Whereas, Patients in the United States spend more on prescription medications than any other industrialized country according to the National Healthcare Expenditure, 333 billion dollars in 2017, up from 236 billion dollars in 2007; and

Whereas, Increases in prescription drug prices have resulted in many patients foregoing medication and putting lives at risk; while other countries such as Britain, the world’s 20 top selling medications are three times cheaper than in the United States; and

Whereas, Data from a study of generic and brand name drug costs published in Health Affairs in January 2019 shows that generic drugs and brand name drugs increased in price from 9 to 21 percent per annum from 2005 through 2016; and

Whereas, Up to 85% of the raw ingredients used in the medications sold in the United States are produced outside of the country while our prices for pharmaceuticals per capita are the highest in the world; and

Whereas, Recent efforts to create an International Pricing Index to allow the Centers for Medicaid and Medicare to negotiate prices for medications in Part B, which leaves the majority of medications prescribed that are in Medicare Part D and from other sources unaffected; and

Whereas, New legislation efforts are focusing on the creation of an International Pricing Index that would identify only the 250 most costly medications each year and negotiate prices for only 25 of these medications per annum, would continue to leave the majority of medications unaffected; and

Whereas, The current legislative proposal would cap the price of medications at 120% of an International Pricing Index for only 25 medications each year, which may potentially still result in consumers experiencing an unfair burden of medication prices for the majority of medications; and

Whereas, The AMA is dedicated to promoting patient-centered quality healthcare that is accessible and affordable; it would be in the best interest for patient care and to minimize cost to better control medication prices; therefore be it
RESOLVED, That our American Medical Association advocate for legislation to create an International Pricing Index that would track global medication prices for all prescription medications and keep U.S. medication costs aligned with prices paid in other countries to help control costs and reduce unreasonable patient financial barriers to treatment (Directive to Take Action); and be it

RESOLVED, That our AMA advocate for legislation that would ensure that patients are charged fairly for prescription medications based on the International Pricing Index and that additional costs will not be arbitrarily assigned or passed onto patients. (Directive to Take Action)

Fiscal Note: not yet determined.

Received: 10/01/19

References:
2) "Retail prescription drug spending grew by $90 billion over four years," Modern Healthcare; https://www.modernhealthcare.com/technology/retail-prescription-drug-spending-grew-90-billion-over-four-years
5) "More Than 300 Groups Seek Halt to CMS Plans for Global Drug Pricing Index", American Journal of Managed Care: https://www.ajmc.com/newsroom/more-than-300-groups-seek-halt-to-cms-plans-for-global-drug-pricing-index
7) "How the U.S. Pays 3 Times More for Drugs", Scientific American: https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/

RELEVANT AMA POLICY

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 formulaic 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.

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.

**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 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.

**Drug Issues in Health System Reform H-100.964**
The AMA: (1) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.
(2) supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.
(3) reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.
(4) reaffirms AMA Policies H-120.974 and H-125.992, opposing the substitution of FDA B-rated generic drug products.
(5) supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.
(6) supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.
(7a) encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.
(7b) encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.
(8) recognizes the role of the pharmacist in counseling patients about their medicines in order to reinforce the message of the prescribing physician and improve medication compliance.
(10) opposes payment of pharmacists by third party payers on a per prescription basis when the sole purpose is to convince the prescribing physician to switch to a less expensive "formulary" drug because economic incentives can interfere with pharmacist professional judgment.
(11) reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.
(12) supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public
disclosure of patient and reporter identities.

(13) opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.

(14) reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.

(15) encourages the use of three compendia (AMA's DRUG EVALUATIONS; United States Pharmacopeial-Drug Information, Volume I; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses.

(16) reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.

(17) reaffirms AMA Policy H-120.983, urging the pharmaceutical industry to provide the same economic opportunities to individual pharmacies as given to mail service pharmacies.


Controlling Cost of Medical Care H-155.966

The AMA urges the American Hospital Association and all hospitals to encourage the administrators and medical directors to provide to the members of the medical staffs, housestaff and medical students the charges for tests, procedures, medications and durable medical equipment in such a fashion as to emphasize cost and quality consciousness and to maximize the education of those who order these items as to their costs to the patient, to the hospital and to society in general.

Citation: (Sub. Res. 75, I-81; Reaffirmed: CLRPD Rep. F, I-91; Res. 801, A-93; CMS Rep. 12, A-95; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmation A-08; Reaffirmed in lieu of Res. 5, A-12)

Patient and Public Education about Cost of Care H-155.980

The AMA, as a part of its program to strengthen the US health care system, supports intensifying its efforts to better understand patient concerns regarding fees and other costs of health care in all settings, including the cost of medication, and supports attempts to relieve these concerns.


Medicare Part B Competitive Acquisition Program (CAP) H-110.983

Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

(1) it must be genuinely voluntary and not penalize practices that choose not to participate;

(2) it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;

(3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;

(4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;

(5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;

(6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;

(7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and

(8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

Citation: Res. 216, I-18

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.


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; (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.


Maximum Allowable Cost of Prescription Medications H-155.962

Our AMA opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services.

Citation: CMS Rep. 2, A-07; Reaffirmed in lieu of: Res. 201, I-11; Reaffirmed: CMS Res. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Reaffirmation: A-17

Managed Care Cost Containment Involving Prescription Drugs H-285.965

(1) Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.

(2) Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-
containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

3. Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Physician penalties for non-compliance with a managed care formulary in the form of deductions from withholds or direct charges are inappropriate and unduly coercive. Prescriptions should not be changed without physicians having a chance to discuss the change with the patient.

4. Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.

5. Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.

6. Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.

7. Our AMA urges pharmacists to contact the prescribing physician if a prescription written by the physician violates the managed care drug formulary under which the patient is covered, so that the physician has an opportunity to prescribe an alternative drug, which may be on the formulary.

8. When pharmacists, insurance companies, or pharmaceutical benefit management companies communicate directly with physicians or patients regarding prescriptions, the reason for the intervention should be clearly identified as being either educational or economic in nature.

9. Our AMA will develop model legislation which prohibits managed care entities, and other insurers, from retaliating against a physician by disciplining, or withholding otherwise allowable payment because they have prescribed drugs to patients which are not on the insurer's formulary, or have appealed a plan's denial of coverage for the prescribed drug.

10. Our AMA urges health plans including managed care organizations to provide physicians and patients with their medication formularies through multiple media, including Internet posting.

11. In the case where Internet posting of the formulary is not available and the formulary is changed, coverage should be maintained until a new formulary is distributed.

12. For physicians who do not have electronic access, hard copies must be available.

Citation: CEJA Rep. 2, A-95; Res. 734, A-97; Appended by Res. 524 and Sub. Res. 714, A-98; Reaffirmed: Res. 511, A-99; Modified: Res. 501, Reaffirmed: Res. 123 and 524, A-00; Modified: Res. 509, I-00; Reaffirmed: CMS Rep. 6, A-03; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmation A-08; Reaffirmation A-10; Reaffirmed in lieu of Res. 822, I-11; Reaffirmation A-14; Reaffirmed: CMS Rep. 05, A-19

Low Cost Drugs to Poor Countries During Times of Pandemic Health Crises H-250.988

Our AMA: (1) encourages pharmaceutical companies to provide low cost medications to countries during times of pandemic health crises; and (2) shall work with the World Health Organization (WHO), UNAID, and similar organizations that provide comprehensive assistance, including health care, to poor countries in an effort to improve public health and national stability.

Citation: (Res. 402, A-02; Reaffirmed: CSAPH Rep. 1, A-12)

1.2.13 Medical Tourism

Medical tourists travel to address what they deem to be unmet personal medical needs, prompted by issues of cost, timely access to services, higher quality of care or perceived superior services, or to access services that are not available in their country of residence. In many instances, patients travel on their own initiative, with or without consulting their physician, and with or without utilizing the services of commercial medical tourism companies. The care medical tourists seek may be elective procedures, medically necessary standard care, or care that is unapproved or legally or ethically prohibited in their home system.

Many medical tourists receive excellent care, but issues of safety and quality can loom large. Substandard surgical care, poor infection control, inadequate screening of blood products, and falsified or outdated medications in lower income settings of care can pose greater risks than patients would face at home. Medical tourists also face heightened travel-related risks. Patients who develop complications may need extensive follow-up care when they return home. They may pose public health risks to their home communities as well.
Medical tourism can leave home country physicians in problematic positions: Faced with the reality that medical tourists often need follow-up when they return, even if only to monitor the course of an uneventful recovery; confronted with the fact that returning medical tourists often do not have records of the procedures they underwent and the medications they received, or contact information for the foreign health care professionals who provided services, asked to make right what went wrong when patients experience complications as a result of medical travel, often having not been informed about, let alone part of the patients decision to seek health care abroad. (IV, V, VI) Physicians need to be aware of the implications of medical tourism for individual patients and the community. Collectively, through their specialty societies and other professional organizations, physicians should:
(a) Support collection of and access to outcomes data from medical tourists to enhance informed decision making.
(b) Advocate for education for health care professionals about medical tourism.
(c) Advocate for appropriate oversight of medical tourism and companies that facilitate it to protect patient safety and promote high quality care.
(d) Advocate against policies that would require patients to accept care abroad as a condition of access to needed services.
Individually, physicians should:
(e) Be alert to indications that a patient may be contemplating seeking care abroad and explore with the patient the individuals concerns and wishes about care.
(f) Seek to familiarize themselves with issues in medical tourism to enable them to support informed decision making when patients approach them about getting care abroad.
(g) Help patients understand the special nature of risk and limited likelihood of benefit when they desire an unapproved therapy. Physicians should help patients frame realistic goals for care and encourage a plan of care based on scientifically recognized interventions.
(h) Advise patients who inform them in advance of a decision to seek care abroad whether the physician is or is not willing to provide follow-up care for the procedure(s), and refer the patient to other options for care.
(i) Offer their best professional guidance about a patients decision to become a medical tourist, just as they would any other decision about care. This includes being candid when they deem a decision to obtain specific care abroad not to be in the patients best interests. Physicians should encourage patients who seek unapproved therapy to enroll in an appropriate clinical trial.
(j) Physicians should respond compassionately when a patient who has undergone treatment abroad without the physicians prior knowledge seeks nonemergent follow-up care. Those who are reluctant to provide such care should carefully consider:
(i) the nature and duration of the patient-physician relationship;
(ii) the likely impact on the individual patients well-being;
(iii) the burden declining to provide follow-up care may impose on fellow professionals;
(iv) the likely impact on the health and resources of the community.
Physicians who are unable or unwilling to provide care in these circumstances have a responsibility to refer the patient to appropriate services.

AMA Principles of Medical Ethics: IV, V, VI

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
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