Whereas, Many seniors look to the federal government to negotiate prices for prescription drugs covered under Medicare; and

Whereas, For seniors 65 years of age and older, 40% have at least five prescription drugs, compared with 23% of 50- to 64-year-olds and fewer than 10% of those under 50;¹ and

Whereas, With increased attention among policymakers towards prescription drug costs, a February 2019 poll found that a majority of adults, including seniors, are in favor of policy options to curb prescription drug costs;² and

Whereas, With the Inflation Reduction Act of 2022, the Centers for Medicare & Medicaid Services (CMS) will be required to negotiate prices of certain prescription drugs beginning in 2026;³ and

Whereas, There are 510 different drugs recognized in the US, but the Inflation Reduction Act of 2022 requires CMS to negotiate the prices of only 10 drugs in 2026, 15 drugs in 2027 and 2028, and 20 drugs in 2029 and each year after;⁴ and

Whereas, The pace of negotiating a miniscule number of prescription prices each year is not beneficial to seniors or the general public; and

Whereas, The business model of making profits for pharmaceutical company’s shareholders should not be at the expense of generating profits; and

Whereas, Seniors should not be stretched to find funding for needed medications; therefore be it

RESOLVED, That our American Medical Association advocate for immediate, timely and transparent negotiations for how Medicare drug prices are set to be incorporated into law (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate to eliminate loopholes such as new usage for current medications (commonly known as patent evergreening) (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for a ban on direct-to-consumer advertising for prescription drugs by no later than five years, in 2027. (Reaffirm HOD policy)
Fiscal Note: Not yet determined

Received: 09/29/22

REFERENCES:

RELEVANT AMA POLICY

Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices H-105.988
1. To support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.
2. That until such a ban is in place, our AMA opposes product-claim DTCA that does not satisfy the following guidelines:
   (a) The advertisement should be indication-specific and enhance consumer education about the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.
   (b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug's or device's approval for marketing.
   (c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.
   (d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as “Your physician may recommend other appropriate treatments,” is recommended.
   (e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable.
   (f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient.
   (g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition.
   (h) In general, product-claim DTCA should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA, a disclaimer should be prominently displayed.
   (i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.
   (j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.
   (k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.
3. That the FDA review and pre-approve all DTCA for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.

4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.

5. That DTCA for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.

6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA.

7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.

8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.

9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claim DTCA and with the Council on Ethical and Judicial Affairs Ethical Opinion E-9.6.7 and to adhere to the ethical guidance provided in that Opinion.

10. That the Congress should request the Agency for Healthcare Research and Quality or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.

11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.

12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.

13. That our AMA supports "help-seeking" or "disease awareness" advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA).

14. Our AMA will advocate to the applicable Federal agencies (including the Food and Drug Administration, the Federal Trade Commission, and the Federal Communications Commission) which regulate or influence direct-to-consumer advertising of prescription drugs that such advertising should be required to state the manufacturer’s suggested retail price of those drugs.


**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

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987

1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state 
departments of insurance.

2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall 
include provisions to maximize the number of PBMs under state regulatory oversight.

3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, 
including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.

4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent 
discrimination against patients, including those related to discriminatory benefit design and mental health 
and substance use disorder parity.

5. Our AMA supports improved transparency of PBM operations, including disclosing: 
- Utilization information; 
- Rebate and discount information; 
- Financial incentive information; 
- Pharmacy and therapeutics (P&T) committee information, including records describing why a medication 
is chosen for or removed in the P&T committee’s formulary, whether P&T committee members have a 
financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy; 
- Formulary information, specifically information as to whether certain drugs are preferred over others and 
patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in 
electronic health records; 
- Methodology and sources utilized to determine drug classification and multiple source generic pricing; 
and 
- Percentage of sole source contracts awarded annually.

6. Our AMA encourages increased transparency in how DIR fees are determined and calculated.

Citation: CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 6, I-20
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)

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)

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. 