# Effect of naloxone access law type variability and enactment on naloxone claims in the Medicaid population from 2013 through 2017

Sarai Connell, Pharm.D., MBA[1]; Ashley Teel Pharm.D.[1,2]; Bethany Holderread, Pharm.D.[1,2]; Burl Beasley D.Ph., M.Ph., M.S. Pharm.[3]; Terry Cothran D.Ph.[1,2]; Grant Skrepnek, Ph.D., R.Ph.[1]; Shellie Keast, Pharm.D., Ph.D.[1,2]

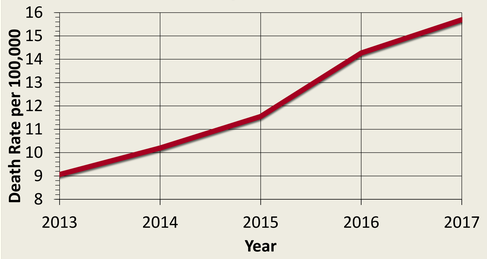
*[1]University of Oklahoma College of Pharmacy; [2]Pharmacy Management Consultants; [3]Oklahoma Health Care Authority*

The UNIVERSITY of OKLAHOMA College of Pharmacy

## Background

- Opioid overdose death rate continue to rise
  - Nationally, the opioid overdose death rate per 100,000 increased by 6.6 over the study period[1]
- As part of overall opioid overdose prevention, states have enacted naloxone access laws (NAL) to expand access to naloxone
- Naloxone is an opioid antagonist that acts to reverse opioid overdoses by blocking the binding of opioids at the mu receptors[2]
- Using Medicaid utilization data to evaluate the effect of the laws on naloxone claims (NALRx) could influence policy makers and decisions associated with naloxone use and opioid overdose

**Mean Opioid Overdose Crude Death Rate by Year[1]**




[1]Centers for Disease Control and Prevention. CDC WONDER: Multiple Cause of Death. Centers for Disease Control and Prevention, Atlanta, GA. https://wonder.cdc.gov/mcd.html.
[2]Lexicomp Online, 2019. Naloxone. Lexi-Drugs. Hudson, Ohio: Walters Kluwer Clinical Drug Information, Inc. Last updated 01/17/2019. Accessed 02/05/2019.

## Objective

- The objective of this study is to assess the effect of various aspects of NALs on naloxone dispensing in the Medicaid population.

The UNIVERSITY of OKLAHOMA Health Sciences Center College of Pharmacy
PMC
PHARMACY MANAGEMENT CONSULTANTS

## Methods

- Primary data sources used for this study were:
  - The 2013-2017 Medicaid State Drug Utilization Datasets available from the Centers for Medicare and Medicaid Services (CMS)[3]
  - NAL dates and law types were compiled from the Prescription Drug Abuse Policy System[4]
- Where state specific data was reported, naloxone claim counts and costs were aggregated by quarter and by payer type
- States having no naloxone use reported or having the primary NAL enactment prior to 2013 were excluded
- Only states with at least 9 quarters of post-NAL enactment data were included in the analysis
- Multivariable generalized estimating equations (GEE) were used for the outcome of NALRx trends and controlling for law type (e.g., standing orders (SO), pharmacist prescribing authority (PPA), third-party dispensing, and per-protocol dispensing), state-specific variables, and year

[3]Centers for Medicare and Medicaid Services, 2018. State Drug Utilization Data. Centers for Medicare and Medicaid Services, Baltimore, MD. https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html.
[4]Prescription Drug Abuse Policy System, 2018. Naloxone Overdose Prevention Laws. National Institute on Drug Abuse, Rockville, MD.

## Results

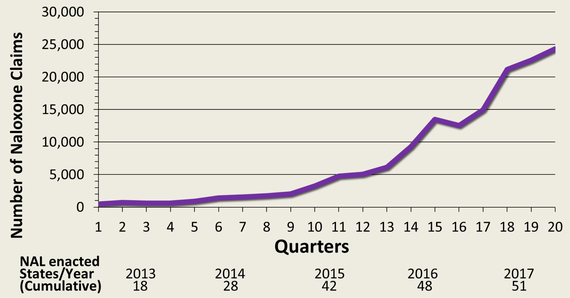
- By mid-2017, every state had passed a NAL
- The year with the most NAL enactments was 2015
- NAL specifications varied by state
  - 46 states allow for third-party prescriptions
  - Pharmacy dispensing without a written prescription is allowed in:
    - 44 states by standing order
    - 14 states by per-protocol orders
    - 7 states have pharmacist prescriptive authority
- A total of 30 states were included in the analysis with 17 states reporting both FFS and MCO NALRx
- Naloxone utilization has increased each year with the greatest increase starting in 2015 (corresponding with the largest number of new law enactments)
- Multivariable analyses indicated that the inclusion of SO and PPA indicated 1.77x and 3.72x higher NALRxs, respectively ($p<0.05$)
- MCOs were also independently associated with 2.58x NALRxs versus FFS ($p=0.017$)
- Additionally, a 1.10x increase in NALRxs was observed for each unit increase in a state's crude overdose death rate ($p<0.001$)

**Number of States with a NAL Passed by Year**

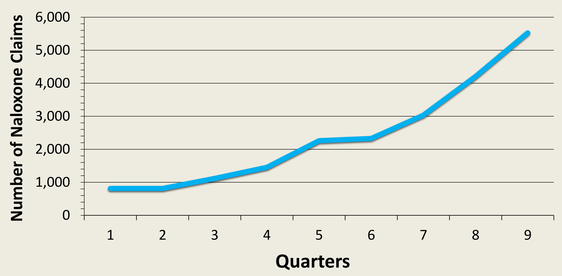
| | Before 2013 | 2013 | 2014 | 2015 | 2016 | 2017 | Total |
|---|---|---|---|---|---|---|---|
| First NAL | 8 | 10 | 10 | 14 | 6 | 3 | 51 |
| Third Party | 5 | 7 | 10 | 16 | 5 | 3 | 46 |
| Standing Order | 0 | 4 | 9 | 15 | 11 | 5 | 44 |
| Per-Protocol | 0 | 1 | 1 | 4 | 6 | 2 | 14 |
| Pharmacist Prescriptive Authority | 0 | 1 | 1 | 2 | 1 | 2 | 7 |

## Results

**National Naloxone Utilization Trend From 2013 to 2017**




**Naloxone Claims Post NAL Enactment**




**Multivariable Regression Results**

| | IRR | P-value | CI |
|---|---|---|---|
| Managed Care Organization | 2.58 | 0.017 | 1.18, 5.63 |
| Year | 0.98 | 0.915 | 0.679, 1.41 |
| Crude Opioid Overdose Rate | 1.10 | <0.001 | 1.06, 1.13 |
| Poverty Level | 1.01 | 0.904 | 0.85, 1.20 |
| Medicaid Population | 1.47 | 0.244 | 0.77, 2.81 |
| State Population | 1.00 | 0.998 | 0.99, 1.00 |
| Third Party Law | 1.77 | 0.381 | 0.49, 6.40 |
| Standing Order Law | 3.32 | 0.005 | 1.44, 7.65 |
| Per-Protocol Law | 0.74 | 0.416 | 0.36, 1.53 |
| Pharmacist Prescriptive Authority Law | 3.72 | 0.025 | 1.17, 11.75 |

IRR = Incidence Rate Ratio; CI = Confidence Interval

## Discussion

- Despite an increasing number of naloxone claims the opioid overdose death rate continues to increase
- Policymakers who have not enacted a pharmacist prescribing authority component may consider this addition to their current NAL
- The higher the opioid overdose rate the greater the number of naloxone claims in Medicaid
- Increased claims for MCOs may be due to the shift to MCO from FFS which occurred during the review period

## Limitations

- This study did not account for changes in coverage criteria or copay for naloxone products
- This data does not account for public health programs that distribute naloxone or commercially insured patients
- Data was suppressed if the prescription count for any NDC was ≤10, which may cause lower numbers for utilization compared to actual utilization for some states
- Enrollment values for each payer type was not accounted for within the analysis
- This study looked at the number of naloxone claims reimbursed, not the number of naloxone products that were used

## Conclusions

- This study shows that the passage of NALs led to an increase in the number of claims for naloxone dispensed to the Medicaid population
- Increased naloxone claims could mean an increase in access for Medicaid members for this life saving drug
- NAL that allow for standing order or pharmacist prescriptive authority are associated with a higher number of naloxone claims in Medicaid
- Previous research found that a standing order for naloxone was associated with increased NALRx, however pharmacist prescriptive authority was not included in that study
- This research adds to current knowledge regarding effective laws for increasing access to naloxone and could assist states in evaluating which legislation to enact in an effort to increase access to naloxone for the Medicaid population

## Disclosure Statement


- Keast, Skrepnek, and Holderread disclose unrelated funding through an unrestricted research grant from AbbVie, Inc; Amgen, Inc; and Otsuka American Pharmaceutical, Inc.
- Keast and Skrepnek also acknowledges unrelated funding from Purdue Pharma for a research fellowship grant.