











FACT SHEET Naloxone Insurance Coverage Mandates

Background

Preventable overdose is a continuing public health crisis. Over 107,000 people died of a drug overdose in 2021, more than any previous year.¹ Opioids were involved in approximately 80% of these deaths.² In addition, a significant number of individuals experience preventable harm due to non-fatal opioid-induced hypoxia. Many of these deaths and injuries could have been avoided if persons experiencing opioid overdose had quickly received naloxone, a full opioid antagonist that reverses most opioid overdoses if administered before the affected individual experiences cardiac arrest.³ Naloxone displaces opioids from the receptors to which they attach, quickly and effectively reversing opioid overdose before it can become fatal.⁴

Around 40% of people who died of overdose were not alone at the time.⁵ Nearly every person who died of a witnessed opioid overdose could have been saved if naloxone was readily available. Earlier administration of naloxone can also reduce overdose-related morbidity, reducing preventable harm. Naloxone is safe, effective, and easy to use, which is in part why the Food and Drug Administration has recently approved one naloxone product, Narcan 4mg, for over-the-counter sales.⁶ While this change will likely enable wider distribution of naloxone into spaces previously hesitant to stock a prescription-only drug for non-pharmacy distribution, it is unclear what effect this move will have on the end-user cost of naloxone.

All state Medicaid programs cover some form of naloxone, although as of 2020 ten states had monthly fill limits that include the medication. However, not all private insurance providers are required to cover naloxone. Many private insurance plans do not cover over-the-counter (OTC) drugs unless required to do so by state law or the Affordable Care Act. In this fact sheet, we detail the state laws that require private insurers to cover at least one formulation of naloxone and those that reduce barriers to access naloxone where it is covered. Because these laws were written during a time when no OTC naloxone formulations were available, none explicitly require coverage for OTC naloxone.

We note that many insurers provide coverage of naloxone even without a mandate, so this document should not be viewed as a list of states where insurance coverage is available. Finally, we note that insurers can provide coverage of OTC medications, and we urge them to cover the currently available OTC naloxone product as well as future OTC naloxone products.

Naloxone coverage mandates

As of April 1, 2023, seven states place some type of requirement on private health insurers to cover naloxone. Table 1 provides a brief overview of these laws. Five additional states have laws that lower the barriers to naloxone if it is covered. Table 2 provides an overview of these additional laws.

Table 1: State laws requiring health insurers to provide coverage of naloxone

State	Effective Date	Citation	Requirement
<u>Arkansas</u>	April 12, 2019	Ark. Code Ann. § 23- 99-1119	A healthcare insurer, including Medicaid: Cannot require prior authorization for a patient to obtain coverage for non-injectable naloxone; Cannot impose any requirement other than a valid prescription and compliance with guidelines issued by SAMSHA for a patient to obtain coverage for non-injectable naloxone; and If utilizing a tiered drug formulary, must place at least one naloxone product on the lowest-cost benefit tier.
Colorado	January 1, 2023	Col. Rev. Stat. § 10- 16-104(5.5)(III)(C)	Most health insurers must provide coverage for at least one opiate antagonist.9
Illinois	September 9, 2015	215 III. Comp. Stat. 5/356z.23	Individual or group policies of accident and health insurance that provide coverage for prescription drugs must include at least one opioid antagonist, 10 including the medication product, administration devices, and any pharmacy administration fees related to the dispensing of the opioid antagonist. This coverage must include refills for expired or utilized opioid antagonists. Further, no individual or group policy of accident and health insurance amended, delivered, issued, or renewed after January 1, 2024 that provides coverage for naloxone hydrochloride shall impose a copayment, in most cases.
Missouri	August 28, 2021	Mo. Rev. Stat. 191.1165	A formulary used by a health insurer or managed by a pharmacy benefits manager, or medical benefit coverage in the case of medications dispensed through an opioid treatment program, must include naloxone. Naloxone may not be subject to: (1) any annual or lifetime dollar limitations; (2) financial requirements and quantitative treatment limitations that do not comply with the Mental Health Parity and Addiction Equity Act of 2008; (3) step therapy; or (4) prior authorization.
New Jersey	July 2, 2021	N.J. Stat. Ann. § 26:2S-38	"A carrier shall ensure that every contract to provide prescription drug benefits, or to authorize the purchase of a contract to provide prescription drug benefits, shall provide coverage for an opioid antidote ¹¹ to covered persons without the imposition of any prior authorization or other utilization management requirements." Applies where the drug is prescribed or administered to the covered person by a licensed medical practitioner who is authorized to prescribe or administer it pursuant to state and federal law or dispensed to the covered person by a licensed pharmacist under a standing order to dispense an opioid antidote.
Rhode Island	January 1, 2017	27 R.I. Gen. Laws § 27-18-82, § 27-19-73, § 27-20-69, § 27-41-86	Every individual or group health-insurance contract, plan, or policy that provides prescription coverage that is delivered, issued for delivery, amended, or renewed in

			the state must provide coverage for at least one generic opioid antagonist ¹² and device. Prior authorization may be required for non-generic forms of opioid antagonists and devices.
Washington	July 28, 2019	Wash. Rev. Code 48.43.760; Wash. Rev. Code 41.05.525	Health carriers must provide coverage without prior authorization of at least one FDA-approved opioid antagonist ¹³ for plans issued or renewed after January 1, 2020. The same requirements apply to any health care plan offered to employees, school employees, or their covered dependents under the state health care authority.

Table 2: State laws that remove barriers to coverage of naloxone

Connecticut	January 1, 2017	Conn. Gen. Stat. §§ 38a-544b; 38a-510b	A group or individual health insurer that provides prescription drug coverage and includes naloxone or a similarly acting and equally safe drug on its formulary may not require prior authorization for that drug.
<u>Delaware</u>	August 13, 2019	Del. Code Ann. tit. 18 § 3571X; 18 § 3343(b)(3)	A group health insurer or health benefit plan that provides prescription coverage for mental illness and drug and alcohol dependence must place at least 1 formulation of naloxone on the lowest tier of the formulary. Prior authorization is prohibited.
Maryland	January 1, 2018	Md. Code. Ann., Ins. § 15-850	An insurer, nonprofit health service plan, or health maintenance organization that provides coverage for prescription drugs through a pharmacy benefits manager that includes an opioid antagonist ¹⁴ on its formulary may not apply a prior authorization requirement for an opioid antagonist unless it provides coverage for at least one formulation of the opioid antagonist without a prior authorization requirement.
<u>Minnesota</u>	July 1, 2020	Minn. Stat. § 62Q.529	A health plan that provides prescription coverage must provide coverage for opiate antagonists ¹⁵ prescribed and dispensed by a licensed pharmacist under the same terms of coverage that would apply had the prescription drug been prescribed by other authorized prescribers.
New York	March 22, 2022	N.Y. Pub. Health Law § 273	When a patient's health care provider prescribes a prescription drug that is on the statewide formulary of opioid dependence agents and opioid antagonists, 16 the department must not require prior authorization unless required by the Department of Health's drug use review program.

Conclusion

Only a dozen states either require private health insurers to cover naloxone, remove barriers to coverage, or both. While the move of some naloxone products over-the-counter will likely expand access to naloxone, those who need it most may still not be able to afford it. Worse, some insurers who currently cover naloxone as a prescription drug may remove it from their formulary once the over-the-counter products become available.

Congress and state governments should act to mandate insurance coverage for naloxone, including OTC naloxone products. Further, community distribution of naloxone directly to people who use drugs should be fully funded by federal and state agencies. Universal access to naloxone is urgently needed to save lives.

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SUPPORTERS

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- ² Press Release, Centers for Disease Control and Prevention (CDC), U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020 But Are Still Up 15% (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm ("The new data show overdose deaths involving opioids increased from an estimated 70,029 in 2020 to 80,816 in 2021.")
- ³ Debra Kerr, Anne-Maree Kelly, Paul Dietze, Damien Jolley & Bill Barger, Randomized Controlled Trial Comparing the Effectiveness and Safety of Intranasal and Intramuscular Naloxone for the Treatment of Suspected Heroin Overdose. 104 ADDICTION 2067–2074 (2009). https://doi.org/10.1111/j.1360-0443.2009.02724.x
- ⁴ See James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 Am. J. EMERGENCY MED. 650 (1994).
- ⁵ Christine L. Mattson et al., Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016 June 2017, 67 MORB. MORTAL WK'LY REP. 34, 945-951 (2018).
- ⁶ FDA Approves First Over-the-Counter Naloxone Nasal Spray, U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-

spray#:~:text=The%20application%20to%20approve%20Narcan,for%20marketing%20without%20a%20prescription, March 29, 2023.

- ⁷ Andrew W. Roberts et al., *Medicaid prescription limits and their implications for naloxone accessibility*, 218 DRUG & ALCOHOL DEPENDENCY 108355 (Jan. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7568500/
- ⁸ For more information on ACA coverage, see Héctor Hernández-Delgado, *Naloxone is Now Available Over-the-Counter. Will it Still be Affordable?*, NATIONAL HEALTH LAW PROGRAM, May 30, 2023, https://healthlaw.org/naloxone-is-now-available-over-the-counter-will-it-still-be-affordable/.
- ⁹ "Opiate antagonist" is defined as "naloxone hydrochloride or any similarly acting drug that is not a controlled substance and that is approved by the federal food and drug administration for the treatment of a drug overdose." Col. Rev. Stat. § 12-30-110(7(d).
- 10 "Opioid antagonist" is defined as "a drug that binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone hydrochloride or any other similarly acting drug approved by the U.S. Food and Drug Administration." 215 III. Comp. Stat. 5/356z.23(b).
- ¹¹ "Opioid antidote" is defined as "naloxone hydrochloride, or any other similarly acting drug approved by the United States Food and Drug Administration for self-administration for the treatment of an opioid overdose." N.J. Stat. Ann. § 26:2S-38(c).
- ¹² "Opioid antagonist" is defined as "naloxone hydrochloride and any other drug approved by the United States Food and Drug Administration for the treatment of opioid overdose." 27 R.I. Gen. Laws Ann. § 27-18-82(b).
- ¹³ "Opioid antagonist" is not defined in the law.
- ¹⁴ "Opioid antagonist" is defined as "(1) naloxone hydrochloride; or (2) any other similarly acting and equally safe drug approved by the federal Food and Drug Administration for the treatment of a drug overdose." Md. Code Ann., Ins. § 15-850(a).
- ¹⁵ "Opioid antagonist" is not defined in the law.
- ¹⁶ "Opioid antagonist" is not defined in the law.