

REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (I-16)
Incorporating Value into Pharmaceutical Pricing
(Resolution 712-A-16)
(Reference Committee J)

EXECUTIVE SUMMARY

Following the adoption of the recommendations of Council on Medical Service Report 2-I-15, “Pharmaceutical Costs,” the Council spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing in the context of rising concerns about pharmaceutical spending. 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 value-based pricing of pharmaceuticals. In addition, at the 2016 Annual Meeting, the House of Delegates referred Resolution 712, which asked that our AMA “advocate with Congress and federal agencies, for any necessary combination of legislation, regulation, negotiation with the pharmaceutical industry, and federal subsidies, to lower the cost of treatment for all Americans infected with Hepatitis C virus using highly effective oral medications, to a price level that would make treatment affordable and accessible.”

The integration of value into pharmaceutical pricing builds upon long-standing AMA policy that supports market-driven mechanisms to control pharmaceutical costs, as well as recognizes that improvements need to be made to ensure that the pharmaceutical marketplace operates efficiently and effectively. Importantly, value-based pricing of pharmaceuticals does not require the establishment of price controls or other mandates that may stifle innovation in the pharmaceutical industry. However, pricing pharmaceuticals based on their value should aim to improve affordability for patients and limit system-wide budgetary impact. As policymakers, insurers and other stakeholders move forward with efforts to integrate value into pharmaceutical pricing, the Council has proposed principles to guide AMA advocacy in this arena, which state that initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs, allow for patient variation and physician discretion, limit administrative burdens on physician practices and patients, and be evidence-based, transparent, objective and involve the input of practicing physicians and researchers.

The Council notes that there continues to be a lack of high-quality data on the cost and value of interventions using pharmaceuticals in practice. Increased comparative effectiveness research on pharmaceuticals is imperative so patients, physicians and other stakeholders are aware of differences between the prescription drugs available within the same category or class. However, in order to be truly effective, the cost of alternatives, as well as cost-effectiveness analysis, should be included in comparative effectiveness research endeavors.

The Council believes that pharmaceutical pricing mechanisms need to take into account a drug’s public health value. For pharmaceuticals that are used to treat or cure diseases that pose unique public health threats, including hepatitis C, the Council supports the use of direct purchasing mechanisms to assure patient access to the treatments they need. Direct purchase arrangements will guarantee prices for prescription drugs as well as volume for manufacturers. As such, lower prices can be achieved in exchange for a larger, guaranteed market for a drug.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-I-16

Subject: Incorporating Value into Pharmaceutical Pricing
(Resolution 712-A-16)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Following the adoption of the recommendations of Council on Medical Service Report 2-I-15,
2 “Pharmaceutical Costs,” the Council spent the past year reviewing the substantial body of
3 American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, and
4 determining whether additional policy was needed to guide future AMA advocacy efforts. In its
5 review, the Council concluded that additional AMA policy is needed to respond to innovative
6 proposals addressing pharmaceutical pricing that could potentially be included in future legislation
7 and regulations, including those that call for value-based pricing of pharmaceuticals.

8
9 At the 2016 Annual Meeting, the House of Delegates referred Resolution 712, “Remove Pricing
10 Barriers to Treatment for Hepatitis C (HCV),” which was introduced by the New Mexico
11 Delegation and assigned to the Council for study. Resolution 712-A-16 asked:

12
13 That our American Medical Association advocate with Congress and federal agencies, for any
14 necessary combination of legislation, regulation, negotiation with the pharmaceutical industry,
15 and federal subsidies, to lower the cost of treatment for all Americans infected with Hepatitis C
16 virus using highly effective oral medications, to a price level that would make treatment
17 affordable and accessible.

18
19 This report provides background on prescription drug spending and pricing; summarizes relevant
20 AMA policy; highlights potential mechanisms to determine the value of pharmaceuticals; assesses
21 the impact of Medicare drug price negotiation and associated AMA policy; and presents policy
22 recommendations.

23
24 **BACKGROUND**

25
26 According to the Assistant Secretary for Planning and Evaluation of the US Department of Health
27 and Human Services (HHS), prescription drug spending was \$457 billion in 2015, accounting for
28 16.7 percent of spending on personal health care services. Of this amount, \$328 billion (71.9
29 percent) was for retail drugs (at outlets that directly serve patients), and \$128 billion (28.1 percent)
30 was for non-retail drugs (by medical providers for drugs they provide directly to patients).¹

31
32 Prescription drug spending increased by 12.6 percent in 2014, with a higher rate of spending
33 growth also estimated for 2015. From 2013 to 2018, prescription drug spending is projected to
34 increase by an average of 7.3 percent per year.¹ Leading contributors to the growth in prescription
35 drug spending in the US include the prices and uptake of brand-name drugs and biologics new to
36 the market, the prices of protected brands, the lessening impact of major patent expirations, invoice

1 price increases of brand-name drugs, biologics and generic drugs, and increases in the number of
2 prescriptions per person.^{1,2} The prices of new treatments for multiple sclerosis, HIV, hepatitis C,
3 oncology and autoimmune conditions have contributed to new brand spending growth, as well as
4 specialty drugs making up 36 percent of drug spending in 2015. At the same time, the uptake levels
5 of specialty drugs have contributed to the growth rate in pharmaceutical spending. For example,
6 approximately 250,000 new patients received treatment for hepatitis C in 2015, with over 400,000
7 patients having been treated with at least one of the six drugs brought to the market in the past two
8 years. In addition, there has been a rapid uptake in the use of PD-1 inhibitors, new immuno-
9 oncology drugs.²

10
11 In 2013, the average annual increase in retail prices for 622 brand name and generic versions of
12 traditional and specialty prescription drugs widely used by older Americans, including Medicare
13 beneficiaries, was 9.4 percent.³ Invoice (list) prices for brand-name prescription drugs and
14 biologics already on the market increased 12.4 percent in 2015, while the average net price for the
15 drugs—i.e., adjusted for rebates and other price concessions by pharmaceutical companies—
16 increased by 2.8 percent.² Cumulatively, between 2008 and 2015, the average price for the most
17 commonly used brand-name prescription drugs, as defined by the Express Scripts Prescription
18 Price Index, increased by 164 percent.⁴ Price increases for older generic drugs moderated in 2015
19 when compared to 2013 and 2014, contributing \$0.5 billion versus more than \$3 billion in spending
20 growth. However, the invoice prices of branded generics notably increased.²

21
22 The level at which drugs are priced impacts health plans, payers, pharmacy benefit managers,
23 employers, physicians and patients. Medicare, Medicaid, employer-sponsored health plans and
24 plans offered in health insurance exchanges have had to make adjustments in response to the higher
25 costs of prescription drugs. Prescription drug prices have been frequently cited as a main
26 justification for higher health insurance premiums, higher prescription drug cost-sharing, additional
27 prescription drug tiers and use of utilization management techniques.

28
29 Approximately 4.4 billion outpatient prescriptions were dispensed in the US in 2015.² In 2013, the
30 average annual retail cost of drug therapy for a prescription drug, based on 477 widely used
31 prescription drugs by older Americans indicated for treating chronic conditions, which include
32 generic, brand and specialty drug products, was \$11,341. The average annual cost of therapy for
33 widely used generic drugs by older Americans was \$283 in 2013, while the average cost of therapy
34 was \$2,960 for widely used brand-name drugs and \$53,384 for widely used specialty drugs.³ The
35 cost of drug therapies impacts patient cost-sharing responsibilities. In 2015, stand-alone Part D
36 prescription drug plans (PDPs) had median cost sharing of \$38 for preferred brand-name drugs,
37 \$80 for non-preferred brand-name drugs, and \$1 for preferred generic drugs. Median cost-sharing
38 in Medicare Advantage prescription drug plans (MA-PDPs) was \$45 for preferred brand-name
39 drugs, \$95 for non-preferred brand-name drugs and \$3 for preferred generic drugs. In 2015, 48
40 percent of enrollees in PDPs with a specialty drug tier and approximately three-quarters of MA-PD
41 enrollees in plans with specialty drug tiers were in plans that required 33 percent coinsurance for
42 specialty drugs.⁵ In commercial plans overall, the average patient cost exposure for a brand
43 prescription filled was \$44 in 2015. The percentage of brand prescriptions with patient cost
44 exposure over \$50 increased to 17 percent in 2015, while the percentage with \$0 patient cost
45 exposure increased to 24 percent. The average patient cost exposure for generic drugs was
46 approximately \$8 in 2015.²

47 48 AMA POLICY ADDRESSING PHARMACEUTICAL PRICING AND VALUE

49
50 Council on Medical Service Report 2-I-15, which established Policy H-110.987, stipulates that our
51 AMA:

- 1 • Encourage Federal Trade Commission (FTC) actions to limit anticompetitive behavior by
2 pharmaceutical companies attempting to reduce competition from generic manufacturers
3 through manipulation of patent protections and abuse of regulatory exclusivity incentives.
- 4 • Encourage Congress, the FTC and HHS to monitor and evaluate the utilization and impact of
5 controlled distribution channels for prescription pharmaceuticals on patient access and market
6 competition.
- 7 • Monitor the impact of mergers and acquisitions in the pharmaceutical industry.
- 8 • Continue to monitor and support an appropriate balance between incentives based on
9 appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and
10 statutory barriers to competition as part of the patent system.
- 11 • Encourage prescription drug price and cost transparency among pharmaceutical companies,
12 pharmacy benefit managers and health insurance companies.
- 13 • Support legislation to require generic drug manufacturers to pay an additional rebate to state
14 Medicaid programs if the price of a generic drug rises faster than inflation.
- 15 • Support legislation to shorten the exclusivity period for biologics.
- 16 • Convene a task force of appropriate AMA Councils, state medical societies and national
17 medical specialty societies to develop principles to guide advocacy and grassroots efforts
18 aimed at addressing pharmaceutical costs and improving patient access and adherence to
19 medically necessary prescription drug regimens.
- 20 • Generate an advocacy campaign to engage physicians and patients in local and national
21 advocacy initiatives that bring attention to the rising price of prescription drugs and help to put
22 forward solutions to make prescription drugs more affordable for all patients, and will report
23 back to the House of Delegates regarding the progress of the drug pricing advocacy campaign
24 at the 2016 Interim Meeting.

25
26 As outlined in Board of Trustees Report 10-I-16, “AMA Initiatives on Pharmaceutical Costs,” the
27 AMA convened a Task Force on Pharmaceutical Costs pursuant to Policy H-110.987, which met
28 four times to develop principles to guide advocacy and grassroots efforts aimed at addressing
29 pharmaceutical costs. The Task Force reviewed the substantial body of AMA policy addressing
30 pharmaceutical costs and pricing, and discussed potential issues and issue combinations to feature
31 in an AMA grassroots campaign, including pharmaceutical cost and price transparency, Medicare
32 drug price negotiation, banning direct-to-consumer advertising and prescription drug reimportation.
33 The Task Force agreed that banning direct-to-consumer advertising and prescription drug
34 reimportation should not be pursued as part of the grassroots campaign at this time, after
35 considering several factors, including political feasibility, as well as the thresholds for AMA
36 support for prescription drug reimportation outlined in Policy D-100.983. The Task Force agreed
37 that increasing transparency among pharmaceutical companies, health plans and PBMs should be
38 the focus of Phase I of the grassroots campaign (remainder of 2016), with the specifics of Phase II
39 of the grassroots campaign (2017) to be determined after the 2016 presidential and congressional
40 elections and after any additional policy is established by the House of Delegates. However, the
41 Task Force agreed that strong consideration should be given to including Medicare drug price
42 negotiation in Phase II of the campaign. Resulting from the work of the Task Force, the AMA
43 launched a grassroots campaign on increasing pharmaceutical cost and price transparency among
44 pharmaceutical companies, health plans and pharmacy benefit managers.

45
46 Previously, at the 2015 Annual Meeting, the House of Delegates adopted Policy H-110.988, which
47 states that the AMA will:

- 48
49 • Work collaboratively with relevant federal and state agencies, policymakers and key
50 stakeholders (e.g., the US Food and Drug Administration, the FTC, and the Generic

1 Pharmaceutical Association) to identify and promote adoption of policies to address the already
2 high and escalating costs of generic prescription drugs;

- 3 • Advocate with interested parties to support legislation to ensure fair and appropriate pricing of
4 generic medications, and educate Congress about the adverse impact of generic prescription
5 drug price increases on the health of our patients;
- 6 • Encourage the development of methods that increase choice and competition in the
7 development and pricing of generic prescription drugs; and
- 8 • Support measures that increase price transparency for generic prescription drugs.

9
10 Addressing the integration of value in the health care system, Policy H-460.909 outlines principles
11 for creating a centralized comparative effectiveness research entity, including a principle that states
12 that the comparative effectiveness research entity must not have a role in making or recommending
13 coverage or payment decisions for payers. Of note, the Patient-Centered Outcomes Research
14 Institute (PCORI), which sunsets in 2019, does not fund studies conducting formal cost-
15 effectiveness analyses or directly comparing the costs of care between two or more alternative
16 approaches to providing care due to restrictions outlined in the Affordable Care Act.

17
18 Policy H-155.960 advocates that sources of medical research funding give priority to studies that
19 collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well
20 as clinical outcomes; and translate research findings into useable information on the relative cost-
21 effectiveness of alternative diagnostic services and treatments. The policy also advocates that
22 health information systems be designed to provide physicians and other health care decision-
23 makers with relevant, timely, actionable information, automatically at the point of care, including
24 relative cost-effectiveness of alternative diagnostic services and treatments. This information would
25 help fulfill the intent of Policy H-450.938, which outlines principles to guide physician value-based
26 decision-making. Policy H-155.960 encourages third-party payers to use targeted benefit design,
27 whereby patient cost-sharing requirements are determined based on the clinical value of a health
28 care service or treatment. Likewise, Policy H-185.939 supports flexibility in the design and
29 implementation of value-based insurance design programs, consistent with outlined principles.
30 Policy H-185.935 supports the appropriate use of reference pricing as a possible method of
31 providing health insurance coverage of specific procedures, products or services, consistent with
32 outlined principles.

33
34 Policy H-450.933 encourages multi-stakeholder efforts to develop and fund clinical data registries
35 for the purpose of facilitating quality improvements and research that result in better health care,
36 improved population health, and lower costs. The policy also encourages national medical specialty
37 societies, state medical associations, and other physician groups to join the National Quality
38 Registry Network and to participate in efforts to advance the development and use of clinical data
39 registries. Finally, the policy supports flexibility in the development and implementation of clinical
40 data registries, and outlines guidelines to help maximize opportunities for clinical data registries to
41 enhance the quality of care provided to patients.

42 43 POTENTIAL MECHANISMS TO DETERMINE THE VALUE OF PHARMACEUTICALS

44
45 During its review of AMA policy addressing pharmaceutical pricing, as well as responses to
46 address the high costs of pharmaceuticals, the Council determined that policy had a noteworthy gap
47 with respect to value-based pricing—an approach that has the potential to impact the prices of drugs
48 across the health care system. Policy H-460.909 defines value as “the best balance between
49 benefits and costs, and better value as improved clinical outcomes, quality, and/or patient
50 satisfaction per dollar spent. Improving value in the US health care system will require both
51 clinical and cost information.” However, the pricing of prescription drugs, which is market-based

1 in nature, is often not clearly commensurate with the drug’s clinical outcomes, and reductions in
2 morbidity and mortality.

3
4 Various public and private payers have moved forward in implementing initiatives to tie drug
5 prices to outcomes. In addition, value frameworks exist to support a transition to basing
6 prescription drug pricing on a balance of value and health outcomes—converting evidence based on
7 patient health outcomes to a price. Two of the value frameworks outlined below provide value-
8 based prices for drugs, while others could be used to measure a drug’s value as part of the shared
9 decision-making process between patients and their physicians. The strength and accuracy of any
10 framework to support value-based pricing of prescription drugs depends on the validity, reliability
11 and comprehensiveness of necessary inputs and data, which could come from clinical trials, clinical
12 data registries and comparative effectiveness research, as well as an integrated information
13 infrastructure.

14 15 *Outcomes-Based Pricing Initiatives*

16
17 Public and private payers have moved forward with initiatives that would tie how much they pay
18 for drugs to patient health outcomes. Cigna entered into value-based contracts with both Amgen
19 and Sanofi/Regeneron for their PCSK9 inhibitors, Repatha and Praluent, which reduce the amount
20 of harmful LDL cholesterol circulating in the bloodstream. Under the agreement, if Cigna enrollees
21 who take the drugs do not achieve reductions in their LDL-C levels as was experienced in clinical
22 trials, the two pharmaceutical companies would give Cigna discounts on the original negotiated
23 price. If the drugs meet or exceed the expected LDL-C reduction target, the original negotiated
24 price remains in place.⁶ Express Scripts has launched its Oncology Care Value Program, which is
25 aiming to align the cost of cancer treatment with its outcomes. This year, the program is focusing
26 on prostate cancer, lung cancer, and renal cell carcinoma.⁴ In addition, the Centers for Medicare &
27 Medicaid Services (CMS) released a proposed rule that put forward a two-phase drug payment
28 model under Medicare Part B, the second phase of which includes a proposal to allow CMS to
29 enter into voluntary agreements with manufacturers to link health care outcomes to payment. As
30 outlined in the proposed rule, these outcomes-based risk-sharing agreements “tie the final price of a
31 drug to results achieved by specific patients rather than using a predetermined price based on
32 historical population data. Manufacturers agree to provide rebates, refunds, or price adjustments if
33 the product does not meet targeted outcomes.” CMS proposed that value would be measured
34 “through data collection likely, though not necessarily, provided by the prescriber,” intended to
35 address factors such as long-term safety and outcomes, effects on individual patients, patient
36 adherence, or impact on utilization and costs.⁷

37 38 *Institute for Clinical and Economic Review (ICER)*

39
40 The Value Assessment Framework developed by ICER includes two components: a drug’s long-
41 term care value and the potential short-term budget impact following a drug’s introduction to the
42 marketplace. ICER determines care value by evaluating a drug’s comparative clinical effectiveness,
43 incremental costs per outcomes achieved, other benefits or disadvantages (e.g., methods of
44 administration, public health benefit) and contextual considerations (e.g., future competition in the
45 marketplace). In measuring incremental costs per outcomes achieved, ICER uses quality-adjusted
46 life years (QALYs) and sets thresholds of reasonable ratios of cost-effectiveness at \$100,000 (high
47 care value) to \$150,000 (intermediate care value) per QALY. ICER measures provisional health
48 system value to assess the short-term budget impact of a drug in comparison with its long-term care
49 value. To measure the short-term budget impact of a drug, ICER estimates the net change in total
50 health care costs during the five years following the launch of a new drug into the marketplace.
51 ICER developed an affordability threshold of a drug’s short-term budgetary impact to serve as an

1 “alarm bell” to indicate whether additional responses may be needed due to a drug’s short-term
 2 budgetary impact. The short-term affordability threshold represents the contribution of a new drug
 3 to the growth in overall health care spending of no more than the anticipated growth in national
 4 gross domestic product plus one percent. Therefore, ICER calculates its value-based price
 5 benchmark using long-term cost-effectiveness as well as potential short-term budget impact,
 6 developing prices to achieve cost-effectiveness thresholds of \$100,000 per QALY and \$150,000
 7 per QALY, as well as a maximum price using its affordability threshold. For example, in its review
 8 of PCSK9 drugs, which have a list price of \$14,350, ICER concluded that the drugs would have to
 9 be priced at \$5,404 to achieve a cost-effectiveness ratio of \$100,000 per QALY; \$7,735 to achieve
 10 a cost-effectiveness ratio of \$150,000 per QALY; and \$2,177 to meet its affordability threshold. In
 11 its review of Entresto, which has a list price of \$4,560, ICER determined that the drug would have
 12 to be priced at \$9,480 to achieve a cost-effectiveness ratio of \$100,000 per QALY; \$14,472 to
 13 achieve a cost-effectiveness ratio of \$150,000 per QALY; and \$4,168 to meet its affordability
 14 threshold.⁸

15

16 *DrugAbacus, Memorial Sloan Kettering Cancer Center*

17

18 DrugAbacus is a tool that could potentially be used to help stakeholders determine value-based
 19 prices for 52 cancer drugs approved between 2001 and 2015. The DrugAbacus price, which is
 20 relevant for a typical treatment period, is calculated using a formula that uses eight domains as
 21 inputs: efficacy, tolerability, novelty, research and development costs, rarity, population burden,
 22 unmet need, and prognosis. Users of the tool determine the weight (i.e., value) to be given to each
 23 domain, which results in a value-based price. Again, the value-based price is dependent on user
 24 inputs and determinations of value. Of note, DrugAbacus includes an indication-specific pricing
 25 feature, which allows users to compare the actual and DrugAbacus price of different indications for
 26 four drugs: Abraxane, Avastin, Nexavar, and Tarceva.⁹

27

28 *National Comprehensive Cancer Network (NCCN) Evidence Blocks*

29

30 NCCN Evidence Blocks provide five key value measures of systemic cancer therapy, meant to be
 31 used in shared decision-making between patients and their physicians. The five value measures—
 32 efficacy, safety, quality of evidence, consistency of evidence, and affordability—are each rated on a
 33 scale of one to five. The value measures provide additional information about specific NCCN
 34 guideline recommendations, and allow physicians and patients to be able to visually compare the
 35 values of available therapies and make their own assessments of value. As of the drafting of this
 36 report, NCCN Evidence Blocks are available for breast cancer; breast cancer risk reduction; central
 37 nervous system cancers gliomas; chronic myelogenous leukemia; colon cancer; head and neck
 38 cancers—very advanced head and neck cancer; hepatobiliary cancers; kidney cancer; malignant
 39 pleural mesothelioma; melanoma; multiple myeloma; non-Hodgkin's lymphomas—diffuse large
 40 B-cell lymphoma; non-small cell lung cancer; ovarian cancer; penile cancer; prostate cancer; rectal
 41 cancer; testicular cancer; and thymomas and thymic carcinomas.¹⁰

42

43 *American College of Cardiology/American Heart Association (ACC/AHA)*

44

45 The ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and
 46 Performance Measures provides a value framework for practice guideline and performance
 47 measurement development that establishes the benefit of diagnostic approaches and treatment
 48 compared with risk (COR), assesses the level/quality of evidence, and gives each
 49 approach/treatment a level of value. CORs can range from class I (highest) to III (lowest). The
 50 level/quality of evidence underlying a diagnostic approach and treatment would be given a value of

1 A, B or C. In addition, the approach or treatment would be given a value level of high,
 2 intermediate, low or uncertain, or value not assessed, based on QALYs gained.¹¹

3
 4 *American Society of Clinical Oncology (ASCO)*

5
 6 In June 2015, ASCO released a conceptual framework to assess the value of cancer treatment
 7 options to be used in shared decision-making. Two versions of the framework were developed:
 8 one for advanced cancer and one for potentially curative treatment.¹² ASCO then opened up the
 9 conceptual value framework to a 60-day public comment period; more than 400 comments were
 10 received. Based on the input and feedback received, ASCO released revised versions of the
 11 framework for advanced disease and adjuvant settings in May 2016. In both frameworks, points are
 12 awarded based on clinical benefit and toxicity, and bonus points can also be applied. Overall, both
 13 versions of the framework use points to determine the net health benefit, and have the net health
 14 benefit and the cost of the regimen side by side in order to assist physicians and patients to assess
 15 value at the point of care. ASCO plans to launch the framework in a software application, which
 16 would allow for the modification of the weight attributed to the elements included in the net health
 17 benefit based on patient preferences and circumstances.¹³

18
 19 *Public Health Approaches to Drug Pricing*

20
 21 The Council notes that Resolution 712-A-16 was focused on lowering the cost of treatments for
 22 hepatitis C, a disease with an incidence rate of 0.7 cases per 100,000 population in 2014 in the US.
 23 Approximately 30,500 acute hepatitis C cases occurred in 2014, with an estimated 2.7-3.9 million
 24 individuals in the US with chronic hepatitis C.¹⁴ The Council notes that different approaches have
 25 been used to directly purchase drugs and vaccines that have been determined to have a high value
 26 in terms of protecting public health. Preventing the spread of infectious diseases, such as hepatitis
 27 C, as well as the occurrence of vaccine-preventable diseases, impacts the treatment burden of these
 28 diseases, in terms of number of individuals affected, and total treatment costs. The Vaccines for
 29 Children (VFC) program is used to provide federally purchased vaccines to children who are
 30 uninsured, underinsured, Medicaid-eligible or Native Americans at no cost. Purchasing vaccines
 31 through VFC ensures access to lower prices for vaccines; the Centers for Disease Control and
 32 Prevention purchases vaccines at a discount, and distributes the vaccines to grantees (i.e., state
 33 health departments and local public health agencies), which in turn distribute them at no charge to
 34 participating public and private VFC providers.¹⁵

35
 36 In addition, the AIDS Drug Assistance Program (ADAP), authorized under Part B of the Ryan
 37 White HIV/AIDS Treatment Extension Act of 2009, is a federally funded, but state-administered
 38 program that provides FDA-approved HIV medications to uninsured or underinsured low-income
 39 individuals living with HIV. ADAPs are required to purchase drugs in the most economic manner
 40 feasible, which can either be 340B pricing or otherwise showing that they pay no more than 340B
 41 prices for drugs covered under ADAP formularies. In June 2015, 197,117 individuals were enrolled
 42 in ADAPs.¹⁶

43
 44 **ANALYZING THE IMPACT OF MEDICARE DRUG PRICE NEGOTIATION**

45
 46 In addition to reviewing and analyzing approaches to value-based pricing of prescription drugs, the
 47 Council, based on feedback received from the Task Force on Pharmaceutical Costs, reviewed
 48 policy addressing Medicare drug price negotiation, and analyzed whether additional changes
 49 should be made to increase the policy's ability to achieve cost savings and political feasibility.
 50 Policy D-330.954 states that our AMA will support federal legislation which gives the Secretary of

1 HHS the authority to negotiate contracts with manufacturers of covered Part D drugs, and will
 2 work toward eliminating Medicare prohibition on drug price negotiation.

3
 4 Policy D-330.954 responds to the “noninterference clause” in the Medicare Modernization Act of
 5 2003 (MMA), which states that the Secretary of HHS “may not interfere with the negotiations
 6 between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may
 7 not require a particular formulary or institute a price structure for the reimbursement of covered
 8 part D drugs.” Instead, participating Part D plans compete with each other based on plan premiums,
 9 cost-sharing and other features, which provides an incentive to contain prescription drug spending.
 10 To contain spending, Part D plans not only establish formularies, implement utilization
 11 management measures and encourage beneficiaries to use generic and less-expensive brand-name
 12 drugs, but are required under the MMA to provide plan enrollees access to negotiated drug prices.
 13 These prices are achieved through direct negotiation with pharmaceutical companies to obtain
 14 rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

15
 16 *Lack of Bipartisan Support*

17
 18 The scope and approach of federal legislation introduced to date that would grant the Secretary of
 19 HHS the authority to negotiate contracts with manufacturers of Part D drugs vary. The Council
 20 notes that, at the time this report was written, none of the bills introduced that would allow the
 21 Secretary of HHS to negotiate drug prices in Part D included any Republican sponsors or
 22 cosponsors. As such, achieving legislative success in this arena considering the current political
 23 atmosphere is unlikely.¹⁷ S. 31/H.R. 3061, the Medicare Prescription Drug Price Negotiation Act
 24 of 2015, and S. 2023/H.R. 3513, the Prescription Drug Affordability Act, include language that
 25 authorizes the HHS Secretary to negotiate Part D drug discounts and prohibits the Secretary from
 26 imposing a national formulary. H.R. 4207, the Medicare Fair Drug Pricing Act of 2015, contains a
 27 provision allowing for an exception to Medicare Part D’s “noninterference clause” for specified
 28 covered part D drugs, which are defined as either sole source drugs or biologics and are not
 29 manufactured by more than two drug manufacturers, or other covered drugs for which there is a
 30 limited ability for Medicare Part D and Medicare Advantage plans to negotiate rebates that have a
 31 significant fiscal impact on Medicare Part D. If the Secretary and the applicable drug
 32 manufacturers are not able to agree on a negotiated price for these specified drugs, the legislation
 33 grants the Secretary the authority to determine the price of the drug based on certain factors,
 34 including the VA price of the drug (if applicable) and what price would ensure affordability and
 35 accessibility. Part D plans could still negotiate for lower prices than the one determined by the
 36 Secretary. The legislation also prohibits the Secretary from establishing or requiring a particular
 37 formulary.

38
 39 An alternative to simply allowing the Secretary of HHS to negotiate drug prices in Part D is to
 40 establish a “public option” in Part D, an approach included in S. 1884/H.R. 3261, the Medicare
 41 Prescription Drug Savings and Choice Act. The legislation would establish a Medicare operated
 42 Medicare prescription drug plan option – a public option. The legislation would authorize the use
 43 of a formulary for this public option, but would not establish a national formulary for all Part D
 44 plans. This public Part D plan would operate nationwide, but would not alter the private insurance
 45 plan administered Part D program.

46
 47 *Limited Ability to Achieve Savings Without Additional Negotiating Leverage*

48
 49 In addition, questions have been raised whether HHS could achieve much greater savings than
 50 what is currently achieved by health plans and pharmacy benefit managers in Part D. The
 51 Congressional Budget Office (CBO), as well as CMS actuaries, have estimated that providing the

1 Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations
 2 taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by
 3 Part D.^{18,19} Therefore, it is projected that legislation granting the Secretary of HHS broad authority
 4 to negotiate drug prices would likely have a negligible effect on federal spending.

5
 6 If the Secretary of HHS were granted the authority to negotiate prices for unique covered Part D
 7 drugs that lack competitor products or therapeutic alternatives, the CBO has stated that there may
 8 be potential savings.¹⁶ However, neither the CBO or the Office of Management and Budget (OMB)
 9 has scored any savings associated with providing the Secretary of HHS the authority to negotiate
 10 drug prices for biologics and high-cost drugs in Medicare Part D, an option which was included in
 11 the Obama administration’s fiscal year 2016 and 2017 budget proposals.^{20,21,22,23}

12
 13 Perhaps of most concern, CBO has acknowledged that, in order for the Secretary to have the ability
 14 to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also
 15 need the “authority to establish a formulary, set prices administratively, or take other regulatory
 16 actions against firms failing to offer price reductions. In the absence of such authority, the
 17 Secretary’s ability to issue credible threats or take other actions in an effort to obtain significant
 18 discounts would be limited.”¹⁸ CMS actuaries have concurred, stating “the inability to drive market
 19 share via the establishment of a formulary or development of a preferred tier significantly
 20 undermines the effectiveness of this negotiation. Manufacturers would have little to gain by
 21 offering rebates that are not linked to a preferred position of their products, and we assume that
 22 they will be unwilling to do so.”¹⁹

23
 24 *Any Positive Impact Primarily Limited to Medicare Part D Beneficiaries*

25
 26 The Council notes that, if allowing for Medicare drug price negotiation would achieve any savings,
 27 the primary impact would be to reduce the cost-sharing of patients enrolled in Medicare Part D
 28 plans, versus patients insured in both private and public plans. At the same time, pharmaceutical
 29 companies could potentially shift costs to commercial health plans, as Medicaid programs already
 30 have access to lower prescription drug prices resulting from existing rebates and other measures. If
 31 Medicare drug price negotiation does indeed cause pharmaceutical manufacturers to shift their
 32 costs to commercial health plans, that may cause plans offered in the exchanges and by employers
 33 to raise their premiums and cost-sharing, which could negatively impact patient access and
 34 adherence.

35
 36 *Unintended Consequences of Amending Policy*

37
 38 Accordingly, the Council believes that amending Policy D-330.954 to increase the likelihood for
 39 cost savings associated with allowing the Secretary of HHS to negotiate drug prices in Medicare
 40 Part D would entail supporting authority for the Secretary to establish a Part D formulary or
 41 develop a preferred tier in Part D. The Council does not support amending the policy in this
 42 fashion, due to its expected impact on patient choice of Part D plans, and patient access to the
 43 prescription drugs they need. If the Secretary were given the authority to establish a Part D
 44 formulary, any drug not on the formulary or at a high tier on the formulary would require an
 45 exception request/appeal by the patient. In addition, formularies include prior authorization
 46 requirements, quantity limits and step therapy requirements. Importantly, expanding the Secretary’s
 47 authority in this fashion may further reduce the political feasibility of the policy. Overall, the
 48 Council believes that value-based pricing may serve as a more politically viable, cost-saving,
 49 choice-saving and fair alternative to the Secretary of HHS negotiating drug prices in Medicare Part
 50 D. In addition, value-based pricing has the potential to impact the prescription drug cost-sharing of
 51 all patients, not just those enrolled in Medicare Part D plans.

1 DISCUSSION

2
 3 The integration of value into pharmaceutical pricing has the potential to build off of long-standing
 4 AMA policy that supports market-driven mechanisms to control pharmaceutical costs, as well as
 5 recognizes that improvements need to be made to ensure that the pharmaceutical marketplace
 6 operates efficiently and effectively. Importantly, value-based pricing of pharmaceuticals does not
 7 require the establishment of price controls or other mandates that may stifle innovation in the
 8 pharmaceutical industry. However, pricing pharmaceuticals based on their value should aim to
 9 improve affordability for patients and limit system-wide budgetary impact. As policymakers,
 10 insurers and other stakeholders move forward with efforts to integrate value into pharmaceutical
 11 pricing, the Council believes that the establishment of principles are necessary to guide AMA
 12 advocacy. Initiatives to determine value-based pricing for pharmaceuticals should aim to ensure
 13 patient access to necessary prescription drugs and allow for patient variation and physician
 14 discretion. In addition, such initiatives should limit administrative burdens on physician practices
 15 and patients. The Council is concerned that some value-based pricing approaches, by being
 16 dependent on the tracking and reporting of outcomes, have the potential to impose administrative
 17 burdens on physicians and patients.

18
 19 Processes that determine value-based prices of pharmaceuticals need to be evidence-based,
 20 transparent, and objective, and involve the input of practicing physicians and researchers. The
 21 Council notes that the strength and accuracy of any framework to support value-based pricing of
 22 pharmaceuticals depends on the validity, reliability and comprehensiveness of necessary inputs and
 23 data, which could come from clinical trials, clinical data registries and comparative effectiveness
 24 research, as well as an integrated information infrastructure. The Council notes that there continues
 25 to be a lack of high-quality data on the cost and value of interventions using pharmaceuticals in
 26 practice. Increased comparative effectiveness research in the pharmaceutical arena is imperative so
 27 patients, physicians and other stakeholders are aware of differences between the prescription drugs
 28 available within the same category or class. The Council believes that the AMA must continue to
 29 advocate for adequate investment in comparative effectiveness research, as called for in Policies H-
 30 460.909 and D-390.961. However, in order to be truly effective, the cost of alternatives, as well as
 31 cost-effectiveness analysis, should be included in comparative effectiveness research endeavors. In
 32 addition, your Council recognizes that clinical data registries, as addressed in Policy H-450.933,
 33 may be useful in measuring and tracking short- and long-term clinical outcomes of
 34 pharmaceuticals.

35
 36 Value-based pharmaceutical pricing can also be incorporated into health insurance benefit design,
 37 to limit patient cost-sharing for pharmaceuticals that have a high clinical benefit. Policies H-
 38 155.960 and H-185.939, which are also relevant to alternative payment models, support the use of
 39 value-based insurance design, determining patient cost-sharing requirements based on the clinical
 40 value of a health care service or treatment. Policy also states that consideration should be given to
 41 further tailoring cost-sharing requirements to patient income and other factors known to impact
 42 compliance. Importantly, Policy H-185.939 states that value-based plan designs that include higher
 43 cost-sharing or other disincentives to obtaining services designated as low-value must include an
 44 appeals process to enable patients to secure care recommended by their physicians, without
 45 incurring cost-sharing penalties.

46
 47 With respect to Resolution 712-A-16, the Council believes that pharmaceutical pricing mechanisms
 48 need to take into account a drug's public health value. For pharmaceuticals that are used to treat or
 49 cure diseases that pose unique public health threats, including hepatitis C, the Council supports the
 50 use of direct purchasing mechanisms to assure patient access to the treatments they need, which
 51 will impact disease transmission rates as well as overall treatment costs. Existing models, including

1 the VFC program and the AIDS Drug Assistance Program, show the potential for using the direct
2 purchasing approach for other drugs. The Council notes that direct purchase arrangements will
3 guarantee prices for prescription drugs as well as volume for manufacturers. As such, lower prices
4 can be achieved in exchange for a larger, guaranteed market for a drug.

5
6 RECOMMENDATIONS

7
8 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
9 712-A-16, and that the remainder of the report be filed.

- 10
11 1. That our American Medical Association (AMA) reaffirm Policies H-155.960 and H-185.939,
12 which support the use of value-based insurance design, determining patient cost-sharing
13 requirements based on the clinical value of a treatment. (Reaffirm HOD Policy)
14
15 2. That our AMA reaffirm Policy H-450.933, which establishes guidelines to help maximize
16 opportunities for clinical data registries to enhance the quality of care provided to patients.
17 (Reaffirm HOD Policy)
18
19 3. That our AMA reaffirm Policies H-460.909 and D-390.961 in support of adequate investments
20 in comparative effectiveness research. (Reaffirm HOD Policy)
21
22 4. That our AMA support value-based pricing programs, initiatives and mechanisms for
23 pharmaceuticals that are guided by the following principles:
24
25 a) Value-based prices of pharmaceuticals should be determined by objective, independent
26 entities;
27 b) Value-based prices of pharmaceuticals should be evidence-based and be the result of valid
28 and reliable inputs and data that incorporate rigorous scientific methods, including clinical
29 trials, clinical data registries, comparative effectiveness research, and robust outcome
30 measures that capture short- and long-term clinical outcomes;
31 c) Processes to determine value-based prices of pharmaceuticals must be transparent, easily
32 accessible to physicians and patients, and provide practicing physicians and researchers a
33 central and significant role;
34 d) Processes to determine value-based prices of pharmaceuticals should limit administrative
35 burdens on physicians and patients;
36 e) Processes to determine value-based prices of pharmaceuticals should incorporate
37 affordability criteria to help assure patient affordability as well as limit system-wide
38 budgetary impact; and
39 f) Value-based pricing of pharmaceuticals should allow for patient variation and physician
40 discretion. (New HOD Policy)
41
42 5. That our AMA support the inclusion of the cost of alternatives and cost-effectiveness analysis
43 in comparative effectiveness research. (New HOD Policy)
44
45 6. That our AMA support direct purchasing of pharmaceuticals used to treat or cure diseases that
46 pose unique public health threats, including hepatitis C, in which lower drug prices are assured
47 in exchange for a guaranteed market size. (New HOD Policy)

Fiscal Note: Less than \$500.

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