PROGRAM EVALUATION DIVISION
NORTH CAROLINA GENERAL ASSEMBLY

June 2017 Report No. 2017-06

Follow-up Report: Prescription Drug Monitoring

In North Carolina, there are four mechanisms to monitor and prevent the abuse of prescribed controlled substances: oversight of prescribers and dispensers, the Controlled Substances Reporting System (CSRS), Medicaid lock-in, and law enforcement. In 2014, the Program Evaluation Division (PED) evaluated the efficiency and effectiveness of North Carolina's system for monitoring and preventing the abuse of prescribed controlled substances and found

- the CSRS was underutilized and lacked important features for security and data analysis;
- prescribing guidelines and continuing education requirements for prescribers were insufficient; and
- the lock-in program had been non-operational since July 2013, costing the Medicaid program an estimated $1.3 to $2 million.

PED recommended the General Assembly direct the development and adoption of statewide prescribing guidelines, require continuing education, and direct the Department of Health and Human Services (DHHS) to modify the CSRS contract to improve performance, improve the effectiveness of the Medicaid lock-in program, and develop a strategic plan and performance management system.

Subsequently, Session Law 2015-241:

- directed DHHS to improve CSRS access and utilization, improve the CSRS contract, and expand CSRS monitoring capacity;
- required adoption of statewide opioid prescribing guidelines and continuing education on the abuse of controlled substances for practitioners;
- directed the Division of Medical Assistance (DMA) to improve the effectiveness and efficiency of the lock-in program; and
- created the Prescription Drug Abuse Advisory Committee (PDAAC) and directed it to develop a statewide strategic plan and performance management system to combat prescription drug abuse.

According to DHHS' Division of Public Health, Injury and Violence Prevention Branch, "an epidemic of unintentional poisoning deaths continues to affect North Carolina." Specifically, unintentional opioid poisoning deaths in the state increased by 39% from 2013 to 2015 (see exhibit 1). DHHS further states that "if current trends continue, unintentional poisoning deaths will surpass motor vehicle deaths as the leading cause of injury death in North Carolina by 2017."

In November 2016, DHHS reported the following actions related to the primary components of PED's evaluation:

Modifying CSRS Contract and Improving Performance:

- The Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMH/DD/SAS) launched CSRS redesign on March 17, 2015, providing prescribers and pharmacists with more intuitive control of the site as well as new features like password reset, registrant's profile update, practitioner's prescribing history, and new easy-to-read reports. See Exhibit 2 for a screenshot of a sample query of the CSRS.

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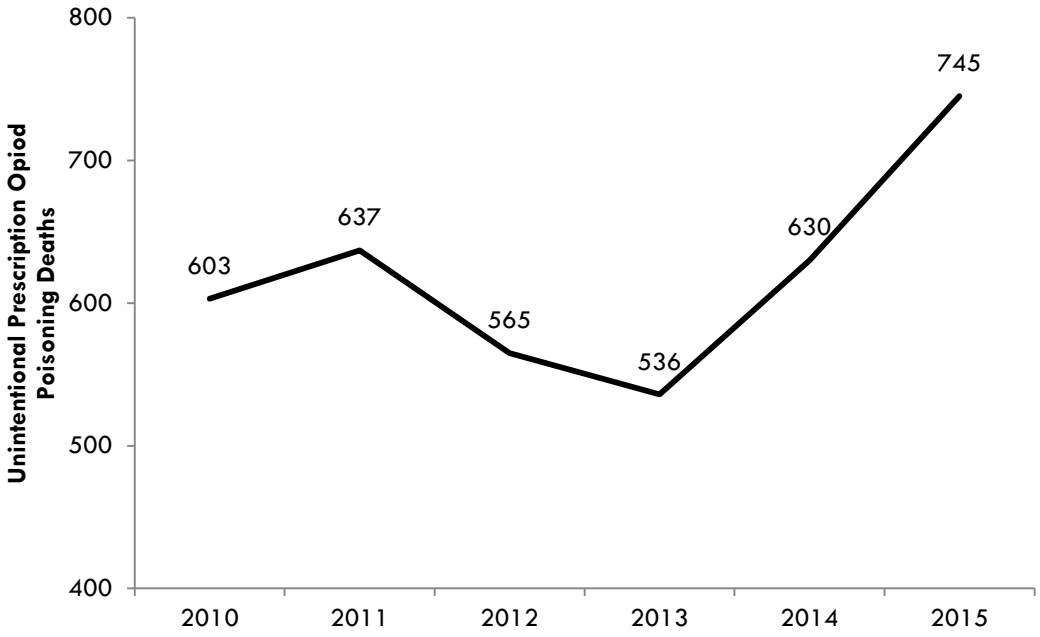
Exhibit 1: Unintentional Prescription Opioid Poisoning Deaths Increased 39% From 2013 to 2015



Source: Program Evaluation Division based on data from the Department of Health and Human Services, Division of Public Health, Injury and Violence Prevention Branch.

Exhibit 2: Sample Query of Recipient Usage in the Controlled Substances Reporting System

Last Name: [redacted]
First Name: [redacted]
Date of Birth: [redacted]

Recipients: 1 out of 1 Recipient(s) Selected - Click to View

Date Dispensed/ Date Prescribed	Drug Name/ NDC	Qty. Dispensed/ Days Supply	Refill #/ Authorized Refills
04/12/2012 04/12/2012	HYDROCODON- ACETAMINOPHN 10- 500 00406036301	30 5	1 3
02/12/2012 02/12/2012	HYDROCODON- ACETAMINOPHEN 5- 500 00406035705	30 2	1 3

Source: Program Evaluation Division based on North Carolina Department of Health and Human Services' Controlled Substance Reporting System's Practitioner's Training Guide (August 2016).

Exhibit 3: Centers for Disease Control and Prevention's Recommendations for Prescribing Opioids for Chronic Pain Outside of Active Cancer, Palliative, and End-of-Life Care

Determining When to Initiate or Continue Opioids for Chronic Pain
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.
Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation
4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.
Assessing Risk and Addressing Harms of Opioid Use
8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

Source: Program Evaluation Division based on Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain (March 2016).

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- DMH/DD/SAS negotiated, developed, and executed a contract with Health Information Designs that included a 17.5% reduction ($46,892) for the cost of maintenance and operation of the CSRS system.
- The reporting requirement was met, and DHHS achieved a 15% cost reduction for the 2016 service contract, resulting in an estimated $33,118 in annual savings.
- DMH/DD/SAS has been involved in a number of analytical projects to provide accurate and timely controlled substances prescribing data to stakeholders.

Prescribing Guidelines and Continuing Education:

- In January 2017, the North Carolina Medical Board (NCMB) voted to replace the current opioid position statement with the Centers for Disease Control and Prevention's (CDC's) Guideline for Prescribing Opioids for Chronic Pain, which was published in March 2016 (see Exhibit 3).
- NCMB implemented a new continuing medical education requirement to ensure licensees who prescribe controlled substances do so in a manner that is safe, appropriate, and consistent with current standards of care. The new requirement will be effective July 1, 2017.
- In April 2016, NCMB launched a first-of-its-kind initiative to increase its oversight of opioid prescribing known as the Safe Opioid Prescribing Initiative (SOPI). This program uses data provided by DHHS to identify prescribers for investigation by the board. Its primary goal is to reduce patient harm and deaths related to prescription opioids by proactively identifying and addressing potentially unsafe prescribing.
- SOPI looks at prescribers who fall in one or both of the following categories: licensees managing large numbers of patients at high daily doses of opioids and licensees who have had two or more patients die of opioid poisoning within 12 months. As of November 2016, NCMB has opened 62 cases based on SOPI criteria.

Medicaid Lock-In Program:

- Per legislation, DMA will conduct an audit within six months of implementation of changes to the Medicaid lock-in program and report on fiscal impact within one year of implementation. DHHS submitted the DMA Legislative Report: SL 2015-268, Section 4.4. (Medicaid Lock-In Program) to the Joint Legislative Program Evaluation Oversight Committee on September 30, 2016.

Statewide Strategic Plan and Performance Management System:

- In September 2014, North Carolina was invited to participate in the National Governors Association Policy Academy on Reducing Prescription Drug Abuse, which resulted in the development of North Carolina's Strategic Plan to Reduce Rx Drug Abuse.
- In accordance with Session Law 2015-241, Section 12F.16(m), the DHHS Prescription Drug Abuse Advisory Committee (PDAAC) was established to continue to develop and implement the plan.
- In May 2017, DMH/DD/SAS was awarded $31 million in federal funding over two years to support the implementation of the Strategic Plan to Reduce Rx Drug Abuse.
- These federal funds will support training for physicians on CDC prescribing guidelines.
- Federal funds will also be used to enhance and increase the capacity of the State's PDMP by integrating the CSRS and patient records within the electronic health records systems of health care facilities, creating a valuable clinical tool for patient care while significantly increasing CSRS registration and utilization throughout the continuum of care.

For more information on this follow-up report, please contact the lead evaluator, Sean Hamel, at sean.hamel@ncleg.net.

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