REPORT 04 OF THE COUNCIL ON MEDICAL SERVICE (A-22)
Parameters of Medicare Drug Price Negotiation
(Alternate Resolution 113-N-21)
(Reference Committee A)

EXECUTIVE SUMMARY

At the November 2021 Special Meeting, the House of Delegates referred the second resolve of Alternate Resolution 113, as well as an amendment proffered during consideration of Alternate Resolution 113. The second resolve of Alternate Resolution 113 asked that our American Medical Association (AMA) reaffirm Policy H-110.980, which outlines principles guiding the use of international price indices and averages in determining the price of and payment for drugs, including those covered in Medicare Parts B and D. In contrast, the amendment to Alternate Resolution 113 opposed reaffirmation of Policy H-110.980, and instead asked our AMA to advocate for Medicare drug price negotiation to reduce prices paid by Medicare for medications in Part B and Part D and physician acquisition costs for medications in Part B.

In addition, the amendment proposed to amend Policy H-110.980[2(a)] by addition and deletion to read as follows:

> 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 exclude countries that have single-payer health systems and use price controls;~~
>
> a. Any international drug price index used to determine Medicare Part D drug prices should be based on a reasonable percentage of the drug's volume weighted net average price in at least six large western industrialized nations;

The Council understands that the introduction of original Resolution 113-N-21, as well as amendments made during consideration of Alternate Resolution 113-N-21, stemmed from strong support in the House of Delegates for the AMA to advocate on the issue of prescription drug pricing more actively and strongly. The AMA has been "at the table," advocating AMA policy on drug pricing with Congress via meetings with legislators and their staff as well as letters and other communications. The AMA also has engaged the Administration through comment letters in response to regulatory activity as well as direct interactions and meetings. Finally, the AMA and members of the Federation have similarly advocated at the state level.

The AMA's advocacy priorities have been to preserve patient access to necessary medications, and limit burdens on and protect physician practices. While recent legislative and regulatory proposals incorporating international drug price averages and/or indices in Medicare drug pricing have not met these and other important thresholds outlined in Policy H-110.980, the Council believes that is not a reason to change AMA policy. AMA policy needs to be able to proactively respond to the more likely path forward on this issue—through regulation, targeting Medicare Part B drug payment—and needs to be consistent across not only all of Medicare, but across all health plans. The Council does, however, see promise in testing the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent. and predictable out-of-pocket costs for select prescription drugs.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 04-A-22

Subject: Parameters of Medicare Drug Price Negotiation (Alternate Resolution 113-N-21)

Presented by: Asa C. Lockhart, MD, MBA, Chair

Referred to: Reference Committee A

At the November 2021 Special Meeting, the House of Delegates referred the second resolve of Alternate Resolution 113, Supporting Medicare Drug Price Negotiation, as well as an amendment proffered during consideration of Alternate Resolution 113. The second resolve of Alternate Resolution 113 asked that our American Medical Association (AMA) reaffirm Policy H-110.980, Additional Mechanisms to Address High and Escalating Pharmaceutical Prices, which outlines principles guiding the use of international price indices and averages in determining the price of and payment for drugs, including those covered in Medicare Parts B and D. In contrast, the amendment to Alternate Resolution 113 opposed reaffirmation of Policy H-110.980, and instead asked our AMA to advocate for Medicare drug price negotiation to reduce prices paid by Medicare for medications in Part B and Part D and physician acquisition costs for medications in Part B.

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This report provides background on the impacts of high and escalating prescription drug prices and costs; outlines proposals to leverage an international price index in Medicare Parts B and D; summarizes significant AMA policy and advocacy on prescription drug pricing; and presents policy recommendations.

BACKGROUND

The Council understands that the intent of the amendments proposed to Policy H-110.980 was to take significant and concrete action to lower Medicare Parts D and B drug prices and associated patient cost-sharing. Some recent legislative proposals that incorporate international price indices and averages in Medicare drug price negotiation, addressed by Policy H-110.980, would not only extend negotiated prices to Medicare and Medicare Advantage, but also to private health insurance unless the insurer opts out. The Council agrees wholeheartedly that unsustainably high and

escalating prescription drug prices and costs constitute a consistent and paramount concern for patients and their physicians, employers, states, and the federal government, underpinning the introduction of legislation, or promulgation of regulations, on both the federal and state levels.

Spending on retail prescription drugs totaled $348.4 billion in 2020, accounting for eight percent of total health spending.[1] Other estimates suggest that spending on prescription drugs as a percent of total health spending is greater when other factors, including the non-retail drug markets and gross profits of other stakeholders involved in drug distribution, payment, and reimbursement are included. Significantly, spending on specialty drugs now constitutes more than one-half of drug spending (53 percent).[2] The most recent National Health Expenditure data showed that retail prescription drug spending was estimated to have increased by three percent in 2020. Drivers behind the lower rate of growth in prescription drug spending include a slower overall utilization of prescription drugs and a higher use of coupons, which resulted in a reduction in out-of-pocket expenditures.[3]

Approximately 6.3 billion prescriptions were dispensed in the United States (US) in 2020, 90 percent of which were dispensed as generics.[4] The retail price differentials between specialty, brand-name and generic drugs are noteworthy. Examining the retail prices of drugs widely used by older Americans in 2020—most of whom are Medicare beneficiaries who would be impacted by the proposed, referred amendments to Policy H-110.980—the average annual retail price of therapy with specialty drugs was $84,442, dropping to $6,604 for brand-name drugs, both dwarfing the annual price of therapy for generics.[5]

In Medicare, patients face different cost-sharing for prescription drugs, depending on whether the drugs are covered under Medicare Part B or D. In general, Medicare Part B covers prescription drugs that typically are not self-administered; Part B drugs can be provided in a physician's office as part of their service. In addition, Part B covers limited outpatient prescription drugs, including certain oral cancer drugs. Most other retail prescription drugs for medically accepted indications that are not covered by other parts of Medicare fall under Medicare Part D. Within Medicare Part D, the typical formulary design consists of five tiers: preferred generics, generics, preferred brands, non-preferred drugs, and specialty drugs. Within these tiers, among all stand-alone Medicare Part D prescription drug plans, median standard cost sharing in 2022 is $0 for preferred generics, $5 for generics, $42 for preferred brands, 40 percent coinsurance for non-preferred drugs, and 25 percent coinsurance for specialty drugs.[6] For prescription drugs covered under Medicare Part B, for traditional Medicare beneficiaries without a supplemental plan, cost-sharing for covered Part B drugs equates to 20 percent of the Medicare-approved amount after paying any applicable Part B deductible, with no out-of-pocket limit.[7]

Overall, in the Medicare program, between 2007 and 2019, Part D program spending grew by an average annual rate of 5.5 percent and amounted to $88.4 billion in 2019. Premiums paid by Part D enrollees for basic benefits (not including low-income subsidy enrollees) amounted to $13.9 billion in 2019, a decrease of 2.1 percent from 2018, before which premiums paid by enrollees had been growing by an average of 12 percent per year.[8] Under Medicare Part B, total drug spending amounted to $37 billion in 2019, with the top 50 drugs ranked by total spending accounting for 80 percent of total Medicare Part B drug spending.[9]

Relevant to legislative proposals that extend drug prices achieved by Medicare drug price negotiation to private health insurance, employer-sponsored health plans as well as health plans sold in the individual market have also had to absorb the higher costs of prescription drugs. Higher costs of prescription drugs often translate to higher premiums, higher prescription drug cost-sharing, and additional prescription drug tiers to accommodate the higher costs of specialty and

certain generic drugs. In 2021, 88 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs.[10]

Overall, patient out-of-pocket costs for retail prescription drugs reached $61 billion in 2020, with non-retail out-of-pocket costs amounting to $16 billion. Across Medicare, Medicaid and commercial health plans, eight percent of patients pay more than $500 per year out-of-pocket for prescriptions. Medicare beneficiaries have a notably higher incidence rate of high out-of-pocket expenses for prescription drugs, with 17 percent paying more than $500 out-of-pocket.[11]

The higher costs of prescription drugs impact patient health outcomes and physician practices. Ultimately, prescription drug costs can impact the ability of physicians to place their patients on the best treatment regimen, due to the regimen being unaffordable for the patient, or being subject to coverage limitations and restrictions, as well as utilization management requirements, by the patient's health plan. In the worst-case scenario, patients entirely forgo necessary treatments involving drugs and biologics due to their high cost.

Increasing patient cost-sharing is associated with declines in medication adherence, which in turn can lead to poorer health outcomes. Among those currently taking prescription drugs, approximately a quarter of adults and seniors have reported difficulties in affording their prescription drugs. Approximately 30 percent of all adults have reported not taking their medications as prescribed at some point in the past year due to cost. Drilling down further, 16 percent of adults have not filled a prescription in the past year due to cost, 22 percent chose to take an over-the-counter medication instead, and 13 percent cut pills in half or skipped doses.[12]

Notably, out-of-pocket costs for prescription drugs are linked to the rate at which patients newly prescribed a drug either do not pick up their prescription or switch to another product. Many health plans have a formulary design with fixed copays for brand drugs of less than $30 for preferred products, with a rate of abandonment of 12 percent or less. For non-preferred brand drugs with a copay of $75, the rate of abandonment is 26 percent or higher. Fifty-six percent of prescriptions with a final cost of over $500 are not picked up by patients.[13]

LEVERAGING AN INTERNATIONAL PRICE INDEX IN MEDICARE PARTS B AND D

Proposals previously put forward by the Trump Administration and members of Congress attempted to lower US drug costs by tying them to international prices, and/or would have used an average of international prices, or an international reference price, to help define whether a price of a drug is excessive. While significant legislation addressing drug pricing has passed in the House of Representatives, negotiations have stalled following House passage. The Biden Administration has also stated that it will not implement a model utilizing an international price index in Medicare Part B without further rulemaking.

Current Status of Prescription Drug Price Negotiation in Medicare Parts D and B

The "noninterference clause" in the Medicare Modernization Act of 2003 (MMA) states that the Secretary of Health and Human Services (HHS) "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Instead, participating Part D plans compete with each other based on plan premiums, cost-sharing and other features, which provides an incentive to contain prescription drug spending. To contain spending, Part D plans not only establish formularies, implement utilization management measures, and encourage beneficiaries to use generic and less-expensive brand-name drugs, but are

required under the MMA to provide plan enrollees access to negotiated drug prices. Similar to how drug prices are determined in other commercial plans available in the employer, individual and small-group markets, these prices are achieved through direct negotiation with pharmaceutical companies to obtain rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

In efforts to lower drug prices and patient out-of-pocket costs in Medicare Part D, multiple bills have been introduced in Congress to enable and/or require the Secretary of HHS to negotiate covered Part D drug prices on behalf of Medicare beneficiaries. However, historically, the Congressional Budget Office (CBO), as well as Centers for Medicare & Medicaid Services (CMS) actuaries, have estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D.[14,15]

In fact, CBO has previously acknowledged that, in order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions. In the absence of such authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited."[16] CMS actuaries have concurred, stating "the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of this negotiation. Manufacturers would have little to gain by offering rebates that are not linked to a preferred position of their products, and we assume that they will be unwilling to do so."[17]

The Council underscores that recent legislative and regulatory proposals that aimed to incorporate international drug price indices or averages in Medicare have targeted Part B in addition to Part D; therefore, it is imperative to understand how prices of Part B drugs are determined as well. Under current law, the Secretary of HHS also does not negotiate prices of and payment for Part B drugs. Instead, Medicare reimburses physicians and hospitals for the cost of Part B drugs at a rate tied to the average sales price (ASP) for all purchasers—including those that receive large discounts for prompt payment and high-volume purchases—plus a percentage of the ASP. Accordingly, any proposal to change how Part B drugs are priced—including the incorporation of international drug price indices and/or averages—also could significantly change how and the level at which physicians are paid for Part B drugs.

Recent Significant Legislative Developments

Legislation preceding Build Back Better, H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, which passed the House of Representatives during the 116th Congress, would have opened the door to the Secretary of HHS to negotiate the prices of certain drugs. Title I of H.R. 3 would require the Secretary of HHS to directly negotiate with manufacturers to establish a maximum fair price for drugs selected for negotiation, which would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. Under H.R. 3, the Secretary of HHS would be required to negotiate maximum prices for: (1) insulin products; (2) with respect to 2023, at least 25 single-source, brand-name drugs that do not have generic competition and that are among either the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest spending under the Medicare prescription drug benefit and Medicare Advantage (MA); (3) beginning in 2024, at least 50 such single-source, brand-name drugs; and (4) newly approved single-source, brand-name drugs with wholesale acquisition costs equal to or greater than the median household income. The negotiated

prices would be offered under Medicare and Medicare Advantage, as well as under private health insurance unless the insurer opts out. An "average international market price" would be established to serve as an upper limit for the price reached in any negotiation, if practicable for the drug at hand, defined as no more than 120 percent of the drug's volume-weighted net average price in six countries—Australia, Canada, France, Germany, Japan and the United Kingdom.[18]

Showing the impact of negotiating leverage, the December 10, 2019 CBO cost estimate "Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act" stated that Title I of the legislation would reduce federal direct spending for Medicare by $448 billion over the 2020-2029 period.[19] In its October 11, 2019 estimate, CBO estimated that the largest savings would be the result of lower prices for existing drugs that are sold internationally, which would be impacted by the application of the "average international market price" outlined in the bill.[20] CBO also estimated that due to the collective provisions of H.R. 3, approximately eight fewer drugs would be introduced to the US market over the 2020-2029 period, with approximately 30 fewer drugs introduced to the US market over the following decade.[21] There would be a reduction of drugs introduced in the US market due to the enactment of H.R. 3 "because the potential global revenues for a new drug over its lifetime would decline as a result of enactment, and in some cases the prospect of lower revenues would make investments in research and development less attractive to pharmaceutical companies….The effects would be larger in the 2030s because of the considerable time needed to develop new drugs and because of the larger effects that would occur when more phases of development are affected."[22] In addition, CBO estimated that "[t]he introduction of new drugs would tend to be delayed in the six reference countries: Australia, Canada, France, Germany, Japan, and the United Kingdom. Prices of new drugs in those countries would rise somewhat."[23]

While H.R. 3 was reintroduced in this Congress, the latest congressional action on drug pricing was a part of H.R. 5376, the Build Back Better Act, which passed the House of Representatives in November 2021. If enacted into law, the House-passed version of Build Back Better would allow the Secretary of HHS to negotiate the prices of a small number of high-cost drugs covered under Medicare Part D (starting in 2025) and Part B (starting in 2027). The negotiation process would apply to no more than 10 single-source brand-name drugs or biologics that lack generic or biosimilar competitors in 2025, ramping up to no more than 20 in 2028 and later years. The drugs selected for negotiation would be required to be among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. All insulin products would also be subject to negotiation.[24]

Certain drugs would be exempt from negotiation, including those that are less than nine years (for small-molecule drugs) or 13 years (for biological products) from their U.S. Food and Drug Administration (FDA)-approval or licensure date. "Small biotech drugs" would also be exempt from negotiation until 2028; these drugs are defined as those which account for 1 percent or less of Part D or Part B spending and account for 80 percent or more of spending under each part on that manufacturer's drugs. In addition, the legislation exempts from negotiation drugs with Medicare spending of less than $200 million in 2021 (increased by the Consumer Price Index for All Urban Consumers (CPI-U) for subsequent years) and drugs with an orphan designation as their only FDA-approved indication.[25]

Due to lack of congressional support for incorporating international price indices/averages into the Medicare drug price negotiation process for drugs covered under Medicare Parts D and B, the Build Back Better Act as passed by the House of Representatives instead establishes an upper limit for the negotiated price (the "maximum fair price") equal to a percentage of the non-federal average manufacturer price (AMP)—the average price wholesalers pay manufacturers for drugs distributed to non-federal purchasers. The "maximum fair price" is defined as 75 percent of the

non-federal AMP for small-molecule drugs more than 9 years but less than 12 years beyond approval; 65 percent for drugs between 12 and 16 years beyond approval or licensure; and 40 percent for drugs more than 16 years beyond approval or licensure. The payment for Part B drugs selected for negotiation would be based on the maximum fair price, versus ASP under current law.[26] The Council underscores that at the time this report was written, there remains insufficient support in the House of Representatives and Senate to incorporate international price indices/averages into the Medicare drug price negotiation process for drugs covered under Medicare Parts D and B.

The significant differences between the drug negotiation provisions of the Build Back Better Act and H.R. 3 cause more limited cost savings and impacts on drug development under the Build Back Better Act. CBO estimated $78.8 billion in Medicare savings in the 2022-2031 period from the drug negotiation provisions in the Build Back Better Act. In addition, CBO estimated that one fewer drug would come to the US market over the 2022-2031 period, four fewer over the subsequent decade, and approximately five fewer the decade after that.[27]

Recent Regulatory Activity

The regulatory process is a pathway that cannot be ignored in its potential to change the way and level at which drugs are paid for under Medicare Part B through the incorporation of international drug price indices or averages. Notably, the AMA has been active in its advocacy efforts in response to regulatory proposals to date. In October of 2018, the Trump Administration released an Advance Notice of Proposed Rulemaking (ANPRM) entitled "International Pricing Index Model for Part B Drugs." The ANPRM did not represent a formal proposal, but rather outlined the Administration's thinking at the time, and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. The ANPRM outlined a new payment model for physician-administered drugs paid under Medicare Part B that would transition Medicare payment rates for certain Part B drugs to lower rates that are tied to international reference prices—referred to as the "international pricing index"—except where the ASP is lower. The international reference price would partly be based on an average of prices paid by other countries. To accomplish this, the proposal would create a mandatory demonstration through the Centers for Medicare & Medicaid Innovation (CMMI), which would apply to certain randomly selected geographic areas, representing approximately 50 percent of Medicare Part B drug spending. Initially, the program would apply only to sole-source drug products and some biologics for which there is robust international pricing data available.

In geographic areas included in the demonstration, CMS would contract with private-sector vendors that would negotiate for, purchase, and supply providers with drug products that are included in the demonstration. CMS would directly reimburse the vendor for the included drugs, starting with an amount that is more heavily weighted toward the ASP instead of the international pricing index, and transitioning toward a target price that is heavily based on the international pricing index. Providers would select vendors from which to receive included drugs, but would not be responsible for buying from and billing Medicare for the drug product. Instead, providers would continue to be entitled to bill a drug administration fee, and would also be entitled to receive a drug add-on fee. While the ANPRM was somewhat short on detail on exactly how this add-on fee would be calculated, it appears the add-on fee would be a flat fee that is based on six percent of the historical average sales price for the drug in question.[28]

In September 2020, an executive order, "Lowering Drug Prices by Putting America First," was issued, and called for testing of payment models to apply international price benchmarking to Part B and Part D prescription drugs and biological products. For Part B, the executive order instructed

the Secretary of HHS to implement rulemaking to test a payment model under which "Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." The executive order defined the "most-favored-nation price" as "the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." For Part D, the executive order instructed the Secretary of HHS to develop and implement rulemaking to test a payment model for high-cost Part D drugs, limiting payment to these drugs to the most-favored-nation price, to the extent feasible.[29]

In November of 2020, the Trump Administration issued an interim final rule entitled "Most Favored Nation (MFN) Model" to establish a model through CMMI that would phase in changing Medicare's payment for approximately 50 Part B drugs that make up a high percentage of Part B spending from paying solely based on manufacturers' ASP to the lowest adjusted international price for the drug, defined as the lowest gross domestic product (GDP)-adjusted price paid by an OECD member country with a GDP per capita (based on purchasing power parity) that is at least 60 percent of the US GDP per capita. Addressing physician payment, the add-on payment based on six percent of ASP for the individual drug would be replaced with a flat payment per dose that would be uniform for all included drugs in the MFN Model. As the model was scheduled to become effective January 1, 2021, on December 28, 2020, the US District Court for the Northern District of California issued a nationwide preliminary injunction in *Biotechnology Innovation Organization v. Azar*, which preliminarily enjoined HHS from implementing the Most Favored Nation Rule. Given this preliminary injunction, the MFN Model was not implemented on January 1, 2021. The interim final rule was formally rescinded in December 2021 and will not be implemented without further rulemaking.[30]

RELEVANT AMA POLICY

AMA policy on prescription drug pricing is diverse, multifaceted, and allows the AMA to advocate on a breadth of issues to tackle high and escalating drug pricing, not limited to Medicare drug price negotiation or opening the door for the use of international drug price indices and averages in Medicare Parts D and B. This strong foundation of AMA policy addressing prescription drug pricing, coverage and payment has allowed the AMA to actively engage on legislative and regulatory proposals on drug pricing on both the federal and state levels.

Significantly, Policy H-110.987 supports legislation that limits Medicare annual drug price increases to the rate of inflation—a significant provision that has been included in recent legislation addressing prescription drug prices. The policy also supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations, as well as for biologics. The policy also supports 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; 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 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. In addition, it advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase. Finally, it states that 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.

Policy H-110.980[3] 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. Policy D-100.983 outlines standards for the importation of prescription drug products. Policy H-110.986 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.

Policy H-110.986 also supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. Finally, it 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.

Numerous policies aim to improve generic drug pricing and access. Policy H-110.988 states that our AMA will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the FDA, the U.S. Federal Trade Commission (FTC), and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs. The policy also states that our AMA will work with interested parties to support legislation to ensure fair and appropriate pricing of generic medications and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients. In addition, the policy encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs; and supports measures that increase price transparency for generic prescription drugs. Policy H-100.950 states that our AMA will advocate with interested parties for legislative or regulatory measures that require prescription drug manufacturers to seek FDA and FTC approval before establishing a restricted distribution system; will support requiring pharmaceutical companies to allow for reasonable access to and purchase of appropriate quantities of approved out-of-patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays; and will advocate with interested parties for legislative or regulatory measures that expedite the FDA approval process for generic drugs, including but not limited to application review deadlines and generic priority review voucher programs. Policy H-110.989 supports: (1) the FTC in its efforts to stop “pay for delay” arrangements by pharmaceutical companies; and (2) federal legislation that makes tactics delaying conversion of medications to generic status, also known as “pay for delay,” illegal in the United States.

AMA policy also addresses other primary stakeholders in the prescription drug pricing arena, including pharmacy benefit managers (PBMs). Policy D-110.987 supports the active regulation of PBMs under state departments of insurance; 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; encourages increased transparency in how DIR fees are determined and calculated; and 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. In addition, the policy outlines provisions to be disclosed as part of improved transparency of PBM operations.

Addressing the impact of prescription cost-sharing requirements on rates of prescription abandonment by patients, Policy H-125.979 contains significant AMA policy provisions promoting improved prescription drug formulary transparency, which address mid-year formulary changes, utilization management requirements and access to accurate, real-time formulary data at the point of prescribing. Policy D-155.994 advocates for third-party payers and purchasers to make cost data available to physicians in a useable form at the point of service and decision-making, including the cost of each alternate intervention, and the insurance coverage and cost-sharing requirements of the respective patient. Policy H-120.919 supports efforts to publish a Real-Time Prescription Benefit (RTPB) standard that meets the needs of physicians, utilizing any electronic health record, and prescribing on behalf of all patients.

AMA policy also recognizes that benefit design can be leveraged to ensure improved prescription drug cost-sharing affordability to promote improved patient adherence to prescribed medication regimens. Policy H-155.960 encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. The policy stipulates that consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance. Similarly, Policy H-110.990 states that cost-sharing requirements for prescription drugs should be based on considerations such as the unit cost of medication, availability of therapeutic alternatives, medical condition being treated, personal income, and other factors known to affect patient compliance.

Shifting to policies directly applicable to the referrals responded to by this report, Policy D-330.954 states that: (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; and (3) our AMA will prioritize its support for the Centers for Medicare & Medicaid Services (CMS) to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Council on Medical Service Report 4-I-19 established a set of safeguards in AMA policy, now Policy H-110.980[2], pertaining to the use of international price indices and averages in determining the price of and payment for drugs. The following principles established in the policy are applicable to the pricing of prescription drugs under any health plan or proposal, and are not solely relevant to drugs covered under Medicare Part D, or even Medicare more broadly:

a. Any international drug price index or average should exclude countries that have single-payer health systems and use price controls;
b. 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;
c. The use of any international drug price index or average should preserve patient access to necessary medications;
d. The use of any international drug price index or average should limit burdens on physician practices; and
e. Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.

Significantly, Policy H-110.980[1] advocates standards guiding the use of arbitration in determining the price of prescription drugs 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; and
i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.

Policy H-155.962 opposes the use of price controls in any segment of the health care industry and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. Applicable to any vendor program that would be established in Medicare Part B to implement a pilot or permanent model implementing international price averages or indices, Policy H-110.983 advocates that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

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

AMA ADVOCACY ON PRESCRIPTION DRUG PRICING

The Council understands that the introduction of original Resolution 113-N-21, as well as amendments made during consideration of Alternate Resolution 113-N-21, stemmed from strong support in the House of Delegates for the AMA to more actively and strongly advocate on the issue of prescription drug pricing. The AMA has been "at the table," advocating for the enactment of AMA policy pertaining to drug pricing with Congress via meetings with legislators and their staff as well as through letters and other communications. The AMA also has engaged the Administration through comment letters in response to regulatory activity as well as direct interactions and meetings. Finally, the AMA and members of the Federation have similarly advocated at the state level.

Showing the diversity and comprehensiveness of AMA policy and advocacy on drug pricing, the Council is providing a summary below to the House of Delegates of recent significant comments, letters and testimony addressing the introduction of and discussions surrounding prescription drug pricing legislation, and the promulgation of regulations addressing drug pricing.

- In March 2022, the AMA submitted a comment letter in response to the proposed rule outlining Medicare Advantage and prescription drug benefit policies for contract year 2023, in which the AMA supported the proposal to require the application of all pharmacy price concessions, including DIR fees, to drug prices in Medicare Part D at the point-of-sale.
- In August 2021, the AMA submitted a letter to congressional leadership to provide our perspective on health care issues related to the budget reconciliation proposal (Build Back Better). The letter supported efforts to eliminate prohibitions on the negotiation of prescription drug prices within the Medicare program and outlined AMA policy addressing the parameters of Medicare drug price negotiation, including the use of international drug price averages/indices, arbitration and value-based drug pricing. The letter also supported efforts to increase transparency in all aspects of the drug pricing process, as well as measures to address increases in prescription drug prices that exceed the rate of inflation. In addition, the letter outlined AMA policy on and support for efforts to cap patient out-of-pocket prescription drug expenses; pay-for-delay agreements between brand and generic drug manufacturers; and limit the use of drug utilization management tools by payers.
- In December 2020, the AMA submitted a comment letter in response to the MFN Model interim final rule, outlining significant concerns regarding the MFN Model and its impact on patient access to essential treatments, as well as the model's financial impact on physician practices.
- In March 2020, the AMA submitted a comment letter in response to the Importation of Prescription Drugs proposed rule.
- In February 2020, the AMA submitted a comment letter in response to released draft guidance regarding the importation of certain FDA-approved human prescription drug and biological products.
- In May of 2019, the AMA testified as part of the hearing before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health titled, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain," submitting answers to follow-up questions after the hearing in August.
- In April 2019, the AMA submitted a comment letter in response to the proposed rule, "Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals

and Creation of a New Safe Harbor Protection for Certain Point-Of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.

- In March 2019, the AMA submitted a letter to the leadership of the House Energy and Commerce Committee in support of its efforts, and pending legislation, to address the escalating prices of prescription medication by removing barriers to market entry for affordable prescription medication and shining a light on anticompetitive practices in the pharmaceutical supply chain that can lead to price escalations.
- In December 2018, the AMA submitted a comment letter in response to the ANPRM on an International Pricing Index Model (IPI model) for Medicare Part B Drugs, in which the AMA highlighted the need for significant reforms to the Medicare Part B competitive acquisition program (CAP) and the IPI model to ensure that beneficiaries have timely access to necessary treatments. The AMA also raised strong concerns with the proposed add-on formula, stating that "reimbursement models based on an 'add-on' formula are intended to adequately reimburse physicians for the costs of acquisition, proper storage and handling, and other administrative costs associated with providing these treatment options for patients. Many drugs included in this model, such as biological products, are complicated drug products that require special attention to handling and storage to remain stable and viable for administration to patients. Drugs that require specific conditions for shipping, storage, and handling result in significantly higher administrative costs to physician practices than many small molecule-type drugs. Due to the special nature of these products, these costs are fixed, and will not decrease as the price of the drug goes down. Given these fixed administrative costs, we are very concerned that, should drug prices decrease as this model predicts, any add-on payment based on an ASP would ultimately decrease with the price of the drug and would no longer be sufficient to cover the administrative costs to the practice. If add-on reimbursement decreases enough that it is no longer sufficient to cover the expenses associated with providing these treatment options, it is likely that practices will no longer be able to offer these options for patients. We strongly urge CMS to consider the impact on the add-on as the IPI model over time could reduce this amount below actual clinician cost."
- In July 2018, the AMA submitted a comment letter in response to *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (Blueprint) Request for Information (RFI). In the letter, the AMA strongly supported a select number of Blueprint provisions to the extent that they would promote the following and recommended prompt regulatory action to: (1) require pharmaceutical supply chain transparency; (2) accelerate and expand regulatory action to increase pharmaceutical market competition and combat anti-competitive practices; (3) ensure prescribers have accurate point-of-care coverage and patient cost-sharing information as part of their workflow, including in the electronic health record; and (4) ensure federal programs and commercial practices billed as lowering prescription medication prices do so for patients directly. The AMA opposed Blueprint proposals that increased patient costs and erected barriers, including onerous insurer paperwork requirements that impede timely patient access to affordable and medically necessary medications and treatments. Further, the AMA opposed policies that would financially penalize physicians and pharmacists for high-cost prescription medication.

DISCUSSION

Since 2004, AMA Policy D-330.954 has supported giving the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs, and in 2017, formally prioritized AMA's support for the CMS to negotiate pharmaceutical pricing for all applicable medications

covered by CMS. As previously referenced in the report, the CBO and CMS actuaries have estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D. In order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, CBO stated that the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions."

Addressing the need for administrative leverage in Medicare drug price negotiations, the Council recognizes that incorporating international drug price indices and averages has become a popular proposal to significantly lower drug prices through said negotiations. However, the Council notes that recent legislative and regulatory proposals have not stopped at incorporating international prescription drug prices in Part D—they have extended to Medicare Part B, as well as to private health plans, unless they opt out. In fact, the proposal closest to being implemented in this arena has been via regulation, and solely addressing payment for prescription drugs in Medicare Part B. Therefore, AMA policy addressing the use of international drug price indices and averages in determining domestic drug prices needs to be consistent across not only all of Medicare, but across all health plans.

Recent legislative and regulatory proposals have not met the criteria established in Policy H-110.980, which guides AMA support for the use of international drug price averages/indices in determining domestic drug prices. Ultimately, the priority for the AMA in its advocacy efforts has been to preserve patient access to necessary medications, and limit burdens on and protect physician practices. While recent legislative and regulatory proposals have not met these and other important thresholds outlined in the policy, the Council believes that is not a reason to change AMA policy. In addition, the Council stresses that on the legislative front, at the time this report was written, there remains insufficient support in the House of Representatives and Senate to incorporate international price indices/averages into the Medicare drug price negotiation process for drugs covered under Medicare Parts D and B. Therefore, AMA policy moving forward needs to be able to respond to the more likely path to incorporate international drug price averages and/or indices in Medicare drug pricing—through regulation, targeting Medicare Part B drug payment.

The amendments proposed to Policy H-110.980 would have significant, negative, unintended consequences for the pricing of and payment for drugs under Medicare Part B, impacting patient access and physician practices. It also could set a dangerous precedent guiding the future payment of physician services. The Council instead firmly supports using arbitration as a lever in prescription drug price negotiations, including in Medicare, instead of a price ceiling based on international prices that does not meet existing policy principles. As such, the Council recommends the reaffirmation of Policy H-110.980. The Council also recommends the reaffirmation of Policy H-110.983, which advocates standards that any revised Medicare Part B Competitive Acquisition Program must meet, as a vendor program has often been proposed along with a model or new program to incorporate international drug price averages or indices in Medicare Part B.

To make patient cost-sharing obligations in the Medicare program more affordable, the Council believes that there is tremendous promise for models under the auspices of the CMMI to test the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent and predictable out-of-pocket costs for select prescription drugs. The Part D Senior Savings Model,[31] which is testing the impact of offering beneficiaries an increased choice of enhanced alternative Part D plan options that offer lower out-of-pocket costs for insulin, is a needed first step in the right direction.

On the whole, there is significant potential for other components of the AMA prescription drug pricing policy agenda to be implemented through legislation and/or regulations, and your Council believes that the focus of AMA advocacy efforts must continue to be multifaceted, diverse and nimble to achieve results for our patients and the physicians who provide their care. Medicare prescription drug price negotiation is only a piece of the larger drug pricing puzzle, which requires interventions to improve transparency and competition in the pharmaceutical marketplace; strengthen regulation of PBMs; limit drug price increases in Medicare to the rate of inflation; and ensure benefit design improves patient medication adherence.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of the second resolve of Alternate Resolution 113-N-21, as well as the referred amendment proffered during consideration of Alternate Resolution 113-N-21, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy D-330.954, which states that our 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; work toward eliminating Medicare prohibition on drug price negotiation; and prioritize its support for the Centers for Medicare & Medicaid Services (CMS) to negotiate pharmaceutical pricing for all applicable medications covered by CMS. (Reaffirm HOD Policy)

2. That our AMA amend Policy H-110.980[2] by addition and deletion to read as follows:

   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 exclude countries that have single-payer health systems and use price controls;~~
   a~~b~~. 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~~c~~. The use of any international drug price index or average should preserve patient access to necessary medications;
   c~~d~~. The use of any international drug price index or average should limit burdens on physician practices; and
   d~~e~~. Any data used to determine an international price index or average to guide prescription drug pricing should be transparent and updated regularly. (Modify HOD Policy)

3. That our AMA reaffirm Policy H-110.983, which advocates standards that any revised Medicare Part B Competitive Acquisition Program must meet. (Reaffirm HOD Policy)

4. That our AMA encourage the development of voluntary models under the auspices of the CMS Innovation Center (CMMI) to test the impact of offering Medicare beneficiaries additional enhanced alternative health plan choices that offer lower, consistent, and predictable out-of-pocket costs for select prescription drugs. (New HOD Policy)

Fiscal note: Less than $500

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