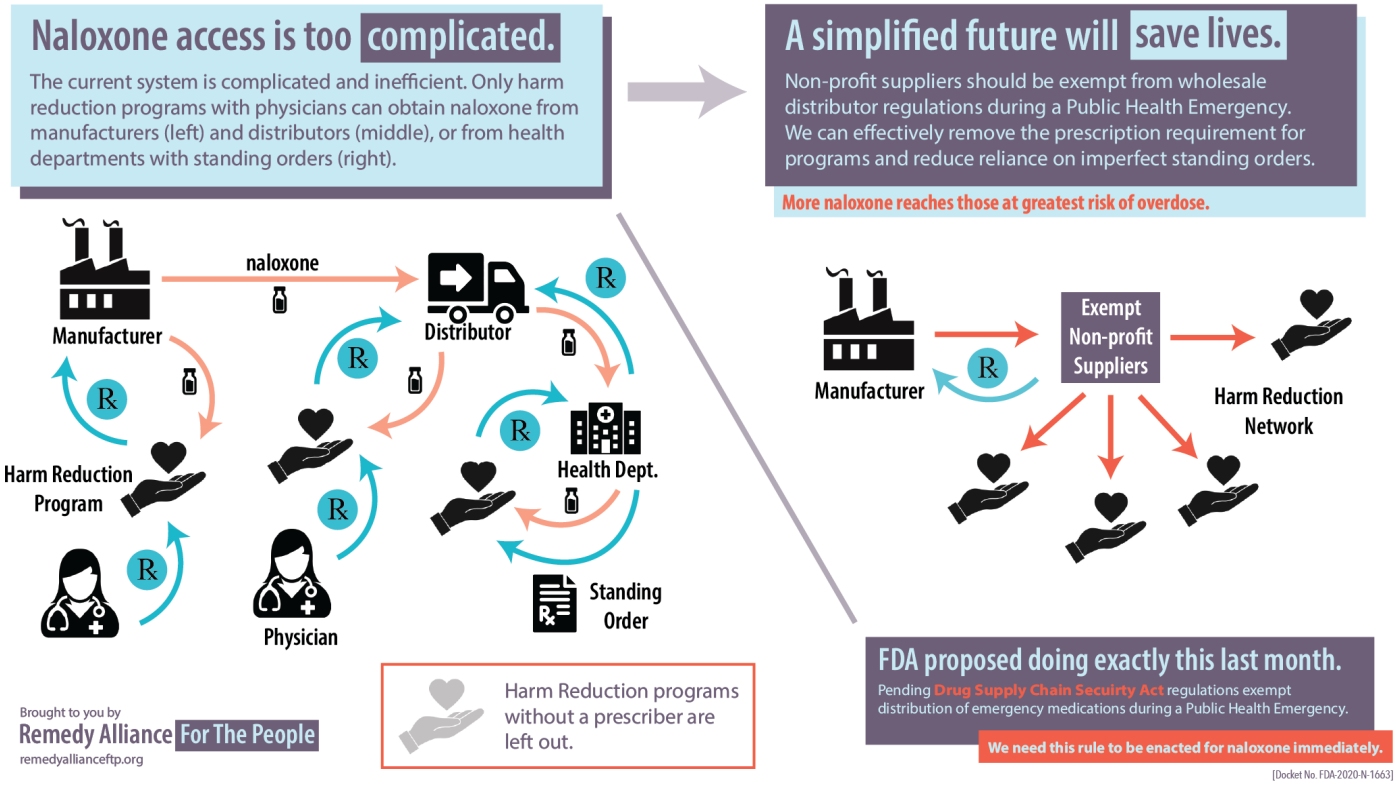

April 1, 2022

FDA routinely issues guidance documents pursuant to 21 C.F.R. 10.115. These documents are used to communicate FDA's policies on various matters, as well as the Administration's interpretations of statutory and regulatory requirements. FDA has recently issued numerous guidance documents in the context of the COVID-19 epidemic, many of which are designed to streamline access to regulated products and otherwise reduce barriers during the pandemic emergency. SAMHSA has also issued exemptions and guidance pursuant to the COVID-19 Public Health Emergency to facilitate clinical practice with medications for opioid use disorder.

In light of the ongoing opioid overdose epidemic and the dramatic disconnect between naloxone need and availability, we are requesting that FDA issue a statement to clarify the Administration's policy with respect to the distribution of naloxone by non-profit organizations that act as a bridge between naloxone manufacturers and harm reduction service providers. Multiple such independent organizations currently operate in the United States, providing medical supplies needed for operation of harm reduction programs.

Specifically, we request that FDA state that the exemption to "wholesale distribution" in 21 USC 353(e)(4)(C) is applicable to non-profit harm reduction organizations that provide any formulation of single entity naloxone. That statutory exemption, which is mirrored in a proposed rule (87 FR 6708 et seq), **exempts "the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration** pursuant to section 319 of the Public Health Service Act..." from the definition of "**wholesale distribution**."

Eligibility

Harm reduction organizations that serve as a bridge between manufacturers and harm reduction service programs clearly meet the requirements of this exemption. The naloxone distributed is used for medical emergencies: Single entity naloxone's only approved indication is the emergency reversal of opioid overdose. Naloxone is distributed to organizations that provide naloxone directly to people at high risk of overdose and those in a position to aid those individuals. Further, the country has been under a Public Health Emergency related to the opioid overdose epidemic since October 26, 2017. FDA has noted on numerous occasions the importance of increasing access to naloxone to help address this emergency, and has taken several unprecedented steps in that direction, including drafting model DFLs and conducting label comprehension studies.

Urgency

While we are aware that regulations implementing this statutory exemption are currently in the notice and comment process, **we cannot wait for them to be finalized during a Public Health Emergency.**

We therefore ask FDA to expeditiously state that the 21 USC 353(e)(4)(C) exemption, applied to single-entity naloxone:

a) is currently controlling law; and
b) applies to harm reduction organizations.

We believe such a clarification - while far from sufficient to fully address the severe lack of naloxone access that continues to plague the country - would be beneficial to efficiently and effectively distribute naloxone to organizations that can get it to those most in need.

Preemption

While we understand that FDA believes that the statutory exemption will not preempt state law until the associated rules are finalized, we also request that the guidance suggest that states follow the FDA's lead and treat non-profit organizations that purchase naloxone directly from the manufacturer and distribute it directly to harm reduction organizations as exempt from state requirements that apply to wholesale distribution of naloxone.

Public Health Impact

In terms of public health impact, we believe that such a statement from FDA would enable harm reduction programs to purchase naloxone without a prescription or physician's DEA registration, facilitate donations from pharmaceutical manufacturers, allow excess naloxone stock held by civic entities (libraries, etc.) to be donated to harm reduction programs to alleviate scarcity, and streamline state naloxone distribution systems. Short of OTC status, the requested statement from FDA would by a major step towards reducing barriers to naloxone procurement by harm reduction programs.

Remedy Alliance For The People represents 150 overdose prevention programs in 40 states that provide nalxone directly to people at greatest risk of overdose. We facilitate the procurement of 1.5 million doses of naloxone each year.

One story worth reading

Minister Blyth Barnow

Faith in Public Life
Newark, Ohio

"Faith In Public Life (FPL) works with faith leaders and grassroots harm reductionists. It took 3 years to get a naloxone distribution program up and running. Our first barrier was the Terminal Distributor of a Dangerous Drug (TDDD) license, which was required in order to personally furnish naloxone. Naloxone is considered a "dangerous drug" in Ohio because of FDA's Rx-only designation. This license was required not just for each organization that wanted to distribute but each site where distributions were to take place. We partner with the Ohio Council of Churches, and they serve over 4,000 congregations in Ohio. It simply was not feasible on an administrative or financial level to obtain the TDDD for all those who wanted to participate.

In Ohio "service entities" were allowed to have naloxone on hand in case of emergency and in 2019 FPL and Harm Reduction Ohio worked with legislators to expand the Ohio Revised Code so that faith communities and harm reduction groups were covered by even the most basic access. At the end of 2020, advocates pushed HB 341 through the legislature which changed the law so that "service entities" were now allowed to personally furnish naloxone if working under a medical directive. Ohio does not have a standing order so FPL sought out and obtained a medical directive.

Then we ran into another barrier. Because we wanted to serve as a hub for naloxone access for congregations and grassroots programs, we were told that we had to apply for a warehouse license. So we then reached out to the Ohio Board of Pharmacy to ask for a waiver and advocate for the removal of this provision. In May 2021 the BOP shared a resolution allowing service entities to transfer naloxone between one another, which relieved us from having to obtain the license.

With all of this in place we were finally cleared to become members of the Remedy Alliance, which we were able to do successfully. Unfortunately, our paperwork went through shortly after the national shortage of affordable naloxone was announced. At that same time a bottleneck in the flow of branded nasal spray Narcan from the Ohio Department of Health had left almost everyone in the state without the naloxone/Narcan they needed. Because there was no simple way to purchase other naloxone products, programs were reaching out for mutual aid from other states and FPL requested mutual aid from Remedy Alliance.

Faith in Public Life received our above ground first shipment of naloxone in January 2022...

after 3 long years of advocacy."

We have no time to waste.

These are the kinds of bureaucratic barriers that programs face under the current regime. The details vary by state, but the outcome is the same: Years of wasted time dealing with administrative burdens when that time could be better spent saving lives. Every day we hear of programs struggling to find prescribers, even when doctors say no Rx is needed.

Who does the prescription requirement serve? In the midst of a public health crisis, it's time to rethink our approach. FDA can act now to immediately expand low-barrier access to naloxone for harm reduction programs.

After 2 decades of unrelenting overdose increase, it's time for new solutions.