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# FISCAL IMPACT REPORT

		LAST UPDATED	
SPONSOR Par	rajón /Sedillo-Lopez	ORIGINAL DATE	2/28/25
SHORT TITLE	Opioid Use Disorder Drug Stocks	BILL NUMBER	House Bill 505
		ANALVST	Klundt

# **ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT\***

(dollars in thousands)

Agency/Program	FY25	FY26	FY27	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
DOH		\$117.0	\$117.0	\$234.0	Recurring	General Fund

Parentheses () indicate expenditure decreases.

#### Sources of Information

LFC Files

Agency Analysis Received From Department of Health (DOH) Health Care Authority (HCA)

# SUMMARY

House Bill 505 requires that retail pharmacies which stock controlled substances maintain a sufficient supply of buprenorphine to meet its average daily dispensing needs plus at least three additional prescriptions. This stock must include both buprenorphine monoproducts and buprenorphine-naloxone combination products.

If a pharmacy's stock falls below these requirements, it must, within three days, either order sufficient replacement stock or request an increased allotment from its wholesale distributor. Wholesale drug distributors are required to report monthly to the New Mexico Board of Pharmacy any instances where they deny or delay a pharmacy's buprenorphine order or deny a request to increase a pharmacy's allotment. The board will forward this data to the Department of Health (DOH), which will analyze and publish biannual reports on buprenorphine access in retail pharmacies. Non-compliance with these provisions may result in penalties.

This bill does not contain an effective date and, as a result, would go into effect 90 days after the Legislature adjourns if enacted, or June 20, 2025.

#### FISCAL IMPLICATIONS

This bill does not contain an appropriation. DOH reported an additional operating impact of \$117 thousand and an additional FTE to implement this bill.

<sup>\*</sup>Amounts reflect most recent analysis of this legislation.

# SIGNIFICANT ISSUES

# DOH reports:

Access to buprenorphine is primarily related to the federal 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 Drug Enforcement Administration (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

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• 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 DOH 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 DOH 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 DOH 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.

# **TECHNICAL ISSUES**

This bill does not address drug shortages, which are unfortunately common. A shortage of one medication or dosage can create a ripple effect, leading to increased demand for alternatives and subsequent shortages of those as well. This could put pharmacies at risk of penalties for circumstances beyond their control.

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