LFC Requestor: KLUNDT, Kelly

2025 LEGISLATIVE SESSION AGENCY BILL ANALYSIS

Section I: General

Chamber: House Category: Bill

Number: 505 Type: Introduced

Date (of THIS analysis): 2/21/2025

Sponsor(s): Cristina Parajón and Antoinette Sedillo Lopez

Short Title: OPIOID USE DISORDER DRUG STOCKS

Reviewing Agency: Agency 665 - Department of Health

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Section II: Fiscal Impact

APPROPRIATION (dollars in thousands)

Appropriation Contained		Recurring or	Fund	
FY 25	FY 26	Nonrecurring	Affected	
\$0	\$0	N/A	N/A	

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or	
FY 25	FY 26	FY 27	Nonrecurring	Fund Affected
\$0	\$0	\$0	N/A	N/A

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY 25	FY 26	FY 27	3 Year Total Cost	Recurring or Non- recurring	Fund Affected
Total	\$0	\$117	\$117	\$234	Recurring	General fund

House Bill 505 (HB505) requires pharmacies to collect and report data on availability of specific pharmaceuticals for

treatment of opioid use disorder. This data would be reported to the New Mexico Department of Health (NMDOH) for analysis. DOH would prepare a biennial report. Funding is provided for one epidemiologist-advanced, pay band 75, annually \$111,186. Additional IT and other support costs for this position would be roughly \$5,000 per year, for a total cost in SFY2026 and SFY2027 of \$117,000 per year.

Section III: Relationship to other legislation

Duplicates: None

Conflicts with: None

Companion to: None

Relates to: None

Duplicates/Relates to an Appropriation in the General Appropriation Act: None

Section IV: Narrative

1. BILL SUMMARY

a) Synopsis

House Bill 505 (HB505) proposes to add a new section to the New Mexico Drug, Device, and Cosmetic Act that would create buprenorphine stocking requirements and reporting requirements for retail pharmacies and wholesale distributors. The bill would require the board of pharmacy to collect data and report to the New Mexico Department of Health (NMDOH) for analysis and reporting.

Retail pharmacies would be required to maintain a sufficient stock of buprenorphine to satisfy the minimum daily stocking requirement, as determined by averaging the amount of buprenorphine dispensed daily in the previous thirty days and rounding to the nearest milligram. Additionally, pharmacies would be required to stock at least one buprenorphine monoproduct and one buprenorphine-naloxone combination product.

Retail pharmacies would not be in violation of the Act if their inventory were to fall below the requirements as long as they order additional stock within three days and request an allotment increase. If the request is denied, the pharmacy must maintain records of the denial.

Wholesale distributors shall provide a report to the board of pharmacy on a monthly basis, in the form and manner prescribed by the board. This report must include each instance the wholesale drug distributor denied or delayed an requested order or threshold increase for the pharmacy.

The wholesale drug distributor report would be required to include:

(1) the name of the retail pharmacy affected; (2) the date the retail pharmacy submitted the order for buprenorphine or requested an increase to the retail pharmacy's threshold of buprenorphine; (3) the date the wholesale drug distributor denied or delayed the retail pharmacy's order for buprenorphine or denied the requested increase in the retail pharmacy's threshold of buprenorphine: (4) the reason the wholesale drug distributor denied or delayed the retail pharmacy's order for buprenorphine or denied the requested increase in the retail pharmacy's threshold of buprenorphine; and (5) any other information required by the board.

The board may impose fines on retail pharmacies and wholesale distributors that violate the requirements.

The board shall submit data gathered pursuant to this section to the New Mexico Department of Health (NMDOH). NMDOH shall analyze the data and publish a biannual report on access to buprenorphine in retail pharmacies. The report shall include:

- 1) Information on the frequency with which each wholesale drug distributor:
 - (a) denied a retail pharmacy's order for buprenorphine;
 - (b) delayed a retail pharmacy's order for buprenorphine due to the retail pharmacy's threshold of buprenorphine; or
 - (c) denied a retail pharmacy's requested increase in the retail pharmacy's threshold of buprenorphine;
- 2) Aggregated data reflecting the reasons reported by wholesale drug distributors for denying a retail pharmacy's order for buprenorphine or a request by a retail pharmacy to increase the retail pharmacy's threshold of buprenorphine;
- 3) A description of how denials or delays of retail pharmacy orders for buprenorphine affected access to buprenorphine;
- 4) A description of how denials of retail pharmacy requests to increase their threshold of buprenorphine affected access to buprenorphine;
- 5) Geographic and demographic disparities in access to buprenorphine in retail pharmacies, to the extent the data is available;
- 6) The impact of insufficient access to buprenorphine in retail pharmacies on initiation of and maintenance of treatment for opioid use disorder, overdose morbidity and mortality, and other health outcomes associated with substance use disorder; and

Is thi	s an amen	dment or s	ubstitution?	□ Yes	No

Is there an emergency clause? \square Yes \boxtimes No

7) Any other relevant information.

b) Significant Issues

In 2023, New Mexico saw 948 drug overdose deaths, with 72.6% (688 deaths) involving opioids, both prescription and illicit. Opioid-related overdose deaths continue to be a significant concern, peaking in 2021, with many cases involving multiple substances. Although opioid overdose-related emergency department visits decreased from 2021 to 2023, opioid use disorder and the availability of treatment remain critical issues in the state.

Adequate access to medication for opioid use disorder (MOUD) remains a key barrier in addressing this crisis. In 2023, opioid overdose-related visits accounted for 72% of all drug overdose-related emergency visits. Despite the urgent need for treatment, many individuals are unable to access the necessary medications due to ongoing supply shortages. Local pharmacies in

New Mexico often report low to no stock of buprenorphine, a vital medication in MOUD, leaving patients without consistent access to prescriptions. Nationally, only 57.9% of pharmacies reported having buprenorphine/naloxone in stock when requested, with significant variability between states and pharmacy chains. New Mexicans face similar challenges in getting their prescriptions filled (https://sourcenm.com/2023/07/06/addiction-medication-scripts-going-unfilled-in-northern-new-mexico/).

The shortage of treatment options also has broader economic impacts. Limited access to services leads to lost productivity, premature death, and higher healthcare costs due to both acute and illnesses (https://www.samhsa.gov/sites/default/files/cost-benefits-prevention.pdf). chronic Expanding substance use disorder treatment services would yield positive economic benefits, reduce criminal iustice costs. and help lower criminal activity (https://www.sciencedirect.com/science/article/pii/S2949875923001352). In 2021, fourteen individuals in New Mexico needed treatment, but only one in seven sought help due to barriers like stigma, limited availability, and eligibility restrictions.

There have been significant efforts by the state and healthcare sectors to improve access to behavioral health and SUD treatment, but access to buprenorphine, considered the gold standard for opioid use disorder treatment, has been unreliable. Removing barriers to buprenorphine and promoting timely access to this medicine has been a stubborn problem that states have had difficulty solving on their own

- There are currently 284 pharmacies in NM
- There are 3 pharmaceutical distributors in NM

Access to buprenorphine is primarily related to the SUPPORT Act, passed by Congress, and several provisions of the Master Settlement Agreement (MSA) for the Opioid Settlement. The SUPPORT Act was passed in an effort to monitor opioid distribution through the establishment of the Suspicious Order Reporting System (SORS), which requires all DEA registrants that distribute controlled substances to report suspicious orders to the DEA. The SORS Online system is used by DEA registrants that distribute (pharmaceutical distributors) controlled substances to other DEA registrants (pharmacies). Registrants maintain compliance with the Act by reporting suspicious ordering when they detect it.

It is important to note that the relevant DEA regulations do not establish thresholds, nor do they require registrants to set thresholds or limits on controlled substance ordering. The DEA does not exclude medications for treatment of opioid use disorder from the requirements. Buprenorphine occupies a counterintuitive space because, while it shares a classification with opioids at the center of the addiction and overdose crisis, it is the gold standard for treatment and the long-term management of addiction. Exempting it from the class being monitored is worth consideration. The DEA does not have requirements in place to ensure pharmacies are able to receive adequate supplies to fill legitimate prescriptions.

The Master Settlement Agreement (MSA) for the Opioid Settlement imposes additional requirements on wholesale pharmacy distributors to place ordering limits on retail pharmacies. These include the use of data-driven systems to flag orders that exceed established thresholds. Once flagged, these orders are automatically cancelled. The manner of determining medication thresholds is proprietary information. If a pharmacy places an order exceeding its threshold, the distributors may cancel the order and potentially report the order as "suspicious" to state and federal law enforcement. Moreover, the settlement agreement prohibits distributors from informing individual pharmacies of their specific threshold levels, how they are calculated, or

when existing orders approach them. This limits a pharmacy's ability to proactively request an increase to its buprenorphine threshold to ensure it can meet local needs. Wholesalers are prohibited from disclosing the algorithms used to determine the thresholds, which would help retail pharmacies avoid overstepping thresholds and triggering cancellations and audits. While the MSA allows for the temporary suspension of these thresholds during declared emergencies—such as the current national emergency related to fentanyl—wholesale distributors have not applied this provision to temporarily lift the thresholds for buprenorphine.

There is currently federal legislative action underway to exempt Buprenorphine from SORS reporting. U.S. Senator Martin Heinrich (D-N.M.) and U.S. Representative Paul Tonko (D-N.Y.) introduced the Broadening Utilization of Proven and Effective Treatment for Recovery Act, or BUPE for Recovery Act, which proposes to increase access to buprenorphine by:

- Requiring the Administrator of the DEA to temporarily exempt buprenorphine from the Suspicious Orders Report System (SORS) for the remainder of the opioid public health emergency; and
- Requiring the U.S. Department of Justice (DOJ) and the U.S. Department of Health and Human Services (HHS) to conduct a thorough assessment at the conclusion of the public health emergency to determine whether buprenorphine needs to be re-included in SORS tracking moving forward.

HB505 would create additional responsibilities regarding data analysis requirements regarding denials for buprenorphine orders from retail pharmacies. New Mexico currently has 282 retail pharmacies. Retail pharmacies routinely reorder medications, sometimes daily, to maintain stock. Without regulations directly impacting wholesale distributor thresholds for buprenorphine or addressing denial of threshold increases, the amount of data related to unfulfilled or denied orders may become too voluminous. While the bill includes language stating that the Board would determine the method for data reporting, close coordination between the Board and NMDOH would be necessary to ensure that data is collected in a format that is readily analyzable and not excessively burdensome.

The bill requires a biennial report from NMDOH detailing the effects of retail pharmacy requests for increased buprenorphine thresholds and the impact on access. The report requires an examination of geographic and demographic disparities in access, and the effects of insufficient access on opioid use disorder treatment initiation and retention, overdose morbidity and mortality, and other health outcomes related to substance use disorder. However, this data would be incomplete as NMDOH would only receive information from wholesale distributors about denials, without data from pharmacies on inventory levels, delays, or unfilled prescriptions. Furthermore, health outcome data related to these issues would require an independent study. The bill does not allocate funds for data analysis or additional studies to fulfill the biennial report's requirements.

The bill mandates only the pharmacy name be included in the report, without specifying the pharmacy's address or zip code. Including this geographic information would significantly improve the analysis of pharmacy order denials and help to identify regional disparities in access to buprenorphine.

2. PERFORMANCE IMPLICATIONS

• Does this bill impact the current delivery of NMDOH services or operations?

 \square Yes \boxtimes No

•	is this proposal related to the NMDOH Strategic Plan? \(\times \) Yes \(\times \) No				
	☐ Goal 1: We expand equitable access to services for all New Mexicans				
	☐ Goal 2: We ensure safety in New Mexico healthcare environments				
	⊠ Goal 3: We improve health status for all New Mexicans				
	☐ Goal 4: We support each other by promoting an environment of mutual respect, trust, open communication, and needed resources for staff to serve New Mexicans and to grow and reach their professional goals				
	This bill would be related to Goal 1 and Goal 3 of the NMDOH Strategic Plan.				
	All New Mexicans deserve equitable access to their medications. There are currently no FDA shortages for buprenorphine (https://dps.fda.gov/drugshortages). Despite this fact, many New Mexicans still have difficulty obtaining their prescription buprenorphine due to lack of availability at their pharmacy.				
	Reliable access to buprenorphine is key to treatment success in individuals with opioid use disorder. Reliable access would greatly improve their health status. People with opioid use disorder are less likely to overdose when they are in long-term treatment with methadone or buprenorphine than when they are untreated. Treatment using agonist medication is associated with an estimated mortality reduction of approximately 50 percent among people opioid use disorder. https://www.ncbi.nlm.nih.gov/books/NBK541393/				
FIS	SCAL IMPLICATIONS				
•	If there is an appropriation, is it included in the Executive Budget Request?				
	□ Yes □ No ⋈ N/A				
•	If there is an appropriation, is it included in the LFC Budget Request?				
	□ Yes □ No ⊠ N/A				
• C	Does this bill have a fiscal impact on NMDOH? ⊠ Yes □ No osts above				
	MINISTRATIVE IMPLICATIONS Il this bill have an administrative impact on NMDOH? ☑ Yes □ No				
	PLICATION, CONFLICT, COMPANIONSHIP OR RELATIONSHIP one.				
	CHNICAL ISSUES The there technical issues with the bill? \square Yes \boxtimes No				
LF	EGAL/REGULATORY ISSUES (OTHER SUBSTANTIVE ISSUES)				
•	 Will administrative rules need to be updated or new rules written? □ Yes ⋈ No Have there been changes in federal/state/local laws and regulations that make this legislation necessary (or unnecessary)? □ Yes ⋈ No 				

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•	Does this bill conflict with federal grant requirements or associated regulations?
	□ Yes ⊠ No
•	Are there any legal problems or conflicts with existing laws, regulations, policies, or programs? \square Yes \boxtimes No

8. DISPARITIES ISSUES

Reducing barriers to access could help reduce wide health disparities related to overdose and access to treatment. According to the CDC, Drug overdose data shows widening disparities. Overdose death rates increased 44% for Black people and 39% for American Indian and Alaska Native (AI/AN) people in one year. Most people who died by overdose had no evidence of substance use treatment before their deaths. A lower proportion of people from racial and ethnic minority groups received treatment for opioid use disorder, compared with White people. (https://www.cdc.gov/vitalsigns/overdose-death-disparities/index.html)

9. HEALTH IMPACT(S)

People with opioid use disorder are less likely to overdose when they are in long-term treatment with methadone or buprenorphine than when they are untreated. Treatment using agonist medication is associated with an estimated mortality reduction of approximately 50 percent among people opioid use disorder. (https://www.ncbi.nlm.nih.gov/books/NBK541393/)

10. ALTERNATIVES

Federal legislation to amend the SUPPORT Act or work through the AG to address barriers presented in the master settlement between wholesalers/ distributors, and pharmacies.

11. WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL?

If HB505 is not enacted, then stocking and reporting requirements would not be enacted for retail pharmacies and wholesale distributors. Additionally, the Board of Pharmacy would not be required to collect this data. In addition, NMDOH would not be required to analyze the data and complete a biennial report.

12. AMENDMENTS

None