Whereas, The United States has over 2 million individuals in its prisons or jails at any given time; and

Whereas, An estimated 41% of incarcerated individuals have a chronic medical condition such as hypertension, diabetes, or asthma, equating to almost 820,000 incarcerated individuals with a chronic medical condition; and

Whereas, Mental illness specifically is increasingly prevalent in the incarceration system, with 20% of individuals in jails and 15% of individuals in prisons estimated to have serious mental illness; and

Whereas, There are significant racial disparities in incarceration rates, with Black people having a per capita imprisonment rate nearly six times that of Whites and nearly double that of Hispanic individuals; and

Whereas, Incarceration generally constrains individuals and restricts their ability to make truly voluntary and unforced decisions, establishing incarcerated individuals as a vulnerable population for which special protections are warranted; and

Whereas, Incarcerated individuals have specific sets of protections with respect to human subjects research under 45 CFR 46 Subpart C, indicating the same acknowledgement by the U.S. government; and

Whereas, The loss of autonomy is even more pronounced for detainees of Immigration and Customs Enforcement (ICE); since non-citizens are not entitled to a lawyer, detainees have very few avenues to ensure complaints they submit are adequately reviewed, and therefore this population is even more captive than even a “standard” prison population composed of citizens; and

Whereas, Despite the constitutional guarantee of healthcare access to incarcerated individuals, the autonomy of incarcerated individuals with respect to their own healthcare is restricted for a variety of reasons, including financial interests of management, the safety of other incarcerated individuals, and discrimination by their providers, all of which can lead to long-term consequences that follow former inmates years after release; and

Whereas, While persons being detained by ICE are entitled to receive medical care and treatment as needed, drug procurement and formulary management differs based on the type of facility an individual is detained at; and
Whereas, ICE manages three types of facilities: service processing centers (SPCs) that are run entirely by ICE, contract detention facilities (CDFs) where third parties contract with ICE to provide detention services, and local, state, and federal jails that ICE may reimburse to house inmates; and

Whereas, The ICE Health Service Corps (IHSC) is the division of ICE responsible for providing medical care to SPCs and for financial reimbursement for medical care, including pharmaceuticals, provided by CDFs and ICE-contracted jails; and

Whereas, IHSC operates a formulary consisting of approved medications that applies to pharmaceuticals prescribed and dispensed at non-IHSC staffed facilities; and

Whereas, Non-formulary prescriptions require prior authorization by IHSC; and

Whereas, The pharmacy benefits provided by IHSC, including the formulary used to determine which medications are pre-approved for inmates, appear to be managed by the pharmacy benefit manager ScriptCare, but there is no public information about how the formulary is set or what factors are used to set the formulary, raising a concerning set of questions about whether decisions made on the basis of financial incentives for ScriptCare or IHSC are impacting the quality of healthcare available to ICE detainees; and

Whereas, There are no universally applies standards for the procurement or availability of medications in jails and prisons; and

Whereas, The Federal Bureau of Prisons maintains its own formulary, but this formulary is not used by state prisons and jails; and

Whereas, The Office of Justice Program only requires that for jail health services a formulary be created, contributing to the lack of formulary standardization across the country; and

Whereas, The National Commission on Correctional Health Care (NCCH) stipulates that departments of correction must have a method for approving off-formulary medications, but these are only recommendations and may not consistently be applied; and

Whereas, This notable lack of standardization has created an opaque situation where the exact criteria used to set formularies for prisons and jails across the nation is unclear and different from institution to institution, leading the American Society of Health-System Pharmacists (ASHP) recently releasing updated guidance that formulary decisions should include representative medical staff from the facility including practicing physicians and other providers, as well as other facility leaders, and patient or family stakeholders; and

Whereas, Because state prison systems have to dedicate 15-23% of their health benefit expenditures to pharmaceuticals, the primary driver of formulary creation tends to be cost reduction; and

Whereas, There are multiple methods that jails and prisons use to procure medications, including direct purchase by Department of Corrections (DOC) physicians, bulk purchases via contracts with private groups, purchase through state universities/academic medical centers when these institutions provide care to inmates, or centralized ordering and distribution as seen in Massachusetts; and
Whereas, Though the Federal Bureau of Prisons has released guidance for securing the lowest-cost medications ethically, these guidelines are not followed universally\textsuperscript{21}; and

Whereas, Pharmaceutical companies may exert influence over these decision makers and even offer free samples or rebates to incentivize their products being preferred on formulary\textsuperscript{22}; and

Whereas, While some may advocate for accepting these reduced-cost drugs as a cost-saving measure, it can be a source of bias and compromises medical necessity being a driver of formulary creation, particularly for inmates who have no choice or agency in where they access their healthcare\textsuperscript{23}; and

Whereas, While existing American Medical Association policy expresses strong support for the ethical provision of medical care to incarcerated individuals (see: D-430.997, Item 9.7.2 of the AMA Code of Medical Ethics), opposes direct-to-consumer (H-105.988) and EHR-facilitated direct-to-provider (D-478.961) prescription drug advertising, and endorses principles for sound formulary design (H-125.985), but has no policy explicitly recognizing the unique protections that must be afforded to vulnerable, captive populations like incarcerated individuals with respect to formulary design and medication procurement; therefore be it

RESOLVED, That our American Medical Association oppose the practice of pharmaceutical marketing towards those who make decisions for captive populations, including, but not limited to, doctors working in a correctional capacity, judges, wardens, sheriffs, correctional officers, Immigration and Customs Enforcement, and other detention administrators (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for the inclusion of physicians in the selection of medications available to vulnerable populations such as incarcerated individuals (Directive to Take Action); and be it further

RESOLVED, That our AMA support and work with state medical societies to support measures to increase transparency in medication procurement, including but not limited to: (1) requiring those responsible for medical procurement to report gifts from pharmaceutical companies over a minimum amount; and (2) centralizing formulary choices in a physician-led office, agency, or commission following the principles of a sound formulary. (New HOD Policy)

Fiscal Note: Not yet determined

Received: 10/12/22

REFERENCES:


RELEVANT AMA POLICY

Support for Health Care Services to Incarcerated Persons D-430.997
Our AMA will:
(1) express its support of the National Commission on Correctional Health Care Standards that improve the quality of health care services, including mental health services, delivered to the nation’s correctional facilities;
(2) encourage all correctional systems to support NCCHC accreditation;
(3) encourage the NCCHC and its AMA representative to work with departments of corrections and public officials to find cost effective and efficient methods to increase correctional health services funding;
(4) continue support for the programs and goals of the NCCHC through continued support for the travel expenses of the AMA representative to the NCCHC, with this decision to be reconsidered every two years in light of other AMA financial commitments, organizational memberships, and programmatic priorities;
(5) work with an accrediting organization, such as National Commission on Correctional Health Care (NCCHC) in developing a strategy to accredit all correctional, detention and juvenile facilities and will advocate that all correctional, detention and juvenile facilities be accredited by the NCCHC no later than 2025 and will support funding for correctional facilities to assist in this effort; and
(6) support an incarcerated person’s right to: (a) accessible, comprehensive, evidence-based contraception education; (b) access to reversible contraceptive methods; and (c) autonomy over the decision-making process without coercion.

Citation: Res. 440, A-04; Amended: BOT Action in response to referred for decision Res. 602, A-00; Reaffirmation I-09; Reaffirmation A-11; Reaffirmed: CSAPH Rep. 08, A-16; Reaffirmed: CMS Rep, 02, I-16; Appended: Res. 421, A-19; Appended: Res. 426, A-19

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.


Pharmaceutical Advertising in Electronic Health Record Systems D-478.961

Our AMA: (1) opposes direct-to-prescriber pharmaceutical and promotional content in electronic health records (EHR); (2) opposes direct-to-prescriber pharmaceutical and promotional content in medical reference and e-prescribing software, unless such content complies with all provisions in Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices (H-105.988); (3) encourages study of the effects of direct-to-prescriber advertising at the point of care, including advertising in EHRs, on physician prescribing, patient safety, data privacy, health care costs, and EHR access for physician practices; (4) opposes the preferential placement of brand name medications in e-prescription search results or listings; and (5) encourages e-prescribing and EHR companies to ensure that the generic medication name will appear first in e-prescription search results and listings.

Citation: Res. 207, I-19; Modified: BOT Rep. 14, A-21;

Expanded Use of the AMA’s Principles of a Sound Drug Formulary H-125.985

Our AMA urges managed care organizations, pharmacy benefit managers, and others who design benefit packages and/or make pharmacy benefit decisions, to utilize the Principles of a Sound Drug Formulary System (as described in BOT Rep. 28, I-00) as they develop their pharmaceutical benefit plan(s) and that the Principles of a Sound Drug Formulary System be readily available on the AMA web site.

Citation: Res. 520, A-01; Amended: Res. 514, A-02; Reaffirmed: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmation A-06; Reaffirmed: CSAPH Rep. 01, A-