REPORT 7 OF THE COUNCIL ON MEDICAL SERVICE (A-18)
Insulin Affordability
(Resolution 826-I-17)
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2017 Interim Meeting, the House of Delegates referred Resolution 826, "Improving Affordability of Insulin," which was sponsored by the American Association of Clinical Endocrinologists and the Endocrine Society, and which directed the American Medical Association (AMA) to: (1) work with relevant medical specialty societies to convene a summit with participation by patients, clinicians, manufacturers, pharmacy benefit managers (PBMs), insurers and the appropriate federal representatives to highlight the dramatic increase in insulin costs and identify potential solutions; (2) pursue solutions to reduce patient cost sharing for insulin and ensure patients benefit from rebates at the point of sale; (3) work with health insurance companies and federal agencies to stabilize drug formularies and reduce non-medical switching by encouraging plans to cover insulin products at the same cost listed on a drug formulary throughout the entire plan year; (4) encourage insulin price and cost transparency among pharmaceutical companies, PBMs and health insurance companies; and (5) work with electronic medical record vendors and insurance companies to integrate current formularies and price information into all systems so physicians and patients can make informed decisions on insulin products to reduce cost burdens on patients. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Annual Meeting.

Approximately six million Americans use insulin, a drug that has experienced dramatic price increases over the past decade. High insulin prices impact stakeholders throughout the health care system, from patients to health plans/payers and PBMs. The Council notes that insulin is one of the many essential drugs across all categories of pharmaceuticals to recently experience remarkable price increases.

A variety of complicated factors contribute to increases in insulin prices, and this report examines opportunities to identify more affordable alternatives to high-priced insulin. The Council recommends supporting physician education initiatives focused on drug price and cost transparency and the cost-effectiveness of insulin therapies. Additionally, the Council recommends that our AMA disseminate relevant model state legislation and provide assistance, upon request, to state medical associations in support of legislative and regulatory efforts to improve drug price and cost transparency. Finally, the Council recommends that our AMA encourage the Federal Trade Commission and Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate.

In addition, the report describes extensive AMA policy and highly visible AMA advocacy that directly respond to the resolves of referred Resolution 826-I-17. Accordingly, the Council recommends reaffirmation of policies which support: monitoring the relationships between PBMs and the pharmaceutical industry; authorizing federal action to address price gouging and increase patient access to affordable drugs; prescription drug price and formulary transparency; value based insurance design and cost-sharing requirements that consider factors known to affect patient compliance; access to information about the out-of-pocket cost of prescription drugs; and continued collaboration with the Food and Drug Administration on controversial issues including drugs, biologics, and pharmaceuticals.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7-A-18

Subject: Insulin Affordability
(Resolution 826-I-17)

Presented by: Paul A. Wertsch, MD, Chair

Referred to: Reference Committee A
(Jonathan D. Leffert, MD, Chair)

At the 2017 Interim Meeting, the House of Delegates referred Resolution 826, "Improving Affordability of Insulin," which was sponsored by the American Association of Clinical Endocrinologists (AACE) and the Endocrine Society (ES), and which directed the American Medical Association (AMA) to:

> (1) work with relevant medical specialty societies to convene a summit with participation by patients, clinicians, manufacturers, pharmacy benefit managers (PBMs), insurers and the appropriate federal representatives to highlight the dramatic increase in insulin costs and identify potential solutions; (2) pursue solutions to reduce patient cost sharing for insulin and ensure patients benefit from rebates at the point of sale; (3) work with health insurance companies and federal agencies to stabilize drug formularies and reduce non-medical switching by encouraging plans to cover insulin products at the same cost listed on a drug formulary throughout the entire plan year; (4) encourage insulin price and cost transparency among pharmaceutical companies, PBMs and health insurance companies; and (5) work with electronic medical record vendors and insurance companies to integrate current formularies and price information into all systems so physicians and patients can make informed decisions on insulin products to reduce cost burdens on patients.

The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Annual Meeting. This report highlights insulin as one among the many prescription drugs to recently experience exceptional price increases, government and legal actions to address insulin affordability, opportunities to identify more affordable options for patients in need, and the strong ongoing efforts of the AMA to address affordability of pharmaceuticals. Finally, this report presents policy recommendations.

BACKGROUND

Approximately 30 million Americans have diabetes,[1] and approximately six million Americans use insulin.[2] As explained by the AACE and the ES, patients with type 1 diabetes need insulin for survival and frequently insulin is the only drug that can control the diabetes of patients with type 2 diabetes.[3] Insulin can be very expensive, and the price has increased dramatically over the course of the past decade. For example, the annual retail price of Humulin R (U-500) 500 units/mL—an insulin marketed by Eli Lilly and Company (Lilly)—increased from $2,487 at the end of 2005 to $15,860 by the end of 2015.[4] Humulin is one of six brand-name drugs that increased in price by 500 percent or more from 2006 to 2015.[5] In general, the mean price per milliliter of insulin increased almost 200 percent, from $4.34 per milliliter in 2002 to $12.92 per milliliter in 2013.[6]

High insulin prices impact stakeholders throughout the health care system. Of course, uninsured patients paying cash for their prescriptions are exposed directly to high insulin prices. Insured patients are also directly impacted by high insulin prices when they are still in the deductible period, when the drug prescribed is not covered by their insurance, when a nonpreferred formulary status for a particular insulin product leads to a higher patient cost-share, and when a Medicare Part D beneficiary is in the "donut hole."[7] As the number of patients enrolled in high-deductible health plans and Medicare Part D continues to rise, more patients will be vulnerable to significant drug prices. Insulin prices also impact health plans/payers and PBMs. The impact of insulin expenditures on Medicare and Medicaid has been noteworthy. For example, expenditures for just one long-acting insulin analogue, glargine, were the second largest of all Medicare expenditures in 2015.[8] In that year, Medicare Part D spent more than $4.3 billion and Medicaid spent more than $1.4 billion on glargine alone.[9]

Pharmaceutical manufacturers, PBMs and others in the pharmacy supply chain continue to blame each other for high drug prices,[10] but some have taken steps that may ameliorate the impact on patients. For example, Novo Nordisk has indicated that it would limit future annual price increase percentages to not exceed single digits, ensure that a lower-priced option for human insulin remains available, and continue support of copay assistance and patient assistance programs, which are described later in this report.[11]

At the same time, it is important to emphasize that insulin is one of the many essential drugs across all categories of pharmaceuticals—brand name, specialty, and generic—to experience remarkable price increases. For example, the brand name drug Wellbutrin XL, used to treat depression, experienced a price increase of 1,185 percent over a ten-year study period ending in 2015.[12] Over the same ten-year study period, the specialty drug Enbrel, used to treat inflammatory and immunological disorders, experienced a 172 percent price increase.[13] Finally, between 2010 and 2015, the generic drug divalproex sodium, an anticonvulsant, experienced a price increase of 450.6 percent.[14] The Council acknowledges that, as with insulin, if patients are not able to take these medications correctly due to affordability, complications can result.

GOVERNMENT AND LEGAL ACTIONS TO ADDRESS INSULIN AFFORDABILITY

The significant and complicated factors contributing to increases in insulin prices have led both state and federal governments, as well as private citizens, to take formal action. To date, at least five states and a federal prosecutor are demanding information from insulin manufacturers and PBMs.[15] In addition, prominent class-action attorneys are bringing lawsuits on behalf of patients.[16] For example, a class action complaint filed in Massachusetts in January 2017 points to evidence that, "In 13 instances since 2009, Sanofi and Novo Nordisk raised the benchmark prices of their long-acting analog insulins, Lantus and Levemir, in tandem, 'taking the same price increase down to the decimal point within a few days of each other'. . . Eli Lilly and Novo Nordisk have engaged in the same lock-step behavior with respect to their rapid-acting analog insulins, Humalog and Novolog."[17] The complaint further alleges that these pharmaceutical companies artificially inflated their list prices to secure positions on PBMs' formularies, with PBMs demanding higher rebates in exchange for including drugs on their preferred-drug lists.[18] Similarly, three of the main insulin manufacturers—Sanofi-Aventis, Novo Nordisk and Lilly—along with three of the largest PBMs—CVS Health, Express Scripts and OptumRx—are subject to a class action lawsuit, alleging that they together caused "rapid and lockstep price increases of more than 150 percent in insulin treatments."[19]

In addition, there has recently been legislative and regulatory action to improve insulin affordability. In November 2016, two US Senators requested that the Department of Justice (DOJ)

and the Federal Trade Commission (FTC) investigate possible collusion among insulin makers.[20] Concerns regarding PBMs became a theme in a February 2018 hearing by the House Energy and Commerce Subcommittee on Oversight and Investigations that was focused on concentration in the health care system.[21] Specifically relevant to this report, Ranking Member of the Subcommittee, Rep. Diana DeGette (D-Colo.), explored whether PBM consolidation contributed to higher prices for insulin.[22] Additionally, the Food and Drug Administration (FDA) is working to "improve transparency and encourage the development and submission of abbreviated new drug applications (ANDAs) in markets with limited competition."[23] To that end, it has developed a list identifying approved new drug application (NDA) drug products that are off-patent and off-exclusivity, and for which the FDA has not yet approved an ANDA. This list of applications was updated in December 2017, and it includes several insulin products (insulin human, insulin lispro protamine recombinant, and insulin lispro recombinant).[24] On the state level, in 2017, Nevada passed an act that requires the state's Department of Health and Human Services to compile a list of prescription drugs that it determines to be essential for treating diabetes.[25] The manufacturers and PBMs associated with essential diabetes drugs will have to submit annual reports to the state containing drug cost information,[26] which will be analyzed by the state and reported on its website.[27] However, pharmaceutical companies have begun challenging the Nevada law in court.[28]

OPPORTUNITIES TO IDENTIFY MORE AFFORDABLE ALTERNATIVES

Value-Based Insurance Design

Value-based insurance design (VBID) uses cost-sharing as a tool to encourage the use of specific "high-value services," which have been defined as those services that are clinically meaningful in the practice of medicine, improve quality of care or clinical outcomes for patients, and are usually standards of care as part of evidence-based guidelines or clinical care pathways.[29] Unlike traditional benefit designs that apply a standard set of cost-sharing requirements to all services and all patients, VBID determines coverage and cost-sharing rules based on an assessment of the clinical value of individual health care treatments or services.

Diabetes management is an especially strong example of VBID's potential. Aligning incentives to encourage blood glucose control prevents long-term complications from diabetes that can be physically and financially devastating to patients and the health care system. As AACE and ES have explained, without adequate control of diabetes, patients have a higher risk of developing microvascular complications such as blindness, kidney disease and nerve damage, and macrovascular complications including heart attacks and strokes.[30] A recent study used actuarial modeling to predict the financial impact of VBID for Medicare beneficiaries, and it used a design that incorporated targeted reductions in cost-sharing for select chronic conditions.[31] The study specifically focused on diabetes patients and included insulin and other glycemic-lowering agents among the high-value services targeted for reduced cost-sharing. The actuarial assumptions of this model indicated that removing cost-sharing for targeted high-value services would increase their use by five to 15 percent, and the fiscal impact of that additional spending would be partially offset by fewer inpatient stays and emergency department visits. The study found that for diabetes patients under this model, member cost-sharing would decrease, societal impact would be close to cost neutral, and the increase in cost to health plans would be "very modest."[32]

Recognizing its potential, VBID is gaining traction as an insurance design to improve affordability. The recently enacted Bipartisan Budget Act of 2018 incorporates the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017, which includes expansion of the Medicare Advantage Value-Based Insurance Design Model to all 50 states by no later than January 1, 2020.[33] The model allows Medicare Advantage plans the

flexibility to reduce cost-sharing or offer supplemental benefits to enrollees with specified chronic conditions, focusing on the services that are of highest clinical value to them. This Act demonstrates growing bipartisan support for the expanded role of VBID principles in public and private payers.

The Role of Biosimilars

Biosimilars may play a unique role in the insulin market. Currently, no insulin glargine products are licensed under the Public Health Service Act, so there is no "reference product" for a proposed biosimilar product. Instead, when Basaglar launched in December 2016, the FDA referred to it as "follow-on" insulin to the originator drug, Lantus. (This definitional confusion should resolve following a change to FDA law in 2020).[34] As with other drugs, the price patients will pay for Basaglar varies depending on their health insurance plan.[35] Additionally, Basaglar experienced uptake that varied based on patients' insurance type.[36] As of March 2017, Basaglar had achieved only approximately five percent market share. However, in the small portion of the market where insurance formularies preferred Basaglar to Lantus, it achieved approximately 50 percent market share.[37] Notably, this year, Basaglar is preferred in Medicare Part D plans, as well as other commercial plans.[38] Another key item to watch is a second follow-on insulin glargine, Lusduna, which gained tentative FDA approval in July 2017, but will not be issued final approval until a patent infringement suit, brought by Lantus' maker, Sanofi, concludes.[39] Due to stringent regulations and the cost of bringing "follow-on" or biosimilar insulins to market, some analysts expect that the mean price of insulin will not decrease as a result of "generic" competition.[40] In contrast, other analysts have speculated that once several follow-on insulin glargine products are actively competing with Lantus and its next-generation insulin glargine brand, discounts and rebates could mean savings of approximately 30 percent, as the market niche becomes saturated.[41]

The Role of Older Insulins

To avoid the high price of many insulin regimens, some physicians and analysts have advocated for use of older, less expensive insulins, when clinically appropriate to do so,[42] and this may vary among patients with type 1 and type 2 diabetes. As a general principle, the more severe the insulin deficiency (for type 1 and for some type 2 diabetes), "the more important it is to have considerable mimicry of normal physiology to successfully lower glucose and do so with safety. Although not superior in overall glycemic lowering efficacy compared to human insulin, the analogs . . . have gained progressive popularity despite their increased cost. Today, analogs used as basal bolus therapy are considered the standard of care for patients who have type 1 diabetes mellitus and are increasingly used in type 2 diabetes."[43]

In fact, the proportion of patients using more expensive, newer insulin analogs has substantially increased, even though data suggests that there is "little clinical benefit" to using insulin analog versus regular human insulin and neutral protamine Hagerdorn (NPH) for type 2 diabetes.[44] In 2000, 19 percent of privately insured adults with type 2 diabetes were using analog insulin, but by 2010, 96 percent of that population was using insulin analogs.[45] The older insulins, however, are still considered to be as effective as the analogs in controlling blood glucose for most patients with type 2 diabetes.[46] Moreover, a vial of NPH (N), human regular (R), or premixed 70/30 N/R insulin (Novolin N, R, or 70/30) can be obtained for as little as $25.[47] At the same time, given the substantial increase in use of insulin analogs since 2000, younger clinicians may not be as well versed in the use of older insulins, with many training programs no longer emphasizing the use of human insulins.[48] Accordingly, guidance and educational materials can help younger physicians become more comfortable with prescribing more affordable insulin alternatives.[49] Consistent with these recommendations, a recent study compared prescription drug spending in the US to nine

other high-income countries and found that US citizens consume a mix of drugs that include a high proportion of newer, more expensive medications without evidence of better health outcomes than the other nine countries examined.[50] The study observed that, unlike the US, the other nine countries have processes to assess not just whether a new drug is effective, but whether it is more effective than existing therapies, and sometimes, whether it is cost-effective.[51] A process for including cost-effectiveness in comparative effectiveness research for pharmaceuticals is consistent with AMA Policy H-110.986, which is detailed in the policy section below.

Improving Price Transparency

With timely, accurate information about what a specific prescription will cost a specific patient, physicians and patients will be in a stronger position to jointly develop optimal treatment plans. As detailed below, the AMA is engaged in significant activity, supported by longstanding policy, to advocate for improved prescription drug price transparency. Improved transparency at the point of sale may also help patients address affordability concerns.

Many health care industry stakeholders can potentially help improve insulin affordability. In November 2017, Surescripts announced a Real-Time Prescription Benefit to advance this goal. Surescripts is collaborating with six electronic health records (EHR) companies (representing 53 percent of the US physician base) and leveraging information from PBMs CVS Health and Express Scripts (representing nearly two-thirds of US patients), "to deliver patient-specific benefit and price information to providers in real time at the point of care. Once integrated with the EHR, the solution will also display therapeutic alternatives so that the prescriber and patient can collaborate in selecting a medication that is both clinically appropriate and affordable."[52] UnitedHealthcare and OptumRx are collaborating to provide a similar tool, specifically for their enrollees.[53] With PreCheck MyScript, before prescribing a medication, physicians can run a pharmacy trial claim to see how much a patient would be charged for a specific medication. The system will also provide lower-cost alternatives, when available.

In addition, pharmacists play an important role. Pharmacists may be aware of less expensive prescription drug options, but pharmacists can be prevented from informing patients of these options due to certain provisions in their contracts with PBMs.[54] For example, a drug formulary can require patients to spend more on a prescription copay than they would be charged if they purchased the drug without insurance.[55] So called "gag clauses" in pharmacy-PBM contracts can bar pharmacists from telling consumers about less expensive options, such as not using their insurance. Moreover, "clawback" provisions can allow PBMs to take back the difference between a higher copay amount and a lower negotiated rate. Bipartisan bills have recently been introduced in both the Senate[56] and the House[57] to prohibit these restrictions on pharmacies and pharmacists.

Additionally, financial assistance programs can help eligible patients, but as the ES has explained, these programs are often inaccessible or overly complicated for the patients who need them the most.[58] For example, the Novo Nordisk Savings Card can help patients save hundreds of dollars on their diabetes medication.[59] However, to be eligible for this program, patients must be enrolled in a commercial insurance plan (patients paying cash and those insured through any federal or state plan are ineligible).[60] Additionally, the discount only applies for up to 24 months, and is subject to maximum benefit limitations.[61] Sanofi-Aventis similarly offers a Sanofi Rx Savings Card, but it too carries eligibility restrictions that are not easily found on its website.[62] Finally, Lilly offers limited time offers for discounts on insulin products, but each offer is subject to eligibility requirements and differing expiration dates.[63]

Some patients may benefit from other forms of financial assistance, but this too is complicated. Patients without health insurance or without prescription drug coverage can apply for patient assistance programs, and the nonprofit NeedyMeds can help patients find programs that offer free or low-cost insulin for those who meet eligibility requirements.[64] Some patients who have prescription drug coverage, especially those with high deductible health plans, may find that cash and coupon prices can be lower than their insurance copay or coinsurance.[65] Websites like GoodRx can help patients find the lowest prices for their insulin.[66] However, companies that provide health insurance and prescription drug coverage have started instituting "copay accumulators," which can significantly impact patients' out-of-pocket costs when using drug coupons.[67] Previously, when patients used copay coupons to reduce the price they pay for their prescriptions, the value of those coupons counted toward their deductible or out-of-pocket maximum. However, the new copay accumulators will not count the coupons' value toward helping patients spend down their deductibles and out-of-pocket maximum. Accordingly, once patients use the full value of their drug coupons, they will be subject to more of the cost than they had been before.[68] Moreover, some insurance companies limit insured patients' abilities to use prescription coupons at all.[69]

AMA POLICY AND ADVOCACY

Extensive AMA policy and highly visible AMA advocacy directly respond to the resolves of referred Resolution 826-I-17 and continue to strive for greater prescription drug cost transparency and affordability.

AMA Policy

The Council agrees with the AACE and ES that a key issue in addressing insulin affordability is working toward reduced patient cost-sharing. AMA policy has historically strongly supported VBID, which can achieve reduced patient cost-sharing. For example, 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. Policy H-185.939 outlines principles to guide the design and implementation of VBID programs, stating that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements, and that coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Supporting the role of physicians in engaging patients in joint decision-making to select an insulin regimen that appropriately balances clinical needs and cost-effectiveness, Policy H-450.938 stipulates that the cost of alternate interventions, in addition to patient insurance coverage and cost-sharing requirements, should be evaluated. Moreover, the policy states, physicians should encourage their patients to participate in making value-based health care decisions.

AMA policy also supports value-based pricing for pharmaceuticals (Policy H-110.986). The policy specifically calls for value-based pricing processes that incorporate affordability criteria and that include cost-effectiveness analyses in comparative effectiveness research. 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. Finally, Policy H-125.977 advocates for economic assistance, including coupons and other discounts for patients, whether they are enrolled in government health insurance programs, enrolled in commercial insurance plans, or are uninsured.

Another key to improving insulin affordability is improving price transparency. Consistent with Resolution 826-I-17 and ES recommendations,[70] Policy H-125.979 supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term. Additionally, the AMA developed model state legislation entitled, "An Act to Increase Drug Cost Transparency and Protect Patients from Surprise Drug Cost Increases during the Plan Year" (AMA Model Act), and it directly addresses the issue of stabilized formularies and cost transparency. The AMA Model Act specifically responds to Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs and health insurance companies. 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, and legislation that authorizes the Attorney General and/or the FTC to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients. In addition, the policy encourages FTC actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives. Also, Policy H-110.991 advocates for greater prescription drug price transparency at the pharmacy point of sale by: (1) advocating that both the retail price and the patient's copay be listed on prescription receipts, (2) pursuing legislation that would require pharmacies to inform patients of the cash price as well as the formulary price of any medication prior to purchase, and (3) opposing provisions in contracts between pharmacies and PBMs that would prohibit pharmacies from disclosing when a patient's copay is higher than the drug's cash price.

Physicians will be in a stronger position to help their patients with insulin affordability concerns if information systems can integrate price information, thus empowering physicians and patients to make informed decisions at the point of prescribing. The AMA Model Act also addresses the issue of timely decision support, consistent with Policy H-450.938, which states that physicians should have easy access to and review the best available data associated with costs at the point of decision-making, which necessitates cost data to be delivered in a reasonable and useable manner by third-party payers and purchasers. In addition, the policy calls for physicians to seek opportunities to improve their information technology infrastructures to include new and innovative technologies to facilitate increased access to needed and useable evidence and information at the point of decision-making. Related, Policy H-125.979 encourages PBMs, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing, and promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide. Similarly, Policy H-110.990 supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can jointly decide on treatment.

Several AMA policies support the FDA's efforts to highlight drugs that are off-patent and off-exclusivity. Specifically, Policy H-100.980 supports a strong and adequately funded FDA to ensure that safe and effective medical products become available as efficiently as possible. The policy also states that our AMA will continue to work with the FDA on controversial issues concerning drugs, biologics and pharmaceuticals to try to resolve concerns of physicians. Related, Policy H-125.984 states that Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process. Finally, Policy H-125.980 supports FDA implementation of the Biologics Price Competition and Innovation Act of 2009 in a manner that places appropriate

emphasis on promoting patient access, protecting patient safety, and preserving market competition and innovation.

Also noteworthy are the many policies establishing a framework for the AMA's approach to improving drug pricing. For example, Policy H-110.998 urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Policy D-110.993 states that our AMA will continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Policy H-110.992 states that the AMA will monitor the relationships between PBMs and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs. Policy H-110.997 supports programs to contain the rising costs of prescription drugs that meet certain criteria, and encourages physicians to consider prescribing the least expensive drug.

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. However, AMA policy makes a departure from its market-based approach to pharmaceutical pricing in Policy D-330.954, which supports federal legislation that gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs. The policy also states that our AMA will work toward eliminating the Medicare prohibition on drug price negotiation.

AMA Activity

AMA Model Legislation: The AMA Model Act referenced previously provides a template that state legislatures can modify to increase prescription drug cost transparency in a variety of ways, and it specifically advances many of the goals of Resolution 826-I-17 with regard to price and cost transparency, as well as integration into EHRs. Specifically, under the AMA Model Act, manufacturers of prescription medication available in any state that implements this act would be required to disclose a variety of their costs, as well as the amount of financial assistance they provide to patients; health insurers and PBMs operating in the state would be required to disclose any discounts or other financial consideration they received that affects the price and cost-sharing of covered medicines placed on a formulary. Consistent with ES recommendations,[71] the AMA Model Act would also authorize a pilot study to integrate transparency data at the point of care, with information such as medicines' formulary status, cost-sharing tier, patient out-of-pocket cost, and coverage restrictions (eg, prior authorization, step therapy, quantity limits) being integrated into the clinical and prescribing workflows of physicians and other health care providers in EHR or electronic prescribing systems. Finally, consistent with Policy H-110.991, the AMA prepared a new model bill that prohibits clawbacks and standard gag clauses in pharmacy-PBM contracts. Several states have enacted and/or are considering similar legislation, and with its new model bill, the AMA will advocate for greater nation-wide adoption of such policies.

AMA State and National Engagement: The AMA has been engaged in legislative and regulatory advocacy concerning prescription drug pricing and costs. For example, in December 2017, the AMA testified at a hearing of the Health Subcommittee of the House Committee on Energy and Commerce on examining the pharmaceutical supply chain. The AMA has been engaged at the National Association of Insurance Commissioners as it develops its Prescription Drug Benefit Management Model Act, including with regard to mid-year formulary changes. On the state level, in 2017, the AMA supported Assembly Bill 762 in New Jersey, which would help provide patients and the legislature with relevant information about the manufacturing, production, research and

development, advertising and other associated costs for prescription medications. Additionally, the AMA continues to urge state medical associations to have the AMA Model Act introduced.

AMA Grassroots Campaign: Pursuant to Policy H-110.987, and consistent with Resolution 826-I-17, in 2016, the AMA convened a Task Force on Pharmaceutical Costs, which met four times to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs. The Task Force agreed that increasing transparency among pharmaceutical companies, health plans and PBMs should be the first focus of the grassroots campaign, which led to the launch of the TruthinRx campaign in 2016. The goal of TruthinRx is to expose the opaque process that pharmaceutical companies, PBMs, and health plans engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency. To date, over 150,000 individuals have signed a petition to members of Congress in support of greater drug pricing transparency. Additionally, the *TruthinRx.org* website provides a template letter that website visitors can customize and directly send to their US Senators and US Representatives, calling on them to support increased transparency in prescription drug prices.[72] Finally, the Council notes that the *TruthinRx.org* website has content specifically addressing insulin pricing.[73] Coordinated with AMA model legislation, and state and national engagement, TruthinRx is continuously updated to reflect advances in AMA policy and pharmaceutical industry activities.

DISCUSSION

The Council lauds the sponsors of Resolution 826-I-17 for highlighting the price increases of insulin and shares the concerns that have led to class action lawsuits, state and federal actions, and congressional requests that the DOJ and FTC investigate possible collusion among insulin makers. The market factors contributing to the insulin price increases are complex and span the pharmaceutical supply chain. Pursuant to Policy H-110.992, the AMA is committed to monitoring the relationships between PBMs and the pharmaceutical industry and strongly discouraging arrangements that could cause a negative impact on the cost or availability of essential drugs. In addition, Policy H-110.987 supports legislation that authorizes the Attorney General and/or the FTC to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients. Building upon these policies, the Council recommends that the AMA encourage the FTC and DOJ to monitor insulin pricing and market competition and take enforcement actions, as appropriate.

As demonstrated by the extensive policy and activity summarized in this report, the AMA is deeply committed to efforts to improve prescription drug affordability in general, and insulin affordability, in particular. In addition to supporting the FTC and DOJ, the AMA has established policy that supports the FDA as it strives to increase access to high quality generic and biosimilar drugs. Specifically, under Policy H-100.980, the AMA affirms its commitment to continuing to work with the FDA on controversial issues concerning drugs, biologics and pharmaceuticals to try to resolve concerns of physicians.

VBID presents a powerful opportunity to reduce patient cost-sharing for high-value services, such as diabetes treatment, and AMA policy strongly supports this model. Policy H-185.939 outlines principles to guide the design and implementation of VBID programs, including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements. Policy H-110.986 specifically supports value-based pricing for pharmaceuticals, and Policy H-155.960 encourages third-party payers to use targeted benefit design, with cost-sharing requirements determined based on the clinical value of a health care service, with consideration given 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. In addition, the policy supports joint physician-patient decision-making, encouraging the development and use of technology to enable physicians and patients to determine the actual price and out-of-pocket costs of prescription drugs prior to making prescribing decisions.

In recent years, the AMA has demonstrated an ongoing commitment to improving prescription drug price transparency. As detailed above, the TruthinRx campaign continues a powerful grassroots campaign for greater transparency in prescription drug pricing, and the AMA Model Act specifically responds to Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs, and health insurance companies. Moreover, pursuant to Policy H-110.987, the AMA 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. Similarly supporting transparency and collaboration across the pharmacy supply chain, Policy H-125.979 supports AMA efforts to encourage PBMs, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing. In this way, health care technology and shared information can promote optimal physician-patient joint decision making. Together, these efforts are accomplishing the goals of Resolution 826-I-17. As a logical next step, the Council recommends that the AMA disseminate the model state legislation it has developed to promote increased drug price and cost transparency and to prohibit "clawbacks" and standard gag clauses in contracts between pharmacies and PBMs that bar pharmacists from telling consumers about less expensive options, such as choosing to pay cash rather than using insurance, to purchase their medication. Moreover, the Council recommends that the AMA provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.

The Council also thanks the AACE and the ES for their expertise and for calling attention to the need for training on the appropriate use of regular human insulin and neutral protamine Hagerdorn for post-graduate physicians, fellows, residents, and students. The Council recommends that the AMA support initiatives, such as those by AACE, ES, and other national medical specialty societies, that strive to fill this gap in continuing medical education. Similarly, to help physicians better understand the complex challenges their patients may face in paying for their medication, the Council recommends that the AMA support physician education regarding drug price and cost transparency and challenges that arise at the pharmacy.

As described above, it is important to continue to view insulin affordability within the context of the much broader issue of prescription drug affordability in the US. The AMA has a deep and longstanding commitment to improving patient access to affordable prescriptions. Recognizing that access to critical drugs across many critical disease states is jeopardized by high prices and continued price increases, the AMA has made a strategic decision to work toward broad-based reforms, rather than to examine one disease state or drug at a time. Otherwise, the AMA would be in a position to require individual summits and advocacy campaigns that are unique to each of the critical pharmaceutical challenges facing AMA members and their patients, which would not be a sustainable advocacy model. Accordingly, the Council's recommendations encourage continued AMA leadership on a broad strategy to address pharmaceutical pricing, while supporting initiatives to improve the affordability of insulin for our patients.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 826-I-17, and that the remainder of the report be filed:

1. That our American Medical Association (AMA) encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate. (New HOD Policy)

2. That our AMA disseminate model state legislation to promote increased drug price and cost transparency and to prohibit "clawbacks" and standard gag clauses in contracts between pharmacies and pharmacy benefit managers (PBMs) that bar pharmacists from telling consumers about less-expensive options for purchasing their medication. (Directive to Take Action)

3. That our AMA provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency. (Directive to Take Action)

4. That our AMA support physician education regarding drug price and cost transparency and challenges patients may encounter at the pharmacy point-of-sale. (New HOD Policy)

5. That our AMA support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies. (New HOD Policy)

6. That our AMA reaffirm Policy H-110.992, which states that the AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs. (Reaffirm HOD Policy)

7. That our AMA reaffirm Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies; supports drug price transparency legislation that requires public notice by pharmaceutical manufacturers when certain price increase triggers are reached; and supports legislation that authorizes the Attorney General and/or the FTC to take legal action to address price gouging by pharmaceutical manufacturers and increase patient access to affordable drugs. (Reaffirm HOD Policy)

8. That our AMA reaffirm Policy H-100.980, which states that the AMA will continue to work with the Food and Drug Administration on controversial issues, including those concerning drugs, biologics, and pharmaceuticals, to try to resolve concerns of physicians. (Reaffirm HOD Policy)

9. That our AMA reaffirm Policy H-125.979, which supports legislation or regulation to ensure that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term. (Reaffirm HOD Policy)

10. That our AMA reaffirm Policies H-185.939, H-155.960 and H-110.986 which support value based insurance design and value based pricing for pharmaceuticals. (Reaffirm HOD Policy)

11. That our AMA reaffirm Policy H-110.990 which supports cost-sharing requirements for prescription drugs that consider factors known to affect patient compliance and the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of prescription drugs prior to making prescribing decisions. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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APPENDIX

Policies Recommended for Reaffirmation

H-100.980 Food and Drug Administration
(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to work with the FDA on controversial issues concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to resolve concerns of physicians and to support FDA initiatives of potential benefit to patients and physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate proposed changes in the FDA and will respond as appropriate.
Policy Timeline Sub. Res. 548, A-92 BOT Rep. 32, A-95 BOT Rep. 18, A-96 Reaffirmed: BOT Rep. 7, I-01 Reaffirmation I-07

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

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

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

H-110.990 Cost Sharing Arrangements for Prescription Drugs
Our AMA:
1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and
3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition.
Policy Timeline CMS Rep. 1, I-07 Reaffirmation A-08 Reaffirmed: CMS Rep. 1, I-12 Reaffirmed in lieu of Res. 105, A-13 Reaffirmed in lieu of: Res. 205, A-17 Reaffirmed in lieu of: Res. 207, A-17

H-110.992 Study of Actions to Control Pharmaceutical Costs
Our AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs.
Policy Timeline Sub. Res. 114, A-01 Reaffirmed: Res. 533, A-03 Reaffirmed: CMS Rep. 4, A-13 Reaffirmed in lieu of Res. 229, I-14

H-125.979 Private Health Insurance Formulary Transparency
1. Our AMA will work with pharmacy benefit managers, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing.
2. Our AMA supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, that formulary information be specific as to generic versus trade name and include copay responsibilities, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.
3. Our AMA will develop model legislation (a) requiring insurance companies to declare which drugs on their formulary will be covered under trade names versus generic, (b) requiring insurance carriers to make this information available to consumers by October 1 of each year and, (c) forbidding insurance carriers from making formulary deletions within the policy term.
4. Our AMA will promote the following insurer-pharmacy benefits manager - pharmacy (IPBMP) to physician procedural policy: In the event that a specific drug is not or is no longer on the formulary when the prescription is presented, the IPBMP shall provide notice of covered formulary alternatives to the prescriber promptly so that appropriate medication can be provided to the patient within 72 hours.
5. Drugs requiring prior authorization, shall be adjudicated by the IPBMP within 72 hours of receipt of the prescription.
6. Our AMA (a) promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide, and (b) supports state medical societies in advocating for state legislation to ensure online access to up-to-date and accurate prescription drug formularies for all insurance plans.
7. Our AMA will continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.
8. Our AMA will develop model state legislation on the development and management of pharmacy benefits.
Policy Timeline Sub. Res. 724, A-14 Appended: Res. 701, A-16 Appended: Alt. Res. 806, I-17

H-155.960 Strategies to Address Rising Health Care Costs
Our AMA:
(1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government;
(2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease;
(b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and
(d) promote “value-based decision-making” at all levels;
(3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training;
(4) will continue to advocate that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers;
(5) will continue to advocate that health information systems be designed to provide physicians and other health care decision-makers with relevant, timely, actionable information, automatically at

the point of care and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; patient-specific clinical and insurance information; prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors;
(6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings;
(7) 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. Consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and
(8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care.
(9) Our AMA will, in all reform efforts, continue to identify appropriate cost savings strategies for our patients and the health care system.
Policy Timeline CMS Rep. 8, A-07 Reaffirmed: CMS Rep. 7, A-08 Reaffirmed in lieu of Res. 828, I-08 Reaffirmation A-09 Reaffirmation I-09 Reaffirmation A-11 Reaffirmation I-11 Appended: Res. 239, A-12 Reaffirmed in lieu of Res. 706, A-12 Reaffirmed: CMS Rep. 1, I-12 Modified: CMS Rep. 2, A-13 Reaffirmed in lieu of Res. 122, A-15 Reaffirmed in lieu of: Res. 121, A-16 Reaffirmed: CMS Rep. 05, I-16 Reaffirmation I-16 Reaffirmed in lieu of: Res. 712, A-17

H-185.939 Value-Based Insurance Design
Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles: (a) Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
(b) Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.
(c) High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan. (d) The methodology and criteria used to determine high or low-value services or treatments must be transparent and easily accessible to physicians and patients. (e) Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design. (f) VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices. (g) Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties. (h) Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence. (i) VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H450.941 and D285.972). Policy Timeline CMS Rep. 2, A13 Reaffirmed in lieu of Res. 122, A15 Reaffirmed in lieu of: Res. 121, A16 Reaffirmed: CMS Rep. 05, I16 Reaffirmation I16