Whereas, Among United States adults, 24% indicate that it is difficult to afford the cost of their prescription medication(s) and 29% state that they have been unable to take their medications as prescribed within the past year (either not filling a prescription, substituting an over-the-counter drug, cutting pills in half, skipping doses, or some combination thereof) due to inability to afford them; and

Whereas, In 2019, 1.49 million Medicare Part D enrollees exceeded the out-of-pocket catastrophic coverage threshold of $6,550, such that they had to pay out of pocket for 5% of total drug costs with no hard cap on total spending by enrollees, resulting in $1.8 billion in out-of-pocket spending by these enrollees for drug costs over the threshold; and

Whereas, Spending on prescription pharmaceuticals constitutes 10% of national health spending, 18% of large employer health benefit expenses, 19% of out-of-pocket spending for Medicare beneficiaries, and 17% of out-of-pocket spending for employees; and

Whereas, One analysis of the economic impact of medication non-adherence among fourteen disease groups estimated the all-causes cost of non-adherence at between $5,271 and $52,341 per patient; and

Whereas, A 2017 study published in Cancer determined that 23.8% of adolescent and young adult cancer survivors (aged 15 to 39 years) experience cost-related medication non-adherence, with Black survivors, uninsured survivors, and survivors with multiple comorbidities suffering the highest rates of medication non-adherence; and

Whereas, Research on patients with hypertension demonstrated that patients with cost-related non-adherence are less likely to have self-reported normal blood pressure (59.5% versus 69.8% for patients without nonadherence); and

Whereas, An analysis by the Kaiser Family Foundation found that 50% of drugs covered by Medicare Part D had list price increases that were greater than the rate of inflation between July 2018 and 2019, with 14% of Part D-covered drugs having list price increases of 10% or more over that year-long timeframe; and

Whereas, Approximately 60% of total Medicare Part D spending ($87 billion) results from the purchase of the 250 top-selling drugs covered by Part D that have one manufacturer and no generic or biosimilar competition; and

Whereas, The number of generic suppliers per market decreased over time from 2004 to 2016, due to both increased exit from markets and decreased market entry; and
Whereas, The median number of drug manufacturers per market in 2016 was two, with 40% of pharmaceutical markets supplied by a sole manufacturer as of 2016\(^9\); and

Whereas, There is evidence that the price of generic drugs is undergoing a statistically significant increase over time, and the price increases are associated with decreasing numbers of manufacturers for each generic drug, as well as alternative measures of increased supplier concentration\(^9\); and

Whereas, According to a 2016 United States Government Accountability Office report, between 2010 and 2015, 315 of the 1,441 generic pharmaceuticals that were available for the duration of the study period (22%) underwent at least one “extraordinary” price increase in Medicare Part D, defined as a price increase of 100% or more\(^10\); and

Whereas, Generic drug shortages in the United States quadrupled between 2005 and 2011, increasing from 61 drugs to 250 drugs\(^11\); and

Whereas, The entry of additional generic manufacturers to a pharmaceutical market frequently results in rapidly decreasing prices, as generic drugs entering the market between 2002 and 2014 lowered drug prices by 51% in the first year\(^11\); and

Whereas, An antitrust investigation into generic manufacturers in 2018 uncovered evidence of a generic “cartel” implicating at least 16 companies, in which anti-competitive price-fixing agreements involving 300 pharmaceuticals resulted in price increases of up to 2,000 percent\(^12,13\); and

Whereas, A National Bureau of Economic Research paper noted that “for products targeting exceptionally small patient populations, the fixed costs of entry and the likelihood of intense post-entry price competition mean that a new entrant is unlikely to earn profits” - in other words, a generic manufacturer is highly unlikely to ever enter the market for some drugs targeted at small patient populations\(^14\); and

Whereas, In 2018, a group of major hospital systems, including the Mayo Clinic and HCA Healthcare, and philanthropies launched a non-profit generic drug manufacturer to produce generic drugs experiencing shortages or dramatic price increases\(^15,16\); and

Whereas, A recent New England Journal of Medicine perspective proposed the creation of a non-profit generic pharmaceutical manufacturer to mitigate generic market failures and sell generic drugs directly to hospitals and other institutional partners, with predetermined contracts to ensure low prices and a minimum volume, which would protect the non-profit manufacturer from being forced out of the market because of price changes\(^17\); and

Whereas, There is federal legislation most recently re-introduced in January 2020 that seeks to establish an Office of Drug Manufacturing within the Department of Health and Human Services to facilitate public manufacturing of generic drugs\(^18-20\); and

Whereas, In recent testimony before the House of Representatives Subcommittee on Regulatory Reform, Commercial and Antitrust Law, economist Craig Garthwaite characterized the proposal to establish a government generic manufacturer for small market drugs as “a potentially viable policy option” to mitigate the market failure resulting from the dearth of competition in markets for generic drugs with insufficient market size to support more than one manufacturer, which creates a natural monopoly\(^21\); and
Whereas, A federal non-profit government manufacturer would be able to focus production of a generic version of prescription drugs on circumstances in which market failures occur, as in scenarios where there are no generic manufacturers within a market or there are two or fewer manufacturers and a significant price increase or a drug shortage\textsuperscript{18,22,23}, therefore be it

RESOLVED, That our American Medical Association support the formation of a non-profit government manufacturer of pharmaceuticals to produce small-market generic drugs. (New HOD Policy)

Fiscal Note: Not yet determined

Received: 10/13/22

REFERENCES:


RELEVANT AMA POLICY

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

1. Our AMA will advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
   a. The arbitration process should be overseen by objective, independent entities;
   b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel;
   c. All conflicts of interest of arbitrators must be disclosed and safeguards developed to minimize actual and potential conflicts of interest to ensure that they do not undermine the integrity and legitimacy of the arbitration process;
   d. The arbitration process should be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question;
   e. The arbitration process should include the submission of a value-based price for the drug in question to inform the arbitrator’s decision;
   f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer;
   g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases;
   h. The arbitration process should include a mechanism for either party to appeal the arbitrator’s decision; and
   i. The arbitration process should include a mechanism to revisit the arbitrator’s decision due to new evidence or data.

2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
   a. Any international drug price index or average should not be used to determine or set a drug’s price, or determine whether a drug’s price is excessive, in isolation;
   b. The use of any international drug price index or average should preserve patient access to necessary medications;
   c. The use of any international drug price index or average should limit burdens on physician practices; and
   d. Any data used to determine an international price index or average to guide prescription drug pricing should be transparent and updated regularly.

3. Our AMA supports the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction.

Citation: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Modified: CMS Rep. 4, A-22

Prescription Drug Prices and Medicare D-330.954

1. Our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS.

Citation: DRAFT
Pharmaceutical Costs H-110.987
1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation.

Pay for Delay Arrangements by Pharmaceutical Companies H-110.989
Our AMA supports: (1) the Federal Trade Commission in its efforts to stop “pay for delay” arrangements by pharmaceutical companies and (2) federal legislation that makes tactics delaying conversion of medications to generic status, also known as “pay for delay,” illegal in the United States.

Price of Medicine H-110.991
Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health
plans to inform patients of the actual cash price as well as the formulary price of any medication prior to
the purchase of the medication; (3) opposes provisions in pharmacies’ contracts with pharmacy benefit
managers that prohibit pharmacists from disclosing that a patient’s co-pay is higher than the drug’s cash
price; (4) will disseminate model state legislation to promote drug price and cost transparency and to
prohibit “clawbacks”; (5) supports physician education regarding drug price and cost transparency,
manufacturers’ pricing practices, and challenges patients may encounter at the pharmacy point-of-sale;
and (6) work with relevant organizations to advocate for increased transparency through access to
meaningful and relevant information about medication price and out-of-pocket costs for prescription
medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare’s
drug-pricing dashboard.

Citation: CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended:
Appended: Res. 126, A-19

Incorporating Value into Pharmaceutical Pricing H-110.986
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 outcomes 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.

Citation: CMS Rep. 05, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS-CSAPH Rep. 01, A-
Reaffirmed: CMS Rep. 6, I-20

Cost of Prescription Drugs H-110.997
Our AMA:
(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that
the following criteria are satisfied: (a) physicians must have significant input into the development and
maintenance of such programs; (b) such programs must encourage optimum prescribing practices and
quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses;
(d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery
for the individual patient; and (e) such programs should promote an environment that will give
pharmaceutical manufacturers the incentive for research and development of new and innovative
prescription drugs;

(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in
prescribing drugs for their patients and encourages physicians to supplement medical judgments with
cost considerations in making these choices;

(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs
and will assist physicians in this regard by regularly publishing a summary list of the patient expiration
dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;

(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and
necessary medical therapies;

(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship
to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates
informed about the findings of these studies;

(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA
A-rated generic); and

(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.


Opposition to Medicare Part B to Part D Changes H-110.982
Our AMA will advocate against Medicare changes which would recategorize Medicare Part B drugs into Part D.

Citation: Res. 217, I-18

Insulin Affordability H-110.984
Our AMA will: (1) encourage the Federal Trade Commission (FTC) and the Department of Justice to investigate insulin pricing and market competition and take enforcement actions as appropriate; (2) support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies; and (3) support state and national efforts to limit the ultimate expenses incurred by insured patients for prescribed insulin.

Citation: CMS Rep. 07, A-18; Modified: Res. 118, A-22

Reducing Prescription Drug Prices D-110.993
Our AMA will (1) 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; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.

Citation: (CMS Rep. 3, I-04; Modified: CMS Rep. 1, A-14; Reaffirmation A-14; Reaffirmed in lieu of Res. 229, I-14)

Co-Pay Accumulators D-110.986
Our AMA will develop model state legislation regarding Co-Pay Accumulators for all pharmaceuticals, biologics, medical devices, and medical equipment, and support federal and state legislation or regulation that would ban co-pay accumulator policies, including in federally regulated ERISA plans.

Citation: Res. 205, I-19; Appended: Res. 212, I-20

Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers H-100.950
1. Our AMA will advocate with interested parties for legislative or regulatory measures that require prescription drug manufacturers to seek Food and Drug Administration and Federal Trade Commission approval before establishing a restricted distribution system.

2. Our AMA supports requiring pharmaceutical companies to allow for reasonable access to and purchase of appropriate quantities of approved out-of-patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays.

3. Our AMA will advocate with interested parties for legislative or regulatory measures that expedite the FDA approval process for generic drugs, including but not limited to application review deadlines and generic priority review voucher programs.

Citation: Res. 809, I-16

Prescription Drug Price and Cost Transparency D-110.988
1. Our AMA will continue implementation of its TruthinRx grassroots campaign to expand drug pricing transparency among pharmaceutical manufacturers, pharmacy benefit managers and health plans, and to communicate the impact of each of these segments on drug prices and access to affordable treatment.

2. Our AMA will report back to the House of Delegates at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign. Citation: Alt. Res. 806, I-17
Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988
1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs.
2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients.
3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs.
4. Our AMA supports measures that increase price transparency for generic prescription drugs.


Cost Sharing Arrangements for Prescription Drugs H-110.990
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;
3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and patient-specific out-of-pocket costs of individual prescription drugs, taking into account insurance status or payer type, 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; and
4. supports public and private prescription drug plans in offering patient-friendly tools and technology that allow patients to directly and securely access their individualized prescription benefit and prescription drug cost information.


Study of Actions to Control Pharmaceutical Costs H-110.992
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.


Cost of New Prescription Drugs H-110.998
Our AMA urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs.

Citation: (Res. 112, I-89; Reaffirmed: Res. 520, A-99; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmed in lieu of Res. 229, I-14)

Public Reporting of PBM Rebates H-110.981
Our AMA will advocate for: (1) Pharmacy Benefit Managers (PBMs) and state regulatory bodies to make rebate and discount reports and disclosures available to the public; and (2) the inclusion of required public reporting of rebates and discounts by PBMs in federal and state PBM legislation.

Citation: Res. 813, I-19