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Title: Put Over-the-Counter Inhaled Epinephrine Behind Pharmacy Counter

Introduced by: Venkat Rao, MD, for the Michigan Thoracic Society

Original Author: Venkat Rao, MD

Referred to: Reference Committee A

House Action: **APPROVED**

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Whereas, the Food and Drug Administration recently approved inhaled epinephrine (Primatene Mist HFA) as over-the-counter (OTC) treatment for patients with mild, intermittent asthma, and

Whereas, the use of inhaled epinephrine is not considered appropriate treatment for the management of asthma - regardless of the level of asthma severity, and

Whereas, several expert panels have produced evidence-based recommendations on the treatment of asthma, and none recommend the use of inhaled epinephrine to treat asthma, and

Whereas, the National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, issued treatment guidelines for management of asthma and recommended against the use of epinephrine for treating asthma exacerbations<sup>1</sup>, and

Whereas, asthma is a serious respiratory condition that affects over 25 million Americans and even patients with mild or intermittent asthma can experience life-threatening asthma exacerbations, and

Whereas, patients that view inhaled epinephrine as an “equivalent substitute” for more effective prescription drugs for asthma management will not have the benefit of more appropriate asthma medications that are proven to reduce asthma exacerbations, improve symptom control and have fewer side effects, and

Whereas, without proper guidance, potential severe adverse outcomes are possible from unlimited access to inhaled epinephrine, and

Whereas, placing inhaled epinephrine behind the counter will give pharmacists the opportunity to counsel patients on the risks and limitations of using inhaled epinephrine to treat asthma symptoms and, when appropriate, guide patients to primary care providers or appropriate specialist to prescribe patients safer and more effective medications, and

Whereas, the Food and Drug Administration does not have the authority to require an OTC drug be placed behind the counter, and

Whereas, pharmacies have the discretion to hold these products behind the counter in the interests of patient health and safety; therefore be it

RESOLVED: That MSMS work with pharmacies within the state of Michigan to move inhaled epinephrine (Primatene Mist HFA) behind the counter; and be it further

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our AMA to work with national pharmacy chains to move inhaled epinephrine (Primatene Mist HFA) behind the counter.

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56 WAYS AND MEANS COMMITTEE FISCAL NOTE: \$25,000 or more as this resolution requires MSMS to engage  
57 in industry and potential legislative advocacy.

**Relevant MSMS Policy:**

Require Prescription for Ephedrine and Pseudoephedrine

MSMS supports limiting the availability of ephedrine and pseudoephedrine for illicit purposes while maintaining legitimate patient and physician access to this medication. (Res9-11)

Pharmacy: Medication Information

MSMS supports the efforts of pharmacies to educate patients and prevent medication-induced problems. (Res110-97A)

**Relevant AMA Policy:**

Over-the-Counter Inhalers in Asthma H-115.972

Our AMA will send a letter to the US Food and Drug Administration (FDA) expressing: 1) our strong opposition to FDA making the decision to allow inhaled epinephrine to be sold as an over-the counter medication without first soliciting public input; and 2) our opposition to the approval of over-the-counter sale of inhaled epinephrine as it is currently not a recommended treatment for asthma.

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<sup>1</sup>"The less beta2-selective agents (isoproterenol, metaproterenol, isoetharine, and epinephrine) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses." National Asthma Education Prevention Program Expert Report 2 (1997) p. 64 figure 3-2.