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WH Wants To Boost Naloxone Access, Makes No Mention Of OTC Switch

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The Biden administration wants to increase access to and affordability of the overdose reversal drug naloxone as part of its broader strategy to address the opioid overdose epidemic, but the administration's plan is focused more on ensuring consistent access across states and makes no mention of switching the drug from prescription to over-the-counter status. Lawmakers, medical groups and harm reduction experts have called for FDA and the Biden administration to switch naloxone from prescription to OTC status since manufacturers have yet to request the switch themselves.

The administration's plan to increase naloxone access is part of the broader White House National Drug Control Strategy unveiled Thursday (April 21). The strategy focuses on two critical drivers of the epidemic: untreated addiction and drug trafficking. It instructs federal agencies to prioritize actions that will save lives, get people the care they need, go after drug traffickers' profits, and make better use of data.

Administration officials say the plan focuses on making make harm reduction interventions, including naloxone, more accessible and affordable. The most important action the United States can take now is to make sure everyone who needs naloxone can access the drug without fear or judgment, a senior administration official said during a press call Wednesday (April 20).

But the strategy makes no mention of making naloxone available OTC, which lawmakers, medical groups and harm reduction experts assert is key to increasing the drug's access.

Naloxone currently is available by prescription as an auto-injector or a nasal spray. Those formulations do not have consumer-friendly drug facts labels, an essential part of prescription-to-OTC switches. Drug makers looking to switch their products to OTC status must show FDA that consumers understand how to use the products without supervision of health care professionals.

FDA for years has encouraged companies to develop OTC options. In 2019, the agency developed a model drug facts label with pictogram directions. It was the first time FDA developed a model drug facts label for an OTC switch. The agency, according to experts, has the authority to force the switch but the agency has so far not exercised that authority.

During the press call Wednesday, a senior administration official said there are inconsistent policies across U.S. states and jurisdictions that make it difficult to access naloxone. The administration wants to ensure harm reduction organizations and first responders have consistent access to and supply of the drug.

"If you are overdosing, your zip code gets to define whether you get to live or die. We want to change that. And one of the aspects of this is to make sure that it is affordable, accessible and can be administered when needed, not be sitting on the shelf," the official said.

The strategy directs HHS to recommend ways to address bottlenecks and increase state and local availability of naloxone. HHS' assessment should also consider supply chain concerns and offer suggestions for how naloxone can be easily and discretely accessible to people with substance use disorder and their family and friends.

The strategy also calls for state and local public health and safety agencies to pool their available data and provide help to those that need better access to naloxone. The data will reveal geographic areas with a pattern of overdoses where vulnerable populations may live, which can facilitate more efficient distribution of naloxone and can guide harm reduction programs' outreach, the administration says.

Federal departments, especially HHS and DOJ, should ensure their grant funds support those types of data-driven collaborations, as well as the collection and dissemination of best practices information.

The White House Office of National Drug Control Policy also is supporting a third-party review of existing federal opioid treatment program regulations to assess whether they should include requirements for naloxone access and training on the drug's use. Those requirements currently don't exist for opioid treatment programs.

Once the review is complete, ONDCP will decide whether it's necessary for federal opioid treatment program regulations to be updated to require overdose prevention education and naloxone training.

The administration's strategy also focuses on three other key areas of opioid treatment and overdose prevention: ensuring people with substance use disorder get the treatment they need, with the goal of having universal access to opioid use disorder medications by 2025; disrupting national criminal organizations and their illicit financial networks and supply chains; and ramping up the federal government's work to close gaps in research and data collection on non-fatal overdoses.

The strategy also directs federal agencies to take actions to prevent new substance use, support people in recovery and advance racial equity in drug policy.

It makes no mention of making substance use disorder treatments available through telehealth.

Earlier this month, Sens. Sheldon Whitehouse (D-RI) and Rob Portman (R-OH) wrote to HHS and the Drug Enforcement Administration urging the agencies to use their authority under the Ryan Haight Act to ensure Americans can continue to access medication-assisted treatment for substance use disorder through telehealth once the COVID-19 public health emergency ends.

Under the Ryan Haight Act, an in-person examination is required in order to prescribe controlled substances such as buprenorphine, which is commonly used in MAT, the lawmakers explained. In March 2020, the in-person requirement was suspended due to the COVID-19 pandemic, which allowed providers to prescribe MAT and other necessary drugs via telehealth. Research shows that the telehealth flexibility has been effective in expanding treatment for substance use disorders, they said. -- *Beth Wang* (bwang@iwpnews.com)