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January 25, 2019

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

Re: Modernizing Part D and Medicare Advantage (MA) To Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. While the AMA appreciates efforts by the Centers for Medicare & Medicaid Services (CMS) to find solutions to skyrocketing drug prices, we have serious concerns with a number of the proposals put forth in this proposed rule. We strongly agree that action needs to be taken to reduce drug prices, increase competition in the pharmaceutical marketplace, and reduce costs to patients; however, we are concerned that the proposals included here would instead serve to limit access to medically necessary treatments for Medicare beneficiaries, increase administrative burdens on physicians, and do little to meaningfully reduce the financial burdens faced by patients. We strongly urge CMS to reconsider the repercussions these proposed changes would have on patients and physicians and work with stakeholders to develop policy proposals that bring about meaningful improvements for patients.

Proposals to Provide Plan Flexibility to Manage Protected Classes

The AMA has serious concerns about the included proposals to “provide plan flexibility to manage protected classes.” As you know, the six Part D protected classes provide important protections to some of the most vulnerable Medicare and Medicaid’s beneficiaries who have clinical need to access more than two different drugs within a therapeutic class to find appropriate therapies. The protected class policy was designed to help mitigate risks and complications that can be associated with interruptions in therapy for patients utilizing drugs within these classes, and past proposals seeking to make changes to these protected classes have been met with significant concerns from across the spectrum of health care stakeholders. Drugs included in the protected classes are not necessarily therapeutically equivalent for many patients. It is therefore critical that access to these important therapies remain protected for patients.

Step Therapy and Other Utilization Management Techniques in Part D Protected Classes

While we appreciate the efforts of CMS to address the negative impact of high drug prices on Medicare beneficiaries, we find the proposal to allow Part D plans to apply more prior authorization (PA) and step therapy requirements to protected class drugs a troubling departure from historical efforts to safeguard treatment access for particularly vulnerable patients. Patients who are prescribed drugs in the six protected drug classes live with serious, life-threatening physical or mental ailments that require immediate access to medically necessary therapy. Moreover, the conditions treated with protected class drugs often involve highly personalized drug regimens that have been tailored—often over long periods of time—to meet the unique clinical circumstances of an individual patient. For example, physicians carefully select and adjust antiretroviral therapy to control viral load in patients with the human immunodeficiency virus. Similarly, oncologists choose individualized chemotherapy based on a particular patient’s response to treatment and/or tumor genotype. Clinicians often must try several treatment options before identifying the most effective drug regimen to control seizure disorders, depression, or mental disorders characterized by psychoses. Implementing new PA and step therapy protocols in Part D plans could result in delays and interruptions of these individualized treatment regimens and lead to negative clinical consequences for patients and increased overall costs for the Medicare program.

Physicians express strong concerns regarding the impact of PA and step therapy on timely patient care. According to a 2017 AMA survey of 1,000 practicing physicians, 92 percent of physicians said that PA can delay a patient’s access to necessary care.¹ These delays may have serious implications for patients and their health, as 78 percent of physicians reported that PA can lead to treatment abandonment, and 92 percent indicated that PA can have a negative impact on patient clinical outcomes.

The AMA has also collected stories from physicians, practice staff, and patients from across the country on its grassroots website (<https://fixpriorauth.org>) to learn more about how PA and step therapy affects patients. The PA and step therapy stories below—some of which involve protected class drugs—speak for themselves:

- “I had to go through prior authorization for a couple of my son’s seizure meds. He had to go days without because they needed ‘prior authorization’ even though the neurologist started him on them while he was admitted due to having 100+ seizures a day.”
- “I have experienced significant delays getting my patients the treatments that they need, including life-saving treatments such as epinephrine autoinjectors for anaphylaxis and inhalers for asthma. I also struggle getting medications approved for . . . critically important psychiatric medications, leaving patients with severe depression and hallucinations untreated with delays ranging from days to weeks.”
- “I have spent hours and hours getting prior authorizations. Many patients just give up. Sometimes patients have to suffer and show they tried a lesser med and failed before the med originally recommended is covered. So meanwhile the patient suffers the symptoms while they are forced to do their trial of cheaper med.”
- “I work in oncology, account receivables and prior authorization. It is heinous work. Treatment is OFTEN delayed while waiting for prior authorization. Honestly... why do you need prior authorization for CHEMOTHERAPY? It is not elective!”

¹Survey summary available at <https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf>.

- “It isn’t wise and it isn’t fair to add this burden to patients and their families, because living with and managing chronic illness is already fraught with many barriers. I am so exhausted.”

A U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) review of Medicare Advantage (MA) service denials in 2014-2016 reinforces the point that utilization management requirements can prevent patients from receiving medically necessary care.² The OIG found that more than 116,800 PA requests that were initially denied were eventually overturned on appeal. **These overturned denials represent specific drugs/services that were medically necessary and the patient needed the treatment.** This figure is particularly concerning because beneficiaries and providers appealed only one percent of denials.

While we have strong overall objections to this policy change, we are particularly troubled by the provision that would allow Part D plans to apply PA and step therapy requirements for ongoing treatment. As previously stated, treatment regimens using protected class drugs have been carefully selected and modified over time by a patient’s physician, who has clinical expertise and first-hand knowledge of the patient and his or her unique clinical situation. Interruptions of these treatments through PA and step therapy places Medicare patients at risk for loss of disease control and subsequent clinical harms. For example, abrupt discontinuation of anticonvulsant therapy could be extremely dangerous and result in uncontrolled seizures in patients with epilepsy. Similarly, interruptions of immunosuppressants could lead to organ rejection in patients who have undergone transplants. Beyond the obvious clinical dangers and human costs in scenarios such as these, disrupting effective ongoing treatment with new PA or step therapy requirements could result in increased overall expenditures for the Medicare program if loss of disease control requires more intensive treatment or hospitalization. While CMS notes that “best practice” utilization management policies would not require a patient who has been stabilized on an existing therapy of a protected class drug to change to a different medication, there is no requirement on Part D plans to institute such protections. **Given the potentially significant negative impact on Medicare patients’ health, we urge CMS to reconsider this overall policy, and in particular the allowance of PA and step therapy for existing therapy with a protected class drug.**

In addition to these serious implications for Medicare patients, we also must underscore the administrative burdens that this policy change will cause for physician practices that are already taxed by numerous regulatory requirements and commercial plan utilization management programs. We also believe that the proposed rule directly undermines the CMS Patients Over Paperwork initiative’s stated goal to reduce administrative burdens, increase efficiencies to improve patient care, and remove regulatory obstacles that prevent physicians from spending more time with patients. The AMA’s 2017 survey shows that practices complete an average of 29.1 PA requests per physician per week, and this PA workload consumes 14.6 hours—**nearly two business days**—per week of physician and staff time. An overwhelming majority (84 percent) of physicians characterized PA-related burdens as high or extremely high. Moreover, PA demands have been growing over time, with 86 percent of physicians reporting that PA burdens have increased over the past five years. CMS suggests that electronic PA (ePA) solves the problem of the increased administrative workload for physician practices that will result from this policy change. While the AMA fully supports standardized automated processes for PA and encourages adoption of this technology by all stakeholders, we must stress that ePA has yet to be widely implemented

² HHS OIG, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, (Sept. 2018), available at <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

throughout the industry and that many physicians' electronic health records (EHRs) do not currently offer this capability.

Beyond just the sheer increased volume of PA and step therapy requirements represented by this policy proposal, other factors in the proposed rule will exacerbate the administrative burdens of delivering health care services. First, as noted in our comments addressing the e-prescribing section of the proposed rule, physicians currently lack granular, patient-specific formulary data at the point-of-care, and any technology solutions to this problem are years away from being widely available. Physicians will therefore be unable to discern these proposed Part D PA and step therapy requirements in their EHRs when prescribing medications. This lack of formulary transparency at the point of prescribing means that coverage restrictions will not be apparent until a Medicare patient arrives at the pharmacy and is unable to fill a prescription due to unmet utilization management requirements. This scenario can lead to delays in necessary treatment or medication nonadherence and treatment abandonment, which presents clear clinical concerns for the Medicare population. Finally, these issues will all be further compounded by CMS' proposal to allow indication-based formulary design, as this increased formulary complexity will complicate plan selection for Medicare patients and intensify existing transparency issues and administrative burdens for physicians.

We also question the assumption that current Part D exceptions and appeals processes are mature and have proven workable. The AMA continues to receive complaints, dating back to the inception of the Part D program, regarding the onerous exceptions and appeal processes used by many Part D plans, detailed at length and with specificity in the AMA's previous correspondence to CMS. These challenges pose administrative documentation and paperwork burdens for physicians and their staff and—more importantly—delay Medicare beneficiaries' access to medically necessary care. We believe that there are far less burdensome and time-consuming methods to ensure safe, clinically appropriate care other than PA and step therapy. The vast majority of medications are electronically prescribed, and e-prescribing systems routinely include clinical decision support to prevent drug-drug interactions, incorrect dosing, adverse events, or prescribing drugs in patients with contraindications or allergies. Moreover, treatment decisions and medical necessity determinations should be made by a physician with first-hand knowledge of the patient and access to the full medical record—not put in the hands of plans with only claims data that do not capture the patient's complete clinical status.

We also note that CMS' proposal to expand use of PA and step therapy in Part D plans does not align with industry-wide, cross-stakeholder efforts to achieve meaningful improvements in utilization management programs and reduce associated administrative burdens. In 2017, the AMA, working with organizations representing physicians, hospitals, patients, and other health care stakeholders, released a set of 21 Prior Authorization and Utilization Management Reform Principles identifying problems with and recommending improvements to PA, step therapy, and other utilization management programs.³ Additionally, the AMA partnered with groups, including the American Hospital Association, American's Health Insurance Plans, the American Pharmacists Association, Blue Cross Blue Shield Association, and the Medical Group Management Association, to release the Consensus Statement on Improving the Prior

³ Principles available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-with-signatory-page-for-slsc.pdf>.

Authorization Process in January 2018.⁴ Notably, the consensus statement includes several recommendations on reducing the overall volume of PAs.

We acknowledge the need to address ever-increasing drug costs for both patients and the overall health care system. However, allowing Part D plans to use PA and step therapy for protected class drugs could result in grave clinical harms, particularly for some of the most vulnerable Medicare patients, and compound the profound administrative burdens already crippling physician practices. **We urge CMS to withdraw its proposal to permit utilization of PA and step therapy by Part D plans for these vital medications and look forward to working with CMS on alternative solutions to managing drug costs that will not negatively impact patients or physicians.**

Exclusion of Therapies with New Formulations

As with the other changes put forth in this proposed rule, the AMA has serious concerns with proposals seeking to remove from formularies medication that is provided in a new formulation, regardless of availability of the older formulation of the drug. This concern is even more pronounced by the application of the policy to single-source drugs or biologicals.

The AMA shares CMS' concern regarding "gaming" of the health care and patent system by brand manufacturers seeking to extend patents, reduce competition, and continue high pricing through introductions of new formulations of existing products with only minor changes. We strongly encourage the HHS, including CMS, to work closely with other departments and agencies, such as the Federal Trade Commission, the U.S. Patent and Trademark Office, and the Food and Drug Administration, to seek ways to address these anticompetitive actions by brand manufacturers. Minor changes to existing formulations solely for the purpose of extending exclusivity or extending the ability to charge higher prices should not be tolerated in our health care system. However, we find it unacceptable to subject beneficiaries to potential loss of access to what may be critical therapies as a method of controlling manufacturer behavior and reducing CMS expenditures.

As discussed above, beneficiaries utilizing protected class therapies are among the most vulnerable of the Medicare and Medicaid populations. Many of these patients have delicate health status and may not be able to tolerate changes or interruptions in their treatment regimens. Given that CMS is proposing to apply this exclusion policy to single-source drugs and biologics, exclusion of new formulations in cases where an older formulation is no longer available could leave beneficiaries without any appropriate treatment. This may lead to rapid decline in health status for certain beneficiaries or result in CMS incurring even higher costs when beneficiaries seek additional health care services. **We strongly urge CMS to protect beneficiaries by reconsidering this proposal and instead work closely with stakeholders and other government departments and agencies to help combat "gaming" behaviors by manufacturers.**

Exclusion of Therapies with Price Increases over the Rate of Inflation

The AMA has serious concerns regarding CMS' proposal to exclude from formularies therapies where there are price increases above the rate of inflation, especially in certain instances. The AMA has

⁴ Consensus statement available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

significant, pronounced concerns about rapidly rising drug prices. Drug price increases have been seen across the board, for both brand therapies still with exclusivity, and generic drug products that have been on the market for years. In some cases, price increases for even older, generic drug products have reached upwards of 1000 percent.

While we strongly support CMS in exploring ways to combat these price increases and ensure drugs are affordable for beneficiaries, we are aware that not all drug price increases are due to unscrupulous behaviors by manufacturers and are sometimes due to legitimate increases in the cost of doing business. Increased costs of raw materials, components in the manufacturing process, etc., may necessitate a modest, justifiable price increase on the part of manufacturers. In these cases, a blanket policy of formulary exclusion would be inappropriate and potentially harmful to patients.

The AMA appreciates the difficulties of creating policies that serve to limit unjustified drug price increases while ensuring that patients maintain access to the treatments they need and appreciates that CMS has limited tools to help combat unscrupulous actions by manufacturers in this space. However, at this time, we do not agree that the right course of action is to remove treatments from Part D formularies, particularly within the protected classes. We also strongly oppose any policy that would remove from formularies all products from a single manufacturer due to a rate increase for even one of that manufacturer's products. As discussed above, beneficiaries utilizing protected class therapies are among the most vulnerable within the Medicare and Medicaid populations and frequently have difficulty with changes or interruptions in treatment plans. Furthermore, drugs within a protected class are not necessarily therapeutic equivalents, meaning that patients cannot necessarily just switch to another drug in the same class after their preferred treatment is removed from a formulary. While we understand the threat of removal from a Part D formulary may serve as powerful negotiating tool in the face of drug price increases, we are not able to say with certainty that this will not have potentially severe negative effects on beneficiaries who do not have the option to easily switch to other therapies. **We suggest instead that the Administration consider pursuing additional authorities that would allow it to pursue action against what can amount to price gouging, price manipulation, and other anti-consumer actions by pharmaceutical manufacturers. We strongly urge CMS to reconsider this proposal and continue working with stakeholders and other government departments and agencies to seek solutions to combat this important problem.**

Part D Explanation of Benefits

The AMA supports efforts by CMS to increase price and cost transparency for all beneficiaries. Transparency is critical in order for policymakers to make sound policy decisions and for patients to work with their physician to make the best possible treatment decisions for a particular patient's health condition and financial status. The AMA continues to make strong calls for increased transparency across all sectors of the pharmaceutical marketplace.

While the AMA is generally supportive of efforts to provide information directly to beneficiaries, some important guardrails must be placed on this information for it to be impactful with the intended audience. Health care information can be confusing and difficult to understand for many beneficiaries, so it is critical that any drug and drug pricing information that is provided directly to beneficiaries incorporate adequate explanation as to what exactly is being presented. For example, the AMA supports providing information that would make beneficiaries aware of price trends for medications they are taking.

However, it must be made clear to beneficiaries whether price increases are being made to the negotiated price or to the beneficiaries' cost sharing and it must explain the difference between the two.

The AMA has some concern about providing beneficiaries with a listing of therapeutic alternatives on an explanation of benefits. While we appreciate the intent behind the proposal and support increasing transparency, we note that "therapeutic alternatives" approved for the same indication are not necessarily therapeutic equivalents for individual beneficiaries. Listing alternative treatments approved for the same indication, when those treatments may not be legitimate options for an individual patient, may serve to only further confuse or mislead beneficiaries about the treatments available to them. Alternatively, the AMA recommends that CMS consider providing a notation that less expensive alternatives may be available for a similar indication and that a patient should discuss options with their treating physician. This would be provided in lieu of a list of specific drugs provided directly to patients. We further recommend that CMS ensure that information regarding less expensive alternatives is provided directly to a prescribing physician so that those options are available to discuss with patients at the point of prescribing.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

We commend CMS for addressing the need for real-time, patient-specific prescription drug coverage information at the point of prescribing in physicians' EHRs. As noted in the proposed rule, formulary and benefit data must be seamlessly integrated within EHR systems, as well as reliable and sufficiently detailed (unlike currently available Formulary and Benefit batch files), to be widely adopted by physicians. Provision of accurate, current information about a patient's prescription benefit will enable physicians and patients to evaluate drug costs and consider possible alternative therapies when selecting a medication regimen. We agree that drug price transparency at the point-of-care has the potential to reduce drug costs for Medicare beneficiaries. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of PA and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. Transparency of coverage restrictions in EHRs can thus prevent medication nonadherence and treatment abandonment.

We support CMS' efforts to expedite industry implementation of Real Time Benefit Tools (RTBT) to support drug pricing transparency. However, the AMA disagrees with the specific approach outlined in the proposed rule, as it would allow Part D plans to support a single RTBT that is required to integrate with only one physician EHR/e-prescribing system. As such, physicians and their EHR vendors could presumably need to support a different RTBT for every Part D plan in order to have access to prescription benefit information for every patient treated by the practice. As noted by CMS, this would be an overwhelming, expensive, and burdensome proposition for vendors and physicians and would discourage adoption of this technology. Expenditures in these proprietary tools would be particularly wasteful if CMS were to mandate a standard RTBT within the next few years, since vendors, physicians, and Part D plans would have to rebuild technology to support the mandated RTBT.

The AMA recommends that CMS reconsider its proposal and instead require plans to support a single RTBT standard, when made available. The National Council for Prescription Drug Programs (NCPDP) has been developing an electronic standard for the communication of real-time prescription drug coverage and pricing information, including therapeutic alternatives, between payers and prescribers over the past few years. The AMA participates in the NCPDP group involved in this effort and expects

that a standard RTBT will be published by NCPDP within the next year. As such, we recommend that CMS wait until this standard has been published and tested by NCPDP and its members before requiring use of RTBTs in Part D plans. We believe that this approach will ensure that physicians have access to accurate, real-time formulary data **across payers**, without which this technology will not realize its full potential. We also note that in its current format, the draft NCPDP RTBT standard supports use of two different syntaxes (SCRIPT and Telecommunication standards). We have concerns that this will create interoperability challenges between EHR vendors and payers who are not using the same syntax. **We therefore support a testing period after the initial publication of the NCPDP RTBT standard to ensure seamless translation between the two different syntaxes and that any RTBT can provide physicians with accurate and complete prescription drug formulary and pricing data across all payers and patients.**

CMS is proposing that patients must specifically consent to the use of their protected health information (PHI) for RTBT access. The rationale for this requirement is to preserve the patient's right under the Health Insurance Portability and Accountability Act (HIPAA) to restrict disclosure of PHI to a payer when a patient self-pays for care. All covered entities—regardless of services performed or tools utilized—are subject to this requirement and must establish procedures to accommodate a self-pay patient's request. The AMA appreciates and supports CMS' attention to patient privacy rights. However, we note that most self-pay patients will likely ask to restrict their information during intake, rather than during the clinician encounter. **Instead of requiring physicians to create a new workflow to obtain consent specifically for RTBT usage, we urge CMS to permit physicians to incorporate RTBT considerations into workflows they have previously established for self-pay patients.** This would not only minimize practice burden, but would also enhance privacy protections by ensuring that patients understand that RTBT use is a component of the information they have the right to restrict.

Medicare Advantage and Step Therapy for Part B Drugs

In September 2018, the AMA and nearly 100 state medical associations and national medical specialty societies sent a letter to CMS outlining major objections to the policy change that allowed MA plans to use step therapy protocols for drugs covered under Part B. We again express our serious concerns regarding this policy change that is now being formalized in the proposed rule; similar to our discussion above on Part D, we believe it has the potential to have a significant negative impact on Medicare patients' timely access to medically necessary care. While we appreciate that CMS has shortened exception and appeal processing timeframes to align with Part D requirements, we maintain that subjecting Part B drugs to step therapy protocols jeopardizes the health of Medicare patients.

Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can undercut the physician-patient decision-making process and delay access to the best therapy for an individual patient. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation, and while a particular drug might be generally considered appropriate for a condition, the presence of comorbidities, potential drug-drug interactions, or patient intolerances, for example, may necessitate the selection of an alternative drug as the first course of treatment. Step therapy requirements often fail to allow for such personalized treatment considerations, resulting in delays in getting patients the right treatments at the right time.

While the care delays associated with step therapy protocols are problematic for patients on any type of therapy, they are particularly concerning where physician-administered drugs are concerned. Individuals

receiving drugs covered under Part B represent an especially vulnerable patient population. Many of the patients who would be impacted by CMS' policy change have serious or life-threatening conditions, such as cancer or autoimmune diseases. For many of these patients, selecting and initiating the most appropriate, personalized therapy at the **beginning of treatment** can be critical to survival or preventing irreversible disease progression. **Simply put, patients with serious medical conditions do not have the luxury of extra time to "fail first."** Forcing Medicare patients to suffer through prolonged periods of ineffective treatment before permitting access to the most appropriate therapy represents suboptimal care. Moreover, any short-term savings in drug expenditures would be far exceeded by subsequent increases in overall Medicare spending if patients receiving less effective first "step" drugs clinically deteriorate and require more intensive medical care or hospitalization.

Although the proposed rule states that step therapy can only be applied to new prescriptions and administrations of Part B drugs, we have serious concerns that ongoing, effective treatment may be disrupted for patients who change MA plans. A plan would have no claims data for a new enrollee to establish that the patient was receiving ongoing therapy and would view a claim for a regularly infused Part B drug as a "new prescription." Physicians frequently complain that patients with commercial insurance are required to retry previously failed therapeutic regimens to meet step therapy requirements after plan changes, and CMS' policy would recreate this illogical and potentially dangerous clinical scenario for Medicare patients. We are also concerned that the proposed "look-back" period of 108 days may not be sufficient to capture all ongoing Part B drug therapies, as dosing regimens for physician-administered medications vary widely across drug class and individual patients. This could again lead to a plan deeming a routinely used Part B drug as a "newly prescribed" medication and subsequent interruptions in ongoing therapy that could have devastating, permanent consequences for Medicare beneficiaries and their health. Dosing delays for biologic medications covered under Part B can result in adverse events or a loss of efficacy when the drug is finally reintroduced if the patient develops antibodies to the drug, rendering what was once a highly effective therapy for the patient now useless. The potential for ongoing Part B drug therapies to be miscategorized by MA plans as "new" risks the long-term health of Medicare patients who have been successfully stabilized on a particular therapy regimen. In addition, clinical complications resulting from loss of disease control could increase overall costs for the Medicare system—the opposite result of this policy's intended effect.

Step therapy also places a significant administrative burden on physician practices. Physicians do not currently have ready access to Part B patient benefit and formulary information, as there is currently no capability making this information available through EHRs or other means at the point of prescribing. This lack of transparency makes it exceedingly difficult to determine what treatments are preferred by a particular payer at the point of care and places practices at financial risk for the cost of administered drugs if claims are later denied for unmet (yet unknown) step therapy requirements. These challenges will be further compounded if, as proposed, MA plans can design complex step therapy protocols that can include both Part B and Part D drugs. Navigating these complicated requirements will be extremely confusing and time-consuming for physicians and their staff. Furthermore, payer exemption and appeals processes can be complicated and lengthy, making them burdensome for both busy physician practices and patients awaiting treatment. At a time when CMS has prioritized regulatory burden reduction in the patient-provider relationship through its Patients Over Paperwork initiative, we urge CMS to reconsider this policy change that will add another layer of administrative complication to an already strained system.

We recognize the challenges involved in finding viable approaches to addressing the rising drug prices that financially burden patients and the health care system. However, a policy change that creates barriers to appropriate and timely treatment for some of our most critically ill patients could have devastating consequences for the health of Medicare beneficiaries and lead to a paradoxical overall increase in health care spending to address clinical complications. **We urge CMS to withdraw its proposal to allow MA plans to utilize step therapy protocols for Part B physician-administered medications and look forward to partnering with CMS to find a better path forward for Medicare patients and physicians.**

Pharmacy Price Concessions to Drug Prices at the Point-of-Sale

The AMA strongly supports the proposed changes to the definition of “negotiated price” and other related changes that CMS has outlined to ensure reduction in cost burden by beneficiaries at the point-of-sale for Part D prescription drugs, increased transparency, and enhanced competition among Part D plan sponsors. The AMA strongly urges CMS to move forward with changing the definition of negotiated price for contract year 2020 along with the other proposed changes.

When all pharmacy price concessions are not reflected in the price of a drug at the point-of-sale, beneficiaries do not benefit through a reduction in the amount that they must pay in cost-sharing and pay a larger share of the actual cost of a drug. While some beneficiaries might see lower premiums, the beneficiaries who are purchasing the prescription drugs would be subsidizing lower premiums for all beneficiaries which results in perverse cost-shifting. In addition, due to the dramatic increase in pharmacy price concessions in recent years, when the point-of-sale price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discount, the negotiated price is less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor. This lack of transparency and consistency in reporting among Part D plan sponsors hinders the ability of beneficiaries to make informed decisions about the Part D plan that meets their need in the plan finder. And, the AMA shares the Agency’s concern that variation in the treatment of these price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program. For the foregoing reasons, the AMA supports the changes proposed by CMS as discussed below.

Considered Regulatory Changes to the Definition of Negotiated Price (§ 423.100)

CMS has outlined several proposed changes to the definition of negotiated price in order to ensure transparency, competition, and lowering costs for beneficiaries who need to purchase medication. CMS proposes to define “negotiated prices” at section 423.100 to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor’s intermediary (that is, the amount the pharmacy would receive net of the maximum possible negative adjustment that could result from any contingent pharmacy payment arrangement). The AMA strongly supports this proposed change. Specifically, CMS is considering deleting the current definition of “negotiated prices” (in the plural) and adding a new definition of “negotiated price” (in the singular) in order to make clear that a negotiated price can be set for each covered Part D drug, and the amount of pharmacy price concessions may differ on a drug-by-drug basis. Again, the AMA strongly supports this approach as it will ensure important transparency for beneficiaries when making Part D plan elections based on the medications that they are prescribed.

CMS is considering the policy that the negotiated price for a covered Part D drug must include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts, such as incentive fees, if these amounts increase prices. The AMA strongly supports this proposal to ensure accuracy and access. This policy creates a strong pressure to ensure payment arrangements are not structured to increase beneficiary cost burdens.

Finally, CMS is considering whether to require Part D sponsors to include pharmacy price concessions in the negotiated price in the coverage gap, for purposes of determining manufacturer coverage gap discounts, as would be required of sponsors in all other phases of the Part D benefit under the approach CMS is considering. The AMA supports this approach. Furthermore, CMS notes it is also considering whether to continue to permit Part D sponsors to elect whether to pass-through non-pharmacy price concessions and other direct or indirect remuneration amounts (for example, manufacturer rebates, legal settlement amounts, and risk-sharing adjustments) to enrollees at the point-of-sale. We strongly urge CMS to consider including requirements that such concessions should be included as pass-throughs to beneficiaries who shoulder the financial burden of increasing prescription medication costs.

Pharmacy Administrative Service Fees

The AMA strongly supports efforts to increase transparency, and thus, the Agency's clarification that when pharmacy administrative service fees take the form of deductions from payments to pharmacies for Part D drugs dispensed to Part D beneficiaries, they clearly represent charges that offset the sponsor's or its intermediary's operating costs under Part D and must be reported as price concessions. The AMA agrees with CMS' statement that where a sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting and must be fully disclosed.

Defining Price Concession (§ 423.100)

The AMA strongly supports the proposal to offer a standardized definition of "price concession" in order to promote consistent reporting, enhanced transparency, and accuracy that should assist CMS with oversight. The AMA supports the decision to define the term broadly to include the following:

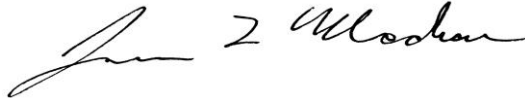
Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source, that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

This definition of price concession may need refinement over time, but the current lack of consistency in defining the term among Part D plan sponsors hinders oversight and efforts to ensure accurate information about Part D plan sponsors and whether beneficiaries are benefiting from price concessions.

The Honorable Seema Verma
January 25, 2019
Page 12

The AMA appreciates the opportunity to provide comment on the important topic of drug prices and how we can best ensure patients have access to the critical, affordable therapies. We look forward to working with CMS to find meaningful solutions to this growing problem. If you have any questions or to continue conversation on this issue, please do not hesitate to contact Shannon Curtis, Assistant Director, Federal Affairs at shannon.curtis@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD