

ONE HUNDRED EIGHTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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May 16, 2024

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G St. NW
Washington, DC 20548

Dear Comptroller General Dodaro:

We write today to request the Government Accountability Office (GAO) conduct a study on the accessibility and affordability of U.S. Food and Drug Administration (FDA)-approved opioid overdose reversal agents, including naloxone and nalmefene.

Overdose reversal medications are safe and effective life-saving tools that can reduce overdose deaths. To date, FDA has approved two opioid overdose reversal agents.¹ As a harm reduction tool, overdose reversal medications play a critical role in a science-based approach to the drug overdose crisis. Despite access to these medications over-the-counter (OTC), we remain concerned that several barriers continue to hinder its widespread uptake and access. These barriers include, but are not limited to, out-of-pocket costs for patients, pharmacy stocking decisions, awareness of drug availability in pharmacies, and unclear insurer reimbursement policies.

Currently, insurance coverage for OTC opioid overdose reversal medications varies across insurers and states. If people are unaware that insurance might cover OTC costs or that standing orders exist, they may avoid purchasing these life-saving medications altogether to avoid out-of-pocket expenses.

¹ U.S. Food and Drug Administration, *Information about Naloxone and Nalmefene* (April 2024)(www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone-andnalmefene#:~:text=The%20agency%20continues%20to%20advance,drugs%2C%20including%20naloxone%20and%20nalmefene.).

As opioid deaths continue to mount, it is imperative we understand these barriers to ensure individuals at high-risk and their social networks have access to life-saving reversal medication. We request that the GAO analyze federal health insurance plans, to the extent data are available, including traditional Medicare and Medicare Advantage, Medicaid and Medicaid managed care, and private group and individual health plans, with a focus on the following questions:

1. How are opioid overdose reversal agents currently covered by selected federal and private health plans?
2. Can naloxone be covered as an over-the-counter drug for individuals –
 - a. Under a group or individual health insurance plan?
 - b. Entitled to benefits under Part A or enrolled under Part B of Medicare?
 - c. Receiving medical assistance under a State Medicaid plan?
3. What is known about the out-of-pocket cost to consumer purchasing naloxone –
 - a. With a prescription, with and without any health plan coverage?
 - b. Over-the-counter, with and without any health plan coverage?
 - c. Pursuant to a standing order?
4. What information is known about other factors impacting coverage, including –
 - a. Barriers in covering naloxone as an over-the-counter drug?
 - b. The availability of naloxone purchased and distributed through public health entities?

By focusing on these core questions, we believe the GAO can provide Congress with important details on the accessibility and affordability of opioid reversal agents to inform future laws and regulations.

Thank you for your attention to this matter. Please have your staff work with Shana Beavin of the Energy and Commerce Committee's Democratic staff and Tara Jordan with the office of Congresswoman Kuster on the scope and details of your work. We trust that you will prioritize this study and eagerly await your response.

Sincerely,



Frank Pallone, Jr.
Ranking Member



Ann M. Kuster
Member of Congress

The Honorable Gene Dodaro

May 13, 2024

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Handwritten signature of Angie Craig in blue ink.

Angie Craig
Member of Congress

Handwritten signature of Lisa Blunt Rochester in blue ink.

Lisa Blunt Rochester
Member of Congress