AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 703
(A-24)

Introduced by: Resident and Fellow Section

Subject: Upholding Physician Autonomy in Evidence-Based Off-Label Prescribing and Condemning Pharmaceutical Price Manipulation

Referred to: Reference Committee G

Whereas, the practice of off-label prescribing, the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, dosage, or route of administration, is a legal and often necessary aspect of medical practice[1-3]; and

Whereas, off-label prescribing is common, accounting for up to one third of all prescriptions and being more common for certain groups including in the treatment of mental health conditions and treatment of the elderly, children, and pregnant people[4]; and

Whereas, the vast discrepancy in prescription drug pricing places an unreasonable financial burden on underinsured patients, for example, $25 per month co-pay with some insurers compared to approximately $1,200 per month without coverage for some GLP-1 medications[5,6]; and

Whereas, pharmaceutical companies are threatening physicians who prescribe certain medications off-label for medically necessary indications, potentially jeopardizing medical licensure and restricting clinical decision-making[5,7]; and

Whereas, such threats interfere with physicians' ability to make appropriate medical judgments for their patients; and

Whereas, timely action is needed to protect physicians' ability to prescribe off-label based on medical necessity without repercussions, ensuring access for vulnerable patient populations, and protecting these vulnerable patient populations from using potentially hazardous fake compounded versions; and

Whereas, differential pricing and restricted off-label use of medications can exacerbate healthcare disparities by limiting treatment access for underserved populations; therefore be it

RESOLVED, that our American Medical Association advocates for transparency, accountability, and fair pricing practices in pharmaceutical pricing, opposing differential pricing of medications manufactured by the same company with the same active ingredient, without clear clinical necessity (Directive to Take Action); and be it further

RESOLVED, that our AMA condemns interference with a physician’s ability to prescribe one medication over another with the same active ingredient, without risk of harassment, prosecution, or loss of their medical license, and calls on regulatory authorities to investigate and take appropriate action against such practices. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

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REFERENCES:

1. Furey K and Wilkins K. Prescribing “Off-Label”: What Should a Physician Disclose? AMA J Ethics. 2016;18(6):587-593. doi: 10.1001/journalofethics.2016.18.6.ecas3-1606. https://journalofethics.ama-assn.org/article/prescribing-label-what-should-physician-disclose/2016-06
2. Meadows WA, Hollowell BD. “Off-label” drug use: an FDA regulatory term, not a negative implication of its medical use. Int J Impot Res. 2008;20(2):135-144.
3. US FDA. Understanding Unapproved Use of Approved Drugs "Off Label”. Updated Feburary 5, 2018. Accessed April 22, 2024. https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label
4. Van Norman GA. Off-Label Use vs Off-Label Marketing of Drugs. JACC Basic Transl Sci. 2023 Feb; 8(2): 224–233.
5. Gibert D. “Insurers clamping down on doctors who prescribe Ozempic for weight loss.” Washington Post. Published June 12, 2023. Accessed April 22, 2024. “https://www.washingtonpost.com/business/2023/06/11/weight-loss-ozempic-wegovy-insurance/?utm_campaign=KHN%3A%20First%20Edition&utm_medium=email&_hsmi=262066865&_hsenc=p2ANqtz-9rIvynBptFsvvj0doDkQYFbvNOgwtFzvPvqY3Lam5feDA5V4gdYZuELna20MTZAFOD_wqPN6lJvzvminl
6. Perez A. How Much is Mounjaro Without Insurance? Ways to Buy. Medical News Today. January 30, 2024. Accessed April 22, 2024. https://www.medicalnewstoday.com/articles/how-much-is-mounjaro-without-insurance
7. O’Mary L. “Insurers Poised to Crack Down on Off-Label Ozempic Prescriptions” WebMD.com. Published June 12, 2023. Accessed April 22, 2024. https://www.webmd.com/obesity/news/20230612/insurers-poised-crack-down-off-label-ozempic-prescriptions

RELEVANT AMA POLICY:

Patient Access to Treatments Prescribed by Their Physicians H-120.988

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. [Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04; Reaffirmation I-07; Reaffirmed: Res. 819, I-07; Reaffirmation A-09; Reaffirmation I-10; Modified: BOT Rep. 5, I-14; Reaffirmed: Res. 505, A-15; Reaffirmed: CMS Rep. 6, I-20; Reaffirmed: Res. 509, I-20; Reaffirmation: I-22; Reaffirmed: CSAPH Rep. 01, A-23; Reaffirmed: CSAPH Rep. 02, A-23]