

July 16, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to the *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (Blueprint) Request for Information (RFI). The AMA strongly supports efforts to identify the causes that have led to increasing prescription medication costs. We welcome working with you and other federal agencies, such as the Federal Trade Commission (FTC), in order to develop and implement well-crafted and effective public policy solutions that would alleviate the financial burdens these high costs impose on patients, physicians, other health care providers, and the health care system.

SUMMARY

Outlined below is a summary of what the escalating cost and complexity of obtaining prescription medication means for patient adherence, timely access, health outcomes, and the overall cost to the health care system. Between 2013 and 2015, net spending on prescription medication increased by 20 percent.¹ Unfortunately, the increase in prescription medication prices has continued to grow inexorably year-over-year. Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on our patients, on physician practices, and the broader health care system.

Patients are increasingly taking greater clinical risks when treatments are cost prohibitive. When patients delay, forgo, or ration their medication, their health status may deteriorate. Patients who cannot afford their medication will eventually require medical interventions in more-costly care settings, such as emergency departments, when their condition is at a more advanced stage of disease. These price increases continue to occur among all segments of the market from innovator biologics to previously low-cost established generics. Physicians see every day that costs have become a major barrier to our patients getting the right medication at the right time.

¹ [The High Cost of Prescription Drugs in the United States, Origins and Prospects for Reform](#), JAMA, 2016; 316(8):858-871.

Physician Voice

*Some of my patients with life-threatening melanoma or severe psoriasis need new, targeted biologics. We need these innovative treatments, but I've watched as they triple in cost years after being released. Why? Dermatologist, California**

Patient Voice

*Since 1998, I was put on Corgard's generic Nadalol. Over the years the medication went from \$5 dollars a month to \$10 dollars then suddenly in 2015 it went to over \$250.00 per month. That did not include what insurance covered. I have never been able to get a straight answer from the manufacturer. –Diane G.**

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 will frequently 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 exceptions request rejections even for common medications. A recent AMA survey showed that the average physician completes 29 prior authorization requests per week, taking them and their staff an average of 14.6 hours. The growing maze of insurer utilization control requirements delay treatment for patients, consume time physicians could be spending with other patients, and add 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.

The high cost of pharmaceuticals not only negatively impacts the patient who requires them and cannot afford them, but the cost is also passed on to other patients both through broad increases to premiums and when physicians and the extended health care team are consumed with repetitive administrative minutiae required to comply with expanding insurer medication management utilization program policies. In addition, the two pincers that patients and physicians are squeezed between—high priced pharmaceuticals and increasingly onerous insurer paperwork requirements—continue to erode the physician-patient relationship, as well as lower morale and fuel burn-out among the health care team members.

Medical Staff Voice

I retired a year ago after 38 years in the same office. One of the biggest reasons why I just couldn't do it any longer was pharmacy prior authorizations. I would sometimes work for 3 months to get an approval only to find out that the patient could not afford the \$900 copay. (Yes, one patient's copay for a specialty injectable was \$900!) And, this patient's income was only a few hundred dollars over the maximum for the drug company's assistance program and he did not qualify for any other assistance. It made me so angry! –Louann W.*

In sum, manufacturers and insurers, far from promoting 21st Century cures, are instead placing previously affordable 20th Century cures and treatments out of the reach of a growing number of patients and pricing 21st Century cures well beyond the reach of those that need them. In light of the foregoing, it is essential that an evaluation of any proposed policy to address this escalation in prescription medication prices be guided by the following principles. The policy solution:

- should result in lower cost prescription drugs, with assured, affordable access for those who need them;
- should increase transparency along the pharmaceutical supply chain;
- should result in increased competition and production capacity in all segments of the pharmaceutical and biological markets;
- should 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;
- should 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
- should not financially penalize physicians and pharmacists as an indirect mechanism to lower prescription medication prices nor favor a site of service.

The AMA has a large body of policies that address the rising cost of prescription drugs and looks forward to continuing a dialogue that will improve access, lower costs, and reduce the administrative burdens without stifling innovation. **Among these policies, the AMA strongly supports a select number of Blueprint provisions to the extent that they would promote the following and recommends prompt regulatory action to: (1) require pharmaceutical supply chain transparency; (2) accelerate and expand regulatory action to increase pharmaceutical market competition and combat anti-competitive practices; (3) ensure prescribers have accurate point-of-care coverage and patient cost-sharing information as part of their workflow, including in the electronic health record (EHR); and (4) ensure federal programs and commercial practices billed as lowering prescription medication prices do so for patients directly.**

The AMA does not support Blueprint proposals that increase patient costs and erect barriers, including onerous insurer paperwork requirements that impede timely patient access to affordable and medically necessary medications and treatments. Further, the AMA opposes policies that would financially penalize

physicians and pharmacists for high cost prescription medication. Neither physicians nor pharmacists set drug prices nor do they establish coverage policies. As detailed below, a number of the proposals that would strip important Medicare Part D prescription drug benefit patient coverage protections away will not only decrease patient access, but will increase the price that patients currently have to pay. Second, the various Medicare Part B prescription drug benefit proposals under consideration, such as moving a select number of medications from Medicare Part B benefit to the Part D benefit, will subject Medicare beneficiaries to higher costs and create challenges to the safe administration of treatments. The AMA welcomes working closely with you to identify where opportunities exist to improve upon these proposals.

DISCUSSION

The following comments provide detailed feedback and recommendations on the key proposals and questions contained in the Blueprint RFI that the AMA urges the Administration to consider.

COMPETITION

The AMA applauds the efforts of the Food and Drug Administration (FDA) to address long-standing concerns that certain FDA requirements and regulations, particularly those surrounding Risk Mitigation and Evaluation Strategies (REMS), are being misused to delay and deter generic competition from entering the market. In the absence of other actions to contain costs, strong competition by generic drug products is essential to ensuring that patients have access to affordable treatments. In order to ensure a thriving market for generic drugs, that market must be free from anticompetitive actions by manufacturers that are intended to keep generic competition at bay.

REMS Misuse

The AMA strongly supports actions over the past year by the FDA to deter the use of REMS in order to primarily create barriers to generic market competition. The AMA supports efforts to compel brand manufacturers to provide samples sufficient for bioequivalence testing as a condition to approval for brand name drugs. We also strongly support allowing the FDA to require a single, shared REMS or to approve separate REMS. We echo the concerns of many other stakeholders in this space that REMS patenting is contrary to public policy on its face and should not be allowed as a condition of FDA approval. We are pleased to see that FDA has prioritized action on abuse of REMS. In addition to supporting regulatory action, the AMA is supportive of legislative efforts that would further expand the FDA's ability to combat anticompetitive abuse of REMS by brand manufacturers. We also support FDA's efforts to challenge the use of restricted distribution arrangements by brand manufacturers for anticompetitive purposes.

Citizen Petitions

In addition to concerns over the misuse of REMS, we are also concerned about the misuse of citizen petitions to chill competition. Citizen's petitions were designed to allow the public to directly petition the FDA where there is concern that FDA action or inaction raises an important product safety or efficacy concern. However, the stakeholder community has become aware that brand manufacturers are on occasion abusing this process, using it as a way to slow the approval of generic competition at the eleventh hour. The AMA strongly urges FDA to consider recommendations made during the 2017 public meeting "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and

Access” to curb this anticompetitive practice, including that a rebuttal presumption be established that late-filed citizen petitions are done for anticompetitive reasons as opposed to advancing product safety and efficacy concerns when submitted by a brand manufacturer. The AMA also strongly supports recommendations offered urging the FDA to establish a specific presumption that brand manufacturer petitions pertaining to generic applications filed within nine months of the expiration date of the primary patent on the brand name product are a delaying tactic. Further, the AMA supports requiring a preliminary finding that such petitions will likely be granted based on compelling evidence in order to proceed to a full review.

Federal Trade Commission and FDA

As agencies with a mutual interest in curbing anticompetitive actions by pharmaceutical manufacturers, the AMA also suggests that FDA consider greater communication and information sharing between FDA and the FTC to ensure that brand manufacturers are not engaging in anticompetitive behaviors, as opposed to those driven by legitimate safety concerns. We encourage FDA and FTC to consider engaging in regular meetings of experts from both agencies and urge collaboration to determine additional necessary authorities needed by each agency to address practices that represent abuse of current FDA laws and regulations for anticompetitive purposes.

Biologics and Biosimilars

The AMA is strongly supportive of FDA efforts to ensure a robust biosimilar market and is pleased to see biosimilar products finally becoming available for patients. With biologic products frequently coming with steep price tags, the development of biosimilars represents one of the few tools currently available to provide patients with lower cost treatment options. However, to ensure uptake of biosimilar products by physicians and patients is successful, FDA needs to ensure that there are no artificial barriers in place that may hinder integration of these products into treatment regimes.

Medical Student Voice

As a 4th year medical student, I'm frequently appalled by the ridiculous prices of some drugs. Some of the priciest are the biologics. I had a patient on a rotation in September with newly-diagnosed adult-onset Still's disease. The patient's discharge from the hospital was delayed because of several disagreements between the medical team and the rheumatologist. One of the points of contention was how the patient would be able to afford the anakinra that the rheumatologist had prescribed for the patient. The patient's insurance would not cover the cost of the drug, upwards of \$25000. I watched as the case manager and social worker tirelessly contacted patient assistance programs. Unfortunately, I finished the rotation before the patient was discharged.—Nikhil J. *

In general, the AMA is concerned with any regulatory actions that draw unnecessary distinctions between biosimilars and their reference products. With new products such as these, actions that seek to make strong distinctions between the reference product and the biosimilar that are not evidence-based and not clinically relevant may have the unintended consequence of giving that product an appearance of being

less safe or less efficacious.² As neither of those is necessarily true for licensed biosimilar products, we urge FDA to consider the impacts that these distinctions may have on uptake of the products. Initially, generic small molecule drugs faced some lag in uptake before gaining buy-in from physicians and patients, and affirmative steps should be taken by the FDA and sister agencies such as the Centers for Medicare & Medicaid Services (CMS) using coverage policies to ensure biosimilar uptake is fast. Given the significant financial implications of these products, it is in the best interest of patients and the health care system to ensure these products find their way in to treatment plans without barriers and bias.

We were pleased to see recent comments by the FDA Commissioner suggesting that FDA would be taking a new look at the Agency's current thinking on biosimilars and his desire to speed these products to market. The AMA would encourage FDA to consider the potential impacts of its regulatory actions, particularly those on interchangeability designations, and their potential role in creating unnecessary distinctions between products that potentially result in bias against a follow-on biological product. We would also welcome action by FDA to ensure these products come to market as quickly and as efficiently as possible, while still maintaining FDA's rigorous safety and efficacy standards. Lastly, we applaud FDA's efforts to provide educational materials for physicians and consumers on these new products and welcome opportunities to work with FDA to inform these communities about these products and their approval process.

Parked Generics

The AMA strongly supports the Administration's proposal to end the ability of generic manufacturers to indefinitely "park" the 180-day exclusivity period granted to them by the Federal Food, Drug, and Cosmetic Act. Frequently the result of "pay-for-delay" settlements resulting from challenges to the patents of brand name manufacturers, parked generic exclusivity can result in significant delays in bringing generic drugs to market. When generic manufacturers delay final approval of their application by FDA as part of a settlement agreement with a brand manufacturer, this effectively blocks all subsequent generics from coming to market for both the length of the delay and the length of the exclusivity period. The AMA, which strongly opposes pay-for-delay settlements and the actions that result therefrom, supports FDA action to begin to run the exclusivity period of the first-to-file generic when subsequent generic products are approved and ready to come to market. At a time of significantly increasing drug prices, increased competition and fair and transparent markets are more important than ever, and anticompetitive behavior such as pay-for-delay settlements and parked exclusivity does not allow either of these to take place.

TRANSPARENCY

To empower patients and lower health care costs, the AMA welcomes the focus of the Blueprint on advancing prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers (PBMs), and health insurers. While the reasons for price increases are complicated and varied, rising costs may adversely affect patients' health when they cannot afford the medications prescribed to them. **Pharmaceutical manufacturers, PBMs, and health insurers contribute to the prescription drug cost equation, ultimately impacting patient cost-sharing, drug tiering decisions, prior authorization policies, and decisions whether to change formularies in the middle of a plan**

² However, the AMA does not support substitution back and forth between the prescribed reference product and the biosimilar unless interchangeability has been established by the FDA or expressly prescribed by the treating physician.

year. As a result, in 2016 the AMA launched a grassroots campaign and website, TruthinRx.org, the goal of which was to expose the opaque process that pharmaceutical companies, PBMs, and health insurers engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency. To date, over 265,000 individuals have signed a petition to Members of Congress in support of greater drug pricing transparency.

Manufacturer Price & Cost Transparency

The AMA strongly supports drug price transparency measures that require pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase. In addition, patients can benefit if pharmaceutical manufacturers are required to publicly disclose a variety of information, which could include research and development costs; expenditures on clinical trials; total costs incurred in production; and marketing and advertising costs.

Coupons and Patient Assistance

The Administration's proposals highlight that some pharmaceutical manufacturers currently offer patient assistance programs, including copay coupons, to assist patients in being able to afford their prescribed medication. The AMA supports economic assistance, including coupons and other discounts, for patients, whether they are enrolled in government health insurance programs, enrolled in commercial insurance plans, or are uninsured. While copay cards and other forms of economic assistance are needed for patients given the current state of the prescription drug marketplace, we are very concerned that copay cards in particular further distort the market. The copay cards enable pharmaceutical manufacturers to keep prices high, offering no downward pressure on high list prices nor providing any incentive for industry to lower the product list prices. PBMs' growing use of copay accumulator benefit designs also limits the success of copay coupons in improving overall medication affordability for patients. Under copay accumulator programs, PBMs do not apply the manufacturer's copay coupon to the patient's deductible or out-of-pocket maximum. When the copay coupon expires or runs out, or the patient exhausts all other forms of co-pay assistance, the patient is suddenly faced with a sudden—and often massive— increase in financial responsibility for the drug, as the coupons have not counted toward his/her deductible.

Medicare Part D Explanation of Benefit

The Blueprint also contains proposals that would require Medicare Part D prescription drug plan sponsors to provide additional information about drug price increases and lower-cost alternatives in the patient's Explanation of Benefits (EOBs). While drug price increases should be made more transparent and publicly available to patients, patient notifications of drug price increases should also be timely. As such, monthly EOBs are not the most effective vehicle to relay said information. Currently, Part D plan enrollees are expected to receive an EOB by the end of the month following the month they fill a prescription using their drug plan coverage. As a result, using EOBs to relay information about drug price increases would mean that patients may have to wait multiple weeks to receive notifications.

The best way for patients to learn about lower-cost alternatives is from their physician(s), who also have the knowledge of whether lower-cost alternatives would be appropriate for a patient's treatment regimen. There may be unintended consequences of including lower-cost alternatives in EOBs, as it can interfere with patient-physician relationships as well as disrupt patient treatment and therapy regimens. However, to ensure that physicians are able to fully discuss the range of treatment options with their patients, along

with their respective costs, it is imperative for third-party payers and purchasers to make such cost and pricing data available to physicians and other providers in a useable form at the point-of-service and decision-making, including the cost of each alternate intervention, and the insurance coverage and cost-sharing requirements of the respective patient. Specifically, PBMs, health insurers, and pharmacists should enable physicians to receive accurate, real-time formulary data at the point of prescribing in electronic health records.

Utilization Management Programs

The AMA is concerned about the utilization management tools frequently used by PBMs and health plans to control costs, as they often have little clinical basis and can simply be a means of shifting costs in the system. For example, prior authorization and step therapy protocols can create significant barriers for patients by delaying the start or continuation of necessary medical treatment, which can negatively affect patient health outcomes. While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances may necessitate an alternative treatment. Furthermore, if a patient switches plans at the end of a year, a new round of step therapy forces patients to abandon the previously effective treatment and repeat a therapy that has been proven ineffective, delays care, and may result in negative health outcomes. In other cases, insurers have limited patients to a 30 day supply (even in months with 31 days) resulting in gaps and adding to another round of prior authorization.

Patient Voice

As an asthma patient I have experienced a step plan requirement, as well as cost so high I can only take half my treatment requirements. In changing my drug insurance company I was told I couldn't take my regular [ADVAIR] [and] I would have to first use their approved meds and then step up to my regular [ADVAIR]. I spent a year in and out of the emergency room being treated for bronchitis and other asthma related problems before I could go back to my [ADVAIR]. All this extra illness and expenses could have been avoided. Plus the cost of the [ADVAIR], even with special help, means I usually only use it once a day. I'm retired and live on my social security.—Sandra F.*

Recognizing these negative impacts, the AMA and other organizations have developed the [Prior Authorization and Utilization Management Reform Principles](#) (Principles). The Principles promote common-sense concepts to improve prior authorization, step therapy, and other utilization management programs. More recently, the AMA, in collaboration with other national provider associations and insurer trade organizations, released the [Consensus Statement on Improving the Prior Authorization Process](#) (Consensus Statement). The Consensus Statement outlines key opportunities for prior authorization reform, including improving transparency for both patients and physicians regarding utilization management requirements, coverage restrictions, and drug costs by including this information at the point-of-prescribing in EHRs and creating protections for patient continuity of care when there is a health plan or mid-year formulary change.

The AMA opposes insurer utilization management programs that do not rely on sound evidence-based clinical criteria. Because of the many concerns with the current utilization management programs

used by PBMs and health plans, **the AMA would oppose any change in the right of patients, their representatives, or prescribers to appeal adverse determination decisions to the Independent Review Entity.** As it is, certain insurers now require patients to file an appeal instead of the treating physician which reduces the number of appeals filed and can lower patient appeal success rate. It is critical that physicians and their patients maintain the ability to question and overturn unfair utilization management decisions that block access to medically necessary treatment.

Physician Voice

[A] long-time patient who has recently changed his insurance coverage [contacted me]. His blood pressure medicine – that he has been stable on for several years now – is not on the drug formulary under his new plan, and he’s down to his last 30 days of therapy. I will have to call his PBM and request a form and a fax number, then fill out the form with some data points, and fax back in the form. Eventually I may get some ideas from the PBM and/or the insurance company about what types of different medications or steps I might prescribe for my patient. I cannot do this on a standard form or electronically via email. The patient is at risk for running out of meds or changing to a less effective treatment that threatens his health! He may end up going to the emergency room or having a serious illness such as a stroke or heart attack. –Family Medicine Physician, South Carolina*

User-Centered Benefit Transparency

In order to maintain cost transparency for patients and keep patients stable on their medications (thereby reducing long-term costs), the AMA urges improved transparency in formularies, prescription drug cost-sharing, and utilization management requirements as well. Requirements and restrictions should be easily accessible by patients and prescribers and unless a change is made for safety reasons, PBMs and health plans should be prohibited from making changes during the duration of the patient’s plan year.

The AMA frequently hears from frustrated physicians about the disruption and confusion that constant changes to their patients’ drug benefits cause. For patients and physician prescribers, it is a moving target throughout the year as to what prescription medication will be covered under the patient’s insurance plan and what restrictions around coverage will be in place. Changes to formulary restrictions can have negative effects on patients and can have a major impact on health care costs. For example, a patient with a chronic medical condition who has been stable on a particular medication may choose her health insurance plan largely because of its coverage of that medication. However, a move by her PBM to remove the medication from her formulary during the middle of her plan year and replace it with another medication that is not effective for her—or which the patient has previously tried and not done well on—could mean potential trips to the emergency room and/or hospitalizations, increased out-of-pocket costs if she has to pay for the drug herself, and potential physician and patient resources spent on appeals and alternative solutions.

Essential Beneficiary Protections

In the same vein, the AMA does not support removing important beneficiary protections to provide plans more flexibility. **As such, the AMA would oppose the proposal outlined in the Blueprint that would**

allow Part D plans to adjust formulary or benefit designs during the benefit year if necessary to address a price increase for a sole source generic drug. As noted above, patients should not be forced to switch to a medication that is less effective, as such switching can destabilize a patient or otherwise divert clinical time of the physician and extended health care team from providing care to other patients.

Rebates, PBM and P&T Committee Transparency

The AMA recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders—but not patients. The AMA is concerned that the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor manufacturers currently have an incentive to lower list prices. As such, the rebates that are being negotiated by PBMs are not resulting in true savings. Moreover, there is little evidence that any savings associated with rebates are being passed through to patients or payers, but the major PBMs continue to reap massive profits while providing no product or service themselves.

Patient Voice

I have [multiple scoliosis] MS and have never had a gap in health insurance coverage since the day I was born. I am a 43 year old, fully employed, independently living, successful female. I take seven prescriptions [and] six are covered by my employer sponsored health plan. My \$5000 per month MS disease modifying drug Aubagio is not covered by [my insurer]. [The insurer] covered my previous injections, but after 10 years I could no longer tolerate the shots. My neurologist, after months of studying options, switched me to a daily pill that has worked wonderfully for me and is actually less expensive than the injection. [My insurer] does not get a rebate for this drug so they will not allow me to use it. – Allison M.*

To improve transparency in this space, the disclosure of rebate and discount information, financial incentive information, and P&T committee information would constitute critical steps forward. **The AMA also would support applying manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale.** This policy would add much needed transparency and ensure that beneficiaries benefit from discounts. More broadly, the AMA supports the regulation of PBMs, which no longer simply negotiate drug prices on behalf of their clients, but rather fully administer the drug benefit creating formularies, making coverage decisions, and determining medical necessity using utilization management tools. Their “benefit management” now largely resembles the typical role of insurers, and they should be treated as such by regulators. Regulators must better understand and control the costs to patients and the system that are resulting from PBM practices.

Gag Clause Prohibition

The Blueprint also highlights another solution to spur increased PBM transparency: allowing pharmacists to disclose the cash price of medications to patients at the point-of-sale. Currently, a health plan’s drug formulary can require patients to spend more on a prescription drug copayment than they would be charged if they purchased the medication without insurance. In these situations, pharmacists may be

aware of this price discrepancy, but contractual provisions (and the PBMs' interpretation of those provisions) can prevent pharmacists from informing patients of other options. The AMA applauds the CMS letter sent to Part D plan sponsors in May explaining that so-called "gag clauses" are unacceptable. However, the AMA urges stronger action to address provisions in PBM-pharmacy contracts that prevent pharmacists from discussing prescription medication prices with patients. As such, **the AMA supports prohibiting Part D plan contracts that prevent pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price. In addition, the AMA supports pharmacists being empowered to inform beneficiaries when prices for their drugs have changed.**

MEDICARE PRESCRIPTION DRUG BENEFIT (PART D) ADDITIONAL COMMENTS

No rationale is provided in the Blueprint for its repeated assertions that the five-part plan for Part D requires adoption of all five parts to effectively lower drug prices. Some of these five proposals will have the opposite of the intended effect. Specifically, the proposal to cut coverage of Part D medication by requiring plans to include only one drug in each class on their formularies instead of two, and allow greater use of restrictive drug utilization management (DUM) policies for drugs in the protected classes, will sharply reduce patient access to medically necessary drugs. Further, it will increase delays and administrative hassles for patients and physicians trying to obtain authorization for formulary exceptions and medication utilization management policies, and increase patients' out-of-pocket costs.

Patient Voice

My medication costs go up and up continually. I have Rheumatoid Disease and am allergic to basic NSAIDs so I have to use more complex (and thus more expensive) medications. I have been on 3 different biologics - Enbrel, Humira, and now Simponi. I failed on the first two due to side effects (bone marrow functioning issues). I was on Enbrel off and on for over 12 years. The price per month when I started was around \$1900. Simponi now costs \$4800 per month. I have good insurance through my work and there is copay assistance - but the structure of how my work insurance pays for it does not allow the use of it more than once per year. So my insurance picks up 100% of it after the first fill. That makes my state administrators look at how they can cover these costs- usually by passing it back to all subscribers in higher premiums. This year they want to form a new committee to review medications and determine which ones they will cover-can you guess what will be eliminated? I have submitted proposals to utilize the copay assistance to its full value, thus saving tons of [money,] but the administrators say it is too complicated. I guess it is easier to just decide not to cover the meds that allow me to move around, dress myself, literally get to work. If I cannot take my meds I will become 100% disabled very quickly.-Cindy C.*

Helping patients obtain their prescribed medications is already among the biggest administrative burdens that practicing physicians face. Despite the Blueprint's suggestion that insurers and PBMs "have found new ways to inform prescribers ... about the formulary options, expected cost-sharing, and lower-cost alternatives specific to individual patients," the AMA has seen no evidence that physicians have access to

this critically important information. Instead, physicians describe drug plan coverage policies as a black hole with no transparency.

As discussed above, when prescribing medications for their patients, physicians have to guess which medications are on the formulary, on the preferred pricing tiers, and subject to medication utilization management policies. If they guess wrong, they either have to prescribe another medication (that may not be the most appropriate one for the patient's needs) or spend hours working to obtain formulary or tiering exceptions or satisfy prior authorization or step therapy requirements. Often, they need to blindly keep prescribing alternative medications until they happen to get one that is on the patient's formulary. Reportedly, some classes of medication, such as those to treat opioid use disorder, present barriers to patient access 100 percent of the time that they are prescribed, even though the medical literature points to these medications as the standard of care for the health condition they treat. Adding to physicians' frustration and patient care delays, even when the medication utilization management requirements are satisfied, they often have to go through the whole procedure again when it is time to renew the prescription.

Instead of allowing insurers to place new hurdles in the way of Medicare patients obtaining the medications that they need to manage their health conditions, the AMA strongly urges the Administration to increase transparency at the point-of-prescribing. The AMA welcomes the opportunity to work with you to identify where there are gaps in the flow of timely, accurate, and complete information on drug formularies, DUM policies, and lower-cost alternatives from plans and/or PBMs to prescribers. We strongly urge you to impose whatever requirements may be needed to ensure this information is available at the point-of-care, without imposing additional health information technology costs or burdens on physicians.

MEDICARE PART B DRUG BENEFIT

Competitive Acquisition Program

As a tool to give buyers a stronger hand in negotiations with drug manufacturers, the Administration proposes to revive the short-lived Competitive Acquisition Program (CAP) established under the Medicare Modernization Act of 2003 and opened for participation from mid-2006 through 2008. According to press reports, the Administration intends to use this existing authority to open bidding on a resurrected CAP in the near future. Ideally, a well-designed CAP might offer an attractive alternative for small and mid-sized practices that do not have the resources or volume to develop the infrastructure needed for drug storage and infusion or to acquire drugs at prices that are lower than Medicare's payment rate. Currently, such practices are being forced to move care from their offices to hospital outpatient departments, where both Medicare and its beneficiaries pay more. Reportedly, 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 that substantial changes will be needed, however.

A hasty resurrection of the original CAP with a few cosmetic changes is bound to fail. A CAP descendent cannot succeed without a significant redesign, consultation with earlier participants, and adequate public input. Any 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 CAP vendors' negotiating power and cost-constraints.

Voluntary Participation: CAP participation must be truly voluntary—aimed at making it possible for physicians to continue providing a wide array of drugs in their offices and allowing them to opt out after an initial try-out period or when a vendor's performance is unsatisfactory. Every effort possible should be made to attract multiple vendors to the program and allow physicians to choose the one that best meets their particular needs. As a positive incentive for physician participation, CAP vendors should be encouraged to include a comprehensive list of drugs, especially those which physicians typically cannot purchase at prices that are lower than Medicare's reimbursement for the drug. Further, administrative burdens to the CAP program must be managed by the vendors and not by the practices for any chance of success.

Patient Protections: A major deterrent to CAP participation for many physicians is the fear that timely access to the most appropriate drugs for their patients will suffer. Key issues that must be addressed include:

- What regulatory requirements and selection criteria will vendors be subject to? Physicians are most likely to sign up in CAP 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. **Timely vendor adoption of newly-approved drugs should be required or incentivized. Mid-year substitutions and eliminations from the vendor's formulary should be prohibited.**
- Will vendors still be responsible for collecting the sizeable co-payments that are usually associated with Part B drugs? If so, physicians determining whether to participate in CAP 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. Will Medicare waive the co-pay for these patients? What about vendors? Will they be required to absorb losses on certain co-payments? Or will they be expected to immediately stop delivery of this patient's drugs to the physician? Could unpaid debt to a CAP vendor be considered in a determination of whether a beneficiary qualifies for Medicaid spend-down eligibility? What happens if the CAP program refuses to deliver the drug for lack of a copay thereby jeopardizing patient care?

Operational Issues: 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). A redesigned CAP 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.
- 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.

Administrative Burden: In the earlier CAP, physicians were subjected to a variety of paperwork requirements that discouraged participation. More recently, the Medicare Payment Advisory Commission (MedPAC) proposed a CAP replacement 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. The plan does not detail how and when savings would be shared with physicians but it appears that the government and the vendor would get a cut off the top with remaining savings distributed either at the will of the vendor or based on some calculation of a physician's contribution to savings. Many of the suggested utilization restraints, such as prior authorization, are vigorously opposed in the physician community and would undoubtedly discourage physician participation in the CAP, especially in view of the ephemeral nature of MedPAC's shared savings provisions. **The central goal of a CAP revival should be the preservation of office-based drug administration and a reversal of the movement of these services from the physician's office to more costly sites of service such as hospital outpatient departments.** There are savings to be had if this goal is met, but they will never be recognized if the CAP becomes just another PBM look-alike.

Other steps that will be necessary to induce CAP 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.

Modifications in Part B Drug Payments

Today, Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers—including those that receive large discounts for prompt payment and high volume purchases—plus a percentage of the ASP. Currently, the percentage add-on is 6 percent, which is then reduced to 4.3 percent under the budget sequester enacted in 2011. Over the years, there have been a number of calls for reductions in the ASP add-on, modifications in the calculation of the ASP, and inflation-related limits on Medicare increases in drug payments. The Administration

proposes several specific changes in the current system that it says will “address abusive drug pricing by manufacturers” and other Administration documents have also referenced proposals to “reduce incentives for physicians to prescribe high-priced drugs.” Specifics are sparse, but it appears that at least one of the proposals would directly affect payments to physicians.

The AMA shares the Administration’s concern that rising prescription medication costs could make life-changing therapies unavailable to a growing number of patients. This problem, however, cannot be solved by reducing Medicare reimbursement to physicians who purchase and administer those drugs and **who have no influence over their prices**. We also wish to emphasize that, as pointed out in several Medicare Payment Advisory Commission reports, proposals to reduce the ASP add-on are based on the assumption that the ASP add-on influences physicians’ choice of drugs rather than on evidence that it actually does. In fact, as the Commission has also noted, physicians’ opportunities to choose between several prescription medications are limited because the right medication is often dictated by individual patient characteristics, stage of disease, and other variants.

As we noted in our comments in opposition to the controversial Obama Administration Part B drug demonstration, we are strongly opposed to any proposal that would reduce Medicare’s current payment drug reimbursement rates and/or convert some or all of the ASP add-on to a single flat fee that would overcompensate physicians for their overhead on some drugs and severely undercompensate them on others. **We appreciate this President’s decision to withdraw the discredited demonstration and would be extremely disappointed if some variation of the payment model proposed in the Obama Administration demonstration is ultimately sent forward by President Trump or HHS.**

Our review of the additional Part B reimbursement revisions that have been listed as under consideration by HHS and the White House reflects these additional concerns:

- Medicare payments to physicians are already lower than what many physicians pay for the drug and associated overhead costs. This is because the government imposes a two percent sequester tax on Medicare drug payments and because the ASP includes discounts and rebates that often are not available to physician practices, but does not factor in wholesaler fees and state taxes paid by many physicians.
- Squeezing down on physician rates will force these practices to stop providing prescription drug treatments in their offices and exacerbate a long-running shift of care out of physician offices and into higher cost hospital outpatient departments. Costs to Medicare and its beneficiaries then will rise, rather than fall, because in addition to paying the physician, Medicare will also make a payment to the facility and the combined payment for the physician and the facility typically exceeds the payment rate for office-based physicians.

Specific Part B Reimbursement Proposals

With regard to the potential revisions listed in the Blueprint and associated documents, the AMA:

- Believes that it could be reasonable to reduce the Wholesale Acquisition Cost (WAC) formula that is used as a substitute for ASP when a drug is new and there is no ASP data available. The size of the reduction should be evidence-based, and we are not sure that an analysis of the data would justify a reduction from 106 percent of the WAC to 103 percent as proposed in the President’s budget. The data will have to be carefully analyzed.

- Supports efforts to make manufacturers accurately report prices for ASP calculations. However, we are opposed to any ASP formula modifications—such as including CAP payment rates in the ASP calculation—that would push ASPs down and make it even more difficult for physicians to purchase drugs at rates that are at or below the Medicare reimbursement rates.
- Is alarmed by the price increases some manufacturers are demanding and would support an inflation limit if it were executed through rebates from manufacturers who exceed the limit as was recommended by MedPAC. However, the Blueprint’s reference to limits “on reimbursement” for drugs with price increases that exceed increases in the consumer price index suggests that the Administration intends to simply cut its reimbursement rate to physicians rather than tackling the drug manufacturers directly. Leaving physicians holding the bag for manufacturers’ excesses would be unconscionable and strenuously opposed by the physician community, whether it is imposed at the individual drug level or as an across-the-board average on all drugs.
- Strongly supports payment neutrality across multiple settings for physician-administered drugs and other services as well. Because there are different payment systems for the hospital outpatient hospital department ambulatory surgical center and physician offices, comparing payment levels in the various settings is technically challenging. But as the Blueprint notes, one key difference is that when a drug is provided in a physician’s office there is a single fee to the physician for administering the drug whereas in the hospital outpatient departments, there will be a payment to the facility as well as the physician. Although the physician’s payment is smaller when the drug is administered in the hospital, the combined facility and physician payment are almost always higher when the drug is administered in the hospital. As noted earlier, this payment gap is driving a shift of care from physicians’ offices to HOPDs and significantly increasing what Medicare and patients pay for drugs. The gap clearly needs to be eliminated. Changes should be budget neutral, however, with any savings from reduced payments to highly paid settings redistributed to payments in the lower paid settings.

Moving Some Part B Drugs to Part D

The 2019 proposed budget by the Administration sought authority to move some prescription medications that are currently covered under Part B into Part D subject to a determination that “there are savings to be gained from the consolidation.” The Blueprint asks which drugs or classes of drugs would be good candidates for moving from Part B to Part D. It then asks how such a shift could be used to “reduce out-of-pocket costs” for beneficiaries without drug coverage or with Part B Medigap policies which we take to mean “how could movement from Part B to Part D be used to reduce spending on the transferred drugs.”

The AMA opposes a full-scale movement of Part B drugs into Part D and has very serious reservations about a more limited approach that would apply only to a few drug categories that now are sometimes covered under Part D and sometimes under Part B. Many of the physician-administered drugs covered under Part B have exacting storage and transport requirements that could not be met at most neighborhood pharmacies and the transport of these drugs from the pharmacy to a physician’s office is potentially dangerous to patients. Often, the correct dose for the drug is dependent on the patient’s current weight and condition and is not known until they have been examined by the physician.

This is why a 2005 HHS report to Congress which examined policy issues involved in moving separately billable Part B drugs to Part D concluded that “the majority of Part B drugs are not good candidates for shifting to Part D because they are provided directly in a physician’s office provider setting rather than being dispensed to a beneficiary by a pharmacy.” Moreover, the report said, under the ASP, Medicare is

already paying market prices for Part B drugs because the ASP formula ties Medicare drug reimbursement rates to those of private payers and essentially piggybacks on the discounts that those large volume purchasers have already wrung out of the manufacturers. There are several other drug categories that are not provided in a physician's office, it pointed out, but moving some of these drugs out of Part B would disrupt other Part B cost constraints such as competitive bidding for durable medical equipment and bundled payment arrangements for hospital outpatient departments and ambulatory surgical centers.

A 2011 report by Acumen LLC under contract to CMS further explored the possibility of consolidating coverage under either Part B or Part D for six drug categories which depending on the circumstances may be covered under either Part B or Part D. All vaccines and parenteral nutrition would have been covered under Part B; all oral anticancer/antiemetic drugs and all immunosuppressants would have been covered under Part D. It found that moving all insulin and inhalants to Part D would increase total Medicare costs and that Part B and D costs were comparable in the other drug categories. Overall, the study projected Medicare would have saved \$151 million a year but that did not include expected increases in administrative costs for the government or providers. Moreover, the savings to Medicare came at the expense of beneficiaries who typically ended up owing more because they were more likely to fall into the Part D coverage gap. "The increase in beneficiary out-of-pocket costs is an important concern," it concluded, "as it could impede beneficiary access to needed medication." The clinical impact would also be deleterious for patients in many cases. For example, typically patients currently receive anti-emetics through IV along with chemotherapy. This substantially reduces the possibility that patients end up in the emergency department. Similarly, for growth factors, data has shown that their use decreases admissions for neutropenic sepsis.

A recent Avalere analysis makes a similar point, but also indicates that any shift of coverage from Part B to D will help some beneficiaries and hurt others. In 2016, it found average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies (\$3,200) than for those covered in Part B (\$2,400). In Medicare Part B, it pointed out, after the initial deductible, beneficiaries have a 20 percent coinsurance requirement for all medical services, including drugs. Three out of four of the 15,000 beneficiaries receiving new cancer therapies under Part B had supplemental insurance to cover the co-pay but those who did not paid \$9,700 out-of-pocket on average. In Part D, 28 percent of the 20,000 beneficiaries receiving new cancer therapies qualified for low income subsidies, but the remainder faced coinsurance that could be as high as 33 percent for specialty tiers and close to 50 percent for non-preferred tiers with out-of-pocket costs that averaged \$4,400. In addition, nine million Medicare beneficiaries enrolled in Part B do not have Part D and their status under the Administration's proposal is not clear.

While many beneficiaries would pay more under this proposal, it also is far from certain that Medicare would save money because for at least some conditions, it appears that costs are lower under Part B than Part D. For example, rheumatologists have pointed out that data recently released by CMS indicates that prices for the two Part D drugs that they use to treat rheumatoid arthritis have risen at a much faster rate than the three Part B drugs that they also use. The Blueprint hopes to change that by giving Part B drug plans more power to extract lower prices from drug manufacturers, but it does so by eliminating important patient safeguards that the AMA had sought and strongly believes must be retained. These rules, which require Part D plans to cover all drugs in six protected classes and at least two drugs in the remaining classes, are critical to ensuring that patients have access to the right drugs for their conditions. Allowing Part D plans to create formularies which severely limit the drugs that are available for treatment does not advance the overarching stated goal of the Blueprint: to ensure patients are able to afford

medically necessary treatment. The strategy would instead reduce insurers' costs while shifting the cost and administrative burdens to patients and the extended health care team to obtain appropriate medication.

VALUE-BASED PRICING

The AMA applauds the Administration for exploring innovative payment models as a tool to aid in lowering federal expenditures on drugs. The AMA has long been interested in the concept of value-based pricing tools as a method to help determine appropriate prices. However, the concept of "value-based pricing" can mean different things to different players in the pharmaceutical marketplace. The AMA is concerned about conversations surrounding "value-based pricing" that really mean payment contracts negotiated on clinical outcomes only, without consideration of other important factors that impact the true value of a drug to the marketplace.

Value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, post-marketing safety and efficacy data, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes. As such, clinical outcomes are an incredibly important piece of the value equation when discussing payment policies for pharmaceuticals. However, the AMA feels strongly that a number of other factors need to be considered in concert in order to determine the true "value" of a drug to physicians, patients, and the health care system and to arrive at an appropriate, value-based price for the product in question. Further, it is not clear that purchasing contracts based on outcomes alone are achieving any measureable savings for those payors that have entered in to them, showing the need for additional transparency in this space. In fact, in the case of products that successfully demonstrate clinical effectiveness, outcomes-based pricing could even be used to justify extremely high prices. Even for pharmaceuticals that do not meet outcomes metrics and warrant the payment of retrospective rebates, such outcomes-based contracts do not result in a lower list price for the drug in question. Importantly, patients do not reap the rewards of reduced out-of-pocket costs under outcomes-based contracts: patients incur costs at point of sale, and outcomes-based contracts are not structured in a way to enable patients to enjoy savings up front.

We agree that federal drug payment policies should be structured so that federal health programs do not pay the full amount for drugs that are not clinically effective for patients. **Value-based prices of pharmaceuticals should be determined by objective, independent entities.** That being said, when discussing the notion of value-based pricing, we strongly encourage HHS to consider "value" as a comprehensive assessment of a range of factors that truly determine a product's value to the marketplace, including patients. In addition to strong consideration of clinical outcomes as an indicator of value, the AMA encourages a value assessment that also weighs factors such as cost, comparative effectiveness research, toxicity/side effects, novelty, budgetary impacts, incremental cost-effectiveness, and impacts on patients such as long-term benefits, patient individual budget, impact on caregivers, variation of clinical response in different patient populations, and the ability of patients to return to work. **A comprehensive review of all factors relevant to determining a drug product's true value will help assure patient affordability, limit system-wide budgetary impact, and determine appropriate payment amounts for those products that incentivize innovation by pharmaceutical manufacturers, ensure that patients have access to the critical drug product they need, and avoid situations where a product's success justifies a price that patients and the system simply cannot afford.**

Initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs and allow for patient variation and physician discretion. The Blueprint raises indication-based payments as a mechanism to support value-based purchasing in federal programs, which would allow high-cost drugs to be priced or covered differently based on the indication being treated in a particular patient. While we recognize that certain drugs generally are more effective in treating certain diagnoses over others, making definitive payment and coverage decisions based on such generalities can have unintended consequences on patients being able to access and afford the prescription drugs they need. Determining payments for and coverage of drugs based on indication has the ability to undermine personalized medicine and the ability for patients to receive treatments appropriate to their unique health characteristics, as well as the ability of physicians to prescribe the most effective course of pharmaceutical treatment for their patients. A blunt indications-based pricing model that assumes an identical clinical response to a particular drug for all patients across age groups, gender, racial/ethnic characteristics, genotypes, etc., could lead to certain subgroups of patients not having access to a medication, even though it may be fully effective in their particular subpopulation. It also needs to be assessed how indication-based pricing would impact the ability of physicians to prescribe drugs for their patients for conditions other than which they have been officially approved, i.e., “off-label” use. For example, a recent FDA approved combination of Ipilimumab and Nivolumab for lung cancer have excellent efficacy (good tumor control for years) in about 20 percent of patients and very little activity in the rest, but outcomes are not known for months. Thus, any approach will have to be carefully evaluated and constructed to capture value.

Several questions were posed in the Blueprint addressing potential implementation and operational difficulties addressing indication-based pricing. For physician-administered drugs, physician practices purchase drugs in advance of treating patients at a certain price, sometimes without knowing the exact number of patients with each indication they will treat. Therefore, there could be a disconnect between the price paid by physician practices for pharmaceuticals, and the amount they are paid for them by federal programs on the back end. In addition, indication-based pricing, as well as outcomes-based pricing, has the potential to place undue administrative burdens on physicians and patients. PBMs and health plans would presumably require the inclusion of diagnoses on all drug claims to support indications-based pricing, which would require additional data entry/capture for both physicians and pharmacists and potentially increase workflow burdens for both provider groups.

340B DISCOUNT PROGRAM REFORM

The AMA supports reforms to the 340B Rebate Discount Program. The AMA urges increased 340B program transparency, including an accounting of covered entities’ 340B savings and the percentage of 340B savings used directly to care for underinsured patients and patients living on low-incomes. The AMA also supports providing the Health Resources and Services Administration (HRSA) with more authority, resources, and staff to conduct needed 340B program oversight. The AMA is concerned that the number of entities qualifying to participate in the 340B program has grown exponentially, far beyond its intended scope, and the most vulnerable patients it was intended to benefit still face high prescription medication prices. Further, even though community-based physician practices have been recognized as providing cost-effective access points for the care of the presumptive intended patient beneficiaries of the 340B program, such practices cannot currently qualify as standalone entities under the 340B Drug Pricing program. The AMA strongly urges that this be addressed to ensure patients benefit from lower cost medication and medical care is delivered more frequently in closer proximity to the patient in lower cost sites of care. We are interested in discussing a number of possible reforms including, for example, if the patient rather than the entity was determined to be 340B eligible on the basis of income or Medicaid

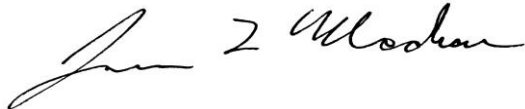
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participation, that patient could choose any site of service, and the provider of the drug could submit to the appropriate pharmaceutical company for the discount, or Medicaid could submit for the discount.

CONCLUSION

The AMA appreciates the opportunity to provide comment and recommendations on the Blueprint RFI. We look forward to working closely with you and other federal agencies to take rapid, direct action where authority exists to lower the costs of the appropriate prescription medication that patients need as determined by their physician, while also reducing the barriers patients and the health care team face in so doing. If you have questions, please contact Margaret Garikes, Vice President, Division of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, sweeping initial "J".

James L. Madara, MD