



May 2, 2022

Dear Senator Baldwin:

Thank you for your letter expressing the need to increase access to naloxone. Emergent is committed to evaluating strategies to help make naloxone accessible to people who need it. We agree that “it has never been more important to adopt opioid overdose prevention and reversal strategies on a wide scale,” including “steps to increase access to affordable naloxone,” and see access to naloxone as a critical component of the larger strategy needed to address the opioid epidemic. Emergent is focused on continuing efforts that will increase awareness, expand access, and help maintain affordability. As Congress asks companies to consider submitting applications to make naloxone available over the counter (OTC), additional policies around safeguarding access to naloxone for patients, particularly vulnerable populations, should be considered in tandem with the discussion around OTC naloxone.

Emergent is a global life sciences company whose mission is to protect and enhance life. We are dedicated to developing, manufacturing, and delivering protections against public health threats, including reversing an accidental opioid overdose. We recognize the critical role of community distribution of naloxone, and we have established discount pricing for harm reduction groups, public health clinics, fire departments, police departments, and other nonprofit organizations.

It is important to note that naloxone is available without a prescription in all 50 states, D.C., and Puerto Rico, through standing orders and other policies, which vary by state. Currently, 100 percent of insured lives in the U.S., including those insured by Medicare and Medicaid, have coverage of naloxone. Medicaid plays a critical role in enabling access to naloxone to low-income adults – more than half of people with opioid use disorder (OUD) have incomes below 200 percent of the federal poverty line.¹ Ninety-nine percent of Medicaid patients have a co-pay of less than \$10 for naloxone, and 86 percent of Medicaid patients have a \$0 co-pay.² Furthermore, more than 60 percent of all insured patients, which includes those covered by Medicaid, Medicare and commercial insurance, have a co-pay of less than \$10 for naloxone and 43 percent of insured patients have a \$0 co-pay for naloxone at the pharmacy counter.³

In its report entitled, “CMS Should Pursue Strategies to Increase the Number of At-Risk Beneficiaries Acquiring Naloxone through Medicaid,” the Department of Health and Human Services, Office of Inspector General, highlights the need to raise awareness of the availability of naloxone under Medicaid, encourages efforts to allow family members and friends to purchase naloxone through the Medicaid program, and encourages co-prescription of naloxone when prescribing high doses of opioids.⁴

Recognizing that a conversion to OTC may result in the loss of insurance coverage and an increase in out-of-pocket expenses, how does Congress intend to address the loss of insurance coverage and protect insured patients such as Medicaid beneficiaries who would not be able to access naloxone through the Medicaid program if the product is available over the counter?

¹ <http://legislativeanalysis.org/wp-content/uploads/2021/12/Model-Expanded-Access-to-Emergency-Opioid-Antagonists-Act-FINAL.pdf>

² IQVIA Claims Data (FY 2021)

³ IQVIA Claims Data (FY 2021)

⁴ <https://oig.hhs.gov/oei/reports/OEI-BL-18-00360.pdf>

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While OTC may be part of the strategy to improve naloxone access, there are many challenges that policymakers and the community are working hard to address, to ensure that naloxone is in the hands of those who need it.

People must understand they may be at risk of an opioid overdose. Recent data shows that more than 70 percent of people using opioids for chronic pain, and almost half of people with OUD believed that they did not need to regularly keep naloxone on hand.⁵ Additionally, only 22 percent of those using opioids for chronic pain, and 35 percent of those with OUD indicated any likelihood of obtaining naloxone in the future.⁶

Increasing awareness of naloxone among the general population is critically important, as overdose deaths continue to climb among the expanded presence of fentanyl. According to recent market research data, almost half of the 'informed public' is unaware of the existence and current availability of opioid overdose reversal medications.

How does Congress intend to act to increase awareness to at-risk populations and address the lack of awareness among the public of the existence of opioid overdose reversal medications and how to obtain them?

It is vital to continue to improve access to naloxone through different channels, in addition to the pharmacy counter. Providing naloxone at the point of emergency room discharge helps to make naloxone more accessible to people who need it. Emergency Department (ED) discharge rates due to an opioid overdose increased by almost 30 percent across the U.S. in 2020, compared to 2018 and 2019, according to Mayo Clinic data.⁷ Patients who visit the ED for an opioid overdose are 100 times more likely to die by drug overdose in the year after being discharged, according to a data analysis funded by the National Institutes of Health, published in May 2020.⁸ Similarly, according to a 2020 Pew Charitable Trust report, people recently released from correctional settings who have a history of opioid use are at high risk of experiencing an overdose.⁹ It is critically important that these at-risk populations have access to naloxone.

How can Congress continue to encourage programs that make naloxone available at no cost or low cost to vulnerable populations that are at risk of an opioid overdose, such as those discharged from Emergency Departments and correctional facilities?

A collective effort to address the stigma associated with substance use disorder (SUD) and/or OUD is foundational to increasing access to naloxone. According to the National Institute on Drug Abuse, stigma may stem from inaccurate beliefs that addiction is a moral failing, instead of a chronic, treatable disease from which patients can recover. Feeling stigmatized can reduce the willingness of individuals with SUD to seek treatment and stigmatizing language can negatively influence health care provider perceptions of people with SUD, which can impact the care they provide.¹⁰ People with SUD may be reluctant to access healthcare, including obtaining

⁵ <https://www.cmeoutfitters.com/wp-content/uploads/2020/09/NAPOP-Pain-Week-Poster-FINAL.pdf>

⁶ <https://www.cmeoutfitters.com/wp-content/uploads/2020/09/NAPOP-Pain-Week-Poster-FINAL.pdf>

⁷ <https://newsnetwork.mayoclinic.org/discussion/emergency-department-visits-related-to-opioid-overdoses-up-significantly-during-covid-19-pandemic/>

⁸ <https://www.nih.gov/news-events/news-releases/emergency-drug-overdose-visits-associated-increased-risk-later-suicide#:~:text=A%20new%20data%20analysis%20funded,relative%20to%20the%20general%20population.>

⁹ https://www.pewtrusts.org/-/media/assets/2020/11/expanded_access_to_naloxone.pdf

¹⁰ <https://nida.nih.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction#ref>



naloxone in pharmacies, which underscores the importance of community distribution programs that provide naloxone free of charge to people who need it.

How does Congress intend to address stigma and continue to support programs that make naloxone available free of charge to those that need it through community distribution?

We will continue to engage with stakeholders and policymakers, and key leaders like you, Senator Baldwin, to discuss OTC naloxone, policies that support increased access, awareness and maintain affordability, as well as ways to address and mitigate the potential unintended consequences.

Thank you for your consideration of these important matters.

Sincerely,

A handwritten signature in blue ink that reads "Robert G. Kramer".

Robert G. Kramer

President and Chief Executive Officer, Emergent