REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-A-25

Subject: Prescription Medication Price Negotiation (Resolution 113-A-24)

Presented by: Stephen Epstein, MD, MPP, Chair

Referred to: Reference Committee A

At the 2024 Annual Meeting, the House of Delegates referred Resolution 113, which was sponsored by the New England Delegation, and asked our American Medical Association (AMA) to support drug price negotiation for all payers, advocate that any medication in which the price rises faster than inflation be automatically added to the negotiation schedule, and support extending the annual Medicare cap on out-of-pocket prescription drug spending to all payers. The following report discusses the history and current state of medication price negotiation, out-of-pocket caps, AMA efforts on the topic, and offers recommendations in line with the spirit of the resolution.

BACKGROUND

Enactment of the Inflation Reduction Act of 2022 (IRA) has had far-reaching impacts in the health care sector, particularly regarding Medicare drug pricing.[1] Most notably, the IRA allows the Centers for Medicare & Medicaid Services (CMS) to directly negotiate the prices of certain high-cost drugs.[2,3] CMS initially selected 10 medications that are considered "high expenditure," are single source, and do not have a biosimilar/generic alternative. Additionally, manufacturers are required to pay rebates to the federal government if the price of medications for Medicare Part B or Part D beneficiaries are raised faster than the rate of overall inflation as measured by the Consumer Price Index for All Urban Consumers (CPI-U).[1,2]

At the time this report was written, there had not been significant movement in either direction regarding implementation of the drug pricing regulations by the Trump administration. However, it seems likely that they will choose to maintain current drug pricing practices put in place by the Biden administration, implement modifications to these practices, or repeal them altogether.[4] A focus on reducing drug prices through Medicare negotiations remains a cause with bipartisan support. Over half of all Americans report believing that Medicare drug pricing should be a "top priority" of the current administration.[5] CMS released a statement declaring that the current administration intends to focus on the issue by negotiating drug prices,[6] although recent actions may indicate a change in focus from the Biden administration. For example, shortly after taking office, President Trump signed executive orders rescinding regulations designed to lower Medicare beneficiaries' drug spending. Specifically, the two-dollar generic out-of-pocket (OOP) cap was removed and the reduction of Medicare payment for accelerated Food and Drug Administration (FDA) medications was reduced.[7] Additionally, three ongoing projects through the CMS Innovation Center designed to explore strategies to lower drug prices were halted .[7] It is also possible that the administration will not directly support nor reject the Medicare negotiations, thereby indirectly supporting drug industry opposition. For example, the administration may choose not to defend the existing laws and regulations against legal challenge or may propose rules designed to exempt more drugs from negotiations.[4]

Pharmaceutical prices are typically categorized in three ways: public list price, net price, and OOP expense for the patient.[8] The public list price of a drug is set by the manufacturer and is typically the starting point for negotiations. The net price of a drug is the amount that is actually paid by the plan sponsor or, in the case of public plans, the government. This price is determined through either negotiation, mostly done by pharmacy benefit managers (PBMs), or in some rare cases by the payer itself. This is also the price that is typically dictated by legislation or regulations when applicable. Finally, patient OOP cost is the amount that the patient pays to receive the medication.[8,9] There are many elements that are incorporated in price determination, such as the number of medications available to treat the same condition, the route of administration of the medication, and the payer. These elements are used to set the prices that are paid by patients and plans.[8,9] Without PBMs, this process is relatively straightforward. Manufacturers sell prescription drugs to pharmacies who, in turn, sell the drug to the patient at a price determined by their insurance coverage and plan. However, the addition of PBMs to this process increases complexity and reduces transparency. These benefit managers become the "middlemen" between manufacturers, pharmacies, insurance companies, and consumers, which allows them to determine the actual OOP cost to the patient.[8,10]

PRICE NEGOTIATION

Private payers engage in drug price negotiation, primarily relying on PBMs to handle the negotiations. PBMs work directly with drug manufacturers to negotiate drug prices and associated rebates to find the lowest cost for the payer. While, in theory, this should lead to beneficiaries having access to lower cost medications, in reality PBMs often favor the higher priced drugs. This is due to the rebates, calculated as a percentage of the list price, that are kept by the PBM and payer, and rarely directly benefit beneficiaries.[11] These rebates are not typically passed on to the patient and, as a result, patients may end up paying a higher price and/or not benefiting from the PBM negotiations.[11,12] Additionally, a significant portion of PBMs are vertically integrated with payers, stifling competition. This lack of competition, which is not just a result of vertical integration but also the process of rebate negotiation, often results in higher insurance premiums for beneficiaries and lower pharmaceutical reimbursement rates.[12] While the negotiation practices of private payers, often via PBMs, may not be as advantageous for patients as it should be, the bottom line is that these payers do currently negotiate drug prices to lower overall insurer costs.

Historically, public payers have not negotiated drug prices in the manner that was implemented by the aforementioned IRA. Since its inception in 2022, the IRA has allowed CMS to negotiate the price of Medicare Part B and D prescription drugs. This negotiation process began in 2024 for Part D and included 10 drugs in the initial negotiation cycle.[1] The Maximum Fair Prices (MFPs) for these 10 drugs will go into effect in January 2026. These drugs include blood thinners and medications to treat diabetes, heart failure, psoriasis, rheumatoid arthritis, blood cancers, and Crohn's disease. Medicare negotiated prices ranged from a price drop as small as $6 and as large as $22,027. Not surprisingly, the drug with the highest list price, Stelara,® showed the most significant price decrease while the drug with the lowest list price, NovoLog®/Fiasp,® yielded the smallest price reduction. A full and regularly updated table of the Medicare negotiated drug prices can be accessed via the Peterson-KFF Health System Tracker. In early 2025, CMS announced 15 additional drugs that will be included in the Medicare drug pricing negotiation schedule. Assuming the cycle of negotiation continues as intended, the MFPs for these drugs will go into effect January 2027.[2,3] CMS projects that the negotiated MFPs will save approximately $1.5 billion in its first year.[2] In order for prescription drugs to be eligible for negotiation, they must meet certain criteria. Specifically, they must be covered by Medicare and be a single brand-name drug or biologic that does not have a therapeutically equivalent generic or biosimilar that is being marketed. Additionally, eligible biologics must be 11 years past the earliest FDA approval or licensure and

name-brand small-molecule drugs must be at least seven years past approval/licensure. Until 2028, negotiation is limited to Part D plans adding 15 drugs each year through 2028. In 2029 Part B plans will be included and the number of negotiated drugs will increase to 20.[1,3,13]

Importantly, there is no "trigger" that automatically includes a medication in future negotiations. However, under the IRA if the cost of a drug rises faster than inflation, manufacturers are required to provide Medicare with rebates.[3] This provision is designed to discourage manufacturers from unnecessarily raising drug prices without valid reasoning, as in 2015 when the manufacturer for Daraprim® increased the price by over 5,000 percent overnight.[3,13] Though a medication's price increasing faster than inflation *might* be a reason for inclusion, it is not *necessarily* a reason. There are valid reasons that a drug price may increase, such as when a medication's treatment value increases or an increase in the cost of raw materials.[14,15] While it is important to discourage unnecessary hikes in drug prices, it is also important to ensure that medications are accessible to patients when needed. Therefore, drugs should not be automatically included in negotiations without complete assessment from appropriate regulators, legislators, and/or experts. A discussion surrounding the criteria states have utilized to select regulated or negotiated medications can be found in CMS Report 8-A-25.

Pharmaceutical manufacturers have pursued litigation to stop these government negotiation practices, citing that the negotiated prices may harm competition and, as a result, innovation. At the time this report was written, there were nine open legal cases against the federal government and/or CMS.[16] These lawsuits generally center around the claim that the program will violate the Fifth Amendment by forcing manufacturers to provide selected medications to the government without fair compensation, that the program limits corporate free speech, and that associated penalties are "excessive fines" which is in violation of the Eighth Amendment. Some cases also claim that the negotiation program violates portions of the Due Process Clause by not allowing for adequate separation of powers.[14,15] To date, none of these legal challenges have been successful in blocking or minimizing the drug negotiation. However, most of these cases are still ongoing and one has recently found minor traction via an appeals court.[17] Most experts following these cases agree that it is likely one will end up being heard by the United States Supreme Court. Although the voracity with which the current administration will defend the program is uncertain, potentially mitigating the need for a Supreme Court ruling.[15,16]

IMPACT OF PRICE NEGOTIATION

While experts do agree that reducing the amount patients pay for drugs will improve medication adherence, and as a result health outcomes, there is some debate regarding whether price negotiation, and particularly the establishment of MFPs, are the best method to reduce drug prices. Some experts suggest that increasing drug price negotiation is a tactic that could be used in tandem with other tactics to lower drug prices in the U.S.[18] Specifically, the Congressional Budget Office (CBO) analyzed a bill asserting more aggressive negotiation and found that it could yield over $450 billion in savings for Medicare over a 10-year period. It is estimated that if the negotiated prices were expanded to commercial insurance plans, anticipated savings to the system could reach the trillion-dollar mark over 10 years.[17] These experts stress that drug price negotiation alone is not likely to solve the problem of U.S. drug prices. However, in tandem with other efforts such as rebate reform, administrative simplification, and increased transparency, costs could be reduced.[17]

Other experts have voiced concerns surrounding the increased use of price negotiation. Many drug manufacturers claim that the implementation of negotiation and MFPs will stifle innovation and potentially prevent, or slow, the development of new pharmaceuticals.[18] Importantly, much of the

resistance to price negotiation has come from entities that benefit from the current system, such as manufacturers, potentially calling the motives of these challenges into question.[14,15,18]

In addition to the lowered costs that may result from negotiation, the price transparency required in the IRA may improve pricing.[17,19] The public access to a drug's Medicare Negotiated Price, the MFP, is a relatively novel level of transparency that may encourage private payers to follow the lead on CMS negotiated prices. While the current legislation does not require private payers to follow the set MFPs, it is common for private insurance companies to eventually follow the lead of CMS.[18] Research has demonstrated that increases in transparency throughout the drug pricing system could be a significant help in lower drug prices overall.[17]

Federal efforts, like the Prescription Pricing for the People Act of 2025, have been introduced to regulated PBM business practices and drug pricing. Additionally, the Transparency in Coverage rule, released in 2020, outlines the requirements for payers/plans to disclose negotiated rates and historical net price for prescription drugs. In addition to federal efforts, a number of states have enacted laws related to portions of the drug pricing process. These laws center around affordability reviews, consumer cost sharing, PBMs, increased transparency, and purchasing processes. However, since none of these state laws have been enacted at a federal level, no impact has been seen nationally.[20] Due to the lack of transparency in the drug pricing process, the result of each specific element, be it negotiation, PBMs, or another aspect, is difficult to assess.

OUT-OF-POCKET CAPS

In addition to introducing CMS drug price negotiations, the IRA also lowered the prescription drug OOP cap for Medicare Part D beneficiaries. Historically, this cap has been between $3,300 and $3,800. Starting in 2025, this has been lowered to $2,000 due to elimination of the coinsurance cost in the catastrophic coverage phase. Experts estimate that if this cap had been implemented in 2021, 1.5 million beneficiaries would have saved in OOP costs.[21]

While the IRA did not expand the prescription drug OOP cap to non-Medicare payers, most, if not all, plans have caps on annual OOP spending. Research has demonstrated that median annual OOP spending on medical expenses ranged between $360 and $1,500 with the top 10 percent spending at least $7,000.[22] Importantly, this is for all medical spending, not just prescription drugs. Because many private payers do not separate prescription drug OOP costs from overall OOP medical costs, it is challenging to make a direct comparison to Medicare levels.[21] Researchers and other experts agree that high OOP costs can be detrimental to patients, some suggesting spending caps as a potential solution to this issue.[23,24] The financial burden of high OOP costs can often lead to patients accruing significant medical debt and potentially forgoing future, necessary treatment. If a patient cannot afford their OOP cost, they may delay or skip treatment altogether, leading to lower medication adherence and poorer health outcomes. OOP caps could have potential to increase prescription drug affordability for patients in turn potentially leading to better health outcomes.[23,24]

While experts agree that high OOP costs can be detrimental to patients, some voice concerns around the unintended consequences of OOP caps such as disproportionate financial burdens to lower income patients.[24,25] If all beneficiaries are given a uniform cap, this may be affordable for some but not for others. Even more importantly, these caps are often not paid for by insurers but rather shifted to patients through premium increases. These premium raises could, and often do, make insurance unaffordable for many beneficiaries. Some experts argue that this could be mitigated by adding income-based eligibility requirements for OOP costs or income-proportional caps.[23,24,25] Nonetheless, it is essential to ensure that the potential economic impacts of universal

OOP caps be weighed against the potential benefits to ensure that patients still have access to reasonably priced insurance coverage.

AMA POLICY AND ADVOCACY

The AMA has undertaken robust advocacy efforts to lower drug costs for patients, especially around regulation and increasing the transparency of PBMs. Specifically, over the past two years the AMA has written a number of letters to payers, regulators, and legislators and testified before both the House and Senate regarding regulation of PBMs. The AMA also has an ongoing grassroots campaign, TruthinRx, designed to support patients and physicians in understanding and fighting the lack of transparency through education and advocacy. Additionally, the AMA has expressed support to federal legislators to implement drug price negotiation, regulators in reducing patient OOP costs, and for reasonable OOP caps on drug spending. The AMA is continuing to work with legislators, regulators, drug manufacturers, and payers to ensure that patients not only have access to affordable medications but also affordable health coverage.

In addition to the advocacy on drug pricing transparency and affordability, the AMA has extensive policies that address the issue. Policies H-110.980 and H-110.987 outline the AMA's efforts to ensure that patients have access to affordable medications. These policies discuss AMA standards for drug affordability, process transparency, and patient access. Policy H-110.980 highlights different strategies and approaches, such as supporting increased transparency and promoting value-based pricing, that the AMA utilizes to ensure that medications are accessible and affordable. Policies H-110.986 and H-110.979 expand on this support for value-based strategies to manage drug coverage. Specifically, H-110.986 discusses AMA support for adding value metrics into drug prices and H-110.979 outlines AMA advocacy for formulary development to incorporate value-based processes. In conjunction with the aforementioned policies that address all payer types, Policy D-330.954 focuses on managing prescription drug prices in Medicare and outlines support for price negotiation. Finally, Policies D-110.987, D-120.988, and D-120.934 target PBMs and the need for increased regulation and transparency. Policy D-120.934 outlines AMA steps to ensure that PBMs do not prevent physicians from appropriately treating patients, Policy D-120.988 details prevention of appropriate treatment by PBMs, and Policy D-110.987 discusses the impacts of these, and other, negative PBM practices.

The AMA also has policy and ongoing advocacy to address concerns from experts surrounding unintended consequences of introducing OOP caps or extending drug price negotiations. Policies H-320.939 and D-320.982, along with the AMA's Fix Prior Auth grassroots campaign, work to mitigate concerns regarding increases in utilization management/prior authorization. Policy H-320.939 outlines the efforts that the AMA has made to reduce the amount of utilization management and fix the system as a whole. Policy D-320.982 outlines strategies, including emerging technology, that could be used to assist in minimizing the impact of utilization management on patients and physicians. Finally, Policies H-165.828, H-290.954, and H-165.824 outline AMA efforts to support the affordability of health insurance for all. Policy H-165.828 centers around the AMA efforts to ensure that health coverage is affordable for all patients, while Policies H-165.824 and H-290.954 center on ACA and public plan affordability.

DISCUSSION

Despite the current uncertainty of Medicare drug price negotiations, the practice of negotiation has been a part of drug pricing in the private sector for decades. The current drug pricing system, hallmarked by close relationships between private insurers and their PBM negotiators, is complicated and opaque. As a result, the system often still yields drug prices that remain

unaffordable for many patients. While this system is not simple to fix, it is possible that the current CMS negotiation efforts may be a step in the right direction. While some experts voice concern that negotiation may stifle innovation, many anticipate that it has the potential to save both consumers and public payers significant amounts of money, helping prescriptions become more affordable. Regardless of the impact of price negotiation, it is clear that payers of all types participate in the negotiation process. For private payers this is often done by PBMs and for public payers via CMS. The Council believes that when used responsibly, prescription drug price negotiation has real potential to make significant changes, and that the AMA should support utilization of all ongoing efforts, to make drug prices affordable. The AMA has a strong body of policy and ongoing advocacy to address drug affordability. Therefore, the Council recommends the reaffirmation of Policy H-110.987, which details the AMA's efforts to encourage regulators, legislators, physicians, and patients to work together towards transparency and affordability in drug pricing. To ensure that this support is explicit for all medications, including those used to manage health and prevent future complications, the Council recommends the adoption of new HOD policy as outlined in Recommendation 1. Additionally, as outlined in the report, PBMs are exceptionally influential in setting drug prices, as they are currently faced with little regulation. Therefore, the Council recommends that Policy D-110.987 be reaffirmed, as it outlines how the AMA continues to hold legislators and regulators accountable to ensure that PBMs are monitored and transparency is increased. The Council believes that this new HOD policy, along with the suggested reaffirmations, will ensure that efforts to increase medication affordability continue.

As previously discussed, OOP costs are another aspect of drug pricing that elicit affordability concerns for patients. Researchers agree that high OOP medical costs can cause significant financial burden to patients and adverse health outcomes. Specifically, when OOP costs are higher, patients are less likely to adhere to treatment and often experience worse health outcomes. However, blanket OOP caps may not be a simple solution to the problem. Experts have called the actual impact of these caps into question and expressed concern that payers might shift costs to patients via premium increases. It is clear that OOP caps need to be handled in a manner that balances the potential positives and negatives. Therefore, the Council recommends the adoption of new HOD policy that supports the establishment of a reasonable OOP prescription drug cap while maintaining patient premiums. The Council believes that this new policy captures the intent of the third resolve of Resolution 113-A-24 while balancing potential unintended consequences.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 113-A-24, and the remainder of the report be filed:

1. That our American Medical Association (AMA) support efforts to ensure that patients have affordable access to medications. (New HOD Policy)

2. That our AMA encourage all payers, both public and private, in efforts to establish a reasonable and affordable cap on patient out-of-pocket prescription drug spending in a manner that does not increase patient premiums. (New HOD Policy)

3. That our AMA oppose drug payment methodologies that result in physician practices being paid at less than the cost of acquisition, inventory, storage, and administration of relevant drugs and other necessary clinical services. (New HOD Policy)

4. That our AMA support considering both the rate of increase and the absolute price of a medication when selecting medications for Medicare drug price negotiation. (New HOD Policy)

5. That our AMA reaffirm Policy H-110.987, which supports efforts to ensure drug prices are affordable to patients. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy D-110.987, which supports efforts to increase PBM transparency and regulation. (Reaffirm HOD Policy)

Fiscal Note: Less than $500

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Policy Appendix

Additional Mechanisms to Address High and Escalating Pharmaceutical Prices, H-110.980
1. Our American Medical Association (AMA) will advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
a. The arbitration process should be overseen by objective, independent entities.
b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel.
c. All conflicts of interest of arbitrators must be disclosed and safeguards developed to minimize actual and potential conflicts of interest to ensure that they do not undermine the integrity and legitimacy of the arbitration process.
d. The arbitration process should be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question.
e. The arbitration process should include the submission of a value-based price for the drug in question to inform the arbitrator's decision.
f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer.
g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases.
h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision.
i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
a. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation.
b. The use of any international drug price index or average should preserve patient access to necessary medications.
c. The use of any international drug price index or average should limit burdens on physician practices.
d. Any data used to determine an international price index or average to guide prescription drug pricing should be transparent and updated regularly.
3. Our AMA supports the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction. (CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Modified: CMS Rep. 4, A-22)

Pharmaceutical Costs, H-110.987
1. Our American Medical Association (AMA) encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.

4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports:
a. drug price transparency legislation that requires 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;
b. legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and
c. the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation. (CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22; Reaffirmed: Res. 801, I-23; Reaffirmed: Res. 801, I-23)

Value-Based Management of Drug Formularies, H-110.979
Our American Medical Association: (1) will advocate that pharmacy benefit managers (PBMs) and health plans use a transparent process in formulary development and administration, and include practicing network physicians from the appropriate medical specialty when making determinations regarding formulary inclusion or placement for a particular drug class; (2) will advocate that any refunds or rebates received by a health plan or PBM from a pharmaceutical manufacturer under an outcomes-based contract be shared with impacted patients; and (3) opposes indication-based formularies in order to protect the ability of patients to access and afford the prescription drugs they need, and physicians to make the best prescribing decisions for their patients. (CMS Rep. 6, I-20)

Incorporating Value into Pharmaceutical Pricing, H-110.986
1. Our American Medical Association (AMA) supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles:
a. value-based prices of pharmaceuticals should be determined by objective, independent entities;
b. 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, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes;
c. processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role;
d. processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients;
e. processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and
f. value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.
2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.
3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size. (CMS Rep. 05, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS-CSAPH Rep. 01, A-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: CSAPH Rep. 2, I-19; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 6, I-20; Reaffirmed: Res. 113, A-23)

Prescription Drug Prices and Medicare, D-330.954
1. Our American Medical Association (AMA) will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS. (Res. 211, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 201, I-11Appended: Res. 206, I-14; Reaffirmed: CMS Rep. 2, I-15; Appended: Res. 203, A-17; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Reaffirmed: Res. 113, I-21; Reaffirmed: CMS Rep. 4, A-22; Reaffirmed in lieu of: Res. 810, I-22)

The Impact of Pharmacy Benefit Managers on Patients and Physicians, D-110.987
1. Our American Medical Association (AMA) supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
5. Our AMA supports improved transparency of PBM operations, including disclosing:

- Utilization information;
- Rebate and discount information;
- Financial incentive information;
- Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
- Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
- Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
- Percentage of sole source contracts awarded annually.

6. Our AMA encourages increased transparency in how DIR fees are determined and calculated. (CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 6, I-20)

Inappropriate Actions by Pharmacies and Pharmacy Benefit Mangers, D-120.988
Our American Medical Association, in cooperation with pharmacy benefit managers, pharmacy companies, and other drug retailing organizations, shall develop model procedures that physicians may use when prescribing off-formulary pharmaceuticals that are medically indicated and that these procedures be in compliance with the Health Insurance and Portability and Accountability Act of 1996. (Res. 528, A-02; Reaffirmation I-04; Reaffirmation A-06; Reaffirmed: CSAPH Rep. 01, A-16)

Evaluating Actions by Pharmacy Benefit Manager and Payer Policies on Patient Care, D-120.934
1. Our American Medical Association (AMA) will take steps to implement AMA Policies H-120.947 and D-35.981 that prescriptions must be filled as ordered by physicians or other duly authorized/licensed persons, including the quantity ordered.
2. Our AMA will work with pharmacy benefit managers, payers, relevant pharmacy associations, and stakeholders to: (a) identify the impact on patients of policies that restrict prescriptions to ensure access to care and urge that these policies receive the same notice and public comment as any other significant policy affecting the practice of pharmacy and medicine; and (b) prohibit pharmacy actions that are unilateral medical decisions.
3. Our AMA will report back at the 2018 Annual Meeting on actions taken to preserve the purview of physicians in prescription origination. (Res. 233, I-17; Reaffirmed: CMS Rep. 05, A-23)

Prior Authorization and Utilization Management Reform, H-320.939
1. Our American Medical Association (AMA) will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.
2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.
3. Our AMA supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm.

4. Our AMA will advocate for health plans to minimize the burden on patients, physicians, and medical centers when updates must be made to previously approved and/or pending prior authorization requests. (CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18; Appended: Res. 812, I-18; Reaffirmed in lieu of: Res. 713, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: Res. 811, I-19; Reaffirmed: CMS Rep. 4, A-21; Appended: CMS Rep. 5, A-21; Reaffirmation: A-22)

Prior Authorization Reform, D-320.982
Our American Medical Association will explore emerging technologies to automate the prior authorization process for medical services and evaluate their efficiency and scalability, while advocating for reduction in the overall volume of prior authorization requirements to ensure timely access to medically necessary care for patients and reduce practice administrative burdens. (Res. 704, A-19; Reaffirmation: A-22)

Health Insurance Affordability, H-165.828
1. Our American Medical Association (AMA) supports modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered employer-sponsored coverage by lowering the threshold that determines whether an employee's premium contribution is affordable to the level at which premiums are capped for individuals with the highest incomes eligible for subsidized coverage in Affordable Care Act (ACA) marketplaces.
2. Our AMA supports legislation or regulation, whichever is relevant, to fix the ACA's "family glitch," thus determining the eligibility of family members of workers for premium tax credits and cost-sharing reductions based on the affordability of family employer-sponsored coverage and household income.
3. Our AMA encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account (HSA) partially funded by an amount determined to be equivalent to the cost-sharing subsidy.
4. Our AMA supports capping the tax exclusion for employment-based health insurance as a funding stream to improve health insurance affordability, including for individuals impacted by the inconsistency in affordability definitions, individuals impacted by the "family glitch," and individuals who forego cost-sharing subsidies despite being eligible.
5. Our AMA supports additional education regarding deductibles and cost-sharing at the time of health plan enrollment, including through the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services.
6. Our AMA supports efforts to ensure clear and meaningful differences between plans offered on health insurance exchanges.
7. Our AMA supports clear labeling of exchange plans that are eligible to be paired with a Health Savings Account (HSA) with information on how to set up an HSA.
8. Our AMA supports the inclusion of pregnancy as a qualifying life event for special enrollment in the health insurance marketplace. (CMS Rep. 8, I-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmation: A-17)

Improving Medicaid and CHIP Access and Affordability, H-290.954
1. Our American Medical Association (AMA) opposes premiums, copayments, and other cost-sharing methods for Medicaid and the Children's Health Insurance Program, including Section 1115 waiver applications that would allow states to charge premiums or copayments to Medicaid beneficiaries.
2. Our AMA encourages the Centers for Medicare & Medicaid Services to amend existing Section 1115 waivers to disallow states the ability to charge premiums or copayments to Medicaid beneficiaries. (Res. 803, I-23)

Improving Affordability in the Health Insurance Exchanges, H-165.824

1. Our American Medical Association (AMA) will:

a. support adequate funding for and expansion of outreach efforts to increase public awareness of advance premium tax credits.

b. support expanding eligibility for premium tax credits up to 500 percent of the federal poverty level.

c. support providing young adults with enhanced premium tax credits while maintaining the current premium tax credit structure which is inversely related to income.

d. encourage state innovation, including considering state-level individual mandates, auto-enrollment and/or reinsurance, to maximize the number of individuals covered and stabilize health insurance premiums without undercutting any existing patient protections.

2. Our AMA supports:

a. eliminating the subsidy "cliff," thereby expanding eligibility for premium tax credits beyond 400 percent of the federal poverty level (FPL).

b. increasing the generosity of premium tax credits.

c. expanding eligibility for cost-sharing reductions.

increasing the size of cost-sharing reductions. (CMS Rep. 02, A-18; Appended: CMS Rep. 02, A-19; Reaffirmed: CMS Rep. 3, I-21)