REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (I-19)
Additional Mechanisms to Address High and Escalating Pharmaceutical Prices
(Reference Committee J)

EXECUTIVE SUMMARY

At the past several meetings of the House of Delegates, significant concerns have been raised regarding how high and increasing drug prices have impacted patients and physician practices. The Council on Medical Service spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, and concluded that additional policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for the use of arbitration, leverage international price indices and averages to determine drug prices, or implement contingent exclusivity periods for pharmaceuticals.

The Council has long prioritized the importance of competition and transparency in the pharmaceutical marketplace, but recognizes that there are multiple situations in which payers have weakened bargaining power, due to lack of competition for some drugs. In addition, there is often limited recourse following an unjustifiable price hike of a prescription medication, leaving patients questioning whether they will be able to continue to afford their medication. As such, the Council recommends policies to promote reasonable pricing behavior in the pharmaceutical marketplace, as an alternative to price controls.

First, the Council recommends principles to guide the use of arbitration in determining the price of prescription drugs, which build upon existing policy in favor of drug price negotiation, and opposed to price controls. Arbitration should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases. Using arbitration will help rebalance the importance of prescription drug affordability with the need for innovation, as an alternative to the status quo, which allows unilateral price setting of drugs by manufacturers without regard to patient access and affordability. Importantly, arbitration provides an incentive for drug manufacturers and payers to arrive at a negotiated price.

The Council stresses that arbitration should be coupled with additional policy proposals that promote value and encourage competition within the pharmaceutical marketplace. The Council believes that incorporating a drug's value and cost-effectiveness as factors in determining its length of market exclusivity has the potential to promote increased competition for therapies that are priced too high in relation to their clinical effectiveness and overall value. As such, the Council recommends support for the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of a drug to its cost-effectiveness at its list price at the time of market introduction.

Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, set a drug's price in Medicare Part B or determine whether a drug's price is "excessive" to trigger additional interventions, the Council recommends safeguards to ensure that such international drug price averages are used in a way that upholds market-based principles and preserves patient access to necessary medications.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-19

Subject: Additional Mechanisms to Address High and Escalating Pharmaceutical Prices

Presented by: W. Alan Harmon, MD, Chair

Referred to: Reference Committee J
(, MD, Chair)

At the past several meetings of the House of Delegates, significant concerns have been raised regarding how high and increasing drug prices have impacted patients and physician practices. The Council on Medical Service spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, determining whether additional policy was needed to guide future AMA advocacy efforts. In its review, the Council concluded that additional AMA policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for the use of arbitration, leverage international price indices and averages to determine drug prices, or implement contingent exclusivity periods for pharmaceuticals.

This report provides background on the impacts of high and escalating prescription drug prices and costs; outlines emerging approaches to address pharmaceutical pricing; and presents policy recommendations.

THE IMPACTS OF HIGH AND ESCALATING PRESCRIPTION DRUG PRICES AND COSTS

Retail prescription drugs account for 10 percent of total health spending,[1] with estimates suggesting that spending on prescription drugs is closer to 15 percent of total health spending when other factors, including the non-retail drug markets and gross profits of other stakeholders involved in drug distribution, payment, and reimbursement are included.[2] Of significance, spending on specialty drugs is approaching one-half of drug spending.[3] The most recent National Health Expenditure projections showed that retail prescription drug spending was estimated to have increased by 3.3 percent to $344.5 billion in 2018, with a 4.6 percent increase in spending expected in 2019. Drivers behind the rate of growth in prescription drug spending include a higher number of new drug introductions, increased utilization of prescription drugs, and an increase in drug price growth. The projected annual growth in prescription drug spending is expected to average 6.1 percent from 2020 through 2027. Contributions to future growth in spending in the prescription drug sector include increased prescription drug utilization resulting from employer and insurer efforts to remove barriers associated with medications for chronic conditions; expected market release of more expensive drugs for conditions including cancer, diabetes, and Alzheimer's disease; the aging of the population; and modifications to pharmacotherapy guidelines.[4]

Approximately 5.8 billion prescriptions were dispensed in the US in 2018, 90 percent of which were dispensed as generics. 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 2017 the average annual retail price of therapy for specialty drugs was $78,781,

dropping to $6,798 for brand-name drugs, and $365 for generics.[5] Overall, the list price of the average brand drug was $657.08 for a 30-day prescription in 2018, a noteworthy increase from $364.92 in 2014. The average prices of brand-name drugs at pharmacies before coupons and discounts are applied were $229 lower than list prices in 2018 for a 30-day prescription.[6] Average generic pharmacy prices for a 30-day prescription were relatively stable from 2014 to 2018, increasing to $19.10 from $18.50.[7]

Health plans, payers, employers, physicians and patients are facing the increasing financial burden posed by prescription drugs, both brand and generic. In the Medicare program, between 2007 and 2017, Part D program spending has seen an annual growth rate of 5.6 percent, and amounted to $79.9 billion in 2017. Premiums paid by Part D enrollees for basic benefits (not including low-income subsidy enrollees) amounted to $14 billion in 2017, which has increased by 13 percent on average annually since 2007. High-cost enrollees are a primary contributor to Part D spending growth, with the associated spending growth for high-cost enrollees resulting from higher drug prices.[8] Under Medicare Part B, drug spending has increased on average by 9.6 percent annually between 2009 and 2017, with the largest driver of this growth in spending being price growth – a combination of increasing prices for existing drugs as well as the introduction of new high-cost drugs in the market. In 2017, $18 billion of total Part B spending was for drugs administered in physician offices, approximately $12.3 billion was for drugs administered in hospital outpatient departments, and $1.8 billion was for drugs provided by suppliers.[9]

Rising and high prescription drug prices are impacting Medicaid budgets and state budgets overall. Under the Medicaid drug benefit, drug manufacturers pay rebates to states in return for Medicaid reimbursement for their prescription drugs. Drug manufacturers are required to pay an additional rebate amount if the average manufacturer price (AMP) for a drug rises faster than inflation. From 2014 to 2017, Medicaid outpatient prescription drug spending before rebates increased from $45.9 billion to $63.6 billion.[10] The $34.9 billion collected in rebates brought net Medicaid spending on prescription drugs down significantly in fiscal year (FY) 2017. The proportion of spending geared to brand-name versus generic drugs in Medicaid increased – from 76.6 percent in FY 2014 to 80.5 percent in FY 2017. This growth resulted from an increase in average spending per claim for brand drugs – from $294 per claim in FY 2014 to $411 per claim in FY 2017. Of note, the share of spending on specialty drugs has significantly increased in Medicaid – accounting for approximately 44 percent of spending in FY 2017.[11]

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, which 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 2018, 88 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs.[12] This year, almost all standalone Medicare Part D plans have a benefit design with five tiers for generic and brand-name drugs and cost-sharing that deviates from the standard 25 percent coinsurance for all covered drugs between the deductible and the initial coverage limit.[13]

The higher costs of prescription drugs are in part passed down to health plan enrollees, and impact 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.

In 2018, overall out-of-pocket costs for prescription drugs reached $61 billion, an increase from $56 billion in 2014. Across Medicare, Medicaid and commercial health plans, 8.8 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 almost 20 percent paying more than $500 out-of-pocket.[14] Nonpreferred generic tiers in many cases have higher copayments than patients have become accustomed to for generic medications. In addition, plans with specialty drug cost-sharing tiers often require coinsurance amounts of 25 to 50 percent, versus requiring a fixed copayment. Considering the costs of many specialty medications, patients could quickly reach their deductibles and out-of-pocket maximums. The increased use and cost of specialty drugs in Medicare could cause the number of Part D enrollees who reach the catastrophic coverage threshold to grow substantially, resulting in increases in Medicare spending to plans for reinsurance.

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, 19 percent of adults have not filled a prescription in the past year due to cost, 18 percent chose to take an over-the-counter medication instead, and 12 percent cut pills in half or skipped doses. Of significance, almost 10 percent of all adults reported that their condition worsened from not taking their medication as prescribed.[15]

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. The rate at which such patients, enrolled in either Medicare or a commercial health plan, abandon their prescription increases significantly once out-of-pocket costs reach $50. At this point, 31.2 percent of commercially insured patients and 27.6 percent of Medicare patients abandon their prescriptions.[16]

High prescription drug costs, and any declines in medication adherence that may result, can also impact physicians participating in alternative payment models (APMs). For example, Part B drug costs are included in calculations of APM financial risk, even though physicians cannot influence or control drug prices. In addition, physicians in APMs can be affected if poor medication adherence leads to complications or exacerbations that in turn lead to emergency department visits and/or hospital admissions.

EMERGING APPROACHES TO ADDRESS HIGH AND ESCALATING DRUG PRICES

Escalating and increasingly unaffordable drug prices have caused the Administration, members of Congress and policy experts to put forward innovative proposals to put downward pressure on prices, or more closely tie a drug's price to its value. Whereas proposals that would allow for binding arbitration and contingent exclusivity periods could build upon existing market-based approaches to address pharmaceutical prices and costs, caution would have to be exercised in implementing proposals that leverage international price indices, so as to not merely import international price controls into the US.

Utilizing Binding Arbitration

An emerging policy option that has been put forward to address high and escalating drug prices is using binding arbitration in the event of failed drug price negotiations in order to settle on the final

price of the drug. Supporters argue that binding arbitration has the potential to build upon the negotiations that currently take place along the pharmaceutical supply chain that determine coverage of and payment for prescription drugs. In the US, binding arbitration is currently used in public-sector labor-management negotiations, and Major League Baseball uses the approach in the event of failed negotiations for baseball players' salaries. While negotiated prices between the pharmaceutical company and the payer/government entity in question would remain the preferred solution, arbitration has the potential to help equalize the bargaining power of both parties of the negotiation, while incentivizing negotiating parties to negotiate in good faith. If negotiations fail to conclude with a price agreeable to both parties, they could submit to final offer arbitration or conventional arbitration.

In final offer arbitration, the arbitrator would be given final bids by the drug manufacturer and the payer/government entity in question. Such bids would be accompanied by data justifying the price put forward by each party, and there would be potential for an independent third party to offer a third price, which can be informed by value-based price benchmarks, comparative effectiveness research, and cost-effectiveness analysis. The arbitrator under final offer arbitration would be required to choose one of three prices: 1) the bid of the drug manufacturer; 2) the bid of the payer/government entity; or 3) the price submitted by the independent third party, if applicable. Alternatively, under conventional arbitration, the arbitrator would not be tied to any of the bids or options put forward; they could select any price they believe is fair.[17]

Case Study: Germany

Germany uses arbitration as one potential pathway to determine the price of a drug in the German market. After a drug is approved by the European Medicines Agency, allowing for the drug to be sold in Germany, a drug manufacturer unilaterally sets the drug's price, applicable for 12 months. At the same time, the manufacturer also is required to submit a report outlining the benefits of the drug to the Federal Joint Committee, comprised of physicians, dentists, hospitals, and health insurers (sickness funds). The Federal Joint Committee forwards the report to the non-governmental Institute for Quality and Efficiency in Health Care (IQWiG), which conducts an assessment of the clinical effectiveness and benefits of the new drug compared with one or more comparator therapies. After the IQWiG submits its finding, the Federal Joint Committee issues a final decision regarding the level of benefit of the new drug relative to existing therapies that treat the condition in question. Such benefits can include prolonged life expectancy, reduction in side effects, health status improvement, shortening of disease duration and quality of life improvement. A drug is then assigned one of six benefit ratings:

1. Major added benefit
2. Considerable added benefit
3. Minor added benefit
4. Nonquantifiable added benefit
5. No evidence of added benefit
6. Lower benefit than comparator(s)

Depending on a drug's benefit rating, and whether there is a reference group to guide a reference price of a drug, a drug manufacturer can either enter into negotiations with Germany's sickness funds (health insurers), or be assigned to a therapeutic class subject to reference pricing – pricing based on other drugs in the same therapeutic class, including generics. Drugs that enter into negotiations have six months from the Federal Joint Committee decision to agree to a price. If they cannot agree on a price, an arbitration panel is required to set a price within three months, which is binding for the following year. Either party can challenge the decision, which would then trigger

IQWiG conducting a cost-benefit analysis. In addition, new findings can serve as cause for the parties to revisit an agreement or arbitration decision after one year.[18,19,20]

Relevant AMA Policy

Policy D-330.954 supports federal legislation which gives the Secretary of Health and Human Services (HHS) the authority to negotiate contracts with manufacturers of covered Part D drugs; and states that the AMA will 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. Policy H-155.962 states that our AMA 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.

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. Policy H-460.909 outlines principles for creating a centralized comparative effectiveness research entity.

Leveraging an International Pricing Index

Recent proposals put forward by the Administration and members of Congress attempt to lower US drug costs by tying them to international prices, and/or would use an average of international prices, or an international reference price, to help define whether a price of a drug is excessive. In October of 2018, the Administration released an Advance Notice of Proposed Rulemaking (ANPRM) for a proposal entitled "International Pricing Index Model for Part B Drugs." The ANPRM did not represent a formal proposal, but outlined the Administration's current thinking and sought stakeholder input on a variety of topics and questions related to this new drug pricing model prior to entering formal rulemaking. At the time that this report was written, a proposed rule on the international pricing index model was expected to be released, which has the potential to differ markedly from what was outlined in the ANPRM.

The ANPRM outlined a new payment model for physician-administered drugs paid under Medicare Part B that will 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 average sales price (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 will 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.

An alternative international drug price index has been put forward, which differs from that introduced in the ANPRM: the Market-Based International Index (MBII). Unlike the international price index included in the ANPRM, the MBII excludes developed countries with single-payer health systems that use price controls. Therefore, unlike the index provided for the ANPRM, the MBII does not include Canada, Finland, Greece, Italy, Spain, Sweden and the United Kingdom. The MBII benchmark has two tiers. The first tier represents 60 percent of the benchmark, and includes the Netherlands, Singapore and Switzerland – countries with truly market-based health systems – as well as Denmark, which does not regulate drug prices. The second tier, which constitutes 40 percent of the benchmark, includes Austria, Belgium, the Czech Republic, France, Germany, Ireland, Japan, Portugal, and Slovakia – countries that have a mix of private and public health insurance.[21]

Legislation has also been introduced in Congress that would use international drug prices to determine whether a drug's price is excessive, trigger additional interventions, and serve as an upper limit in drug price negotiations. Senator Bernie Sanders (I-VT) and Representative Ro Khanna (D-CA) have introduced S 102/HR 465, the Prescription Drug Price Relief Act of 2019. Notably, under the bill, the price of a prescription drug would be considered "excessive" if the domestic average manufacturing price exceeds the median price for the drug in Canada, the United Kingdom, Germany, France, and Japan. Even if a drug's price does not meet this criterion, or if pricing information is unavailable in at least three of the five countries, a drug's price could still be considered excessive if it is higher than reasonable in light of factors outlined in the legislation, including cost, revenue, and the size of the affected patient population. If brand-name drugs are found to be excessively priced, the drug would be included on a public excessive price database. Open, nonexclusive licenses would be issued for the drug; and review of corresponding applications for generic drugs and biosimilar biological products would be expedited to facilitate competition as well as the entry of lower-cost options into the marketplace.[22,23]

In addition, Congressman Frank Pallone (D-NJ) has introduced HR 3, the Lower Drug Costs Now Act of 2019. The legislation would incorporate an international price average as part of authorizing the Secretary of HHS to negotiate drug prices, limited to drugs that lack competition and have the greatest financial impact to the Medicare program and the US health system as a whole, as well as insulin. The Secretary of HHS would directly negotiate with drug 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. In addition, the drug manufacturer would be required to offer the negotiated price to private group and individual health insurance plans. 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. There would be a financial penalty if a pharmaceutical manufacturer does not participate in or comply with the negotiations.

Relevant AMA Policy and Advocacy

Pursuant to AMA Policy, the AMA submitted comments in response to the "International Pricing Index Model for Part B Drugs" in December 2018. 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. 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.

Tying Pharmaceutical Pricing to Market Exclusivity

Brand-name drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or conditions affecting less than 200,000 individuals in the US, or affecting more than 200,000 individuals but for which there is not a reasonable expectation that the sales of the drug would recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative products that include an entirely new active ingredient – a new chemical – have five years of market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies on the effects of a drug upon children are submitted for Food & Drug Administration (FDA) review and meet the statutory requirements. Biologic manufacturers have 12 years of exclusivity for innovator (brand-name) products. Innovator biologics also have additional patent protection that generally exceeds exclusivity period by a few years.[24]

Exclusivity periods for pharmaceuticals are not tied to the list price at which they enter the market, nor to the rate at which they increase in price from year to year. The Council notes that two potential options have been proposed to more closely tie drug market exclusivity to pricing behavior. First, a policy strategy has been put forward to implement contingent exclusivity periods

for new brand drugs. Under this policy option, drug manufacturers with a newly approved drug would be able to set their list price at whatever they wish, but the length of the exclusivity period would depend on whether their list price is reasonable, ie, if it aligns with the drug's value. Multiple options could be utilized to assess a drug's value, including cost per quality-adjusted life year (QALY), or a value-based price benchmark. Contingent exclusivity periods, therefore, could potentially lengthen the exclusivity period for drugs with lower cost per QALY, and reduce the exclusivity period for drugs priced too highly to align with their value. For example, in the case of an innovator biologic, a biologic with a low cost per QALY could see its exclusivity period extended to 15 years from 12 years, whereas a biologic priced too high relative to its value could have its exclusivity period set to 7 years.[25]

Second, Senator Richard Durbin (D-IL) and Representative Jared Golden (D-ME) introduced S 366/HR 1188, the Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act, which would shorten (but not automatically void) the Food, Drug, and Cosmetic Act market exclusivity period for prescription drugs that experience sudden increases in price. Under the FLAT Prices Act, an increase of the wholesale acquisition cost of a prescription drug of more than 10 percent over a one-year period, more than 18 percent over a 2-year period, or more than 25 percent over a three-year period would result in a reduction of market exclusivity of 180 days. For every five percent increase over these thresholds, the market exclusivity would be reduced an additional 30 days. Manufacturers would be required to report such price increase within 30 days of meeting the criteria for a price increase. Failure to report within the allotted time would result in 30 days of reduced exclusivity daily until the report is submitted. The Secretary of HHS would have discretion to grant a waiver to a manufacturer if the Secretary determines that the price increase is justified and does not unduly restrict patient access to the drug or impact public health.[26,27]

Relevant AMA Policy

Policy H-110.987 supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations. 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-110.986 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.

DISCUSSION

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on patients, on physician practices, and the broader health care system. Patients delay, forgo, or ration their medication when treatments are cost-prohibitive, putting their health at risk. At a time of significantly increasing drug prices, and the launch of products with high list prices, the Council believes that more needs to be done to improve access to and lower the costs of prescription drugs, without stifling innovation.

The Council has long prioritized the importance of competition and transparency in the pharmaceutical marketplace, and believes that negotiation of drug prices between drug manufacturers and payers should continue to be the preferred mechanism to determine how drugs are covered and paid for. That being said, the Council recognizes that there are multiple situations in which payers have weakened bargaining power, due to a drug's lack of competition in the marketplace. In addition, there is often limited recourse following an unjustifiable price hike of a prescription medication, leaving patients questioning whether they will be able continue to afford their medication. As such, the Council recommends policies to promote reasonable pricing behavior in the pharmaceutical marketplace, as an alternative to price controls.

First, the Council recommends principles to guide the use of arbitration in determining the price of prescription drugs, which build upon existing policy in favor of drug price negotiation, and opposed to price controls. Of note, arbitration can serve a role in many circumstances, from negotiating drug prices in Medicare Part D, to any negotiations that take place following a drug product's market entry, as executed in Germany. The Council believes that arbitration should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases. Using arbitration will help rebalance the importance of prescription drug affordability with the need for innovation, as an alternative to the status quo, which allows unilateral price setting of drugs by manufacturers without regard to patient access and affordability. Importantly, arbitration provides an incentive for drug manufacturers and payers/government entities to arrive at a negotiated price.

To ensure that there is a pathway to use arbitration in Medicare Part D, the Council recommends the reaffirmation of Policy D-330.954, which supports removing the current prohibition that restricts the Secretary of HHS from being able to negotiate drug prices in Part D. In whatever setting arbitration for drug prices is used, the Council underscores that the process should be overseen by objective, independent entities, which would have the authority to select neutral arbitrators or an arbitration panel, with strong conflict-of-interest protections built in.

The Council believes that as part of the arbitration process, and to guide the results, the use of comparative effectiveness research and cost-effectiveness analysis will be critical. Related, the

arbitration process should include the submission of a value-based price benchmark for the drug in question to inform the arbitrator's decision, pursuant to Policy H-110.986.

The Council stresses that arbitration should be coupled with additional policy proposals that promote value and encourage competition within the pharmaceutical marketplace. The Council believes that incorporating a drug's value and cost-effectiveness as factors in determining its length of market exclusivity has the potential to promote increased competition for therapies that are priced too high in relation to their clinical effectiveness and overall value. As such, the Council recommends support for the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of a drug product to its cost-effectiveness at its list price at the time of market introduction.

Finally, with the introduction of proposals that would use the average of a drug's price internationally to serve as an upper limit in drug price negotiations, set a drug's price in Medicare Part B or determine whether a drug's price is "excessive" to trigger additional interventions, the Council recommends safeguards to ensure that such international drug price averages are used in a way that uphold market-based principles and preserve patient access to necessary medications. In addition, the Council recommends reaffirmation of Policy H-110.983 outlining standards for any revised Medicare Part B Competitive Acquisition Program, which is relevant considering recent proposals to incorporate an international pricing index in Medicare Part B.

The Council believes that the recommendations of this report add to the already large body of AMA policies that address the high cost of prescription medications, which guide AMA advocacy efforts to improve patient access to medication while reducing their costs and balancing the need for appropriate innovation incentives. Pursuant to these policies, the AMA supports: (1) requiring manufacturer and pharmaceutical supply chain transparency; (2) increasing competition and curtailing anti-competitive practices; (3) ensuring 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) streamlining and modernizing the utilization control methods used by health insurers in response to higher prescription drug costs.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) 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; and
i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data. (New HOD Policy)

2. That our AMA 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;
    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. (New HOD Policy)

3. That our AMA support 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. (New HOD Policy)

4. That our AMA reaffirm Policy H-110.983, which advocates that any revised Medicare Part B Competitive Acquisition Program meet certain outlined standards to improve the value of the program by lowering the cost of drugs without undermining quality of care. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy H-110.986, which outlines principles for value-based pricing programs, initiatives and mechanisms for pharmaceuticals, and supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-460.909, which outlines principles for creating a centralized comparative effectiveness research entity. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy D-330.954, which states that our AMA will work toward eliminating Medicare prohibition on drug price negotiation. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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