

Removing naloxone's Rx status is an essential step to save lives

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What's the news: As the drug-overdose epidemic continues to worsen, the AMA is maintaining its pressure on regulators, legislators and manufacturers to expand availability to naloxone. This includes making the opioid-related overdose-reversing drug available over the counter (OTC).

The Biden administration is considering such a move, according to Health and Human Services Secretary Xavier Becerra remarks that were strongly supported by the AMA.

Most recently, the AMA has written Rahul Gupta, MD, director of the White House Office of National Drug Control Policy (ONDCP), to encourage him to make naloxone available over the counter to help end the drug-overdose epidemic that is being fueled by growing levels of illicit fentanyl, fentanyl analogs, and drugs contaminated with illicit fentanyl.

“The AMA urges removing the prescription status of naloxone as an essential step to save lives from opioid-related overdose because it will help make naloxone more readily available to patients everywhere,” AMA Executive Vice President and CEO James L. Madara, MD, wrote in a letter (PDF) to Dr. Gupta.

Given clear guidance from the Food and Drug Administration (FDA), “there is no moral, medical or safety-related reason for these life-saving overdose reversal agents to remain locked under prescription regulations,” the AMA’s CEO wrote.

Previously, the AMA urged naloxone manufacturers (PDF) to submit applications for naloxone OTC status to the FDA. This includes Emergent BioSolutions and Teva (makers of a nasal spray application), and Hikma Pharmaceuticals (makers of a branded nasal application and generic intramuscular application).

Also contacted and encouraged to apply for OTC status for their naloxone products were: Akorn Inc; Adamis Pharmaceuticals Corporation; Kaleo, which previously made an injectable form of naloxone

known as Evzio; and Pfizer.

These companies, however, have not taken any action.

Some manufacturers are claiming naloxone is not safe for OTC status, even though the American Pharmacists Association House of Delegates adopted policies last year to support expanding the availability of naloxone as both a prescription and nonprescription medication.

“We have tried everything we can, but manufacturers need more than the nation’s physicians’ encouragement—they need your specific urging and advocacy to remove the prescription status of naloxone,” Dr. Madara wrote to Dr. Gupta. “That is what the nature of this epidemic needs, and we are confident that your leadership can help us reach that lifesaving result.”

Previously, the AMA has urged a wide cross section of national stakeholders to encourage manufacturers to submit OTC applications. In addition to advocating action from the National Governors Association on the issue (PDF), the AMA has pressed national organizations representing state legislators, insurance commissioners, attorneys general, state medical boards, pharmacy boards, health officials, Medicaid directors, drugmakers and health plans to use their sway to make naloxone available OTC.

Why it’s important: The national toll from the worsening drug-overdose epidemic is tops more than 100,000 deaths annually, according to provisional data released by the Centers for Disease Control and Prevention last fall.

“Deaths from drug overdose continue to contribute to overall mortality and the lowering of life expectancy in the United States,” according to National Center for Health Statistics’ data brief No. 428, which was published in December and provides a sobering examination of the numbers behind this epidemic.

“If not for naloxone, tens of thousands of additional Americans would likely have died, which is why we need to remove all barriers to naloxone,” Dr. Madara wrote. “At this point in the nation’s overdose epidemic, we must remove all potential barriers to naloxone.”

Learn more: The AMA and Manatt have released a toolkit to guide states on removing barriers to evidence-based patient care.

Find state- and specialty-specific resources at the AMA's End the Epidemic website, explore overdose-related data metrics on the AMA’s overdose data dashboard, and read about the inspiring physicians who are helping patients with substance-use disorders or chronic pain.

Also, read why this is a critical year to address the worsening drug-overdose crisis.