RESOLUTION 28-23

Title: Physician Right to Prescribe Approved Devices and Drugs

Introduced by: Venkat Rao, MD, for the Genesee County Delegation

Original Author: Venkat Rao, MD

Referred To: Reference Committee E

House Action: **DISAPPROVED**

Whereas, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and other state and federal agencies have attempted to restrict a physicians best medical judgement in the prescribing of medicines and devices off-label, and

Whereas, the U.S. government passed Medicare by assuring physicians that it would never interfere with the practice of medicine but has done so extensively, and

Whereas, the Consolidated Appropriations Act, 2023, included language allowing the FDA to prevent physician and patient access to drugs or devices which are already approved, and

Whereas, the FDA wishes to interfere in the practice of medicine, and

Whereas, off-label use of approved medicines and devices is often the standard of care, and

Whereas, more than 20 percent of all practice related prescriptions are written for off-label use; therefore be it

RESOLVED: That MSMS advocate against any state of Michigan attempts to restrict off-label prescribing; and be it further

RESOLVED: That the MSMS Delegation to the American Medical Association (AMA) ask the AMA to advocate against any attempts to restrict off-label prescribing; and be it further

RESOLVED: That MSMS Delegation to the American Medical Association (AMA) ask the AMA to seek repeal of the FDA authority contained in the Consolidated Appropriations Act, 2023 to restrict a physician's right to prescribe off-label use of drugs and devices.

WAYS AND MEANS COMMITTEE FISCAL NOTE: $1,000-$2,000

Relevant MSMS Policy:

Off Label Policy (23-22)
RESOLVED: That MSMS support AMA Policy, "Patient Access to Treatments Prescribed by Their Physicians H-120.988" as a basic medical right and responsibility of a physician to provide the best care available to our patients; and be it further

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our AMA to amend AMA Policy, "Patient Access to Treatments Prescribed by Their Physicians H-120.988." by **addition** as follows: 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. **7. OUR AMA SUPPORTS PHYSICIAN AUTONOMY WITH REGARD TO DECIDING APPROPRIATE DOSING.**

Oncology Advisory Panel
MSMS supports the establishment of an oncology advisory panel to advise all health insurance carriers about the efficacy, appropriateness and routes of administration for off-label indications of U.S. Food and Drug Administration-approved drugs used in anti-neoplastic therapy.

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.

Sources:

1. https://www.nejm.org/doi/full/10.1056/NEJMp0802107
2. https://pubmed.ncbi.nlm.nih.gov/17290639/
3. https://www.wsj.com/articles/the-fda-wants-to-interfere-in-the-practice-of-medicine-physicians-patients-medical-devices-treatment-11673562165
4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4743297/
5. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/410250