REPORT 2 OF THE COUNCIL ON MEDICAL SERVICE (I-26)
The Impact of the Inflation Reduction Act on Physician Practices
(Reference Committee J)

EXECUTIVE SUMMARY

At the 2025 Interim Meeting, the House of Delegates adopted Policy D-110.980, which asks that the American Medical Association (AMA) study the impact of the Inflation Reduction Act (IRA) drug price negotiation on physician-owned practices, with a focus on oncologic practices, and patient access.

The Council reviewed data related to drug pricing and payment in the United States, including the impact of drug affordability on patients and physicians. The Council discussed different drug payment models and how these models may, or may not, benefit patients and physicians. Among these payment models, the Council reviewed the commonly used Average Sales Price-based reimbursement payment model used for many physician-administered drugs, including those covered under Medicare Part B. This report highlights the challenges that this payment model can cause for physicians and physician practices, especially smaller/community-based practices, such as lagging and inadequate payments. Further, the Council reviewed information regarding updates to the IRA drug price negotiation and its initial implementation. The Council reviewed the potential impacts of these negotiated Maximum Fair Prices (MFPs) and how payment structures would change for physician practices, highlighting the potential revenue loss for practices that utilized a high number of Part B/physician-administered drugs. However, the report also outlines the uncertainty of this area as the IRA negotiated MFPs for Part D drugs have just begun to be implemented and the initial round of Part B negotiated MFPs are yet to be released. The Council highlights information on how these negotiated prices could affect physician practices, particularly in the specialties of oncology and hematology, as they are most likely to see the largest financial impact. Finally, the Council reviewed AMA advocacy efforts and existing policy which highlight the need for transparency, affordability, and fair payment for prescription drugs.

The Council firmly believes in the importance of ensuring that physician practices are able to remain financially viable, while also acknowledging that it will take time to realize the full impact of the IRA Medicare negotiated prices. The Council recommends adoption of new policy to advocate for Medicare prescription drug price negotiation and price effectuation toward ensuring that: 1) actual acquisition costs decrease in a manner commensurate with reductions in drug prices; and 2) all payments cover the cost of acquisition, storage, inventory, administration, and other necessary clinical services, highlight administrative simplicity, and are timely, affordable, and transparent for patients and physicians. The Council believes that this policy allows support for alternatives to the traditional payment models while also ensuring that the IRA negotiation does not have a negative impact on patients or physicians. Additionally, the Council recommends amendments to Policy D- 110.980 to support continued monitoring, reporting, and advocacy on Medicare drug price negotiation. Finally, the Council recommends the reaffirmation of Policy H-110.956, which works to safeguard fair and timely payment for physicians and practices for biologic/biosimilar drugs. The Council believes that the combination of the new policy, amended policy, and reaffirmed policy builds on a strong foundation to ensure not only patient access to affordable medications, but also to financially health physician-owned practices.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-26

Subject: The Impact of the Inflation Reduction Act on Physician Practices

Presented by: A. Patrice Burgess, MD, Chair

Referred to: Reference Committee J

At the 2025 Interim Meeting, the House of Delegates adopted Policy D-110.980, "Study on Impact of Inflation Reduction Act on Oncology, Other Physician Practices," which asks that:

1. Our American Medical Association (AMA) will work with relevant stakeholders to conduct a comprehensive study on the impact of the Inflation Reduction Act's (IRA) drug price negotiation provisions, particularly for drugs covered under Medicare Part B and physician administered drugs due to concerns it could jeopardize patient access to critical therapies as the IRA's potential for reimbursement reductions may lead to less availability of these medications in smaller, community-based clinics where a significant amount of care is.

2. Our AMA will specifically evaluate the potential impact on the sustainability of community-based physician practices, with a particular focus on oncology practices.

3. Our AMA will consider using the findings of this study to inform its advocacy efforts to ensure that any future drug pricing policies balance patient affordability with the stability of physician practices, patient access, and the continued advancement of drug innovation.

This report provides an overview of drug pricing in the United States, drug payment models, and the IRA drug price negotiation provisions. Further, although the data are limited and preliminary, this report outlines potential impacts of IRA drug price negotiation on physicians, practices, and patients.

BACKGROUND

In the United States, prescription drug spending represents a major portion of overall health costs, leading to serious concern for many Americans. Prescription drug spending makes up approximately 10 percent of all national health dollars, and as much as 20 percent of spending for large employers and Medicare.[1,2] This is a major point of concern for many patients as 60 percent of adults report worrying about being able to afford prescription drugs, approximately 40 percent report rationing or skipping doses as a result of cost, and over two-thirds report that prescription drug price affordability is getting worse.[2,3] Further, this can also be a major obstacle for physician practices, especially when dealing with high-cost physician-administered drugs.

The American prescription drug pricing system is both complicated and opaque, with drug manufacturers, payers, and pharmacy benefit managers (PBMs) setting prices, and requiring physicians and patients to navigate the system.[4] Within employer sponsored plans, drug price

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negotiations are typically handled by PBMs who act as middlemen between the payer and the manufacturer, negotiating lower prices for the payers. Manufacturers often incentivize PBMs to place their drugs favorably on the formulary via rebates and discounts. Cost savings are often calculated based on a list price, which serves as the starting point for future negotiations and is commonly inflated to allow for larger rebates and/or discounts.[4] While these savings should be passed on to patients, they often are not, and as a result, patients often pay more out-of-pocket for higher-priced drugs.[4] To further exacerbate the issues around opacity and expensive drug prices, many PBMs are vertically integrated with payers and/or pharmacies, thereby enabling practices which may limit competition, often driving prices up further and limiting patient choice.[5]

DRUG PAYMENT MODELS

Under the commonly used buy-and-bill model, the purchasing entity, typically a physician office, hospital, or outpatient infusion center, will buy and store the medication, administer it to the patient, and bill the payer. The purchaser is then paid for the medication at a rate that is pre-set either by legislation with public payers or contractual agreement with private payers.[6,7] Drugs covered under Medicare Part B are typically administered in a healthcare setting and have a more complicated payment system, with the administering entity, often a physician's office, hospital, or infusion center, entering into this buy-and-bill system. In contrast to Medicare Part D drugs, which include mostly traditional, non-physician administered prescription medications, Part B drugs are typically those that require administration by a healthcare professional. These injectable/infused drugs often include chemotherapy, immunosuppressives, and certain vaccines such as influenza and COVID-19. Under Part B, reimbursement is set at the Average Sales Price (ASP) plus six percent, often referred to as ASP+6, with 20 percent cost-sharing paid by the patient. This is slightly modified for qualifying biosimilar medications in that these medications are paid at an ASP plus eight percent rate to incentivize their use over the typically more expensive reference biologic.[6,7] However, due to Medicare sequestration on Part B drugs, the actual payment rate is as low as ASP+4.3. This means that if the ASP of a medication is $100, the purchasing entity would be paid $104.30, or $106.30 if the drug is a qualifying biosimilar.

While this system seems to be straightforward, it does pose a number of distinct challenges for purchasing entities, especially smaller and community-based physician practices, as payment rate updates often lag, making them inadequate to cover actual costs. Since payment rates are updated quarterly, purchasing entities are paid based on the ASP rate from two quarters prior instead of the current rate.[8] Even when rates are updated accurately, research shows that in just over a third of cases, clinics are inadequately reimbursed.[9] Since the medications are typically administered in office settings, there are associated fixed costs such as complex drug storage, staffing, shipping, inventory management, compliance with drug compounding protocols, drug preparation, acquisition, and administration. These costs are unique to physician administered drugs and add to the typical costs associated with running a physician practice such as information technology, patient debt, prior authorization, and other administrative burdens.[10] As a result, physician practices that utilize these drugs, commonly oncology practices, struggle to remain financially viable.[6,10] Because larger health systems have more patients, the fixed cost per patient is lower which allows the ASP plus payment system to cover the costs. Further, larger health systems are often able to negotiate lower initial drug prices. However, for smaller community-based practices, the combination of the lower patient load with a less powerful negotiation position often leads to the ASP plus payment being inadequate to cover the actual costs of delivering medication therapy.[9] This system also places the financial risk on the purchasing entity instead of the pharmacy or payer as is more common with non-physician-administered drugs, such as Part D drugs.[10]
In response to criticisms of the buy-and-bill model, some experts suggest moving toward value-based payment models, which are sometimes referred to as "financial risk-based" or "outcomes-

based," but rely on associating a drug's performance with its cost.[11] For example, if a drug performs well and treats a disease effectively, the price may go up, but if a drug does not effectively treat the disease, then the price may decrease. Historically, this model has been challenging, as the collection of data faces many obstacles. While technology enables real-time patient data collection, making data more readily available, there are concerns around reliability, accessibility, operations, and data privacy that must be addressed before this pricing model can be successfully implemented.[11] These types of models are especially attractive to entities that purchase larger quantities of drugs, where contractual agreements include full or partial reimbursement to the purchaser if predetermined outcomes are not met.[11] For example, the University of Pittsburgh Medical Center (UPMC) entered a contract with AstraZeneca for the drug Brilinta, a blood thinner used to lower the risk of heart attack and stroke, in which payment depended on outcome and the health system was able to reduce the monthly cost for UPMC patients from $40 per month to just $10.[12]

Although outcomes-based payment models are relatively rare, with only a quarter of pharmaceutical executives reporting usage, reports have shown that a majority of pharmaceutical company and PBM directors seem to be open to entering into these types of models.[11] However, research suggests that while cost savings for consumers can result from these types of models, value-based drug pricing is often tied to significant price instability, which can result in less effective and/or lower long-term cost savings.[13] Further, there is often debate as to how "value" should best be defined with concerns about equity, especially for those with a disability or chronic illness. When drugs are not curative, the maximum health utility formula for patients who take it can be lessened and as a result the value of the drug can be artificially lowered.[14] Further, this type of drug pricing model may place smaller clinics and offices at a disadvantage as they may have less resources to track patient outcomes and lower bargaining power when negotiating with manufacturers.

While not applicable for all types of drugs, the so-called "mortgage" payment model could be utilized when the quantity and cost of a drug is appropriate. When a drug is extremely high cost, does not have direct competition, and is not widespread in its usage, purchasers may be able to utilize a mortgage buying model.[14,15] This model allows for the upfront costs to be spread over time and is relatively common with about half of surveyed pharmaceutical leaders reporting that they used this model at least once. Within this model the drug purchaser and drug manufacturer enter into an agreed upon payment schedule and/or financial payments when a treatment milestone is reached.[15] Proponents of this type of model argue that its implementation allows the payer to spread costs and potentially reduce downstream costs. However, critics of the mortgage model argue that it may not actually reduce any costs and that the tracking of milestones to trigger payment may place additional administrative burdens on physicians and their offices or practices.[15]

IRA NEGOTIATION

While none of these payment models are a perfect fit, research has shown that drug payment and reductions in cost are top issues for the majority of Americans. Polls show that 77 percent of Americans across political party affiliation support an increased focus on drug pricing affordability. Further, nine out of ten Americans support the need for federal legislative action to reduce the cost of drugs, with three-quarters supporting legislation limiting pharmaceutical company influence. Although many voters currently report a worsening in drug price affordability, the issue itself is not new. The IRA was enacted in 2022, and targeted a number of affordability issues, including drug pricing. The law included out-of-pocket spending caps, vaccine coverage for Medicare and/or Medicaid beneficiaries, and a requirement that if the price of a selected medication rises faster than the overall rate of inflation, the manufacturer is required to pay rebates to the Federal government.

A particularly impactful change included in the law was the allowance for the Centers for Medicare & Medicaid Services (CMS) to directly negotiate the prices of high expenditure drugs.[16] To be eligible for CMS selection for negotiation, drugs must be single source and not have a biosimilar/generic alternative. Negotiated prices are set as the Maximum Fair Price (MFP), and the medication must be available to all Medicare beneficiaries at, or below, the set MFP. Further, each year CMS is required to publish explanations of MFPs, called initial price applicability year (IPAY), which allows for greater insight to the negotiation process and what data points CMS is using.[17] IPAY summaries have been released for the first two rounds of negotiations and demonstrate that CMS seems to be relying on manufacturer-provided data, clinical evidence, and public comment to complete structured and evidence-heavy reviews.[17,18]

Currently, private payers are not required to match these prices for their beneficiaries, with experts divided on whether they will. Although some experts posit that MFPs may eventually serve as a benchmark for private payers which could lower the prices of those drugs, others advocate that the MFPs should be legislatively required to be honored by private payers as well.[19] While it will take time to see if private payers choose to incorporate Medicare negotiated MFPs, there may be some level of impact as research shows that around two percent of those with private plans are currently taking at least one of the drugs included in the initial round of negotiations.[19]

The initial list of 10 Part D drugs selected for negotiation was released in late 2023 with negotiations occurring in 2024 and the negotiated MFPs taking effect January 1, 2026. Negotiation for these 10 initial drugs resulted in an average savings of about 60 percent and largely targeted drugs that treated conditions such as diabetes, cancer, and heart diseases.[16,17] For example, Imbruvica, a drug used to treat blood cancers, saw a 38 percent reduction in cost while Januvia, a drug used to treat diabetes, heart failure, and kidney disease, saw a 79 percent cost reduction.[20] The second round of negotiations occurred in 2025 and included 15 Part D drugs, with the prices scheduled to go into effect at the start of 2027. Negotiated prices for the second round of 15 Part D drugs boasted savings as high as 85 percent for consumers.[16,17] For example, Janumet, a medication used in the treatment of Type 2 Diabetes, saw the greatest cost reduction with a negotiated price of $80 for a 30-day supply, down from a list price of $526. Further, although the smallest cost reduction was seen by the drug Calquence, which is used to treat types of blood cancer, this drug still had a cost decrease of 40 percent.[16] Notably, this round of negotiations also targeted popular GLP-1 medications Ozempic, Rybelsus, and Wegovy, resulting in a 71 percent decrease from the previous list prices.[17] The third cycle of drugs, currently being negotiated, includes for the first time Medicare Part B drugs. These prices will go into effect in January 2028 and include six drugs covered under Part B along with nine Part D covered drugs.[17] While MFPs have not been released for the drugs currently under negotiation, the first two cycles have resulted in an average cost reduction just over 60 percent. Although higher cost drugs, often those covered in Part B, have seen slightly lower cost reductions, if the current round of negotiation follows suit of the first two, selected Part B drugs may see a reduction between 40 and 60 percent. Full details on the drugs included in all rounds of negotiation can be found in Appendix A.

IMPACT OF IRA NEGOTIATION

Although the initial round of negotiated prices has only been in effect since the start of 2026, and Part B medications were not included in the first two rounds, some physicians and experts have begun to voice concerns about the potential impact of the negotiated MFP, especially on smaller/community-based physician practices. While the negotiated Part D prices are unlikely to have any major impact on physicians or practices, it is possible that the forthcoming Part B negotiated prices may.[10] For Part B drugs selected as a part of Medicare negotiation, physician payment will shift from ASP+6 to MFP+6, or 106 percent of the MFP. As a result of this shift, it is

likely that physician payment for the drugs will decrease. For example, should a drug's ASP be $1,000, the ASP+6 reimbursement for the physician would be $1,060. If the drug's negotiated MFP were to be set at the average cost reduction, 62 percent, the new price would be $380. Based on the updated physician payment model of MFP+6, the physician/practice would receive about $403. While the acquisition cost for the practice should also decrease, this drop in payment could be significantly problematic, especially for smaller community-based practices that do not have as much overhead capital to cover costs associated with elements like storage, staffing, or administration or if physician offices are required to pay the non-MFP cost for the drug upfront and be reimbursed later.[10] While these changes are only guaranteed to occur for medications selected for negotiation and only for Medicare beneficiaries, it is possible that private payers will seek to negotiate drug prices based on the publicly available IRA negotiated MFPs, potentially leading to further issues for physicians related to private payer rates.[19]

While many experts do believe that the lower negotiated MFPs will benefit physician practices that purchase the drugs as they may lead to lower costs, physicians who practice in these settings, especially smaller community-based practices, have voiced significant concern. Estimates anticipate reductions of approximately 64 percent, or as much as $19 billion, in Medicare add-on payments and an anticipated a 13-21 percent reduction in Medicare Advantage (MA) add-on payments for physicians/providers who administer negotiated oncology/hematology drugs. This means that if an oncology/hematology practice currently receives $100,000 in payment for these high-cost drugs, after the implementation, assuming the average 64 percent reduction, this could be reduced to as little as $19,000 from Medicare and MA. As previously mentioned, larger hospitals and health systems are likely better suited to be able to manage these payment and cost changes, however it is anticipated that smaller practices and/or hospitals may struggle significantly. The closures of these community clinics, hospitals, or physician practices are likely to exacerbate health disparities and create or expand care deserts for patients.[10]

Although the impacts of these negotiations on patients have yet to be seen, some experts believe that the negotiations have the potential to save patients money and may improve coverage. Some research has begun to show, however, that patient out-of-pocket (OOP) savings are marginal, if they are present at all. Differences in Part D plans will likely impact how much, or if, patients save money. Beneficiaries whose OOP cost is a set copayment will likely not save money, or not as much money, as beneficiaries whose OOP costs are calculated as a percentage of the cost.[21] While the Medicare plan would save money by paying the MFP instead of the non-negotiated price, the savings may not reach the patient. Further, since the IRA MFP prices are only required to be honored for Medicare beneficiaries, it is unknown if these prices would carry over to those with other forms of health insurance. Should payers choose to continue to use non-negotiated prices, it is possible that beneficiaries of non-Medicare plans may see no net benefit to the IRA negotiated prices. However, it is also possible that public payers will choose to rely on the negotiated MFPs, which could result in significant cost savings for both companies and patients. While initial research does support this prediction that patients may have reduced OOP spending, the full impact of the IRA on patient costs has yet to be seen as only 10 drug MFPs have been implemented. Further, since the IRA requires Part D plans to cover all the drugs selected for negotiation, preliminary results suggest that coverage has improved among Part D plans.

While some findings anticipate improvements for patients, others voice substantial concern regarding the potential for unintended consequences. Research shows that overall pharmaceutical gross margins have decreased as a result of the IRA negotiations. Since these funds are the primary source of funding for research and development (R&D), some studies have shown a link between decreases in gross margins and overall innovation, with one study projecting internal rates of return on negotiated drugs dropping between three and five percent. While this may not seem like a

substantial decrease, the authors argue that over the long-term drug companies may redirect funding away from R&D for products that are more likely be negotiated, potentially limiting innovation in this area.[22] However, since these reductions in internal revenue are still relatively small, there is no guarantee that R&D will be limited in practice given that experts posit that there is not a direct correlation between successful innovation and R&D dollars.[23] Further, there is concern that payers and/or PBMs may increase utilization management as a method to control costs and maintain formularies.[24] This could result in not only delays in patient access, but also to increased cost and time for physicians to combat the utilization management.

AMA POLICY AND ADVOCACY

The AMA has a relatively large body of policy related to ensuring that prescription medications are available and accessible to patients in a manner that is economically sustainable for physician practices. Policies H-110.980 and H-110.987 outline efforts to ensure that medications are affordable for patients through process transparency, limits on patents, legislative/regulatory changes, and limits on anticompetitive practices. Policy H-110.980 also ensures that price indexes should be multifaceted and ensure for patient access and limited burdens on physician practices. Policy H-110.956 works to ensure that payment to physician practices for biosimilars and biologic drugs is fair and timely. Policies D-110.987, D-120.988, and D-120.934 target PBM practices that negatively impact patients and physicians. Finally, Policy D-110.987 supports active PBM regulation and efforts to ensure transparency throughout PBMs and their coverage determinations.

To address Medicare drug price negotiation specifically, Policy D-330.954 indicates AMA support for federal legislation that allows the Department of Health and Human Services to negotiate contractual agreements with manufacturers for covered Part D medications. This policy also supports the elimination of Medicare prohibition on drug price negotiation, which was accomplished by the IRA, and directs the AMA to prioritize support for CMS negotiation of all applicable and covered medications. Policy D-110.980, the motivating policy for this report, outlines the need for study of the IRA negotiation on physician practices in order to guide future advocacy efforts.

The AMA also has pursued robust advocacy efforts to lower drug costs and ensure payment to physicians is reasonable. The AMA has an ongoing grassroots campaign, TruthinRx, designed to support patients and physicians in understanding and fighting the lack of transparency and subsequent high drug prices. In addition to this campaign, the AMA has continually supported PBM and drug pricing reform to legislators as well as provided guidance regarding regulation of drug pricing in Medicare to both CMS and the Department of Health and Human Services. The AMA has provided testimony to the House of Representatives Energy and Commerce Subcommittee on Health and Ways and Means Subcommittee on Health related to lowering health care pricing for Americans. Finally, the AMA has voiced concern to Congress and CMS related to issues surrounding physician drug reimbursement and the need for improvement to payment rates.

DISCUSSION

The cost of prescription medications, especially those administered in-office, is a major issue in American healthcare and one that the IRA was designed in part to address. The opacity of the current drug pricing system, paired with increasing drug prices, has further complicated the issue. Historically, a combination of PBMs, payers, and drug manufactures have negotiated the price of prescription drugs. However, with passage of the IRA and its Medicare drug price negotiation, this system now also includes the federal government. The IRA allows for CMS to negotiate with drug manufacturers to set an MFP for each of the selected drugs. In 2024, this included 10 Part D drugs,

in 2025 negotiations included 15 Part D drugs, and in 2026 includes six Part B drugs. Since the negotiated prices have not been released, it is still to be seen if Part B drugs see similar price reductions to the previously negotiated Part D drugs.

Currently, Part B drugs are paid based on a "buy-and-bill" model, meaning the purchasing entity buys and administers the drug and then is later paid for the cost. For Medicare, the payment rate for these physician-administered medications is ASP+6, or ASP+8 for some biosimilars. However, after sequestration, these payment rates can be as low as ASP+4.3. This payment system can be particularly problematic for smaller physician-owned/community practices as the payment rates do not cover the full cost of necessary fixed costs like staffing, administration, and procurement. While the aforementioned reductions in cost from the IRA may help in reducing patient costs, there is significant concern that practices, patient access, and/or drug innovation may be negatively impacted.

When the IRA negotiated Part B drug MFPs go into effect, the payment system will transition from ASP+6 to MFP+6. Estimates suggest that this could have significant impacts on the payments made to practices, especially those that administer the oncology/hematology drugs included in the negotiation schedule. While the cost of purchasing the drug should decrease, the aforementioned fixed costs for these practices may not dissipate at the same rate. Since payment is calculated as a percentage of MFP, the cushion designed to cover fixed costs will decrease at a rate that may not be sustainable for practices. While larger hospitals and health systems may be able to cover these costs and often face lower fixed costs due to higher patient volume, smaller community based/physician-owned practices are less likely to be able to. Experts voice concern that this change in payment may result in the closure of these smaller practices which would have detrimental impacts on patient access.

Due to the recency of its implementation, the full impact of the IRA Medicare drug price negotiation has yet to be seen; however, some initial steps can be taken now to maintain physician practice viability and patient access. In order to ensure that physician practices are able to acquire medications needed for patients, it will be essential to ensure that any drug price negotiation, and related price caps, should be set and implemented in a manner that does not require physicians or practices to "front" the related costs. Supporting alternatives to the traditional buy-and-bill model that ensures payment covers all associated costs, including acquisition, inventory, storage, administration, and associated clinical services, while also maintaining administrative simplicity and patient access and affordability will be essential. As the IRA Medicare negotiation MFPs are put into place the full impact will become clearer and additional, more specific action steps may be identifiable, thus ongoing monitoring is also important.

To address these potential concerns, the Council recommends the adoption of new policy that will ensure practice viability, administrative simplicity, timely access, transparency for negotiated drug prices, and that decreases in price are commiserate with acquisition cost. The Council notes that this policy advocates for adequate payment based on actual acquisition cost, and thus physicians/physician practices would be protected during a transition period between ASP and MFP calculated reimbursements. Further, the Council recommends amendments to Policy D-110.980 to reflect the completion of this report as well as ensure continued monitoring of this issue. The amendments also retain the portion of the policy that ensure advocacy efforts will balance sustainability of practices and drug innovation with patient access and affordability, and guarantee that the policy is applicable to any Medicare drug price negotiation, not just the negotiation related to the IRA specifically. Finally, to work to secure fair and timely physician payment the Council recommends the reaffirmation of Policy H-110.956 which focuses on fair and timely biosimilar and biologic drug payment.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That our American Medical Association (AMA) advocate that Medicare prescription drug price negotiation and associated maximum fair price effectuation, for all Medicare-covered drugs, are implemented in a manner that minimizes financial risk and cash-flow burdens for physicians or community practices to front costs and supports the following:
   a. Practices' actual acquisition costs decrease commensurate with reductions in drug prices;
   b. Any drug payment covers the cost of acquisition, storage, inventory, drug administration, and any other necessary related clinical service(s);
   c. Administrative simplicity for physicians and their practices;
   d. Timely and affordable patient access to medications prescribed by their physician; and
   e. Drug price transparency for patients, physicians, and non-physician providers (New HOD Policy)

2. That our AMA amend Policy D-110.980 to read as follows:

   ~~Study on~~ Impact of ~~Inflation Reduction Act~~ Medicare Drug Price Negotiation on ~~Oncology, Other~~ Physician-Owned Practices

   ~~1. Our American Medical Association will work with relevant stakeholders to conduct a comprehensive study on the impact of the Inflation Reduction Act's (IRA) drug price negotiation provisions, particularly for drugs covered under Medicare Part B and physician-administered drugs due to concerns it could jeopardize patient access to critical therapies as the IRA's potential for reimbursement reductions may lead to less availability of these medications in smaller, community-based clinics where a significant amount of care is provided.~~

   ~~2.~~ 1. Our AMA will ~~specifically evaluate the potential~~ report on the impact of the Medicare Part B drug price negotiation on the availability of Medicare Part B medications to patients and the sustainability of independent physician practices at A-28 ~~a particular focus on oncology practices~~.

   ~~3.~~ 2. Our AMA encourages ~~will consider using the findings of the study on the impact of the Inflation Reduction Act (IRA) drug price negotiation provisions on the sustainability of community based practices to inform its advocacy efforts to ensure that~~ any future drug pricing policies to balance patient affordability and access, with the stability of physician practices~~, patient access,~~ and the continued advancement of drug innovation. (Modify Current HOD Policy)

3. That our AMA reaffirm policy H-110.956 which ensures fair and timely payment for physicians and physician practices for biologic and biosimilar drugs. (Reaffirm HOD Policy)

Fiscal Note: Minimal

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Council on Medical Service Report 2-I-26
The Impact of the Inflation Reduction Act on Physician Practices
Policy Appendix

Additional Mechanisms to Address High and Escalating Pharmaceutical Prices H-110.980

1. Our American Medical Association 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 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% 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% 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; Reaffirmed: CMS Rep. 04, I-24; Reaffirmed: CMS Rep. 06, A-25)

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987
1. Our 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-19Reaffirmed: CMS Rep. 6, I-20; Reaffirmed: CSAPH Rep. 02, I-24; Reaffirmed: CMS Rep. 06, A-25; Reaffirmed: CMS Rep. 04, I-25)

Inappropriate Actions by Pharmacies and Pharmacy Benefit Managers D-120.988
Our AMA, 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 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)

Prescription Drug Prices and Medicare D-330.954
1. Our American Medical Association 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-11; Appended: 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)

Study on Impact of Inflation Reduction Act on Oncology, Other Physician Practices D-110.980
1. Our American Medical Association will work with relevant stakeholders to conduct a comprehensive study on the impact of the Inflation Reduction Act's (IRA) drug price negotiation provisions, particularly for drugs covered under Medicare Part B and physician-administered drugs due to concerns it could jeopardize patient access to critical therapies as the IRA's potential for reimbursement reductions may lead to less availability of these medications in smaller, community-based clinics where a significant amount of care is provided.
2. Our AMA will specifically evaluate the potential impact of the Inflation Reduction Act on the sustainability of community-based physician practices, with a particular focus on oncology practices.
3. Our AMA will consider using the findings of the study on the impact of the Inflation Reduction Act (IRA) drug price negotiation provisions on the sustainability of community based practices to inform its advocacy efforts to ensure that any future drug pricing policies balance patient affordability with the stability of physician practices, patient access, and the continued advancement of drug innovation. (Res. 234, I-25)

Payment for Biosimilars H-110.956
1. Our American Medical Association supports the revision of the Average Sales Price (ASP) calculation of biologic/biosimilar drugs to more accurately represent the cost of drugs for the physician practice.
2. Our AMA encourages public and private payers to implement comprehensive payment structures that allow for fair and timely payment for biologic/biosimilar drugs that:
a. Maintain patient access to biologic/biosimilar drugs prescribed by their physician consistent with AMA Policy H-100.940;
b. Account for physician/practice administrative and acquisition costs, including but not limited to, obtaining, storing, and administering the drug through a payment rate that covers these costs;
c. Incentivize the use of biosimilars when safe, clinically appropriate, and agreed upon by the patient and physician; and
d. Ensure that patient out-of-pocket costs are affordable. (CMS Rep. 04, I-25)

Appendix A
Medicare Negotiation Drugs

Drug Name	Manufacturer	Common Uses	Negotiated MFP	List Price	Percent Discount	Start Date
Januvia	Merck & Co., Inc.	Type 2 Diabetes	$113	$527	79%	2026
NovoLog/ Fiasp	Novo Nordisk	Diabetes	$119	$495	76%	2026
Farxiga	AstraZeneca	Type 2 Diabetes, Heart Failure Chronic Kidney Disease	$178	$556	68%	2026
Enbrel	Amgen Inc.	Rheumatoid & Psoriatic Arthritis, Plaque Psoriasis, Ankylosing Spondylitis	$2,355	$7,106	67%	2026
Jardiance	Boehringer Ingelheim & Eli Lilly	Type 2 Diabetes, Heart Failure Chronic Kidney Disease	$197	$573	66%	2026
Stelara	Janssen Biotech Inc.	Plaque Psoriasis, Psoriatic Arthritis, Crohn's Disease, Ulcerative Colitis	$4,695	$13,836	66%	2026
Xarelto	Bayer and Johnson & Johnson's Janssen	Blood Clots (DVT, PE, and AFib stroke prevention)	$197	$517	62%	2026
Eliquis	Bristol Myers Squibb & Pfizer	Blood Clots (DVT, PE, and AFib stroke prevention)	$231	$521	56%	2026
Entresto	Novartis Pharmaceuticals	Heart Failure	$295	$628	53%	2026
Imbruvica	Pharmacyclics LLC & Janssen Biotech Inc.	Blood Cancers and Autoimmune Conditions (CLL, SLL, WM, cGVHD)	$9,319	$14,934	38%	2026
Ozempic, Rybelsus, Wegovy	Novo Nordisk Inc.	Type 2 diabetes, Cardiovascular disease and obesity/ overweight	$274	$959	71%	2027
Trelegy Ellipta	GlaxoSmithKline Intellectual Property Development Ltd.	Asthma; Chronic obstructive pulmonary disease	$175	$654	73%	2027
Xtandi	Astellas Pharma US, Inc.	Prostate Cancer	$7,004	$13,480	48%	2027
Pomalyst	Bristol-Myers Squibb Company	Kaposi sarcoma; Multiple myeloma	$8,650	$21,744	60%	2027
Ofev	Boehringer Ingelheim Pharmaceuticals	Idiopathic pulmonary fibrosis	$6,350	$12,622	50%	2027
Ibrance	Pfizer	Breast Cancer	$7,871	$15,741	50%	2027
Linzess	AbbVie	Chronic idiopathic constipation; Irritable bowel syndrome	$136	$539	75%	2027
Calquence	AstraZeneca UK Limited	Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma	$8,600	$14,228	40%	2027
Austedo; XR	Teva Branded Pharmaceutical Products R&D LLC	Chorea in Huntington's disease; Tardive dyskinesia	$4,093	$6,623	38%	2027

Drug Name	Manufacturer	Common Uses	Negotiated MFP	List Price	Percent Discount	Start Date
Breo Ellipta	GlaxoSmithKline Intellectual Property Development Ltd.	Asthma; Chronic obstructive pulmonary disease	$67	$397	83%	2027
Xifaxan	Salix Pharmaceuticals Inc	Hepatic encephalopathy; irritable bowel syndrome	$1,000	$2,696	63%	2027
Vraylar	AbbVie	Bipolar I; Major depressive disorder; Schizophrenia	$770	$1.376	44%	2027
Tradjenta	Boehringer Ingelheim Pharmaceuticals	Type 2 Diabetes	$78	$488	84%	2027
Janumet; XR	Merck Sharp & Dohme LLC	Type 2 Diabetes	$80	$526	85%	2027
Otezla; Otezla XR	Amgen	Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis	$1,650	$4,722	65%	2027
Trulicity	Amgen	Type 2 diabetes; cardiovascular disease	*Currently under negotiation*			2028
Biktarvy	Gilead Sciences	HIV type 1 infection	*Currently under negotiation*			2028
Orencia*	Bristol Myers Squibb	Psoriatic & Rheumatoid arthritis;	*Currently under negotiation*			2028
Cosentyx*	Novartis	Plaque psoriasis; Psoriatic arthritis	*Currently under negotiation*			2028
Erleada	Janssen Biotech Inc. (Johnson & Johnson)	Prostate Cancer	*Currently under negotiation*			2028
Kisqali	Novartis	Breast Cancer	*Currently under negotiation*			2028
Entyvio*	Takeda Pharmaceutical Company Limited	Crohn's Disease, Ulcerative Colitis	*Currently under negotiation*			2028
Verzenio	Eli Lilly	Breast Cancer	*Currently under negotiation*			2028
Botox*	Allergan Aesthetics (AbbVie)	Chronic migraine; Overactive bladder; Spasticity; movement disorders	*Currently under negotiation*			2028
Lenvima	Eisai Co. and Merck & Co	Thyroid cancer; Endometrial cancer; Liver cancer; Kidney cancer	*Currently under negotiation*			2028
Xolair*	Genentech & Novartis Pharmaceuticals	Asthma; Chronic spontaneous urticaria	*Currently under negotiation*			2028
Rexulti	Otsuka Pharmaceutical and Lundbeck	Major depressive disorder; Schizophrenia; Agitation associated with dementia due to Alzheimer's disease	*Currently under negotiation*			2028
Xeljanz; Xeljanz XR	Pfizer	Psoriatic arthritis; Rheumatoid arthritis; Ulcerative colitis	*Currently under negotiation*			2028
Anoro Ellipta	GlaxoSmithKline	Chronic obstructive pulmonary disease	*Currently under negotiation*			2028
Cimzia*	UCB, Inc. (Union Chimique Belge)	Crohn's disease; Plaque psoriasis; Psoriatic & Rheumatoid arthritis;	*Currently under negotiation*			2028

List price is based on the previous calendar year's price | Start date begins on the first day of the year
**Indicates the medication may be covered under Medicare Part B (all other medications covered under Medicare Part D)*