicians prescribe higher cost drugs to obtain a higher add-on payment. Despite exhaustive consideration of this spurious assertion, including by the Medicare Payment Advisory Commission (MedPAC), no evidence has been produced to that end. Instead, physicians prescribe treatments based on the most clinically appropriate treatment.

As this will be a novel program, the AMA does not support a large-scale, mandatory implementation of this demonstration program, given the potential of unintended and adverse consequences for patients. Further, any large-scale implementation of a demonstration program of the size outlined in the ANPRM with mandatory participation would also run afoul of CMMI's waiver authorities which by statute entail a two-phase approach to models. Phase one of a model is to be well-defined in scope and population to ensure the statutorily required assessment of the model's impact on costs and patient care is reasonable rigorous and accurate. Only after the assessment of impact on costs and patient care may the model be expanded under phase 2.[3]

Vendor. As currently specified, the IPI model would include a number of private-sector vendors that supply the drugs and biologicals that CMS specifies. The IPI model would be similar to the CAP, as the model vendors rather than the health care providers would take on the financial risk of acquiring the drugs and would also bill for the drugs. The AMA appreciates this aspect of the proposal. Medicare would pay vendors for the included drugs based on the "target price" driven by the international pricing index, which the Agency anticipates would lower both the amount Medicare pays for included drugs and beneficiary cost-sharing. CMS outlines additional vendor provisions that the AMA supports, including:

- Innovative delivery mechanisms to encourage physicians and hospitals to obtain drugs through the vendor's distribution arrangements, such as electronic ordering, frequent delivery, onsite stock replacement programs, and other technologies;
- Physicians and hospitals in the model test areas have the opportunity to select the vendors that best provide customer service and support beneficiary choice of treatments;
- Physicians and hospitals would be able to contract with multiple vendors for different drugs and to change vendors; and
- Vendors would not operate formularies.

The AMA supports expansive latitude in the selection of the vendors among the range identified in the ANPRM (such as group purchasing organizations, wholesalers, distributors, specialty pharmacies, Part D sponsors, and potentially individual or groups of physicians and hospitals and/or manufacturers). However, few physician practices participated in CAP because it significantly increased inventory costs, made it difficult to provide patients with same day dosage or regimen changes, and added significant burden to the billing and collection process. This experience with the earlier CAP—under which about half of all physicians who signed up dropped out and the program's only vendor withdrew in the third year—makes it clear the new vendors will need to learn lessons from the CAP shortcomings. Several key takeaways that should be applied to any new vendor program:

[3] Given the potential for CMMI waiver authority to serve as an end run around congressionally mandated Agency obligations and beneficiary rights, the statutorily specified §1115A phase 2 requirements mandate a finding that phase 1 demonstration saves cost without comprising care or improves care without driving higher costs, which is clearly designed to prevent the national roll-out of untested hypotheses to the majority of Medicare beneficiaries that could prove harmful to patients or drive higher costs. It is unreasonable to conclude therefore that Congress intended a national roll-out could be achieved by simply fashioning a model as phase 1.

- Physicians are most likely to voluntarily participate if vendors can deliver all the drugs their patients are likely to need. In selecting vendors, CMS should give priority to those who can deliver a comprehensive list of drugs that will provide physicians with choices among different drugs that can be used to treat a particular condition;
- Timeliness is measured in hours—not days—for deliveries and adjustments in treatments;
- Timely vendor adoption of newly-approved drugs should be required or incentivized;
- Mid-year substitutions and eliminations from the vendor's stock should be prohibited; and
- Vendors should be responsible for collecting the sizeable co-payments that are usually associated with Part B drugs. As a result, physicians determining whether to participate in the IPI model will need to know that there are specific steps in place to assist Medicare beneficiaries who do not have supplemental insurance or sufficient resources to cover the co-payments. Under the current system, physicians sometimes continue treatment and forgive the co-pays in these circumstances, but under the CAP, they could only administer the drug if they forgave its entire cost, an option which is not sustainable except in extremely limited circumstances. We urge Medicare to provide waiver of the co-pay for these patients. Vendors must be prohibited from stopping delivery of the patient's drugs to the physician.

There are a variety of operational issues which will also have a significant impact on patients, such as maintaining integrity of the medication throughout the chain of custody and ensuring that appropriate drugs are available on a timely basis (including emergencies) for all patients (including those at satellite clinics). The IPI model should also focus on reducing and compensating for the additional costs associated with ordering and tracking drugs at the individual patient level rather than buying them in bulk. Specifically:

- Vendors should not be instructed or allowed to hold up shipments of the second or third round of a drug until claims for the initial treatment have been filed and approved;
- Vendors should not be allowed to delay delivery of the ordered drug until after a claim has been filed and approved;
- Given the wide range of circumstances in which a physician will have immediate need for a drug that had not been ordered, CMS should work with the medical profession to develop a list of situations in which the physician is automatically entitled to provide a drug in their private stock and then order a replacement from the vendor. The option should not be limited to life-threatening situations but should also take patient circumstances such as proximity to treatment and needed pain relief into consideration;
- All treatment options must be available for patients participating in the program, including drugs that are being used off-label and drugs for which other alternatives exist. Determination of the appropriate treatment must rest with the physician, not the vendor; and
- Vendors must be able to provide next day delivery to any location where the patient is being treated and physicians not be prohibited from transporting drugs to a satellite location.

In the previous Part B drug vendor program, physicians were subjected to a variety of paperwork requirements that discouraged participation. More recently, the Medicare Payment Advisory Commission (MedPAC) proposed a Part B drug vendor replacement program that would impose a number of burdensome new utilization restraints on physician participants with the goal of extracting large price reductions from manufacturers and then sharing any savings with other parties, including physicians.

Many of the suggested utilization restraints, such as prior authorization, are vigorously opposed by the physician community and would undoubtedly discourage physician voluntary participation in the IPI model as they hinder patient care and access which ultimately harm patient health outcomes. Other steps that will be necessary to induce participation and remain true to the Administration's goal of putting patients over paperwork include:

- CMS should not set unreasonable deadlines (14 days in the original CAP) for claims submission;
- Information that physicians are required to include on the drug order should be limited. There is no need for the order to include much of the "additional patient information" demanded of physicians in the prior program;
- Ensure an adequate number of vendors to ensure choice and access to needed treatments;
- Address the amount of vendor fees as physicians could end up subsidizing vendors and continue to struggle to recover costs; and
- Account for the continued special handling and storage charges for certain medications that are subject to United States Pharmacopeia standards and the fact that physicians will still be responsible for acquiring and storing physician administered drugs for commercially insured patients.

Potential Alternative to ASP Add-on Payments. In addition to the Medicare drug administration payment, CMS proposes that physicians (and other participants) would receive an "drug add-on amount." The proposal indicates that this add-on would amount to six percent of the average sales price (ASP) of the drug in question. The proposal also indicates that this amount would not be further subject to the sequester. While in the initial year of model this amount would likely be sufficient to keep physicians whole and ensure that reimbursement is sufficient to cover the costs acquisition, storage, and other administrative fees associated with providing the drug product to patients, the AMA has serious concerns about the ultimate impact of the proposed add-on amount.

Reimbursement models based on an "add-on" formula are intended to adequately reimburse physicians for the costs of acquisition, proper storage and handling, and other administrative costs associated with providing these treatment options for patients. Many drugs included in this model, such as biological products, are complicated drug products that require special attention to handling and storage to remain stable and viable for administration to patients. Drugs that require specific conditions for shipping, storage, and handling result in significantly higher administrative costs to physician practices than many small molecule-type drugs. Due to the special nature of these products, these costs are fixed, and will not decrease as the price of the drug goes down. Given these fixed administrative costs, we are very concerned that, should drug prices decrease as this model predicts, any add-on payment based on an ASP would ultimately decrease with the price of the drug and would no longer be sufficient to cover the administrative costs to the practice. If add-on reimbursement decreases enough that it is no longer sufficient to cover the expenses associated with providing these treatment options, it is likely that practices will no longer be able to offer these options for patients. We strongly urge CMS to consider the impact on the add-on as the IPI model over time could reduce this amount below actual clinician cost.

We are also concerned about the impact of the proposed IPI model and its overall impact on costs to physician practices. The Administration proposes to allow the vendors to charge administrative fees to

physician practices as part of their agreement to provide drug products to those practices included in the model. While we understand that third-party vendors must have a financial incentive in order to participate in the program, allowing vendors to charge physician practices administrative fees would add new, potentially significant increased costs to physicians in acquiring and providing treatments to patients without any adequate changes to the reimbursement model to compensate practices for these costs. A declining add-on payment, coupled with new acquisition costs payable to vendors would likely make this model untenable for physician practices without significant changes to the reimbursement model to adequately reimburse physicians for the costs associated with providing these treatment options for patients.

Included Drugs. CMS has proposed that the IPI model would initially focus on single source drugs and biologicals that are identified from international pricing data. The model would begin with these two broad groups of drugs—single source drugs and biologicals—but could over time include multiple source drugs and Part B drugs provided in other settings. We are concerned that starting with single source drugs and biologicals will raise structural access issues. Often, these are medications with no or extremely limited substitution options. We urge CMS to undertake modeling and simulation of the impact if vendors are unable to obtain these drugs at the reimbursement amount. There is a distinct possibility of immediate adverse patient impact if none of the vendors are able to secure needed clinical treatments. We urge CMS to evaluate narrow and targeted approaches based on a range of drug attributes and solicit feedback on such modeling. Also, before any additional drugs are added, we urge CMS to obtain public comment on the initial performance of the model. As for differentials on drug payment based on specialty, the AMA urges CMS to simplify and streamline to avoid an overly complicated model.

Quality. While CMS is required to evaluate the performance of a CMMI demonstration, we are concerned with the possibility of yet more reporting obligations. Collection of data should rest with the vendor and should not divert physician or other clinical and administrative time away from direct patient care. The Obama Administration proposed an ASP demonstration that would have resulted in burdening physician practices with a long litany of reporting requirements. In light of the tremendous progress that has been made in digital medicine and patient engagement tools, we urge CMS to allocate budgeting and funds to administer directly or in conjunction with vendors assessment programs. CMS is urged to arrange for sampling and other virtual tracking capabilities to assess a host of relevant factors including: patient experience, medication management, medication adherence, and access and utilization.

The AMA looks forward to working closely with the Administration to fashion a model that can be tested and evaluated to both improve access while addressing the high cost of Part B drugs. If you have questions, please contact Shannon Curtis, Assistant Director, Federal Affairs at 202-789-8510 or shannon.curtis@ama-assn.org.

Sincerely,

James L. Madara, MD