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Title: Naloxone Price Increase

Introduced by: Gunjan Malhotra, MD, for the Wayne County Delegation

Original Author: Gunjan Malhotra, MD, Kaitlyn Dobesh, Peter Szatkowski, and Eric Walton

Referred to: Reference Committee B

House Action: **AMEND**

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Whereas, naloxone is an opioid antagonist available as a reversal agent for opioid overdoses<sup>1</sup>, and

Whereas, states have worked extremely hard to increase access to naloxone by passing legislation in 40 states that offer clinicians various levels of immunity from criminal or civil prosecution for third-party prescriptions, and

Whereas, in 42 states, criminal or civil immunity is granted to bystanders who possess or use illegal drugs when they provide emergency services to someone who has overdosed, including administering naloxone or calling emergency responders<sup>2</sup>, and

Whereas, 40 states have passed legislation allowing access to naloxone via standing prescription orders at pharmacies, pharmacist prescription authority, or collaborative practice agreements<sup>2</sup>, and

Whereas, the price of naloxone products has increased significantly since 2009: Injectable or intranasal, 1 mg-per-milliliter vial (2 mL) manufactured by Amphastar increased from \$20.34 (2009) to \$39.60 (2016); 0.4 mg-per-milliliter vial (10 mL) manufactured by Hospira increased from \$62.29 (2012) to \$142.49 (2016); and the auto-injector, two-pack of single-use prefilled auto-injectors (Evzio) manufactured by Kaleo increased from \$690.00 (2014) to \$4,687.50 (2017)<sup>2</sup>, and

Whereas, naloxone bulk purchasing programs -- modeled after federal government purchasing of vaccines -- could help reduce the price of naloxone for communities, as seen with the Massachusetts bulk purchasing program that reduced the price for both first-responders and municipalities, and

Whereas, Wisconsin, New York, and Ohio also have negotiated rebate programs with the pharmaceutical manufacturers<sup>2,3,4</sup>, and

Whereas, the US federal government could use federal law 28 U.S.C. section 1498, which permits contracts with manufacturers to produce cheaper generic formulations of patented products for federal use during public health emergencies, to negotiate for lower drug prices as done with ciprofloxacin during the 2001 anthrax threat<sup>2,5</sup>, and

Whereas, increased competition through introduction of generic options could lower drug prices and could be accomplished by incentivizing generic development with accelerated approval and waived fees or importing international generic drugs that meet US Food and Drug Administration (FDA) standards<sup>2,6</sup>, and

52           Whereas, making naloxone an over-the-counter drug (as discussed by the FDA previously)  
53 would attract additional manufacturers, due to easier FDA authorization, which could reduce prices<sup>2,7</sup>;  
54 therefore be it

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56           RESOLVED: That MSMS advocate for negotiating with pharmaceutical companies to lower  
57 prices for naloxone while maintaining needed supply; and be it further

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59           RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) ask our  
60 AMA to amend existing AMA policy, Increasing Availability of Naloxone H-95.932, by addition (**bold**  
61 **type**) and deletion (~~striketrough~~) as follows:

62           1. Our AMA supports legislative, ~~and~~ regulatory, **and national advocacy** efforts ~~that to~~  
63 increase access to **affordable** naloxone, including **but not limited to** collaborative practice  
64 agreements with pharmacists and standing orders for pharmacies and, where permitted by law,  
65 community based organizations, law enforcement agencies, correctional settings, schools, and other  
66 locations that do not restrict the route of administration for naloxone delivery.

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69 WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE

**Relevant AMA Policy:**

**Study OTC Availability of Naloxone D-95.974**

1. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.
2. Our AMA will study and report back at the 2016 Annual Meeting on ways to expand the access and use of naloxone to prevent opioid-related overdose deaths.

**Increasing Availability of Naloxone H-95.932**

1. Our AMA supports legislative and regulatory efforts that increase access to naloxone, including collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community based organizations, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.
2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.
3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.
4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.
5. Our AMA supports liability protections for physicians and other health care professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law.
6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.

**Prevention of Opioid Overdose D-95.987**

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.

<sup>1</sup> <https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone>

<sup>2</sup> <http://www.nejm.org.proxy.lib.wayne.edu/doi/full/10.1056/NEJMp1609578>

<sup>3</sup> <http://www.sciencedirect.com/science/article/pii/S0749379700002105>

<sup>4</sup> [http://www.masslive.com/politics/index.ssf/2016/11/state\\_bulk\\_buying\\_of\\_anti-over.html](http://www.masslive.com/politics/index.ssf/2016/11/state_bulk_buying_of_anti-over.html)

<sup>5</sup> <http://content.healthaffairs.org/content/35/5/791.full>

<sup>6</sup> <http://www.ajhp.org.proxy.lib.wayne.edu/content/72/17/1426.1.long>

<sup>7</sup> [http://www.mccaskill.senate.gov/imo/media/doc/SCA\\_Mylan\\_6\\_3\\_16.pdf](http://www.mccaskill.senate.gov/imo/media/doc/SCA_Mylan_6_3_16.pdf)