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EXPLAINER

Policymakers should allow the distribution and use of expired naloxone

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To make a dent in the persistent **overdose** crisis, experts recommend **expanding layperson access to the opioid overdose antidote, naloxone**. Harm reductionists suggest that one **potentially effective, and affordable, way to do this is by continuing to distribute the medication beyond its expiration date**. This explainer examines whether expired naloxone is safe and effective and the implications for policy.

Expired naloxone is still safe and effective

Research confirms that naloxone remains both safe and effective for years after production and packaging. This finding recently led the U.S. Food and Drug Administration (FDA) to extend the official shelf life of **intranasal products** to four years. But the medication's stability goes even further than that.

Research has consistently **shown** naloxone to remain stable—and thus effective and safe—for years beyond its set expiration date. In fact, a recent **study** examined injectable naloxone stored at public safety agencies that were as much as 27 years past their respective expiration dates. The analysis found that the majority of samples retained therapeutic levels of naloxone, and there were few degradation-related byproducts, none of which presented a health or safety concern. This held true for samples that were decades beyond expiration, and across sample types, although ampules were slightly more stable than prefilled syringes.



Naloxone holds up in extreme conditions

It is noteworthy that laypeople and first responders often lack access to medical-grade storage, and that naloxone must be easily and quickly accessible for it to have maximum utility. Therefore, scientists have begun to assess the medication's stability under “real world” conditions.

In the study referenced above, expired doses of naloxone had been kept in a variety of unknown and undocumented conditions that included police cars, fire trucks, and ambulances. While there is no data to identify potential patterns in how specific conditions affected naloxone's stability, the fact the doses were likely exposed to non-temperature-controlled environments and that the vast majority of samples demonstrated such high stability is promising.

In line with this, an experimental study sought to mimic the potential conditions if people were to store naloxone in their vehicle, which can come with extreme temperatures and temperature variation. The researchers exposed ampules of injectable naloxone to cycles that included either room temperature and extreme heat or periods of freezing and thawing over a period of 28 days. Neither temperature extreme led to degradation that would undermine the medication's integrity.



Knowing that naloxone is safe and effective means that organizations can embrace its distribution in ways that minimize supply chain challenges and make the most of funding resources.

These scientific findings mean that the organizations that administer and distribute naloxone can feel very confident making use of recently expired doses. The ability to distribute expired naloxone doses allows these organizations—many of which rely on taxpayer funds or operate on limited budgets—to ensure their supplies can weather fluctuations in [availability](#) of and need for the medication while minimizing waste and making the most of their funds.

Policy can improve naloxone access via expired doses

Despite the potential of expired naloxone to help improve and stabilize access to the medication, state and institutional [policies](#) may [prevent](#) organizations from administering or distributing it. Analyses suggest state [guidance](#) is [mixed](#) as to whether they allow the [distribution](#) and [administration](#) of expired medications by emergency medical providers, public health agencies, or community-based organizations.

The FDA can alleviate some potential for waste and supply stability issues by continuing to re-evaluate and update naloxone expiration dates in line with science. In the meantime, given the safety profile of expired naloxone, states can facilitate distribution and administration of expired doses by:

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| Updating state law so that it does not prohibit the distribution or administration of expired naloxone, especially to or by nonprofit organizations that directly serve people who use drugs | Extending immunity for administering and dispensing naloxone to include expired doses | Encouraging relevant agencies and organizations to make use of recently expired naloxone | Defining an evidence-based framework to allow retail pharmacies to sell or donate recently expired doses of naloxone |

As overdose deaths continue to ravage communities across the United States, it is essential to keep working to improve access to naloxone. The administration and distribution of expired naloxone has become a tool used by harm reduction organizations to stabilize supplies and optimize use of limited funds. But those efforts can be hampered by policy. However, a growing body of evidence suggests that restricting expired naloxone is unwarranted. It is time for policymakers and public health decision-makers to catch up with the science and follow an increasingly common refrain among harm reduction organizations:

“Expired naloxone is better than no naloxone.”

For more information, please contact:

Stacey McKenna
Resident Senior Fellow, Integrated Harm Reduction
smckenna@rstreet.org