Rule Impact Statement (2025)

A. Purpose of the proposed rule and legal authority *(75 OS § 253(B)(2)(b)(1), 75 OS 303(D)(2)(a))*

The proposed revisions update coverage language to allow for new opioid overdose reversal agents as they become available on the market, in order to ensure timely access to life-saving medical products.

Legal Authority: The Oklahoma Health Care Authority Act, Section 5007 (C)(2) of Title 63 of Oklahoma Statutes; The Oklahoma Health Care Authority Board.

B. Brief description of the proposed rule *(75 OS 253(B)(2)(b)(3))*

The proposed revisions update coverage language to allow for new opioid overdose reversal agents as they become available on the market. Current policy specifies coverage for Naloxone by name, which was appropriate when it was the only available option. As additional opioid overdose reversal agents are now available, the revised language broadens coverage to include other clinically appropriate agents, ensuring timely access and alignment with evolving federal and clinical standards.

C. Classification of proposed rule *(75 OS 253(B)(2)(b)(2))*
Classification: ☐ Major ☒ Nonmajor
Justification: (Include estimate of total implementation and compliance costs over 5 years and basis for estimate. If ≥ $1,000,000 → classified as major.) No budget impact
Total annual implementation and compliance costs: None anticipated.
Methodology used to calculate costs *(75 OS 253(B)(2)(b)(7)):* N/A

***D.* Description of affected classes of persons most likely to be impacted by the proposed rule** *(75 OS 253(B)(2)(b)(4), 75 OS 303(D)(2)(b))*

None anticipated.

E. Description of classes who will benefit from the proposed rule *(75 OS 253(B)(2)(b)(5), 75 OS 303(D)(2)(c))*

Members needing access to opioid reversal agents may benefit, if additional products are brought to market that in some way surpass the effectiveness or cost-effectiveness of Naloxone.

F. Comprehensive economic impact analysis *(75 OS 253(B)(2)(b)(6), 75 OS 303(D)(2)(d))*
Methodology used to calculated costs *(75 OS 253(B)(2)(b)(7)):*

No economic impact analysis conducted. No impacts anticipated from allowing additional products of a new class to be administered.

G. Probable costs and benefits to OHCA and other agencies *(75 OS 253(B)(2)(b)(6), 75 OS 303(D)(2)(e))*

No costs anticipated. Benefits may include the ability to offer more cost-effective, newer, or better opioid antagonist products.

H. Economic impact on political subdivisions and whether their cooperation is required *(75 OS 253(B)(2)(b)(8), 75 OS 303(D)(2)(f))*

No impact on political subdivisions anticipated. No cooperation required from political subdivisions.

I. Economic impact on small businesses *(75 OS 253(B)(2)(b)(9), 75 OS 303 (D)(2)(g))*

No impact on small businesses anticipated.

J. Measures taken to minimize compliance costs and assessment of less costly, less intrusive, or nonregulatory alternatives *(75 OS 253(B)(2)(b)(10), 75 OS 303(D)(2)(h)) N/A*

K. Effect of the rule on public health, safety, and the environment *(75 OS 253(B)(2)(b)(11), 75 OS 303(D)(2)(i))*

Potential positive impacts on public safety by offering additional life saving opioid reversal agents.

L. Detrimental effects if the proposed rule is not implemented *(75 OS 253(B)(2)(b)(12), 75 OS 303(D)(2)(j))*

Limitations on access to medication. Potentially lost cost savings if new products come to market at lower price or with better effectiveness than Naloxone.

M. Summary of and preliminary comparison to existing or proposed federal regulations *(75 OS 303(D)(2)(n))*

No existing or proposed federal regulation directly relates to this. FDA has approved one new product in the category and more may come in the future.

N. Analysis of alternatives to adopting the proposed rule *(75 OS 303(D)(2)(l))*

Not adopting the rule would limit the available opioid overdose reversal agents to only Naloxone, and not other FDA-approved products.

O. Estimates of internal OHCA employee time and other resources used to develop the proposed rule *(75 OS 303(D)(2)(m))*

Development of the proposed rule began before the requirement to track employee time and resources used to develop the rule. Estimated at 100-150 hours of employee time.

P. **Date statement prepared or modified** *(75 OS 253(B)(2)(b)(13), 75 OS 303(D)(2)(k))* Prepared 11.26.2025
Modified 12.29.2025