Federal Policymakers Should Urgently and Greatly Expand Naloxone Access

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Since March 2020, the US federal government has invested tremendous public health effort in COVID-19 responses by expediting the availability of vaccines and novel therapeutics. Meanwhile, addiction care providers, public health workers, and people who use drugs have been sounding alarms about the pandemic's collateral damage, which has contributed to the ongoing surge of unintentional fatal overdoses. Reduced access to addiction treatment and services combined with fentanyl infiltrating drug supplies resulted in an estimated 100 000 fatal overdoses in 2020 alone.[1] Although the Centers for Disease Control and Prevention (CDC) has released official health advisories[2] and the US Department of Health and Human Services (HHS) has supported widespread implementation of expanded distribution and use of naloxone in high-risk populations, there is not enough naloxone in the hands of those who need it most. Only one naloxone prescription is dispensed for every 70 high-dose opioid prescriptions nationwide.[3] In communities that experience disproportionate rates of overdose from illicit opioids, a recent study suggests that nonurban areas have lower naloxone distribution relative to overdose deaths than urban areas do.[4] Given the pervasiveness of this national crisis, it is critical to saturate our communities now with naloxone. The 2021 Model Expanded Access to Emergency Opioid Antagonists Act is a first step in aiming for uniform naloxone access because it provides a legislative template that states could eventually choose to implement.[5] We call on federal policymakers and regulators to take one step further to increase naloxone availability by (1) making naloxone available over the counter (OTC), (2) increasing funding for community-based programs focusing on harm reduction, (3) permanently eliminating insurance copayments and prior-authorization requirements, and (4) mandating coprescribed and codispensed naloxone with all higher-risk opioid prescriptions and medications for opioid use disorder.

OVER-THE-COUNTER NALOXONE

First, we call for an intranasal naloxone formulation to be switched to an OTC status and for mandates for insurers to cover OTC cost.[6] Traditional naloxone access points, such as local pharmacies, health care facilities, and syringe service programs, are not universally available in all communities and often lack round-the-clock availability. We envision naloxone at a subsidized cost at low-barrier access points such as gas stations and convenience stores, where people at risk for overdose could have 24-hour access. Naloxone has a benign safety profile with no significant clinical effect if opioids are not present, is rarely associated with severe adverse reactions when administered in the community,[7] and meets all 4 US Food and Drug Administration (FDA) criteria to become an OTC product.[6] Even though the FDA Center for Drug Evaluation and Research supported development of OTC naloxone products by proactively developing model consumer-friendly drug fact labels in 2020,[8] naloxone remains under prescription-only status. The opioid overdose crisis continues to ravage communities; thus, we call for federal policymakers within the US Department of Health and Human Services or the FDA to facilitate OTC approval of at least one formulation of naloxone, with or without manufacturer requests or

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approval. This is a crisis that demands bold and immediate action.

EXPAND FUNDING FOR COMMUNITY-BASED PROGRAMS

Second, we call for a focused effort to increase funding for all community-based programs concentrating on harm reduction. These community programs often engage people who use drugs and members of racial minority groups who have historically faced stigma and been excluded from health care systems and pharmacy-based naloxone access. People who use drugs are most likely to use naloxone to reverse a witnessed opioid overdose[9] and thus are a key population to equip with naloxone. Currently, states can seek funding toward purchasing naloxone from the Substance Abuse and Mental Health Services Administration via formula-based block grants that can be distributed to governmental and nongovernmental agencies. Although the American Rescue Plan Act of 2021 is expanding block grant availability to community harm reduction services and is an important step toward expanding access, many nongovernmental organizations, community health centers, and harm reduction organizations do not receive these federal funds and have to use their limited budgets to purchase naloxone formulations at cost or rely on mutual aid networks.[10] Manufacturing disruptions of generic naloxone in 2021 have limited the supply of this lower-cost formulation, forcing community-based programs to stretch funds for costlier formulations to sustain their naloxone demands.[11] Given the number of lost lives and the 2021 National Drug Control Strategy specifically calling for investment and dissemination of evidence-based harm reduction efforts, including naloxone access, we advocate that expansion of funding for community harm reduction organizations be coupled with securing an affordable and permanent naloxone supply for these organizations. Strategies used during the COVID-19 pandemic for procurement of vaccinations could be considered to expand naloxone availability to community health programs, including federal mass purchasing and stockpiling.

ELIMINATE INSURANCE COPAYMENTS

Third, we call for removing patients' financial barriers to obtaining naloxone by the permanent elimination of copayment and preauthorization requirements. This was done at the federal level by leveraging the Affordable Care Act to provide rapid coverage of preventive services to enable covering costs for community COVID-19 vaccinations.[12] In general, individuals with medication copays are less likely to pick up a prescription and have naloxone available when it is needed. All state Medicaid programs cover naloxone; however, even though Medicaid covers almost 40% of nonelderly adults with opioid use disorder, in 2018, it only paid for 5% of all naloxone sold in the United States.[13] Furthermore, the CDC has reported that 71% of Medicare prescriptions, compared with 42% of commercial insurance carriers, require copayments upwards of $80,[14] a financial barrier to naloxone access. In response, private insurers have attempted to address this by implementing no member cost sharing[15] or copayment waivers.[16] Other state-level responses include New York's naloxone copayment assistance program and mandate requiring that the cost of opioid antagonists be covered by health insurance.[5] Although these efforts and programs are isolated successes, we call for federal funding to enable elimination of copays to reduce costs for the public.

MANDATE COPRESCRIBING

Fourth, there should be a federal mandate for prescribers to coprescribe naloxone with all higher-risk opioid prescriptions and medications for opioid use disorder (methadone, naltrexone, or buprenorphine-naloxone) and for pharmacists to codispense naloxone. Coprescribing is an established concept and practice, included in the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, which recommends that providers consider coprescribing to patients receiving daily opioid dosages of 50 morphine milligram equivalents or greater or receiving benzodiazepines,[17] and was supported by the 2021 Model Expanded Access to Emergency Opioid Antagonists Act. State legislatures that implemented coprescribing mandates have seen substantial increases in naloxone prescribing, engagement of a larger and more diverse set of prescribers, expanded geographic reach, and reductions in opioid-related harm.[18–20] In 2018, a panel of experts at the Drug Safety and Risk Management Advisory Committee narrowly voted against a coprescribing mandate, citing concerns for potential risks of drug shortages, diverting naloxone from community programs, rise in health care costs, institutional racism benefiting insured patients, and threats to provider autonomy in identifying patient risk.[21] Instead, this committee recommended changing opioid prescription labels to encourage coprescription, which

was released as an FDA mandate in July 2020 to opioid drug manufacturers.[22] Although it remains unclear if these label changes were widely implemented, they serve as a mere nudge for providers to have discussions with their patients about the importance of naloxone, whereas mandatory coprescribing will facilitate increased distribution of this life-saving medication. We also encourage that future coprescribing mandates be coupled with proactive approaches to ensure that coprescribing does not exacerbate health inequities, given the presence of systemic racism faced by persons using illicit opioids, including Black, Indigenous, and People of Color communities that have had inequitable access to health care, pharmacies, and insurance benefits. Furthermore, manufacturing supply chains should be augmented to ensure that coprescribing does not cause drug shortages. If these coprescription policies were applied on a national scale, there would be dramatic increases in naloxone availability with spillover to the community, awareness about what overdose is and how it can be prevented, and creation of a sustainable culture of opioid safety.

Every overdose death is preventable. Ensuring equitable access to and saturating communities with naloxone is critical, given the more than 1 million persons who have died of drug overdose since 1999. We must move beyond public health advisories and take federal policy actions to make naloxone available OTC, expand funding for community-based programs providing harm reduction, eliminate naloxone copayments and prior authorizations, and mandate coprescribing naloxone with high-risk prescriptions and medications for opioid use disorder to save lives. The ongoing surge in overdose deaths during the COVID-19 pandemic is a warning that immediate and comprehensive steps must be taken to reduce deaths. To curb overdose, we need to greatly increase naloxone access in all communities. AJPH

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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