



January 17, 2023

RE: Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use; Request for Comments [Docket No. FDA-2022-N-2673]

On behalf of Community Counseling Centers of Chicago (C4), I am writing to comment on the above Federal Register notice on the safety and effectiveness of naloxone hydrochloride products for non-prescription use. Aligning with both the evidence-based practices outlined by SAMHSA and the Biden-Harris Administration's comprehensive approach to addressing substance use disorders, C4 believes in harm reduction as a practical solution to destigmatizing drug use and building access to healthcare, social services, and clinical treatment to achieve the strongest health outcomes for our communities. C4 supports the availability of naloxone without a prescription and believes low-barrier access to this life-saving medication is necessary to prevent more overdose deaths.

Historically, both substance use and seeking treatment have been greatly stigmatized, the latter heavily burdened by policy that requires clients demonstrate their worthiness in order to obtain care. While grassroots organizations have worked to make naloxone available without barriers, clinical capacity for overdose prevention is limited; stigma surrounding addiction and substance use and fear of institutional intervention lead many individuals to resist engaging in formal treatment, and insufficient investment in the behavioral health sector further prevents providers from being able to reach everyone who needs help. These limitations have been exacerbated by a lack of safe supply, which increases the likelihood of an accidental overdose death.

Data from the Centers for Disease Control and Prevention show an almost 15 percent increase in overdose deaths from 2020 to 2021. In Cook County, IL, where C4 operates, preliminary data from the Medical Examiner's Office show 1,599 opioid overdose deaths in 2022, and the county is on pace to surpass its 2021 overdose death record. Unsurprisingly, patterns of historic disinvestment and inequity persist; the Chicago community areas with the most concentrated opioid-related deaths are those on the south and west sides, where the unemployment and uninsurance rates are far higher than the state average. In addition, a significant majority of the individuals who die from overdoses in Cook County are Black and Latine.

Further, requiring emergency services to administer this life-saving medication places an unnecessary barrier to care for an individual experiencing overdose. Public access naloxone kits have been tested in simulated environments to determine their efficacy; in a study performed by the Michigan chapter of the American Medical Association, 98 percent were administered correctly. Lastly, EMS workforce shortages spurred on by low wages, burnout, and safety concerns reinforce the need for naloxone to be accessible as a first aid response until emergency services can arrive.

Naloxone can be safely administered by those without medical training and is already frequently and successfully used by non-medical personnel in emergency situations. Low-barrier, prescription-free access puts a lifesaving medication in the hands of the people who need it most and helps reduce the shame and stigma associated with substance use.

C4 appreciates the opportunity to comment and applauds the FDA for its work on this issue.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Kerri Brown', is written over a faint, light blue circular stamp or watermark.

Kerri Brown
Chief Executive Officer and President