

October 3, 2025

Good Afternoon,

As all of you are aware, lowa HHS has supported several different naloxone initiatives over the past few years to expand access and save lives during opioid overdoses. These initiatives include:

- An Administration Initiative that provides naloxone kits to Iowa Law Enforcement and non-EMS Regulated fire departments, to be used for administration purposes in the event they encounter someone experiencing a suspected opioid overdose
- An Administration Initiative that provides naloxone kits to Iowa Businesses,
 Organizations and Schools, to be used for administration purposes in the event they encounter someone experiencing a suspected opioid overdose
- A Narcan Distribution Initiative that provides Narcan kits to approved entities for the purpose of distributing these kits to individuals defined as a person in a position to assist.
- A Secondary Distribution Initiative that provides Kloxxado kits to approved entities for the purpose of distributing these kits to individuals defined as a person in a position to assist.

While there has been success with all of these initiatives, it's important that as we continue to address opioid misuse, we stay current as to the latest research, best practices and maintain fiscal responsibility in order to ensure long-term sustainability.

As a result of our ongoing evaluation, Iowa HHS has decided to discontinue support of Kloxxado (8 mg naloxone) for all of the current Naloxone Administration and Secondary Distribution Initiatives. This decision is supported by several key considerations:

 In a study conducted with the New York State Police and published by the U.S. Centers for Disease Control and Prevention (CDC) in the Morbidity and Mortality Weekly report (MMWR), it was stated:

Despite the increased naloxone concentration in the 8-mg intranasal product, no significant differences were found in the survival of aided persons, or the number of doses administered by law enforcement by formulation, suggesting that, in this field test, the increased dosage did not provide added benefit, even in light of the increased prevalence of synthetic opioids, including fentanyl, in the drug supply.

It was also noted that recipients of the 8 mg dose had approximately 2.5 times higher risk of opioid withdrawal symptoms (vomiting, abdominal pain, diaphoresis) without any measurable improvement in outcomes. In addition, the



Food and Drug Administration (FDA) and manufacturer materials also note that the clinical significance of the higher dose has not been established.

 In a <u>study</u> published in the International Journal of Drug Policy, researchers concluded that:

The development and marketing of more powerful opioid antagonists should be viewed with great skepticism. Since opioid antagonists are commonly purchased for the public in bulk by state health agencies, a relatively small number of purchasing decisions can impact thousands of individuals. State health agency staff, public health professionals, policymakers, and clinicians should be aware that more potent, longer-acting opioid antagonists are not necessary and may have unintended consequences.

 While the cost for many of the naloxone products on the market has steadily declined, there is still a difference in pricing between the 8mg version of naloxone (Kloxxado) and the 4mg version (Narcan). With Kloxxado currently costing approximately \$9 more per kit, the data suggests lowa HHS could extend resources further and maintain greater statewide access by focusing on the 4 mg formulation-without compromising reversal effectiveness.

Because lowa HHS understands that this change in practice may be seen as a reduction in the number of naloxone kits available for lowans, two additional changes are being made. First, the maximum number of Narcan kits that can be ordered for distribution purposes is being increased to 20 cases per month (240 kits), as opposed to the previous limit of 17 cases per month. In addition, in collaboration with the Office of the Attorney General of Iowa, Iowa HHS has elected to receive as part of the Teva Opioid Settlement, a total of 8,658 naloxone kits (4 mg version) on an annual basis that will be used to continue supporting opioid overdose reversal medication availability. These kits will be made available in the near future as part of a one-time request opportunity and will be in addition to the monthly 20 case limit.

To assist with the transition to this new approach, lowa HHS will fulfill routine requests (for current Secondary Distribution entities) for Kloxxado kits received through November 7, 2025. No new Secondary Distribution applications will be accepted after the date of this notice. This transition ensures lowa HHS remains grounded in evidence, responsive to evolving best practices, and committed to making naloxone widely available in a sustainable way.

If you have any questions, please feel free to reach out to us through the SOR Helpdesk at sor@hhs.iowa.gov.

Thank you for your continued partnership and commitment to addressing the opioid crisis in lowa.

SOR Staff