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February 15, 2022

The Honorable Rahul Gupta, MD  
Director  
White House Office of National Drug Control Policy  
1800 G Street, NW  
Washington, DC 20503

Dear Director Gupta:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am writing to urge your support to help increase the availability of naloxone in the nation's pharmacies and in the community at-large. The AMA greatly appreciates that the Office of National Drug Control Policy (ONDCP) already has made increasing access to naloxone a high priority to save lives from an opioid-related overdose. We believe that additional steps are necessary, however, to ensure this life-saving medication is more widely available. Specifically, the AMA strongly encourages action to remove the prescription status of naloxone to make it more available over the counter (OTC) and for purchase and distribution by harm reduction organizations. We strongly support comments recently made by Department of Health and Human Services (HHS) Secretary Xavier Becerra in December that HHS is considering how to make naloxone available OTC. We offer several suggestions below.

The nation's drug overdose epidemic killed more than 100,000 Americans in the last year, according to the U.S. Centers for Disease Control and Prevention (CDC). The CDC, ONDCP, and many others understand that the dangers of illicitly manufactured fentanyl, combined with increasing polysubstance use, make the epidemic more deadly than ever, particularly during the ongoing COVID-19 pandemic. 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. We agree with the CDC that "naloxone saves lives—but only if it's readily available when an overdose occurs." **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.**

Removing the prescription status of naloxone was addressed by the [U.S. Food and Drug Administration \(FDA\) back in 2017](#). The Deputy Director in the Division of Nonprescription Drug Products said that the final piece the FDA needed for OTC status for naloxone was an application from manufacturers. **The FDA has taken unprecedented steps to develop a model drug facts label, use instructions, and has evaluated the efficacy of those instructions, [clearly stating](#): "We conclude that the results of this study are acceptable to support use of the tested naloxone DFL in the OTC setting."** As the overdose epidemic has worsened, given the FDA's clear guidance there is no moral, medical, or safety-related reason for these life-saving overdose reversal agents to remain locked under prescription regulations.

The AMA has done everything we can to encourage naloxone manufacturers to take additional actions to increase access to low- or no-cost naloxone. Some manufacturers have provided discounts to states or municipalities for their life-saving products. Some manufacturers have given limited amounts of their products to harm reduction organizations for free. These efforts have helped, but they are not enough. The AMA has tried repeatedly to urge naloxone manufacturers to further reduce costs and take actions more consistent with the needs of the drug overdose epidemic, but manufacturers claim they are doing all they can do. The AMA has encouraged manufacturers to submit the necessary application to make naloxone OTC, but they have consistently declined.

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A few months ago, we renewed our call for OTC status to manufacturers, including Emergent BioSolutions and Teva (makers of a nasal spray application), and Hikma Pharmaceuticals (makers of a branded nasal application and generic intramuscular (IM) application). A copy of our letter can be found [here](#). In response, some manufacturers claim naloxone is not safe for OTC status. Others claim that their price discounts are sufficient. Some manufacturers have not responded to the AMA at all. 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. That is what the nature of this epidemic needs, and we are confident that your leadership can help us reach that life-saving result.

In addition to manufacturers' intransigence, there are additional barriers facing patients being able to access naloxone behind the counter. These include the high cost for those without health insurance, hesitance to dispense naloxone to a person at risk of overdose, and "persistent stigma" surrounding naloxone, according to public health researchers. This is despite physicians' increased prescribing of naloxone, support for OTC naloxone from the [American Pharmacists Association](#), and pharmacy chains' public support for standing orders. Other barriers include largely absent prominent pharmacy signage promoting naloxone availability, stigma and time pressures that serve as a barrier for some pharmacists, and lack of public education about standing orders.

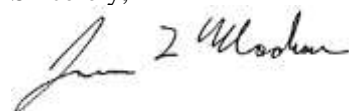
It is also important to note that removing prescription status does not mean that health insurance plans have to stop providing coverage for naloxone. Under the Affordable Care Act, OTC aspirin and certain contraceptives are covered by insurance. Coverage for OTC naloxone could be achieved through legislation, if necessary. It would be better, however, if decisions to continue access to affordable naloxone as a covered benefit were made among employers and payers and pharmacy benefit managers. The AMA will continue to advocate for such coverage as part of a comprehensive strategy to broaden access to naloxone. We further urge all federal programs to continue to provide naloxone via Medicare, Medicaid, the Veterans Health Administration, and the Federal Employees Health Benefits Program. The nation needs this combined strategy of providing naloxone through multiple access points.

In addition to all payers continuing to provide naloxone as a covered benefit, the AMA urges all employers to make sure this occurs because we want to ensure that every person who would benefit from naloxone has access to this life-saving medication for themselves, a family member or friend, or a person whom they might encounter in the community. Removing prescription status simply adds access points for those who may not want to use their insurance and/or ask their pharmacist or physician. **At this point in the nation's overdose epidemic, we must remove all potential barriers to naloxone.**

In sum, the AMA asks your support to: (1) take all necessary steps to make naloxone available and remove its prescription status; and (2) continue the ONDCP's efforts to ensure naloxone is available and affordable for all persons regardless of insurance status and to community-based organizations that expand naloxone access in the communities where it is most needed.

Thank you for your consideration. If you have any questions, please contact Sandy Marks in our Federal Affairs unit at [sandy.marks@ama-assn.org](mailto:sandy.marks@ama-assn.org) or 202-789-4585.

Sincerely,



James L. Madara, MD