North Carolina Needs to Strengthen Its System for Monitoring and Preventing the Abuse of Prescribed Controlled Substances

A presentation to the

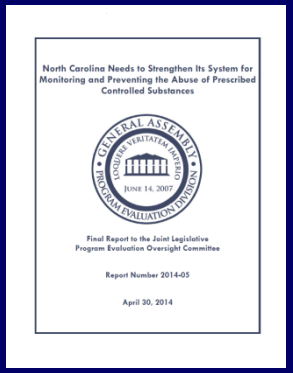
Joint Legislative Program Evaluation Oversight Committee

April 30, 2014

Sean Hamel, Senior Program Evaluator

Handouts

The Full Report


North Carolina Needs to Strengthen Its System for Monitoring and Preventing the Abuse of Prescribed Controlled Substances

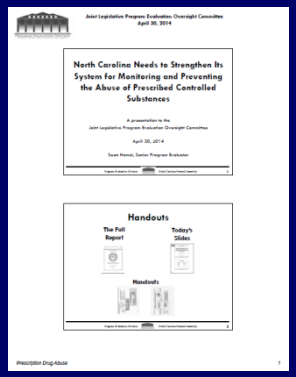
GENERAL ASSEMBLY OF NORTH CAROLINA
PROGRAM EVALUATION DIVISION
JUNE 14, 2007

Final Report to the Joint Legislative Program Evaluation Oversight Committee

Report Number 2014-05

April 30, 2014

Today's Slides


Joint Legislative Program Evaluation Oversight Committee
April 30, 2014

North Carolina Needs to Strengthen Its System for Monitoring and Preventing the Abuse of Prescribed Controlled Substances

Handouts

The Full Report

Today's Slides

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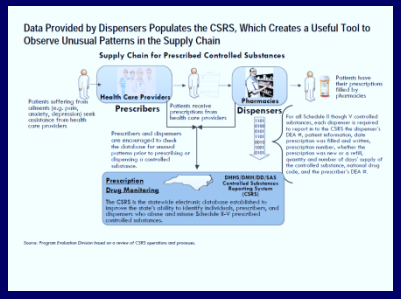
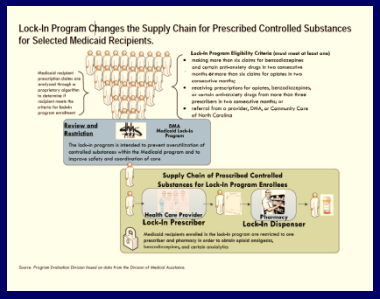
Prescription Drug Abuse

Two Handouts


Data Provided by Dispensers Populates the CSRS, Which Creates a Useful Tool to Observe Unusual Patterns in the Supply Chain

Supply Chain for Prescribed Controlled Substances

Health Care Providers
Prescribers
Pharmacies
Dispensers
Patients have their prescriptions filled by pharmacies
Patients suffering from ailments (e.g. pain, anxiety, depression) seek treatment from health care providers
Patients receive prescriptions from health care providers
Prescribers and dispensers are encouraged to check the database for unusual patterns prior to prescribing or dispensing a controlled substance.
For all Schedule II though V controlled substances, each dispenser is required to report to the CSRS the dispenser's DEA registration number, date prescription was filled and written, prescription number, whether the prescription was new or a refill, quantity and number of days' supply of the controlled substance, national drug code, and the prescriber's DEA #.
Prescription Drug Monitoring
DHHS/DMH/DD/SAS Controlled Substances Reporting System (CSRS)
The CSRS is the statewide electronic database established to improve the state's ability to identify individuals, prescribers, and dispensers who abuse and misuse Schedule II–V prescribed controlled substances.
Source: Program Evaluation Division based on a review of CSRS operations and processes.


Lock-In Program Changes the Supply Chain for Prescribed Controlled Substances for Selected Medicaid Recipients.

Lock-In Program Eligibility Criteria (must meet at least one)
- making more than six claims for benzodiazepines and certain antianxiety drugs in two consecutive months or more than six claims for opiates in two consecutive months;
- receiving prescriptions for opiates, benzodiazepines, or certain antianxiety drugs from more than three prescribers in two consecutive months; or
- referral from a provider, DMA, or Community Care of North Carolina

Medicaid recipient receives claims data for analysis through a proprietary algorithm to determine if recipient meets the criteria for the program enrollment

Review and Restriction
DMA Medicaid Lock-In Program
The lock-in program is intended to prevent overutilization of controlled substances within the Medicaid program and to improve safety and coordination of care

Supply Chain of Prescribed Controlled Substances for Lock-In Program Enrollees
Health Care Provider
Lock-In Prescriber
Pharmacy
Lock-In Dispenser
Medicaid recipients enrolled in the lock-in program are restricted to one prescriber and pharmacy in order to obtain opioid analgesics, benzodiazepines, and certain sedatives.
Source: Program Evaluation Division based on data from the Division of Medical Assistance.

Evaluation Team

Sean Hamel, Evaluation Lead

Jeff Grimes, Senior Evaluator

Pamela Taylor, Principal Evaluator

Special thanks to:

University of North Carolina at Chapel Hill
Injury Prevention Research Center

Our Charge

Evaluate North Carolina's system for monitoring and preventing the abuse of prescribed controlled substances

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Overview of Findings

1. The State lacks adequate prescribing guidelines and continuing education requirements

2. Performance of the Department of Health and Human Services (DHHS) Controlled Substance Reporting System (CSRS) is hindered by access barriers, a lack of data connectivity, and limited analytical capacity

3. The lock-in program is non-operational, costing the Medicaid program an estimated $1.3 million to $2 million; even when operational, the program suffered from several shortcomings

Overview of Findings

4. The contract for the CSRS lacks important features and costs the State more for less functionality

5. There is no coordinated strategy or performance management system for monitoring the abuse of prescribed controlled substances

Overview of Recommendations

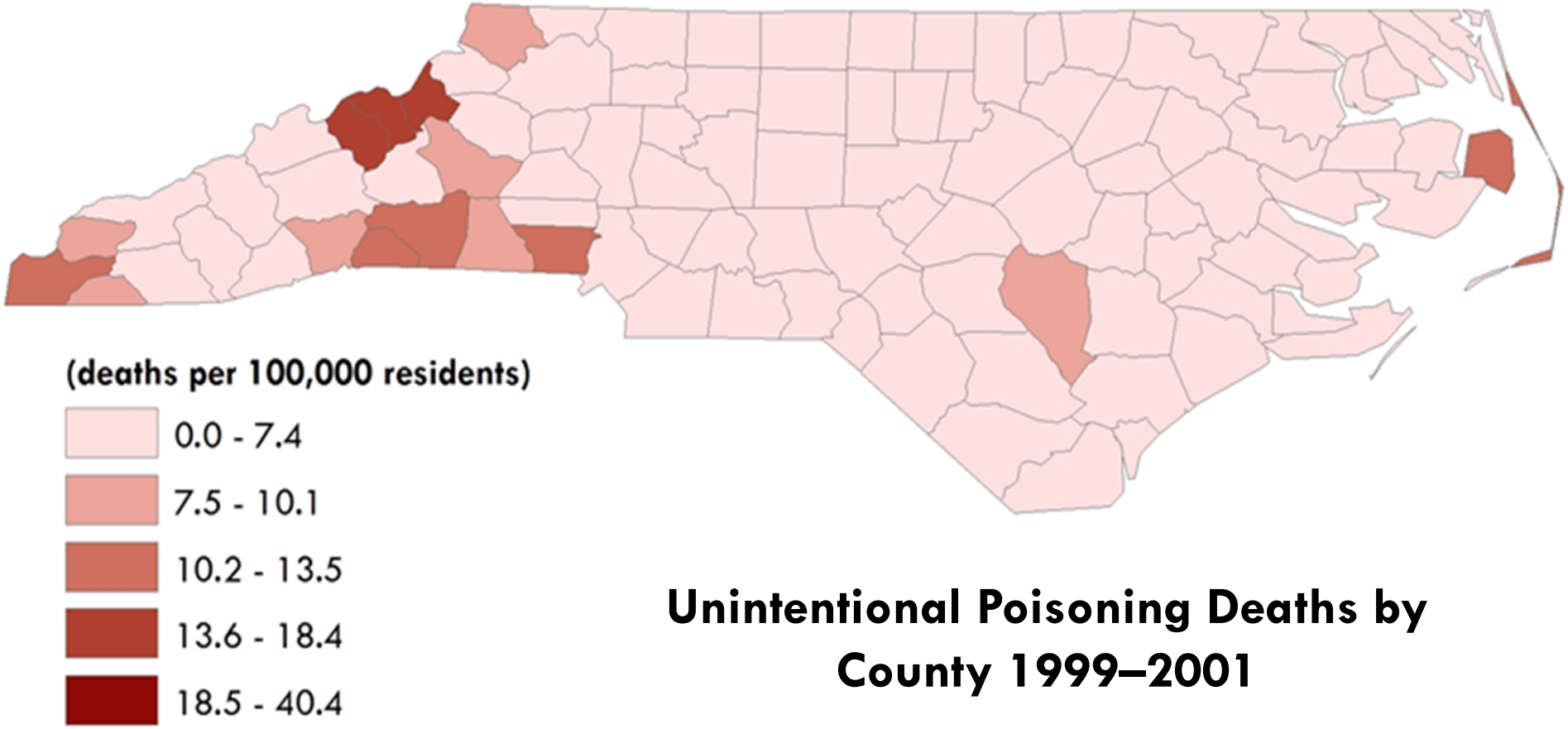
1. Direct state officials and occupational licensing boards to develop and adopt statewide opioid prescribing guidelines
2. Require continuing education for prescribers on the abuse of controlled substances
3. Improve CSRS access and utilization
4. Modify the contract with Health Information Designs for the CSRS to improve performance and functionality

Overview of Recommendations

5. Expand monitoring capacity by establishing data use agreements with the Prescription Behavior Surveillance System
6. Direct the Division of Medical Assistance to improve the effectiveness and efficiency of the Medicaid lock-in program
7. Establish a strategic plan and performance management system to monitor prescription drug abuse

Background

Unintentional Poisoning Deaths Have Grown by 300% Over 10 Years



Unintentional Poisoning Deaths by County 1999–2001

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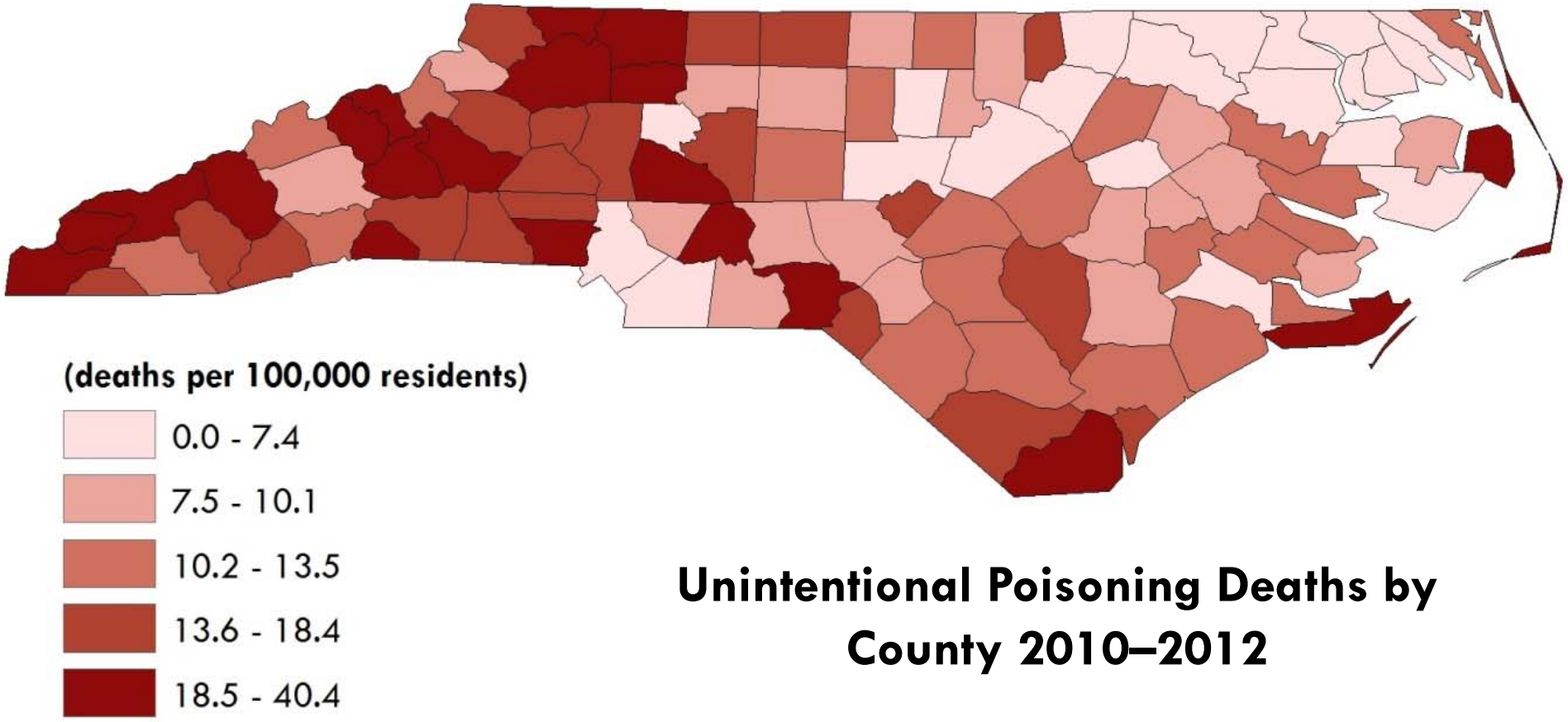
Unintentional Poisoning Deaths Have Grown by 300% Over 10 Years



Unintentional Poisoning Deaths by County 2010–2012

Report pp. 3-4

Controlled Substances

- Federal code and state law categorize these drugs by their potential for abuse and by the severity of their addictiveness
- Schedules include prescription drugs that have a currently accepted medical use
- Opioids, stimulants, and depressants are the most commonly abused prescribed controlled substances

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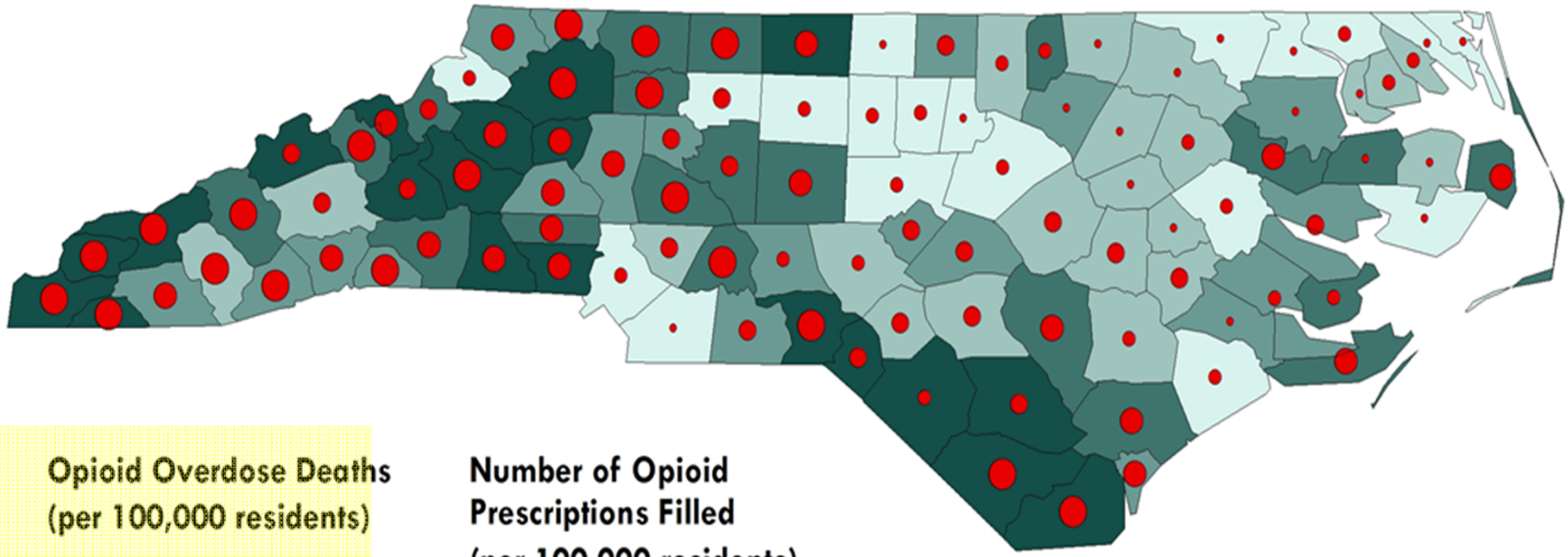
Overdose Death Rates Increase with Opioid Prescribing Volume



Note: This exhibit reflects a two-year average of county population, opioid overdose deaths, and opioid prescribing volume between 2010 and 2011.

Report pg. 7

Societal Costs Associated with the Abuse of Prescribed Controlled Substance

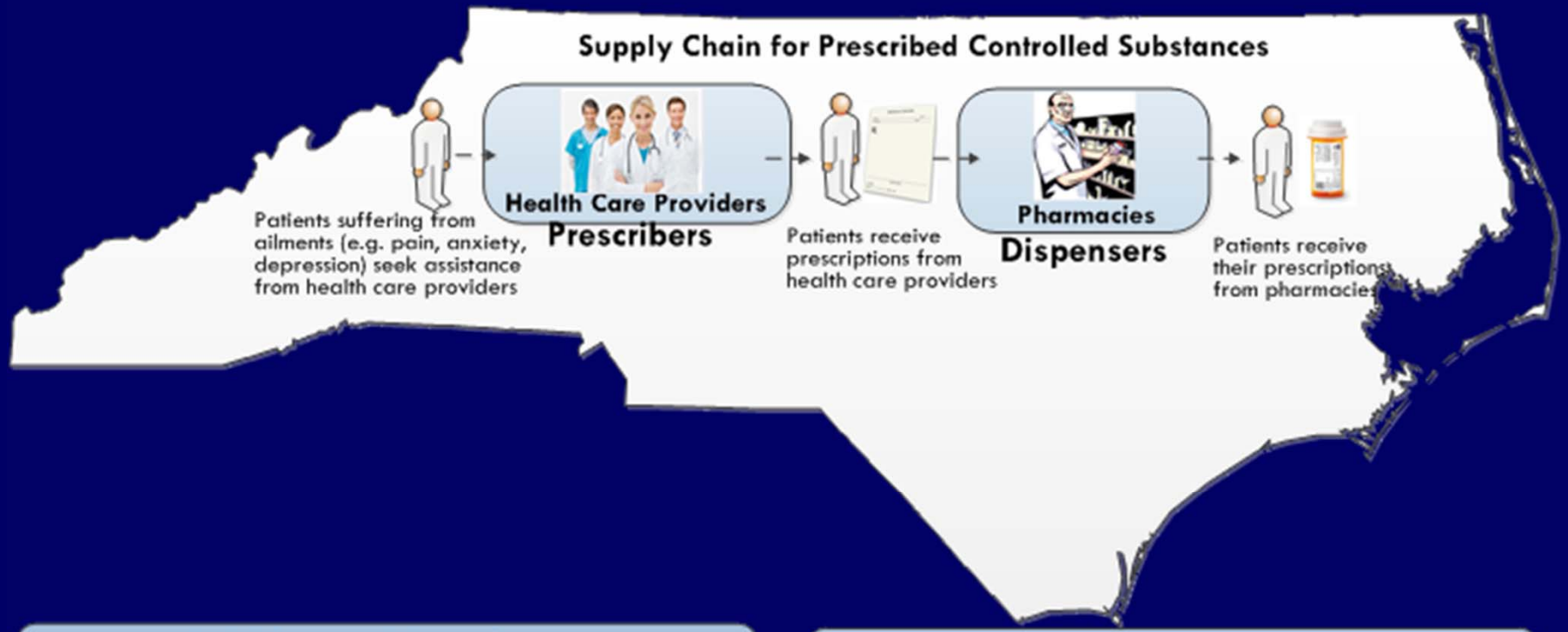
- For every one unintentional poisoning death
  - 10 people are admitted to treatment facilities
  - 32 people are admitted to the emergency room
- Cost to public and private medical insurers nationally is estimated at $72.5 billion per year

Report pp.4-5

System for Monitoring the Abuse of Prescribed Controlled Substances

Oversight of Prescribers and Dispensers — Health care regulatory boards ensure clinical care standards are being met through licensure, guidelines, and continuing education of health care providers

Prescription Drug Monitoring Program — The CSRS is the statewide electronic reporting system established to improve the state's ability to identify individuals, prescribers, and dispensers who abuse and misuse Schedule II-V prescribed controlled substances



Medicaid lock-in — The lock-in program is intended to prevent overutilization of controlled substances within the Medicaid program and to improve safety and coordination of care

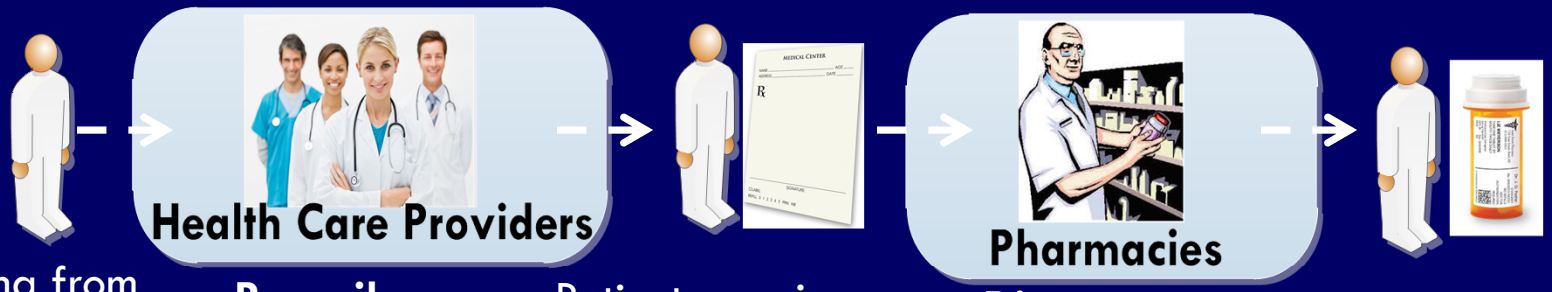
Law Enforcement — The SBI's Diversion and Environmental Crimes Unit investigates the diversion of prescribed controlled substances by licensed prescribers, dispensers, and individuals

Findings

Finding 1.
North Carolina's system lacks adequate statewide prescribing guidelines that apply to all health care providers and continuing education requirements for prescribers

Occupational Licensing Boards Regulate Prescribers and Dispensers

Supply Chain for Prescribed Controlled Substances



Patients suffering from ailments (e.g. pain, anxiety, depression) seek assistance from health care providers

Prescribers

Patients receive prescriptions from health care providers

Dispensers

Patients have their prescriptions filled by pharmacies

Health Care Regulatory Boards ensure clinical care standards are being met through

- licensure;
- enforcement;
- education; and
- guidelines.

Oversight of Prescribers and Dispensers

North Carolina Board of Dental Examiners
North Carolina Board of Nursing
North Carolina Board of Pharmacy
North Carolina Board of Podiatry Examiners
North Carolina Medical Board

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Prescribing Guidelines

- Written guidelines are an important tool for regulation and oversight of prescribers
- There are no statewide prescribing guidelines
- The NC Medical Board policy on pain management does not meet the criteria for trustworthy clinical practice guidelines
  - policy is out-of-date
  - policy lacks definition and would be enhanced by supplementary tools

Report pp. 10-12

Health Care Provider Education

- Continuing education ensures medical providers stay up-to-date on proven medical advances, procedures, and practices
- Health care providers are not required to obtain continuing education on appropriate prescribing or dispensing of controlled substances
- 11 states require continuing education in either pain management or prescribing of controlled substances

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Finding 2.
Performance of the Controlled Substances Reporting System (CSRS) is hindered by access barriers, a lack of interstate data connectivity, and limited analytical capacity

The CSRS is a Monitoring Tool

Supply Chain for Prescribed Controlled Substances

Patients suffering from ailments (e.g. pain, anxiety, depression) seek assistance from health care providers

Prescribers

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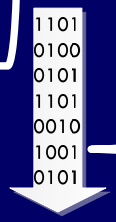

For all Schedule II though V controlled substances, each dispenser is required to report in to the CSRS the dispenser's DEA #, patient information, date prescription was filled and written, prescription number, whether the prescription was new or a refill, quantity and number of days' supply of the controlled substance, national drug code, and the prescriber's DEA #.

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CSRS Registration is on the Rise but Utilization Remains Low

- Registration for the CSRS has grown steadily since Fiscal Year 2009-10
  - Only 38% of opioid prescribers registered with CSRS
  - 68% of those prescribing the most opioids registered with CSRS
- CSRS used less than 6% of the time a prescription for a controlled substance was written or filled

Report pp. 19-20

Streamlining Access and Expanding Capacity Can Improve Utilization

- Linking CSRS data to the North Carolina Health Information Exchange (NC HIE)
- Granting federal law enforcement agents the ability to request information directly from the CSRS
- Establishing interstate data connectivity
- Expanding the monitoring and surveillance capacity of the State by participating in the Prescription Behavior Surveillance System (PBSS)

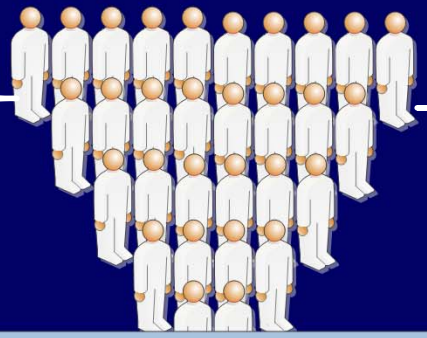
Report pp. 19-24

Finding 3.

The State's Medicaid lock-in program has been non-operational since July 2013, costing the Medicaid program an estimated $1.3 million to $2 million; even when operational, the program suffered from shortcomings that limited its effectiveness and cost savings

Lock-in Program Modifies the Supply Chain for Select Medicaid Recipients

Medicaid recipient prescription claims are analyzed through a proprietary algorithm to determine if recipient meets the criteria for lock-in program enrollment



Lock-In Program Eligibility Criteria

- making more than six claims for benzodiazepines and certain anti-anxiety drugs in two consecutive months **or** more than six claims for opiates in two consecutive months;
- receiving prescriptions for opiates, benzodiazepines, or certain anti-anxiety drugs from more than three prescribers in two consecutive months; or
- referral from a provider, DMA, or Community Care of North Carolina

Review and Restriction

DMA Medicaid Lock-In Program

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Supply Chain of Prescribed Controlled Substances for Lock-In Program Enrollees

Health Care Provider

Lock-In Prescriber

Pharmacy

Lock-In Dispenser

Medicaid recipients enrolled in the lock-in program are restricted to one prescriber and pharmacy in order to obtain opioid analgesics, benzodiazepines, and certain anxiolytics

Currently the Medicaid Lock-in Program is Non-operational

- New Medicaid recipients who meet lock-in program criteria cannot be enrolled in the program
- Current enrollees are no longer restricted to one prescriber and one pharmacy
- This gap in functionality cost the Medicaid program an estimated $1.3 million to $2 million from July 2013 to March 2014

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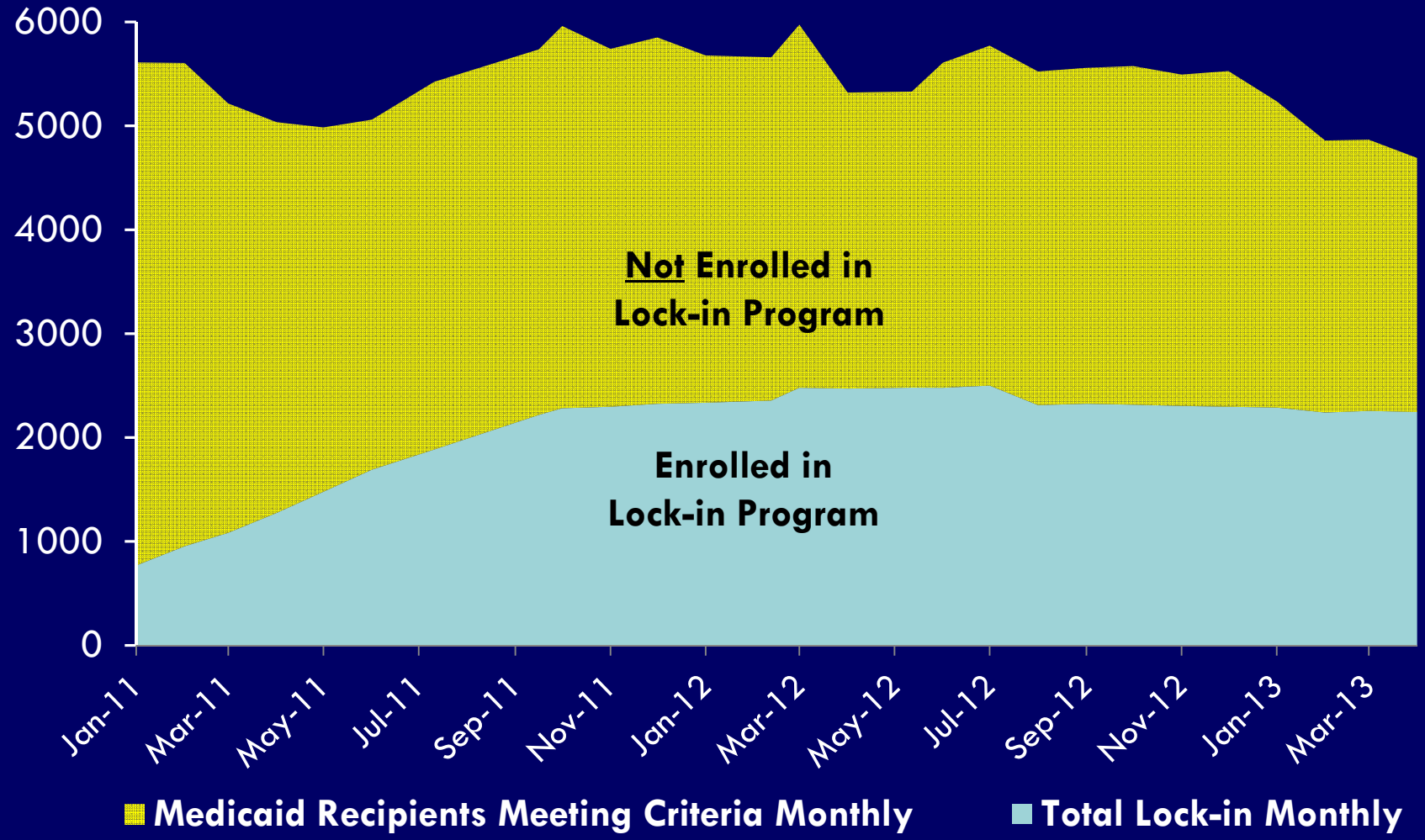
DMA Failed to Enroll All Medicaid Beneficiaries Who Met the Lock-in Criteria



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Several Changes Would Improve the Effectiveness of the Lock-in Program

- Expanding eligibility to include stimulants
- Leveraging CSRS data for cash payments
- Conducting an internal audit
- Increasing lock-in duration period which could save the State an estimated $2.8 million

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Finding 4.
The contract for the Controlled Substances Reporting System fails to incorporate internal controls for user access, lacks important features for security and data analysis, and costs the State more for less functionality

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CSRS Contract Lacks Important Features

Contract Feature	North Carolina	Washington
Internal Controls Features		
Specifies procedures to deactivate user accounts or remove users from system		✓
Verifies whether users have active DEA numbers		✓
Ensures users cannot create duplicate accounts		✓
Security Features		
Complies with federal, state, and departmental privacy and security laws, regulations, and rules	✓	✓
Meets privacy and security standards of the Health Insurance Portability and Accountability Act	✓	✓
Specifies password management standards		✓
Requires security controls meet or exceed federal standards for information security		✓
Data Analysis Features		
Allows authorized staff to search, correlate, query, and match records on all variables in the database	✓	✓
Transfers a copy of the database		✓
Allows batch reporting of files based on a list of clients		✓
Provides de-identified reports		✓
Provides ad-hoc reports that cannot be produced through the system online		✓

N.C. Spend $43,346 More Annually than Washington for a System with Less Functionality

	North Carolina	Washington	Difference
Base Cost (system software, hardware, and help desk operation)	$220,785	$99,639	$121,146
Additional functionality			
• SiteKey authentication at login for additional security	__	$36,000	$(36,000)
• Interstate data sharing connection	__	10,000	(10,000)
• Health information exchange connection	__	15,000	(15,000)
• Manual entry of veterinarian prescribing data by HID	N/A	16,800	(16,800)
Sub-total		$77,800	$(77,800)
Total Cost	$220,785	$177,439	$43,346

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Finding 5.
North Carolina lacks a coordinated strategy and performance management system for monitoring and preventing the misuse of prescribed controlled substances

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No Statewide Goals, Objectives, or Performance Management System

- 11 different state-level entities have a role in monitoring the abuse of prescribed controlled substances
- No strategic approach exists to address the prescription drug abuse epidemic
- North Carolina could use a strategic plan to
  - implement a performance management system
  - ensure better coordination and accountability among 11 state entities

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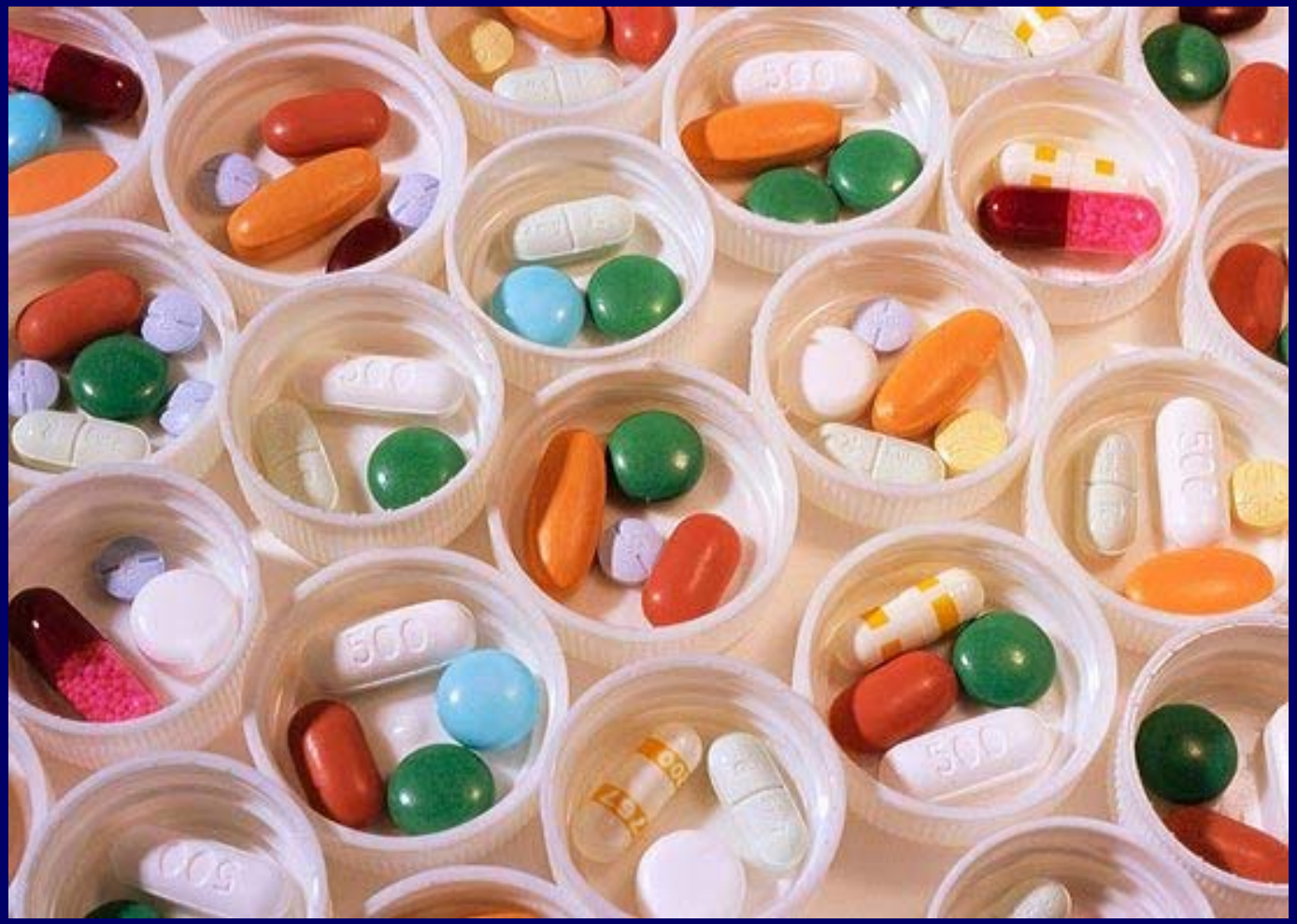
Recommendations



Recommendation 1.
The General Assembly should direct state health officials and the occupational licensing boards to develop and adopt statewide opioid prescribing guidelines

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Developing Statewide Guidelines

State Health Officials

- State Health Director
- Director of Medical Assistance
- Director of the Division of Mental Health, Developmental Disabilities and Substance Abuse Services
- directors of medical, dental, and mental health services within the Department of Public Safety

Occupational Licensing Boards

- North Carolina Board of Dental Examiners
- North Carolina Board of Nursing
- North Carolina Board of Podiatry Examiners
- North Carolina Medical Board

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Criteria for Statewide Guidelines

- Guidelines should meet criteria set forth by the Institute of Medicine of the National Academies
  - make recommendations for clinical actions based on review of empirical evidence
  - rate the strength of each clinical recommendation
  - rate the quality of evidence used to support recommendations for clinical action
  - explain and assess the benefits and harms associated with options for alternative treatments

Guidelines should be completed by December 31, 2014 and adopted by July 1, 2015

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Recommendation 2.
General Assembly should direct health care provider occupational licensing boards to require at least one hour of continuing education on the abuse of controlled substances as a condition of license renewal for providers who prescribe controlled substances

Report pp. 45-46

Required Continuing Education

- Require at least one hour of continuing education for prescribers of controlled substances
- Course offerings should include, but not be limited to
  - instruction on controlled substance prescribing practices
  - controlled substance prescribing for chronic pain management

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Recommendation 3.
The General Assembly should amend state law to enable improved Controlled Substances Reporting System access and utilization

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Improving Access and Utilization

- Changes to state law would
  - allow the CSRS to contribute data to the North Carolina Health Information Exchange
  - provide access to the CSRS for U.S. Drug Enforcement Administration's Office of Diversion Control for bona fide investigations

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Recommendation 4.

The General Assembly should direct DHHS to modify the contract for the CSRS to improve performance, establish user access controls, establish data security protocols, and ensure availability of data for advanced analytics

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New Contract Features

The contract should include

- Health Information Exchange connection
- Interstate connectivity
- Account updates
- Prescriber number validation
- Data security protocols
- Data transfer
- Ad-hoc reporting

Report modifications to Joint Legislative Program Evaluation Oversight and the Joint Oversight Committee on Health and Human Services by November 2014

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Recommendation 5. Expand monitoring capacity by establishing data use agreements with the Prescription Behavior Surveillance System

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Recommendation 6. Direct the Division of Medical Assistance to improve the effectiveness and efficiency of the Medicaid lock-in program

Report pp. 44-45

Lock-in Program Improvements

- Establish written procedures for the operation of the lock-in program and use of CSRS data
- Expand eligibility and extend lock-in duration to two years
- Improve communication materials
- Increase program capacity
- Program Integrity should conduct internal audit

Report pp. 44-45

Recommendation 7.
Direct the Secretary of the Department of Health and Human Services to develop a strategic plan and performance management system to monitor prescription drug abuse

Report p. 20

Summary of Findings

1. The State lacks adequate prescribing guidelines and continuing education requirements

2. Performance of the CSRS is hindered by access barriers, a lack of interstate data connectivity, and limited analytical capacity

3. The lock-in program is non-operational, costing the Medicaid program an estimated $1.3 million to $2 million; even when operational, the program suffered from shortcomings

Summary of Findings

4. The contract for the CSRS lacks important features and costs the state more for less functionality
5. There is no coordinated strategy or performance management system

Summary of Recommendations

1. Develop and adopt statewide opioid prescribing guidelines
2. Require continuing education on the abuse of controlled substances
3. Enable improved CSRS access and utilization
4. Modify the contract for the CSRS to improve performance and functionality

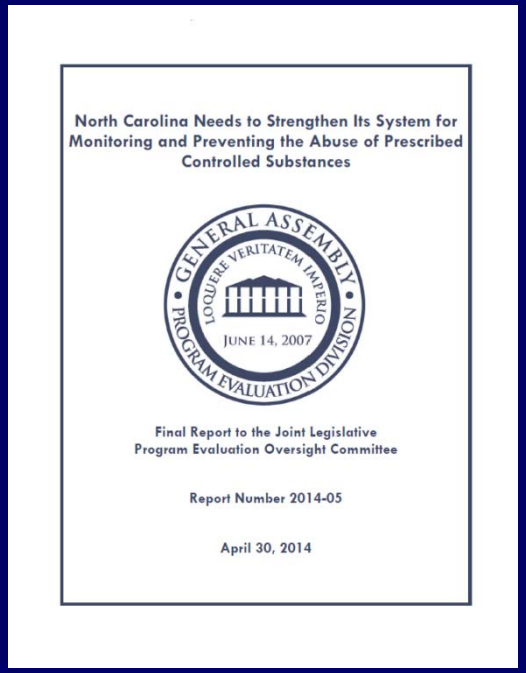
Summary of Recommendations

5. Expand monitoring capacity by establishing data use agreements with the Prescription Behavior Surveillance System
6. Direct the Division of Medical Assistance to improve the effectiveness and efficiency of the Medicaid lock-in program
7. Establish a strategic plan and performance management system to monitor prescription drug abuse

Legislative Options

- Accept the report
- Refer it to any appropriate committees
- Instruct staff to draft legislation based on any of the report's recommendations

Report available online at www.ncleg.net/PED/Reports/reports.html



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