

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



**Final Report to the Joint Legislative
Program Evaluation Oversight Committee**

Report Number 2014-05

April 30, 2014



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April 30, 2014

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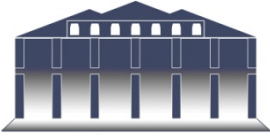
The 2013–15 Program Evaluation Division work plan directed the division to evaluate the efficiency and effectiveness of North Carolina's system for monitoring and preventing the abuse of prescribed controlled substances as part of a larger review of adult alcohol and drug abuse programs, prescription drug abuse, and programs for veterans.

I am pleased to report that the Department of Health and Human Services cooperated with us fully and was at all times courteous to our evaluators during the evaluation.

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Turcotte".

John W. Turcotte
Director



PROGRAM EVALUATION DIVISION

NORTH CAROLINA GENERAL ASSEMBLY

April 2014

Report No. 2014-05

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

Summary

This evaluation examines the system for monitoring and preventing the abuse of prescribed controlled substances. In North Carolina, there are four mechanisms to monitor and prevent the abuse of prescribed controlled substances: the oversight of prescribers and dispensers, the prescription drug monitoring program (PDMP), Medicaid lock-in, and law enforcement.

In the area of oversight, the State would benefit from more robust prescribing guidelines and continuing education requirements for prescribers. Guidelines and continuing education are important for ensuring standards for clinical care.

The State can improve the PDMP by increasing utilization of the Controlled Substances Reporting System (CSRS) through streamlining access and removing barriers to use of CSRS data. In 2012, doctors and pharmacists used the CSRS less than 6% of the time a prescription for a controlled substance was written or dispensed. The CSRS also lacks important features for security and advanced data analysis and fails to incorporate internal controls for user access. These issues are related to the Department of Health and Human Services' (DHHS') contract for the operation of the CSRS, which has not maximized the value of limited resources.

North Carolina's ability to prevent the abuse of prescribed controlled substances is hampered by the Division of Medical Assistance's lock-in program being non-operational since July 2013, which has cost the Medicaid program an estimated \$1.3 million to \$2 million. Even when it was operational, the lock-in program suffered from shortcomings that limited its effectiveness and cost savings.

North Carolina lacks a coordinated strategy and system for monitoring and preventing the abuse of prescribed controlled substances. Several state entities participate in the system, but no single strategy exists to link goals and objectives to operations of the system's entities. Without these administrative tools, the State cannot monitor its efforts to reduce the abuse of prescribed controlled substances.

To address these findings, the General Assembly should direct state health officials to develop statewide prescribing guidelines, direct health care regulatory boards to adopt these guidelines, and require continuing education in opioid pain management for prescribers of controlled substances. In addition, the General Assembly should direct the Department of Health and Human Services to:

- modify the contract for the CSRS to improve performance, strengthen access controls, improve data security, ensure advanced analytics, and enter into a data-sharing agreement expanding analytical capacity;
- improve the effectiveness and efficiency of the Medicaid lock-in program; and
- develop a strategic plan and performance management system to monitor prescription drug abuse.

Purpose and Scope

The Joint Legislative Program Evaluation Oversight Committee directed the Program Evaluation Division to evaluate the efficiency and effectiveness of North Carolina's system for monitoring and preventing the abuse of prescribed controlled substances.¹

Three central research questions guided the study:

- What is the structure of North Carolina's system for prescribed controlled substance monitoring and abuse prevention?
- Is the state's system for prescribed controlled substance monitoring and abuse prevention effective?
- How can North Carolina's system for prescribed controlled substance monitoring and abuse prevention be improved?

The Program Evaluation Division collected data from several sources, including

- review of state laws, administrative rules, and position statements governing the prescribing, dispensing, and use of controlled substances;
- administrative queries and interviews with officials from the Department of Health and Human Services' Divisions of Medical Assistance, Mental Health, Developmental Disabilities and Substance Abuse Services, and Public Health;
- administrative queries and interviews with health care provider regulatory boards;
- analysis of controlled substance prescribing and dispensing data in North Carolina;
- analysis of public health statistics on controlled substances poisonings and deaths in North Carolina;
- review of staffing and costs for monitoring and preventing the abuse of prescribed controlled substances;
- interviews with state law enforcement officials;
- interviews with federal officials from the U.S. Department of Defense, U.S. Department of Justice's Drug Enforcement Administration, and the U.S. Department of Veteran's Affairs;
- literature review of scientific research on prescribed controlled substances;
- research on laws, policies, and practices concerning prescribed controlled substances in other states; and
- interviews with other states.

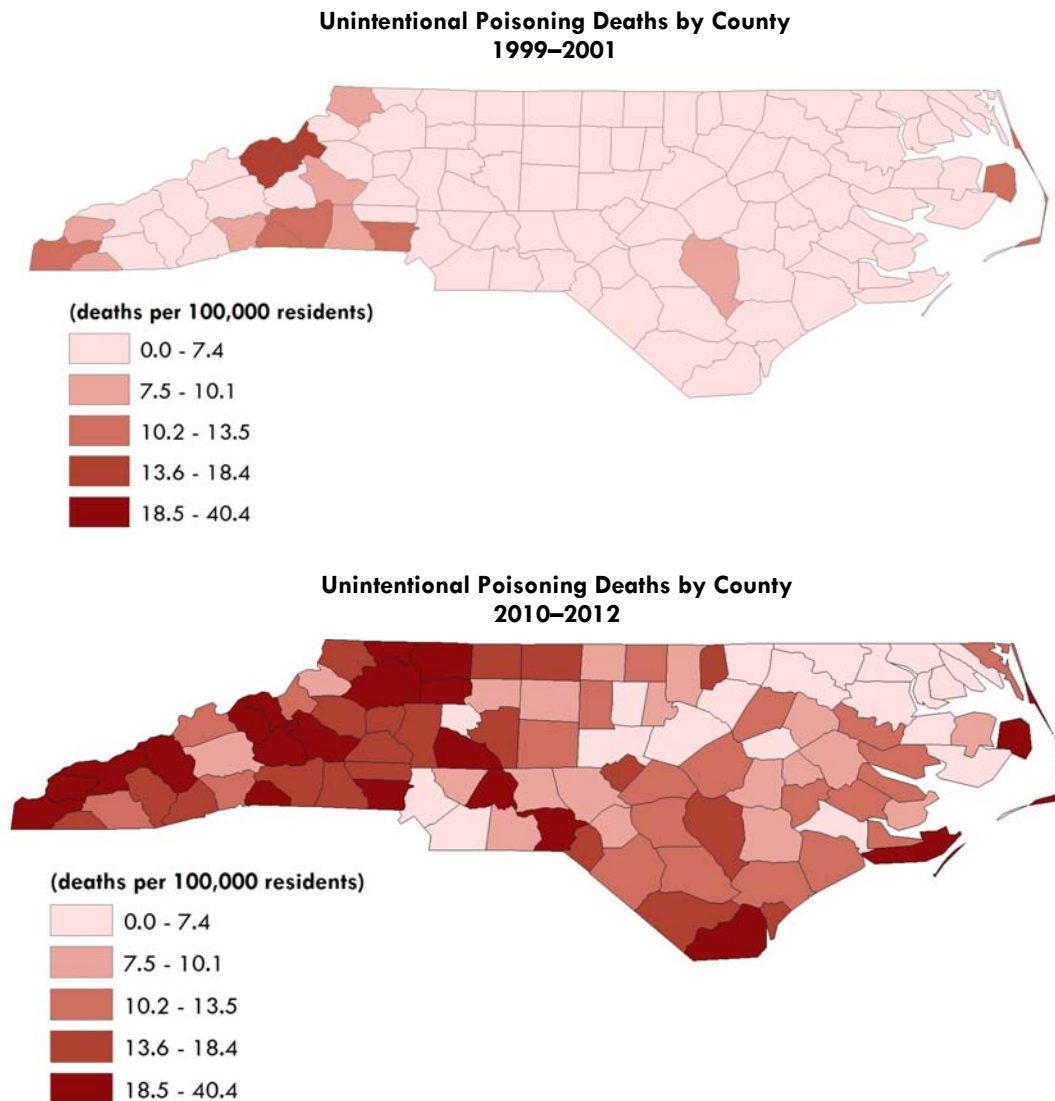
This report has acronyms that appear throughout the background, findings, and recommendations. Appendix A provides a list of acronyms used throughout this report.

¹ This study is part of a larger review of adult alcohol and drug abuse programs, prescription drug abuse, and programs for veterans. This evaluation excludes treatment options for prescribed controlled substances because this topic will be examined in a separate report.

Background

In North Carolina, unintentional poisoning deaths have grown at an alarming rate. According to the North Carolina Division of Public Health, the number of these deaths has increased by nearly 300%. From 1999 to 2001, there were fewer than 7.4 deaths from unintentional poisoning per 100,000 residents for most North Carolina counties. By 2012, unintentional poisoning deaths had doubled in the majority of counties, with 21 counties having more than 18.5 deaths per 100,000 residents.² These rates are consistent with other states in the southeast. Exhibit 1 shows how the death rates from unintentional poisonings have increased over the last decade. From 2008 to 2012, 91% of these deaths are attributable to medication.

Exhibit 1: Unintentional Poisoning Death Rates in North Carolina Have Increased in the Last Decade



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

² The U.S. Centers for Disease Control defines an unintentional poisoning as a poisoning in which the individual exposed to the substance is not attempting to cause harm to himself or herself or others. These deaths include unintentional overdoses from prescription or recreational drugs. Other potential poisons include exhaust fumes and gases, pesticides, acids, organic solvents, and petroleum products.

Medications such as opioids, stimulants, and depressants are the most commonly abused prescribed controlled substances. Controlled substances include classes of legally permissible prescription drugs that have a currently accepted medical use in the United States and a potential for abuse that may lead to physical or psychic dependence on the substance (see Exhibit 2). Federal code and state law categorize these drugs by their potential for abuse and by the severity of their addictiveness³ and require the Department of Health and Human Services to establish and maintain a reporting system of prescriptions for all Schedule II through V controlled substances.⁴ In 2012, over 17.4 million prescriptions for Schedule II–V controlled substances were dispensed in North Carolina.

Exhibit 2: Description of Controlled Substances

State Definition of Controlled Substances	Examples of substances	Legally Permissible	Included in CSRS
Schedule I: Has a high potential for abuse, no currently accepted medical use in the United States, or lacks accepted safety for use in treatment under medical supervision.	<ul style="list-style-type: none"> Cocaine Heroin Methaqualone (Quaalude) 	No	No, outside the system as an illegal substance
Schedule II: Has a currently accepted medical use in the United States or a currently accepted medical use with severe restrictions. The abuse of the substance may lead to severe psychic or physical dependence.	<ul style="list-style-type: none"> Morphine Oxycodone (Oxycontin) Methadone Fentanyl (Sublimaze, Actiq) Amphetamine 	Yes	Yes
Schedule III: Has a potential for abuse less than the substances listed in Schedules I and II and a currently accepted medical use in the U.S. Abuse may lead to moderate or low physical dependence or high psychological dependence.	<ul style="list-style-type: none"> Anabolic steroids Any compound, mixture, or preparation or any suppository dosage form containing amobarbital, secobarbital or pentobarbital Ketamine 	Yes	Yes
Schedule IV: Has a currently accepted medical use in the United States and limited physical or psychological dependence relative to the substances listed in Schedule III.	<ul style="list-style-type: none"> Depressants such as alprazolam (Xanax), clonazepam (Klonopin), diazepam (Valium), and Zolpidem (Ambien) Stimulants such as phentermine (Suprenza) and modafinil (Provigil) Analgesics such as butorphanol (Stadol) Narcotic drugs such as buprenorphine (Buprenex) 	Yes	Yes
Schedule V: Has a currently accepted medical use in the United States and limited physical or psychological dependence relative to the substances listed in Schedule IV.	<ul style="list-style-type: none"> Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams Not more than 100 milligrams of opium per 100 milliliters or per 100 grams 	Yes	Yes
Schedule VI: Has no currently accepted medical use in the United States, a relatively low potential for abuse in terms of risk to public health and potential to produce psychic or physiological dependence liability based upon present medical knowledge, or a need for further and continuing study to develop scientific evidence of pharmacological effects.	<ul style="list-style-type: none"> Marijuana Tetrahydrocannabinols Synthetic cannabinoids 	No	N/A

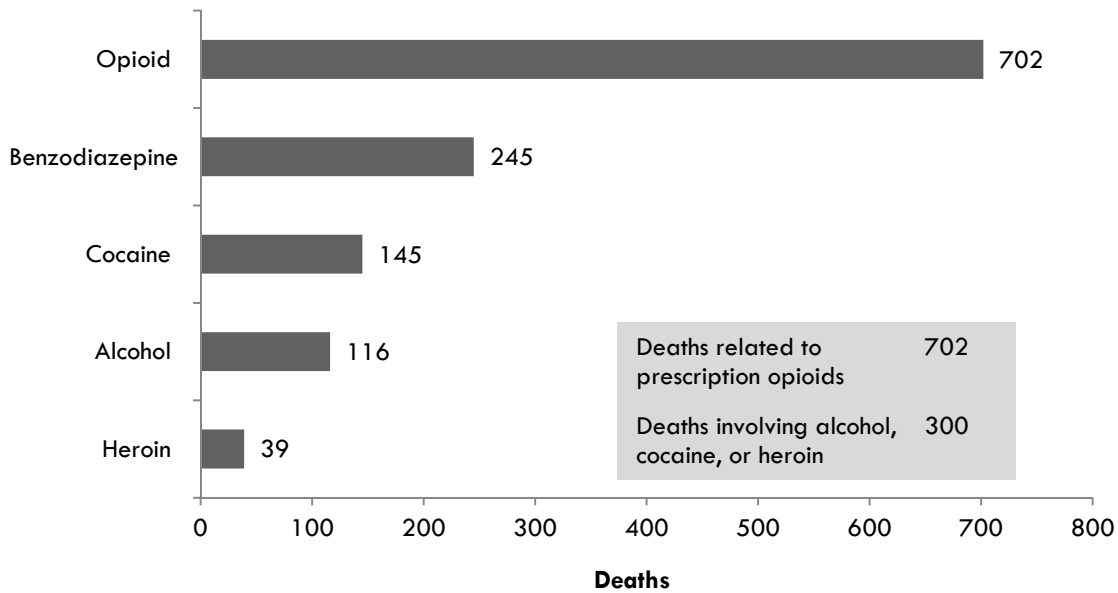
Source: Program Evaluation Division based on a review of General Statutes.

³ N.C. Gen. Stat. § 90-5.

⁴ N.C. Gen. Stat. § 90-113.73.

Opioid pain medications are of particular concern because of their addictive nature and their link to unintentional poisoning deaths. From 1999 to 2012, deaths involving opioid pain medications such as methadone, oxycodone, and hydrocodone increased by over 400% in North Carolina. As Exhibit 3 shows, in 2010 opioid medications were responsible for more deaths than alcohol, cocaine, and heroin combined.

Exhibit 3: In 2010, There Were More than Twice as Many Deaths in North Carolina Related to Prescription Opioids than Deaths from Alcohol, Cocaine, and Heroin Combined



Note: Opioids include morphine, fentanyl, hydrocodone, methadone, and oxycodone. Benzodiazepines include clonazepam, diazepam, and alprazolam. Unintentional poisoning deaths are defined as deaths where the underlying cause was related to the controlled substances listed above.

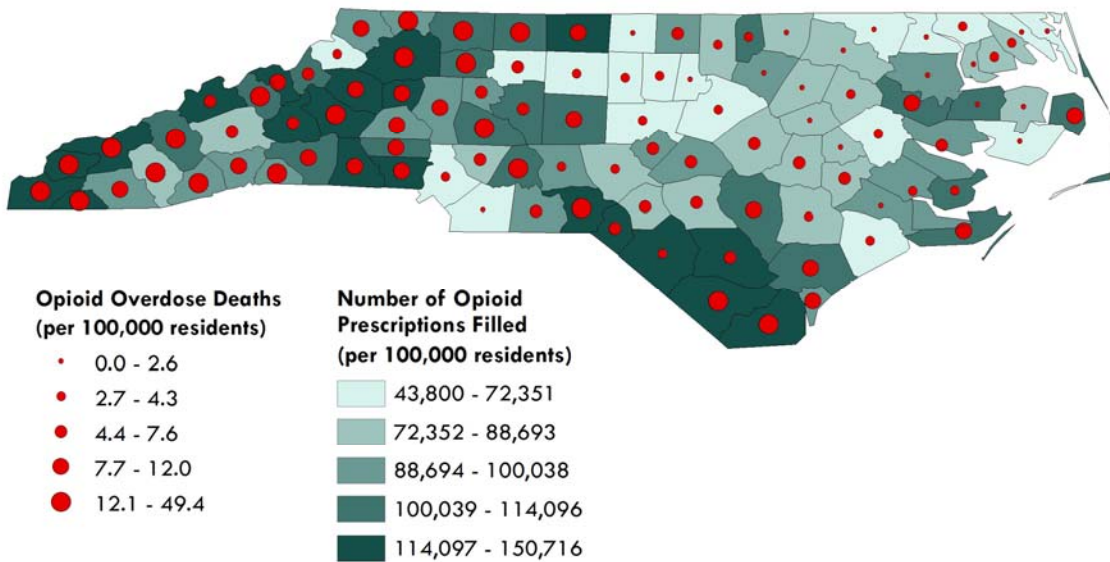
Source: Program Evaluation Division based on data from the Department of Health and Human Services, Division of Public Health, Injury and Violence Prevention Branch.

Most prescribed controlled substances involved in overdose deaths originate from a prescription. According to the U.S. Centers for Disease Control (CDC), very few overdoses from prescribed controlled substances result from drugs obtained through pharmacy theft. Exhibit 4 shows a map of state opioid prescribing and death rates by county. Darker county shading represents higher volume of opioid prescribing; the larger the dot, the higher the death rate per 100,000 residents. The map demonstrates a correlation between county-level opioid prescribing volume and opioid overdose deaths.⁵

Over 90% of accidental overdose deaths are caused by over-the-counter, prescription, or illicit drugs and medications. A 2010 national study on drug use and health found that more than three out of four people who abuse or misuse prescription painkillers use drugs prescribed to someone else. Exhibit 5 shows that 44% of accidental overdoses (for more commonly abused prescribed controlled substances) were associated with prescriptions written to individuals that had been filled within 60 days of death.

⁵ Correlation coefficient = .57.

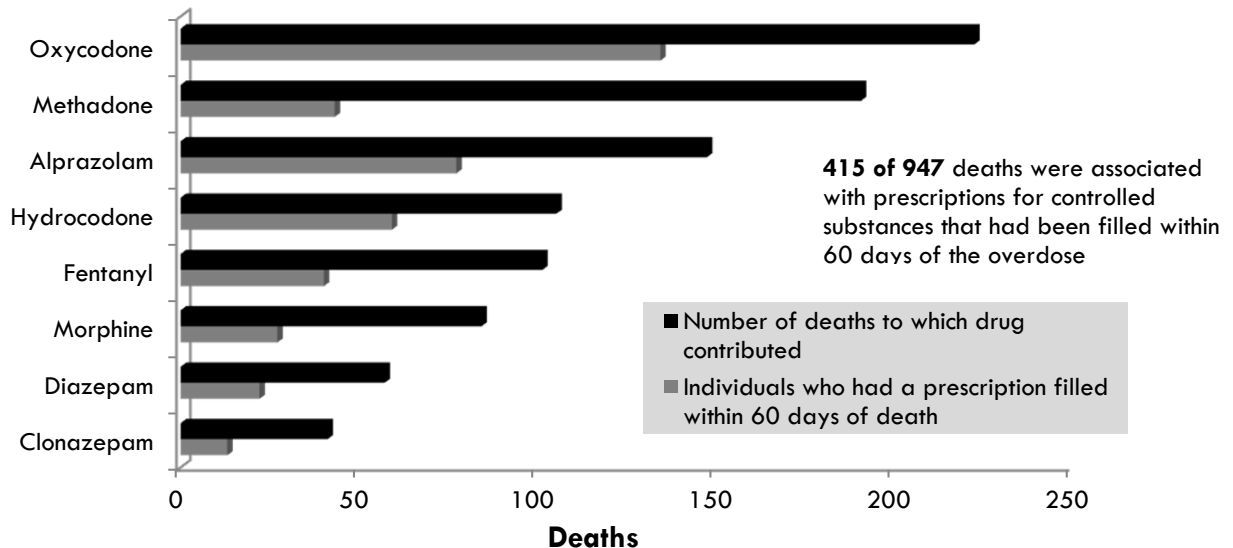
Exhibit 4: As Opioid Prescribing Volume Increases So Do Opioid-Related Overdose Death Rates



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

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 5: In 2010, 44% of North Carolina Accidental Overdose Deaths Were Associated with Prescriptions for Controlled Substances that Had Been Filled within 60 Days of Death



Note: This exhibit reflects accidental overdose deaths associated with the most commonly abused controlled substances and is not an exhaustive list of controlled substances that contributed to all accidental overdose deaths in 2010.

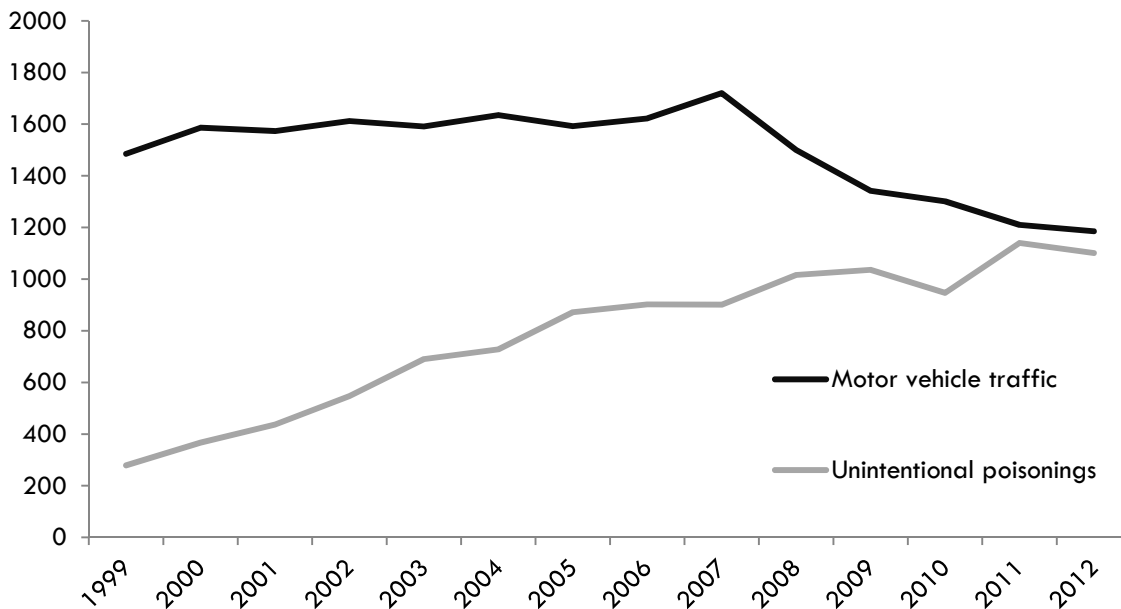
Source: Program Evaluation Division based on data from the Department of Health and Human Services, Division of Public Health, Injury and Violence Prevention Branch.

The National Institutes of Health identifies prescription drug abuse as occurring in the following ways:

- taking a medication that has been prescribed for somebody else;
- taking a drug in a higher quantity or in another manner than prescribed; or
- taking a drug for another purpose than prescribed.

The societal costs of prescribed controlled substance abuse are substantial. In 2010 at the national level, the number of deaths from unintentional poisoning, including drug overdoses, exceeded the number of motor vehicle traffic-related deaths. As Exhibit 6 shows, the number of deaths from unintentional poisoning in North Carolina has grown dramatically since 1999 and is on track to surpass deaths related to motor vehicle traffic.

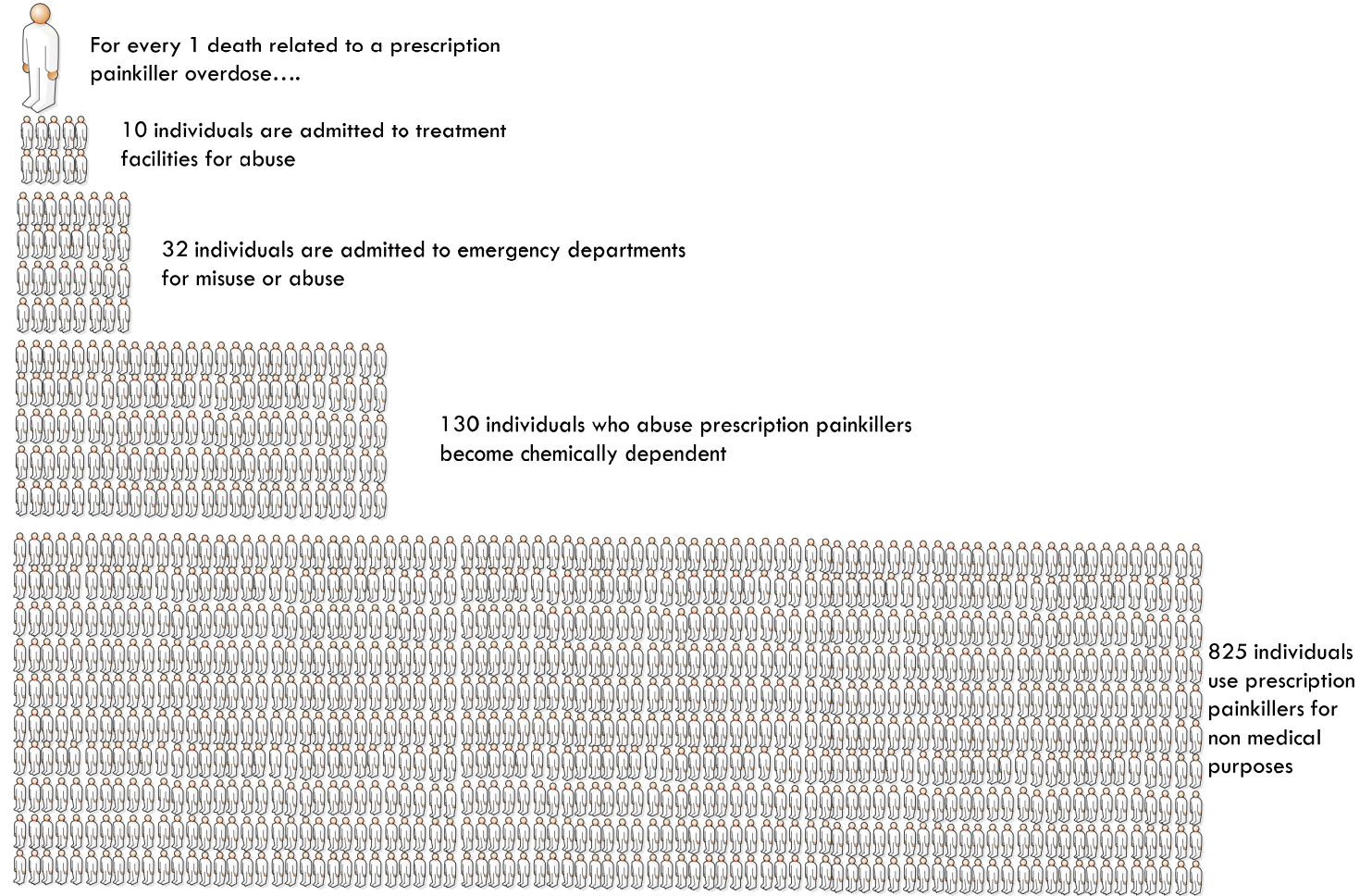
Exhibit 6: In North Carolina, Deaths from Unintentional Poisonings are on Track to Surpass Motor Vehicle Traffic-Related Deaths



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

The number of deaths associated with unintentional poisoning is a growing concern. However, there are additional societal costs associated with this epidemic. The CDC estimates that for every one death associated with unintentional poisoning, 10 people are admitted to treatment facilities. Exhibit 7 provides a visual representation of the CDC’s estimated social cost. According to the National Drug Intelligence Center’s National Drug Threat Survey, violent crime and property crime associated with the abuse of prescribed controlled substances is increasing. Elevated crime rates often result in higher budgetary expenditures. Moreover, the estimated national cost of the abuse of prescribed controlled substances to public and private medical insurers is \$72.5 billion per year. These costs are passed along to consumers and taxpayers through higher health insurance premiums.

Exhibit 7: CDC's Estimated Societal Cost of One Death Related to Prescribed Controlled Substances



Source: The U.S. Centers for Disease Control.

Efforts to reduce the abuse of prescribed controlled substances focus on the prevention of diversion. Diversion occurs when controlled substances that are legal and medically necessary are supplied or used illegally or without medical necessity. Although national surveys and monitoring systems have documented widespread abuse of prescription drugs, and numerous scientific articles have discussed the problems associated with diversion, empirical data on the scope, magnitude, and patterns of diversion remain absent from the literature. Sources of diversion are widespread and include

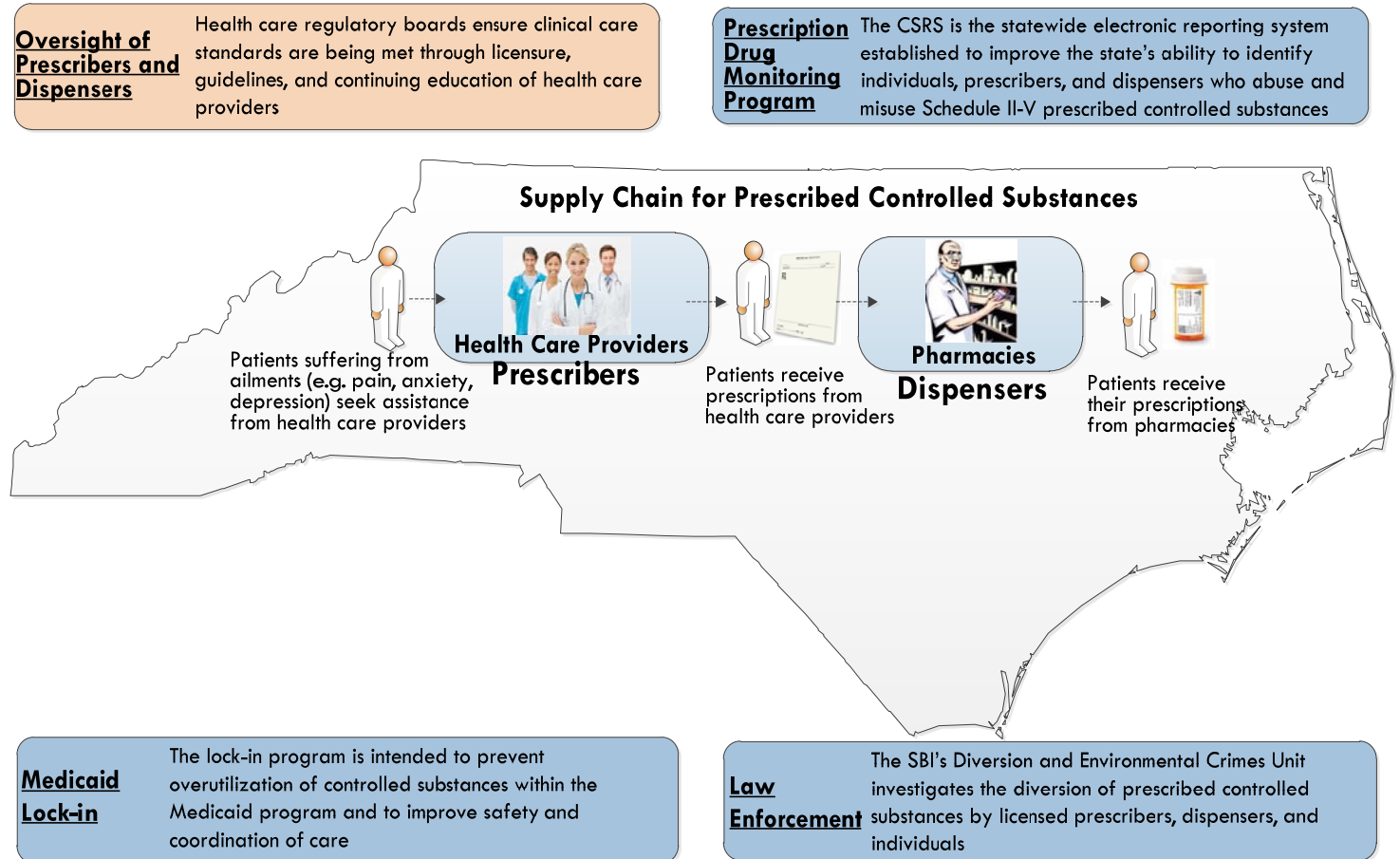
- “doctor shopping” by individuals who visit numerous physicians to obtain multiple prescriptions;
- theft, forgery, or alteration of prescriptions by patients, medical providers, or pharmacists;
- the illegal sale of prescriptions by physicians and those who are colloquially referred to as “loose pharmacists;”
- robberies and theft from manufacturers, distributors, and pharmacies;
- undercounting and pilferage or recycling of medications by pharmacists and pharmacy employees;

- Medicare, Medicaid, and other insurance fraud by patients, pharmacists, and street dealers; and
- medicine cabinet thefts by cleaning staff, repair personnel, and family members in residential settings.

This report focuses on four mechanisms North Carolina possesses to monitor and prevent the abuse of prescribed controlled substances. These mechanisms become more clearly understood within the context of the supply chain for prescribed controlled substances, which can be seen in Exhibit 8. For the purposes of this report, the supply chain is limited to the process for acquiring prescribed, or licit, controlled substances.⁶ Three groups are involved in the supply chain for prescribed controlled substances:

- patients seeking help from health care providers;
- health care providers who write prescriptions (prescribers); and
- pharmacies that fill prescriptions (dispensers).

Exhibit 8: The Supply Chain and Mechanisms for Monitoring the Abuse of Prescribed Controlled Substances



Note: CSRS stands for the Controlled Substances Reporting System. SBI stands for the State Bureau of Investigation.

Source: Program Evaluation Division.

⁶ Because the scope and magnitude of diversion is not clearly quantifiable, the supply chain for illicitly acquired controlled substances is not displayed.

Patients suffering from chronic or acute symptoms seek assistance from health care providers. Licensed health care providers such as physicians, dentists, podiatrists, mid-level practitioners, or other registered practitioners are authorized to write prescriptions to treat patients. There are approximately 41,308 health care providers authorized to prescribe controlled substances in North Carolina. If a hospital or clinic does not directly administer controlled substances, patients go to pharmacies to fill their prescriptions. Approximately 3,350 hospitals, clinics, and pharmacies are registered to dispense prescribed controlled substances in North Carolina.

North Carolina's system for monitoring and preventing the abuse of prescribed controlled substances involves four mechanisms:

- oversight and regulation of prescribers and dispensers by state health care regulatory boards;
- operation of the Controlled Substances Reporting System (CSRS), the State's prescription drug monitoring program;
- operation of the Medicaid lock-in program to review behavior of patients with high usage of prescribed controlled substances; and
- enforcement of state laws for the misuse and diversion of controlled substances.

Oversight and Regulation of Prescribers and Dispensers. Oversight and regulation of prescribers and dispensers is intended to ensure that practicing health care providers meet the requisite competence and character to be granted a license and to ensure that such individuals apply the appropriate clinical care standards to their patients. Within North Carolina, five occupational licensing boards have the responsibility to regulate and oversee health care providers who are authorized by federal law to prescribe controlled substances:

- North Carolina Board of Nursing;
- North Carolina Board of Dental Examiners;
- North Carolina Board of Pharmacy;
- North Carolina Board of Podiatry Examiners; and
- North Carolina Medical Board.

As Exhibit 6 shows, health care providers offer an early point of intervention along the supply chain for prescribed controlled substances.

Prescription Drug Monitoring Programs. Prescription drug monitoring programs (PDMPs) operate statewide electronic databases of prescribed controlled substances. Information collected by PDMPs is often used to

- support the monitoring of legitimate medical use of controlled substances;
- identify and prevent drug abuse, misuse, and diversion;
- facilitate the identification of individuals addicted to prescribed controlled substances and enable intervention and treatment of these individuals;
- identify trends to inform public health initiatives; and
- inform policy-making.

North Carolina's PDMP is operated by the Controlled Substances Regulatory Branch within the Division of Mental Health, Developmental Disabilities, and

Substance Abuse Services, in the Department of Health and Human Services. The Controlled Substances Reporting System (CSRS), administered by the branch, is an electronic database that contains data on prescribed controlled substances dispensed in the State. State law established the CSRS to improve the State's ability to identify individuals who abuse prescribed controlled substances.⁷ The CSRS is an important tool because this repository serves as the State's primary information system for monitoring the behavior of prescribers, dispensers, and patients.

Medicaid lock-in. The Medicaid lock-in program is designed to prevent overutilization of controlled substances and to improve safety and coordination of care. The lock-in program works by restricting select Medicaid enrollees to one prescriber of controlled substances and one pharmacy. Lock-in enrollees are then required to obtain all prescriptions for controlled substances from their designated lock-in prescriber and lock-in pharmacy in order for Medicaid to pay the claim. Lock-in can decrease the overutilization of controlled substances and the inappropriate use of health care services. In addition, because North Carolina administers and pays a portion of Medicaid program expenses, lock-in offers the potential of cost savings by reducing costs to Medicaid for controlled substances and associated health care services.

Law Enforcement. Law enforcement entities only become involved when patients, prescribers, and dispensers are suspected of illegal activity. Within North Carolina, the State Bureau of Investigation (SBI) is responsible for statewide enforcement of the federal Controlled Substances Act. The SBI's Diversion and Environmental Crimes Unit (DECU) investigates large-scale multi-jurisdictional drug cases, diversion issues with healthcare facilities and pharmacies, cases involving medical providers, and suspicious and overdose deaths involving prescription narcotics. The DECU also provides assistance to local law enforcement and district attorney's office. The DECU relies on prescriber and dispenser data contained in the CSRS to inform and build diversion investigations.

In 2013, the General Assembly adopted measures to improve the system for monitoring and preventing the abuse of prescribed controlled substances, including

- expanding CSRS reporting by authorizing unsolicited, automated reporting to oversight boards and prescribers;
- streamlining prescriber access by authorizing delegate accounts;
- making data more timely by reducing the reporting interval for pharmacies to the CSRS from every seven days to every three business days;
- enhancing Medicaid lock-in capabilities by requiring reporting of prescription payment method to the CSRS;
- providing the Attorney General with the option to refer unusual patterns of prescribing to appropriate local law enforcement;
- allowing DECU agents to share information from the CSRS with other SBI agents involved in drug investigations;

⁷ N.C. Gen. Stat. § 90-5.

- deterring unlawful use of the CSRS by increasing the maximum penalty from \$5,000 to \$10,000;
- providing protection to an individual seeking medical attention for themselves or a friend for a drug-related overdose; and
- providing immunity from civil or criminal liability for individuals who prescribe and/or administer medications to reverse overdoses.

Although these changes will improve North Carolina's system for monitoring and preventing abuse of prescribed controlled substances, the State has yet to conduct a full evaluation of this system. This report seeks to identify further improvements North Carolina could make to strengthen the system for monitoring and preventing the abuse of prescribed controlled substances.

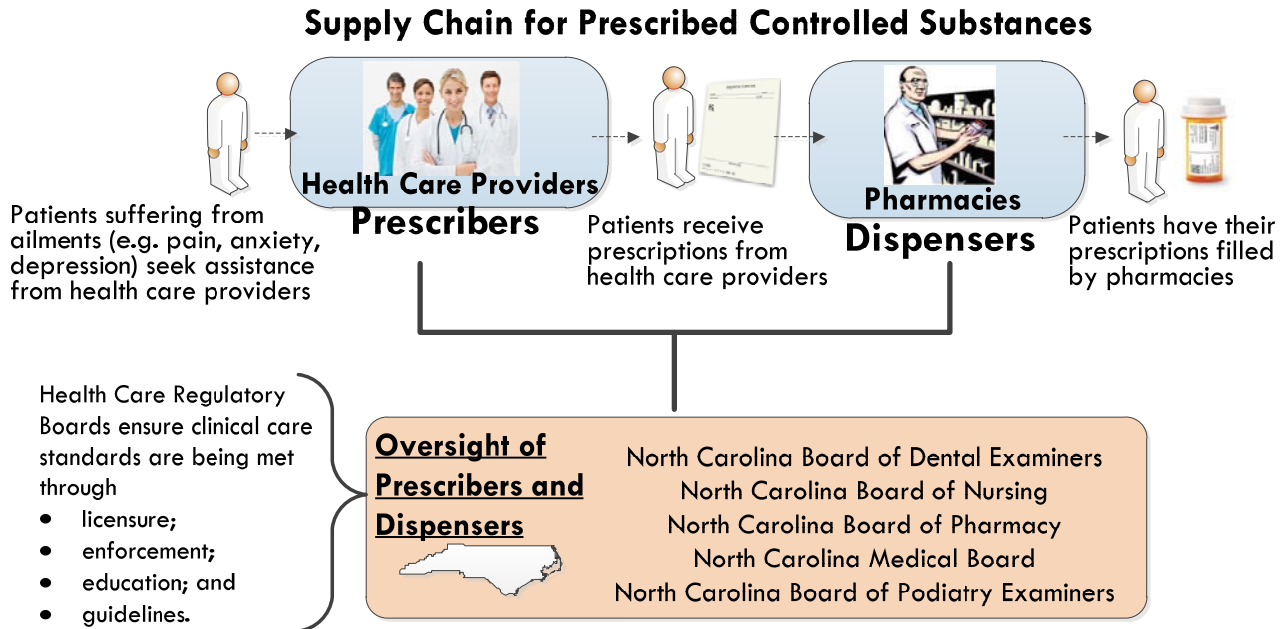
Findings

Finding 1. North Carolina's system for monitoring and preventing the abuse of prescribed controlled substances lacks adequate statewide prescribing guidelines that apply to all health care providers and continuing education requirements for prescribers.

The occupational licensing boards oversee and regulate health care providers and pharmacies that prescribe and dispense controlled substances. These boards provide licensure, publish guidelines, establish continuing education requirements, and enforce policy, administrative rules, and state law. These oversight and regulatory tools ensure prescribers and dispensers meet competence and character requirements to be granted a license and ensure health care providers are applying appropriate clinical care standards to their patients.

Exhibit 9 shows how the state occupational licensing boards are involved in the supply chain for prescribed controlled substances. These boards have three tools to ensure clinical care standards are being met: licensure, education, and guidelines. The exhibit also shows the importance of these boards in overseeing and regulating health care providers or prescribers, who are a patient's first stop along the supply chain and offer an early opportunity to intervene to prevent abuse.

Exhibit 9: Occupational Licensing Boards Oversee and Regulate Prescribers and Dispensers



Source: Program Evaluation Division based on a review of occupational licensing board oversight.

Written guidelines are an important tool for regulation and oversight of prescribers. Medical guidelines are typically statements or policy positions intended for clinical practices that include recommendations for optimizing patient care. Guidelines are based on a systematic review of evidence and developed by a panel of multidisciplinary experts. Guidelines also provide a clear explanation of the logical relationships between alternative care options and health outcomes and provide ratings of both the quality of evidence and the strength of recommendations.

Guidelines for prescribing controlled substances are an effort to educate health care providers and improve the care and safety of patients. Research conducted in 2005 by the State of Washington suggests opioid-related deaths may be preventable through use of prudent guidelines regarding opioid use for chronic pain.⁸ Guidelines related to opioid-based pain treatment have grown in prevalence due in part to research that indicates patients receiving higher doses of prescribed opioids are at increased risk for overdose death. For example, recent scientific studies have found

- patients with chronic pain receiving higher doses of opioids (50-100mg/day) were more than four times as likely to die from an overdose as chronic pain patients receiving lower doses (1-20mg/day).⁹
- patients receiving 100 mg/day or more of opioids were almost nine times as likely to die from an overdose.¹⁰

⁸ Franklin, G.M et al. (2005). Opioid Dosing Trends and Mortality in Washington State Workers' Compensation, 1996–2002. *American Journal of Industrial Medicine*, 48(2), 91–99.

⁹ Dunn, K.M. et al. (2010). Opioid Prescriptions for Chronic Pain and Overdose. *Annals of Internal Medicine*, 152(2), 85-92.

¹⁰ Bohnert, A.S.B. et al. (2011). Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths. *Journal of the American Medical Association*, 305(13), 1315-1322.

North Carolina does not have statewide prescribing guidelines that apply to all health care providers. In the absence of statewide guidelines, each health care regulatory board is responsible for establishing prescribing guidelines for the providers they oversee. The North Carolina Board of Dental Examiners and the North Carolina Board of Nursing have not established prescribing guidelines.¹¹ The North Carolina Medical Board oversees and regulates the remainder of physicians in the State and has adopted a policy for the use of controlled substances in the treatment of pain. Representatives from the North Carolina Medical Board state that this policy serves as the board’s guidelines.¹² However, as Exhibit 10 shows, according to the criteria established by the Institute of Medicine of the National Academies, the North Carolina Medical Board’s current policy on pain management does not meet the criteria for clinical practice guidelines compared to the federal government and other states.¹³

Exhibit 10: North Carolina Medical Board’s Policy on Pain Management Does Not Meet Criteria for Trustworthy Clinical Practice Guidelines

	North Carolina	Federal Government	Ohio	Utah	Washington
Pain management guidelines document	Policy for the Use of Controlled Substances for the Treatment of Pain	Management of Opioid Therapy for Chronic Pain	Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain	Utah Clinical Guidelines on Prescribing Opioids	Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain
Scope of guidelines	Chronic pain	Chronic pain	Chronic, non-cancer pain	Acute and chronic pain	Chronic, non-cancer pain
Issued by	North Carolina Medical Board	Departments of Veterans Affairs and Defense	Governor’s Cabinet Opiate Action Team	Utah Department of Health	Washington State Agency Medical Directors’ Group
Last updated	September 2008	May 2010	May 2013	August 2008	2010
Follows Criteria for Trustworthy Clinical Practice Guidelines					
Developed by multi-disciplinary experts	No	Yes	Yes	Yes	Yes
Based on a review of evidence	No	Yes	Yes	Yes	Yes
Rates the quality of evidence reviewed	No	Yes	No	Yes	Yes
Explains alternative care and assesses benefits and harms of alternative treatment	No	Yes	No	Yes	Yes
Rates the strength of recommendations	No	Yes	No	No	No

Note: The Institute of Medicine of the National Academies established criteria for trustworthy clinical practice guidelines in 2011.

Source: Program Evaluation Division based on a review of pain management guidelines in North Carolina, at the federal level, and in other states.

¹¹ The North Carolina Medical Board and the North Carolina Board of Nursing jointly share jurisdiction over advanced practice nurses.
¹² The North Carolina Board of Podiatry Examiners adopted this policy statement in February of 2011.
¹³ Guidelines from the federal government, Ohio, Utah, and Washington state were chosen for comparison because stakeholders and other subject matter experts cited these entities as having robust prescribing guidelines.

The North Carolina Medical Board's Policy for the Use of Controlled Substances for the Treatment of Pain was not developed for North Carolina.

The policy was adopted from the Federation of State Medical Boards. The policy does not document the empirical evidence reviewed to inform the guidelines, nor does the policy include ratings of the empirical evidence used to support clinical care recommendations. The policy does not explain alternative care or assess benefits and harms of alternative treatment, nor does it rate the strength of the clinical recommendations.

The policy is out-of-date. Literature states that changes in empirical evidence, the resources available to health care professionals, and improvements in technology are all possible reasons for updating clinical guidelines. The North Carolina Medical Board's policy statement was adopted in 1996. The board modified the policy in 2005 based on the Federation of State Medical Board's *Model policy for the use of controlled substances for the treatment of pain*, and amended it again in 2008. The policy has not been updated since 2008, and in the intervening time period there have been significant developments regarding evidence-based opioid prescribing levels and the likelihood of overdose death.¹⁴ As a result, other states have developed clinical recommendations based on opioid dosing thresholds. During the course of this evaluation the North Carolina Medical Board acknowledged its policy is out-of-date and has taken measures to draft new opioid prescribing guidelines. As of March 2014, the North Carolina Medical Board has adopted new draft prescribing guidelines for the purpose of soliciting external review and comments from stakeholders and the public. Because these guidelines are still in draft form, the Program Evaluation Division reviewed the currently applicable guidelines for this report.

Compared to the federal government and other states, the North Carolina Medical Board's policy lacks definition and would be enhanced by supplementary tools. According to the Institute of Medicine of the National Academies, clinical guidelines are typically statements or policy positions that include recommendations for clinical practices intended to optimize patient care. Recommendations for clinical care are often supplemented by tools health care providers can use to aid the implementation of these recommendations. Exhibit 11 shows the North Carolina Medical Board's policy compared to guidelines of the federal government and other selected states. The North Carolina Medical Board's policy makes recommendations for using the State's controlled substances reporting system and performing routine and/or random drug testing. These recommendations are made for high-risk patients; however, the policy does not define the criteria for a high-risk patient. By contrast, the State of Washington and Utah guidelines provide an opioid assessment tool to assist health care providers in identifying high-risk patients. Compared to federal and other states' guidelines, the North Carolina Medical Board policy does not make recommendations for dosing thresholds or provide any tools to supplement recommendations for clinical care. Meanwhile, the State of Washington provides tools for assessing patient pain, opioid dose calculation and risk assessment, pain management agreements, and drug testing.

¹⁴ Bohnert, A.S.B. et al. (2011). Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths. *Journal of the American Medical Association*, 305(13), 1315-1322.

Exhibit 11: North Carolina's Prescribing Guidelines Lack Definition and Clinical Tools

	Fed. Government	North Carolina	Ohio	Utah	Washington
Recommendations to optimize patient care include					
Patient education	●	●	●	●	●
Setting a dosage threshold for physician consultation	●	○	●	●	●
Use of PDMP to review patient behavior	○	◐	●	●	○
Specialty consultation for addiction or other co-occurring conditions	●	●	●	●	●
Patient pain treatment agreements	●	●	●	●	●
Routine and/or random drug testing to confirm appropriate use	●	◐	○	●	●
● = Included in guidelines ◐ = Included in guidelines but ill-defined ○ = Not included in guidelines					
Guidelines include clinical tools for					
Function and assessment of pain	X	X	X	✓	✓
Opioid dosing calculations	✓	X	X	X	✓
Opioid risk tool	X	X	X	✓	✓
Patient pain management agreement	✓	X	X	✓	✓
Patient education resources	X	X	X	X	✓
Urine drug testing	✓	X	X	✓	✓
✓ = Guidelines include clinical tools X = Guidelines do not include clinical tools					

Source: Program Evaluation Division based on a review of federal and other state guidelines.

Health care provider education is another tool for the State to ensure that regulatory boards are licensing competent medical professionals.

Educating prescribers on the abuse of controlled substances is important because interventions by health care providers can be effective in reducing substance abuse.

In 2000, a national survey of medical residency programs found only 56% of programs required substance abuse disorder training. Of those programs, the number of hours required varied between 3 and 12 classroom hours.¹⁵ A 2008 follow-up survey found progress in medical school, residency, and post-residency substance abuse education, yet efforts have not been uniformly applied in all residency programs or medical schools. As a result, the role of North Carolina health care provider regulatory boards in ensuring that prescribers receive continuing education is important.

North Carolina health care provider regulatory boards do not require licensees to obtain continuing education on the importance of appropriate prescribing or dispensing of controlled substances. After completing their initial education and training, health care providers engage in continuing education activities to stay up-to-date on and adopt proven medical advances. State law grants authority to the boards to require a licensee to submit evidence of the licensee's continuing competence through the completion of continuing education units.¹⁶ Each health care provider board has annual requirements for license renewal. However, none of the health

¹⁵ Isaacson JH, Fleming M, Kraus M, Kahn R, Mundt M. (2000) A National Survey of Training in Substance Use Disorders in Residency Programs. *Journal of Studies on Alcohol and Drugs*. 61(6), 912-915.

¹⁶ N.C. Gen. Stat. § 90-31.1 (North Carolina Board of Dental Examiners), N.C. Gen. Stat. § 90-171.23(b)(20) (North Carolina Board of Nursing), N.C. Gen. Stat. § 90-85.17 (North Carolina Board of Pharmacy), N.C. Gen. Stat. § 90-5.1.(a)(4) (North Carolina Medical Board), N.C. Gen. Stat. § 90-202.11 (North Carolina Board of Podiatry Examiners).

care provider regulatory boards require topic-specific continuing education for all their licensees.

Nationally, the American Society of Addiction Medicine (ASAM), the American Medical Association (AMA), and the National Alliance for Model State Drug Laws (NAMSDL) have all taken positions on health care provider education and training associated with the abuse of controlled substances. In a 2012 policy statement, NAMSDL identified components of strong prescription drug monitoring statutes which included requirements for health care providers to receive education on proper prescribing practices, pharmacology, and the identification, treatment, and referral of patients addicted to or abusing controlled substances. The House of Delegates policy-making body of the AMA has called on the association to promote doctor training on the correct use of controlled substances in an effort to reduce substance abuse. The ASAM recommends mandatory prescriber education on the risks associated with controlled substances as part of any public policy response to the issue.

Currently, 11 states require continuing education in either pain management or prescribing of controlled substances.¹⁷ For example, Iowa's Board of Medicine has adopted rules requiring all licensed physicians to complete continuing education on chronic pain medication management. According to the board, the change represents an effort to assist physicians in reducing patients' abuse of pain medications. Under the rules, physicians who regularly provide primary health care to patients, including emergency room physicians, family physicians, general practice physicians, internists, neurologists, pain medicine specialists, and psychiatrists seeking renewal of their license, must complete two hours of accredited training on chronic pain management and two hours of accredited training on end-of-life care every five years.

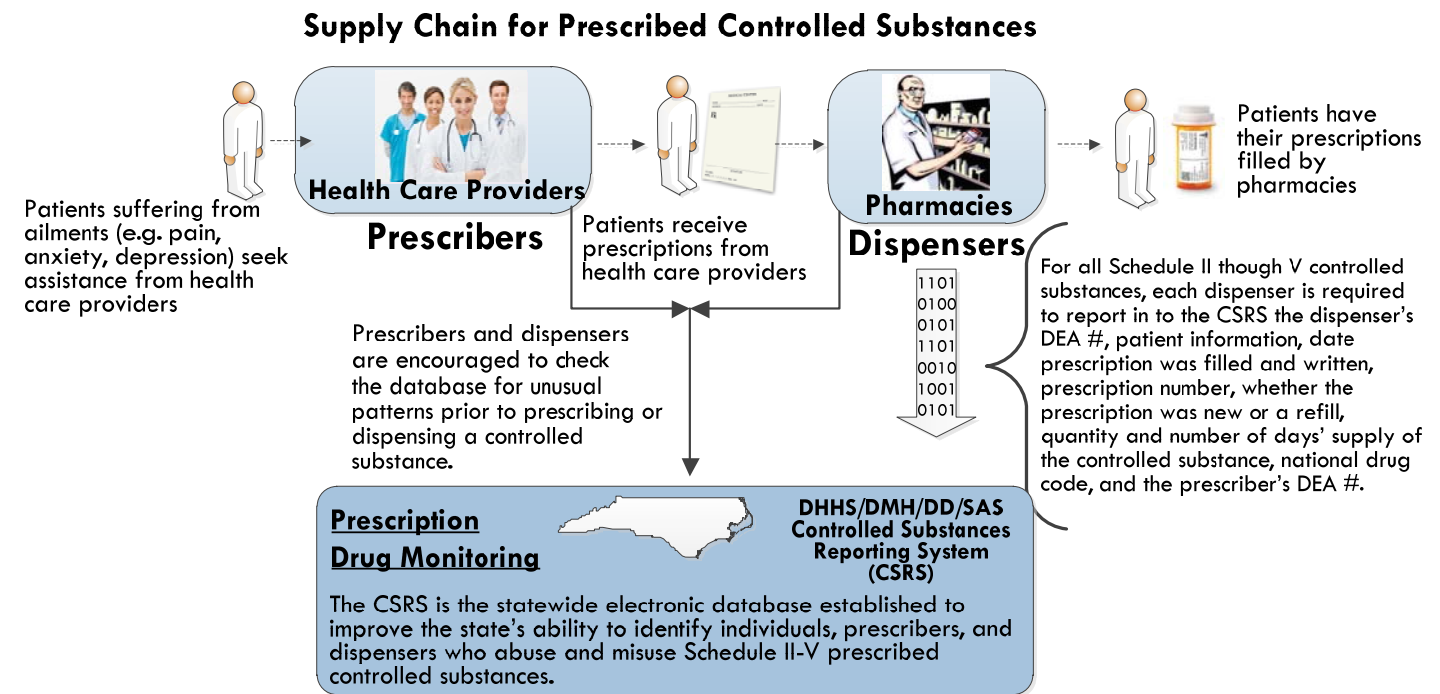
In summary, clinical practice guidelines are statements or policy positions that include recommendations for practice intended to optimize patient care. Of North Carolina's health care regulatory boards, only the North Carolina Medical Board has adopted a policy for the use of controlled substances for the treatment of pain. However, the policy does not meet criteria for trustworthy clinical guidelines and is out-of-date. The recommendations for clinical care are not comprehensive and fail to define high-risk patients. Furthermore, the occupational licensing boards that regulate and oversee health care providers do not require all licensees to obtain continuing education on the abuse of prescribed controlled substances. Oversight and regulation of health care providers by the occupational licensing board can be strengthened by focusing on establishing statewide prescribing guidelines and requiring topic-specific continuing education on the abuse of prescribed controlled substances.

¹⁷ States that require continuing education units in either pain management or prescribing controlled substances are California, Iowa, Massachusetts, New Mexico, Ohio, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.

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

The Controlled Substances Reporting System (CSRS) is North Carolina’s prescription drug monitoring program (PDMP). State law established the CSRS in 2005 as a statewide electronic database intended to improve monitoring of the abuse of prescribed controlled substances. Exhibit 12 shows how the electronic database is populated by dispensers. Once registered, prescribers, dispensers, and other users access the CSRS through a website and can check the CSRS database for unusual patterns prior to prescribing or dispensing a controlled substance.

Exhibit 12: Data Provided by Dispensers Populates the CSRS, Which Creates a Useful Tool to Observe Unusual Patterns in the Supply Chain



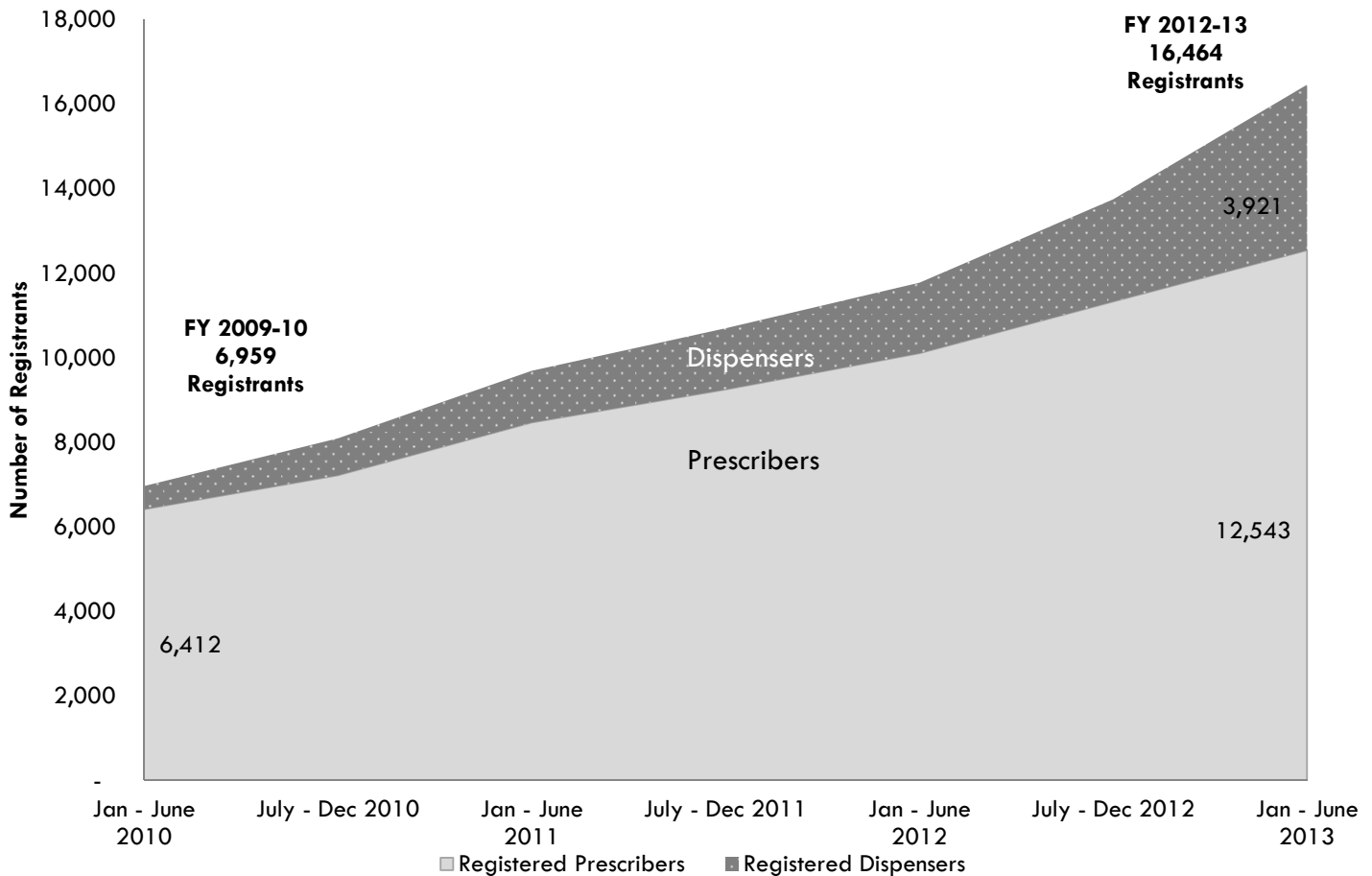
Source: Program Evaluation Division based on a review of CSRS operations and processes.

Access to data and information maximizes the utility of the CSRS for the widest range of appropriate end users. Access not only refers to who has the legal authority to use the CSRS but actual registration and utilization of the CSRS. North Carolina has received the Harold Rogers Prescription Drug Monitoring Program grant from the U.S. Department of Justice for development of the CSRS. As part of this grant, the State is required to report several performance measures, including the registration and use of the CSRS, to the federal government on a biannual basis.

As Exhibit 13 shows, since Fiscal Year 2009–10 the number of prescribers and dispensers registered to access the CSRS has more than doubled. The occupational licensing boards have taken the initiative to improve access to registration by hosting registration online through their websites. Previously, registration was paper-based and required notary certification. Now, the prescriber’s or dispenser’s state license number provides the authentication

that is otherwise fulfilled by the notary requirement. In addition, the North Carolina Board of Nursing is poised to require CSRS registration for licensure of nurse practitioners. These measures will ensure that registration continues to grow.

Exhibit 13: Registration for the CSRS Has Grown Steadily Since 2010



Source: Program Evaluation Division based on CSRS registration data.

The Program Evaluation Division sought to determine if CSRS registrants include the health care provider population prescribing controlled substances that pose the greatest risk for overdose death. Analysis showed that of the 1,672 health care providers who prescribed opioid units in 2012, 38% were registered to use the CSRS. These registration rates improve among individuals who prescribe the most opioids; 68% of those prescribing the most opioid units are registered to use the CSRS.¹⁸ These results demonstrate CSRS registration efforts are targeting the most appropriate users of the system. However, this performance measure is not currently being tracked by the Controlled Substance Regulatory Branch (CSRB) because operations data such as registration is not being paired with prescribing data contained in the CSRS.

¹⁸ Individuals who prescribe the most opioids are defined as those in the 75th percentile of opioid prescribing in 2012.

Despite increased registration, the CSRS appears to be underutilized. The CSRS records each time a prescriber, dispenser, or individual authorized to conduct investigations queries the records associated with a patient, customer, or open case. Even though the number of CSRS queries has grown by 85% since Fiscal Year 2010-11, a closer look at the numbers suggests the CSRS is underutilized. In 2012 there were 17.4 million prescriptions for controlled substances dispensed in North Carolina. In that same time frame the CSRS was queried by prescribers and/or dispensers 1 million times, or 6% of the time a prescription for a controlled substance was written or filled.¹⁹

While the CSRS may be underutilized, mandating its use poses enforcement challenges. In 2013 the General Assembly considered a bill that would have mandated the use of the CSRS. Senate Bill 286 would have required each person authorized to prescribe or dispense a controlled substance to review all information pertaining to the patient in the CSRS for the preceding 12-month period to determine if the prescription is medically necessary and appropriate.²⁰ During this evaluation, officials from the CSRB, State Bureau of Investigation (SBI), and the health care provider oversight boards expressed concern that mandating use of the information system could compromise the utility of the CSRS as a clinical care tool. Furthermore, some officials raised questions over how such a requirement would be enforced and who would have the resources to enforce such a law.

Utilization of the CSRS remains low, but streamlining how users access the CSRS and removing barriers to access provides opportunities to increase utilization by health care providers and law enforcement. The CSRS is accessed through a website that requires sign-in and password authentication, which can be time-consuming and cumbersome. Linking CSRS data to a Health Information Exchange (HIE) could provide a single point of entry for health care providers to access accurate information on admission records, diagnoses, treatment, prescriptions, and procedures, etc. that is integrated into the workflow of the healthcare provider.²¹ Currently, HIEs are not able to access CSRS information.

The General Assembly enacted Session Law 2011-337 establishing the North Carolina Health Information Exchange (NC HIE). The purpose of the NC HIE is to improve the quality of health care delivery by facilitating and regulating the use of a voluntary, statewide health information exchange network for the secure electronic transmission of individually identifiable health information among health care providers, health plans, and health care clearinghouses. State law requires all hospitals with electronic health records systems to connect to the NC HIE for purposes of reporting clinical data on services paid with Medicaid funding.

Currently, NC HIE is working toward statewide implementation. As of December 2013, NC HIE estimated it would have its services in 20 different hospitals across the State by January 2014. Linking CSRS data to the NC HIE would improve standards for clinical care by

¹⁹ Prescriptions for controlled substances can be queried through the CSRS multiple times.

²⁰ This bill is not eligible for consideration during the 2014 short session.

²¹ Electronic HIEs allows doctors, nurses, pharmacists, other health care providers, and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety, and cost of patient care.

- allowing patient-level information on prescribed controlled substances to become part of the workflow of the medical provider; and
- reducing the time and effort needed for prescribers and dispensers to access a patient's prescription history.

Linking individual CSRS data to the NC HIE would require changes to the CSRS contract which would cost the State an estimated \$5,100 for a one-time connection to the NC HIE and \$15,000 in annual service fees.

State law prevents the Drug Enforcement Administration (DEA) from requesting or obtaining patient, prescriber, or dispenser records from the CSRS; removing this barrier would increase the frequency of use of the CSRS and allow the State to focus resources on its own investigative priorities. Enforcement of controlled substance laws is a responsibility shared by state and federal governments. The Drug Enforcement Administration (DEA) is the federal agency performing nationwide enforcement. Within North Carolina, the State Bureau of Investigation (SBI) Diversion and Environmental Crimes Unit (DECU) has the law enforcement responsibility. Both law enforcement entities have a common objective of reducing diversion, which occurs when controlled substances that are legal and medically necessary are supplied or used illegally or without medical necessity.

The SBI caseload consists mostly of large-scale prescription drug fraud rings typically involving 10-30 suspects that often become multi-jurisdictional, with SBI leading investigations in collaboration with other states, local, federal, and regulatory agencies. The DECU has 13 agents who investigate large-scale, multi-jurisdictional drug diversion cases.²² From Fiscal Years 2004–2007, DECU caseload grew by an estimated 370%. Since Fiscal Year 2009, the DECU has averaged 26 cases per year per agent.

Currently, access to the CSRS database is granted to agents assigned to the DECU for bona fide diversion investigations. State law also authorizes DECU agents to share information from the CSRS within SBI. The DEA must access CSRS data through the DECU. This arrangement requires the DECU to open an official case, which is time-consuming, cumbersome, and diverts resources away from state priorities. Both federal and state law enforcement officials report this arrangement as being a burden on resources. Granting federal law enforcement agents the ability to request information directly from the CSRS would allow both agencies to focus time and resources on their own cases, improving investigative efficiencies and increasing the caseload capacity for both law enforcement agencies.

Other states have removed this administrative barrier by providing information directly to the DEA. Two states in the southeast allow the DEA access to PDMP information:

- Virginia law directs the state PDMP to provide information relevant to a specific investigation of a patient, dispenser, or prescriber to an agent of a federal law enforcement agency with authority to conduct drug diversion investigations. To obtain this information, federal officers must comply with federal law and departmental regulations.

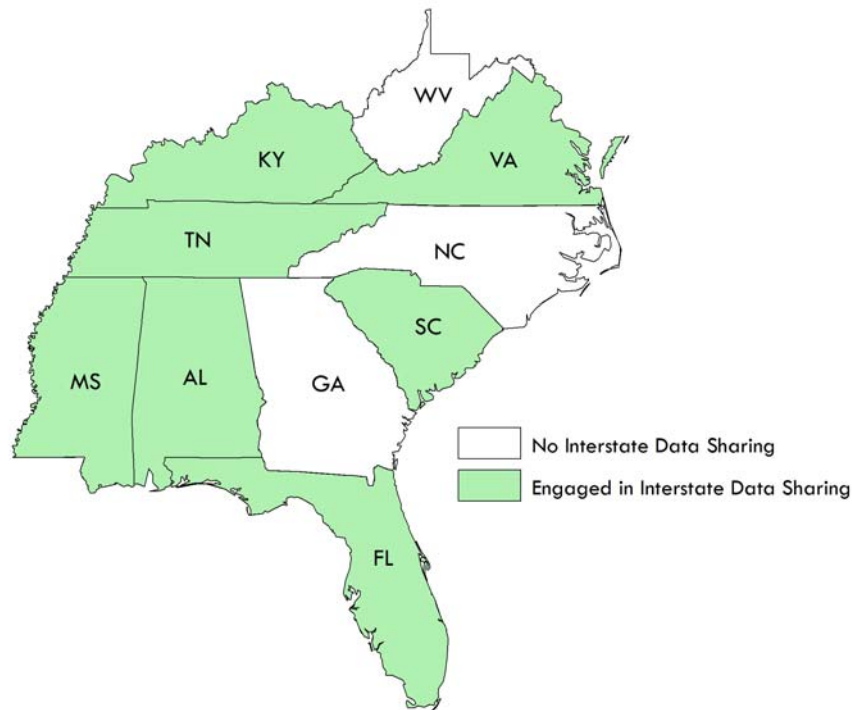
²² The DECU also works on investigations related to environmental crime, but DECU staff estimate these investigations account for only 10% of its workload.

- Kentucky law authorizes the Cabinet for Health and Family Services to disclose information from the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system to federal law enforcement entities. In Kentucky, federal law enforcement officers are authorized to query KASPER to obtain individual patient information. Due to the volume of information involved, system requests on prescribers and dispensers must be sent to and processed by KASPER staff.

Establishing interstate data connectivity would broaden the State’s ability to monitor the abuse of prescribed controlled substances. Enabling interstate data connectivity is increasingly important in North Carolina because the SBI reports that many of their investigations include multiple states with assistance from local, federal, and other law enforcement agencies. Enabling interstate data sharing would allow North Carolina to collaborate more closely with other states. For states that have urban areas that straddle or are close to the state border, interstate connectivity is essential. For example, given the population size of Asheville and Charlotte and their proximity to borders, establishing interstate data connectivity with South Carolina and Tennessee would be advantageous for North Carolina. Combining data from neighboring states increases the capacity to identify diversion and unusual prescribing practices among participating states.

As of January 2014, 24 states participated in interstate data sharing between PDMPs under a variety of statutory and regulatory protocols; North Carolina is not one of these 24 states. Exhibit 14 shows the 10 states in the southeast region, including the three states that do not participate in interstate sharing of prescribed controlled substances data.

Exhibit 14: North Carolina is a Gap in the Southeast for Interstate Controlled Substances Data Sharing



Source: Program Evaluation Division based on data from the Prescription Drug Training and Technical Assistance Center at Brandeis University.

In order to participate in interstate data sharing, a state must:

- enact legislation enabling it to share live patient data with other states;
- identify at least one other state to serve as an exchange partner; and
- establish a memorandum of understanding to share with the identified exchange partner(s) or ratify the Prescription Drug Monitoring Interstate Compact (the compact).

The compact provides a secure and authorized way to exchange prescription drug monitoring program data among member states. However, it does not mandate how member states operate their individual programs. The compact establishes consistent policies among member states to minimize the cost of nationwide data sharing and establishes security requirements for the shared use and exchange of data. According to the Council of State Governments, the compact is nearly complete and ready for state participation.

Interstate data sharing is a capability that can be built into the contract with the CSRS vendor. The Program Evaluation Division estimates that this enhanced capability would cost the State \$40,035 in one-time connection development and \$10,000 annually for service fees. The cost for the initial, one-time connection can be covered with federal grant funding.

Coordinating with federal health care providers broadens North Carolina's ability to monitor the abuse of prescribed controlled substances. North Carolina has a large military presence with an estimated 116,000 active duty service members²³ and 766,000 veterans. State PDMP coordination with the Department of Veterans Affairs (VA) and the Department of Defense is a best practice because it expands the State's system for monitoring the abuse of prescribed controlled substance.

Prescriptions for veterans are dispensed within the Veterans Health Administration (VHA) system. In North Carolina such prescriptions for controlled substances are dispensed at

- four medical centers (in Asheville, Durham, Fayetteville, and Salisbury); and
- four community-based outpatient clinics (in Charlotte, Durham, Greenville, and Wilmington).

Currently the VHA is developing software to allow daily transmission of dispensing data for Schedule II-V controlled substances into the CSRS.²⁴ Prior to a national rollout of this capability in August of 2014, the VHA plans to pilot these collaborative operations at seven test sites around the country. One pilot location is the Durham VA medical center. These changes will create a more robust state system for monitoring the abuse of prescribed controlled substances because the CSRS will now contain data on prescribed controlled substances dispensed within the VHA system.

Department of Defense prescribers and dispensers are under the administration and oversight of the Defense Health Agency's Health Care Operations Directorate. Military retirees and active duty service members

²³ North Carolina has an estimated 190,896 active duty service member dependents.

²⁴ Mail order prescriptions will be part of the data exchange if the prescription was dispensed and mailed from North Carolina.

receive health care through military treatment facilities and a network of civilian health care professionals, institutions, and pharmacies. Since military retirees and active duty service members are served through a civilian network, prescriptions filled by that network are reported into the CSRS.

North Carolina can expand the monitoring and surveillance capacity of the State by participating in the Prescription Behavior Surveillance System (PBSS). The PBSS is a jointly funded federal initiative of the U.S. Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) that is administered by the PDMP Center of Excellence at Brandeis University. The intent of this initiative is to develop a longitudinal multi-state PDMP database made up of de-identified data, which serves as an early warning detection tool. Early warning detection is important because it is timelier than relying on data from emergency departments or state medical examiners. States meeting the participation requirements must establish a data use agreement to provide de-identified CSRS data to the PBSS.

Participation in the PBSS enhances a state's monitoring capacity. The initiative has developed 43 different measures of patient, prescriber, and pharmacy-level behavior that are analyzed and shared with states. Participating states receive quarterly reports across the various measures. The PBSS also offers more specialized analysis based upon a state's interest. Providing data to the PBSS may require additional financial resources. However, states can get reimbursed for these costs.

In summary, the CSRS is an important tool, but utilization remains low. Measures can be taken to increase and remove barriers to utilization. Establishing interstate data sharing is a best practice and would allow the State to broaden its monitoring capabilities. Lastly, the State can expand its monitoring and surveillance capacity by participating in the PBSS.

Finding 3. The Department of Health and Human Services' Division of Medical Assistance'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 programs are important because prescription drug abuse is a problem within the Medicaid population and these programs reduce state health care costs and improve continuity of care. However, technological problems have rendered North Carolina's Medicaid lock-in program inoperable since July 2013, costing the Medicaid Program an estimated \$1.3 million to \$2 million.²⁵ When the program was operational it violated state law by not locking in all recipients that met the criteria, which limited the program's effectiveness and corresponding cost savings. Expanding program enrollment criteria, enhancing patient and health care provider education, leveraging use of Controlled Substances Reporting System (CSRS) data, and increasing the lock-in duration period all provide opportunities to improve operations and increase State cost savings by an estimated \$2.8 million.

²⁵ The lost cost savings are attributed to the inability of the Division of Medical Assistance to place new Medicaid recipients into the lock-in program.

The U.S. Centers for Disease Control recommends the implementation of Patient Review and Restriction programs, also called “lock-in” programs. The purpose of the Division of Medical Assistance’s Medicaid lock-in program is to reduce state health care costs and improve continuity of care for Medicaid recipients. These programs enable state Medicaid programs to rein in overuse, and possible abuse, of physician services and prescription drugs without having to terminate Medicaid benefits altogether by restricting patients suspected of overuse to a single health care provider and/or pharmacy.

Lock-in programs are important because prescription drug abuse is a problem within the Medicaid population. Nearly 1.6 million North Carolinians receive health insurance through North Carolina’s Medicaid program, which serves low-income parents, children, seniors, and people with disabilities who meet eligibility requirements.

Research on prescription drug abuse in the Medicaid population has found Medicaid enrollees are more likely to die as a result of unintentional overdose than the general population. Specifically, in North Carolina the Medicaid population is overrepresented in the number of unintentional overdose deaths, comprising approximately one-fifth of the state’s population but accounting for one-third of unintentional overdose deaths.²⁶

Medicaid enrollees exhibiting drug-seeking behavior are costly because of claims for unnecessary prescriptions and associated office visits, emergency room visits, or diagnostic tests. A 2009 Government Accountability Office (GAO) report examined fraud and abuse related to controlled substances within state Medicaid programs. North Carolina was one of five states examined in the report, which identified tens of thousands of Medicaid enrollees and providers engaged in potentially fraudulent and abusive purchases of controlled substances across the five states. One example cited in the report involved a North Carolina Medicaid enrollee who received 1,300 oxycodone pills over a 24-month period. These prescriptions came from 25 different prescribers and were filled by nine different pharmacies. The report further noted that, at the time, North Carolina had never placed the enrollee in a restricted recipient program, and recommended that states implement programs to detect and prevent prescription drug fraud and abuse.

In response to the GAO report, the Medicaid lock-in program was designed to improve coordination of care and reduce Medicaid expenditures. In 2010, the General Assembly passed a law requiring the Department of Health and Human Services’ (DHHS’) Division of Medical Assistance (DMA) to administer a lock-in program.²⁷ In October 2010, DMA placed the first group of enrollees into the lock-in program. According to state law and DMA policy, enrollees who met one or more of the following criteria were to be locked-in to one prescriber and one pharmacy:

- 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;

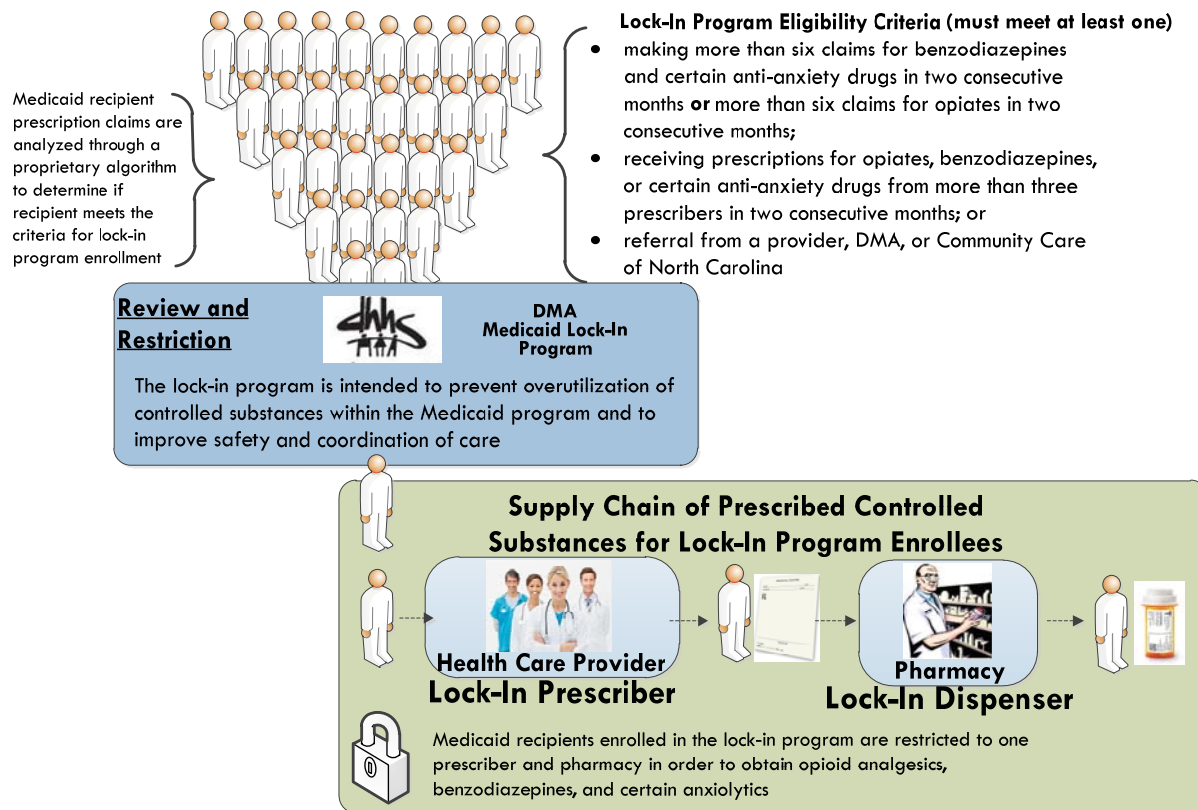
²⁶ Whitmire, J. and Adams, G. (2010). *Unintentional Overdose Deaths in the North Carolina Medicaid Population: Prevalence, Prescription Drug Use, and Medical Care Services*. Raleigh, NC: State Center for Health Statistics.

²⁷ N.C. Sess. Law 2010-31, Section 10.34.

- 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.²⁸

Unlike other mechanisms the State possesses for intervening in the supply chain for prescribed controlled substances, the lock-in program restricts the supply chain only for Medicaid recipients who meet specific criteria. Exhibit 15 shows how the lock-in program changes the supply chain for select Medicaid recipients.

Exhibit 15: Lock-In Program Changes the Supply Chain for Prescribed Controlled Substances for Selected Medicaid Recipients.

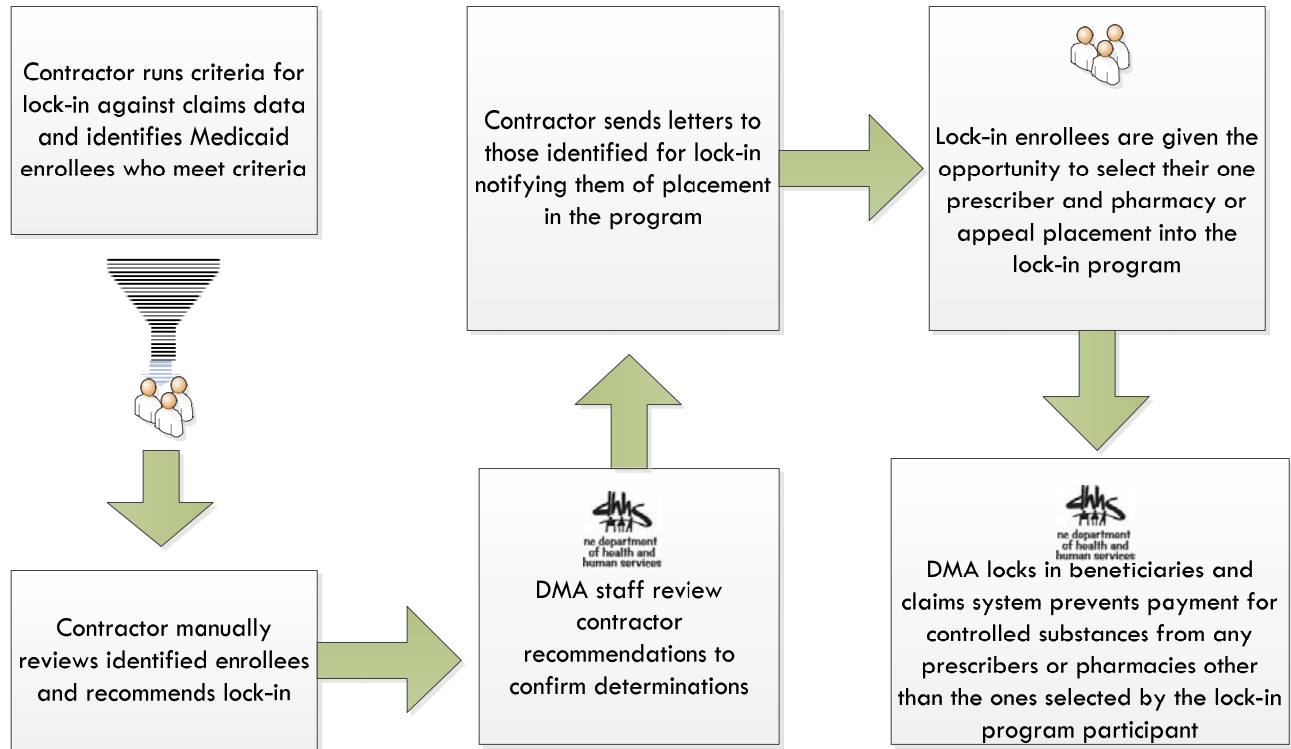


Source: Program Evaluation Division based on data from the Division of Medical Assistance.

Once enrollees were identified for lock-in, DMA would individually review each case to confirm they met criteria for placement in the lock-in program. Enrollees were placed in the program for one year, at which time they were removed from the program if they no longer met the criteria. In case of an emergency, there was a provision that allowed for reimbursement for a four-day prescription fill from a different prescriber and pharmacy once during the year-long lock-in period. Exhibit 16 describes the administrative process DMA and its contractor followed to enroll individuals in the lock-in program.

²⁸ Community Care of North Carolina is a statewide non-profit network that provides a medical home model of care for Medicaid enrollees.

Exhibit 16: Administrative Process of Medicaid Lock-In Program Enrollment



Source: Program Evaluation Division based on data from the Division of Medical Assistance.

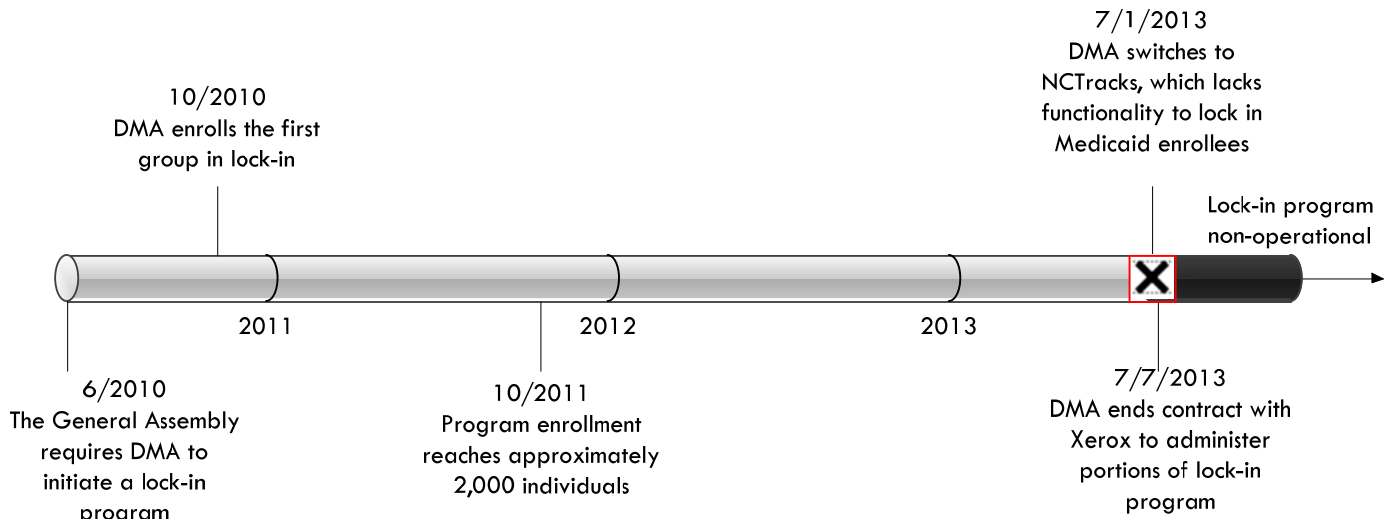
When DHHS switched to the new Medicaid management information system, NCTracks, the Medicaid lock-in program became non-operational. The functionality to operate the lock-in program was not in place when NCTracks went live. As a result, NCTracks data cannot currently be used to support the operation of the Medicaid lock-in program. Non-operation of North Carolina’s Medicaid lock-in program means:

- new Medicaid recipients who meet lock-in program criteria cannot be restricted to one prescriber and one pharmacy; and
- the approximately 2,200 Medicaid recipients enrolled in the program are no longer restricted to one prescriber and one pharmacy.

Because the Medicaid program saves money when enrollees are in the lock-in program, the inability to add new enrollees has cost the Medicaid program an estimated \$1.3 million to \$2 million from July 2013 to March 2014.

Planning by DHHS for the transition of the lock-in program following the implementation of NCTracks has been inadequate and risks further delay in reinstating program operation. DHHS contracted with Computer Sciences Corporation (CSC) for the development and implementation of NCTracks. Because lock-in enrollees are identified by analyzing Medicaid claims data that is contained in NCTracks, DHHS made the decision to have CSC, the vendor of NCTracks, take on responsibility for administering portions of the lock-in program that DMA had previously contracted with Xerox to provide. Consequently, DMA ended its contract with Xerox one week after NCTracks went live. See Exhibit 17 for a timeline of lock-in program implementation.

Exhibit 17: Timeline of Medicaid Lock-In Program Implementation



Note: DMA stands for the Division of Medical Assistance.

Source: Program Evaluation Division based on information from the Division of Medical Assistance.

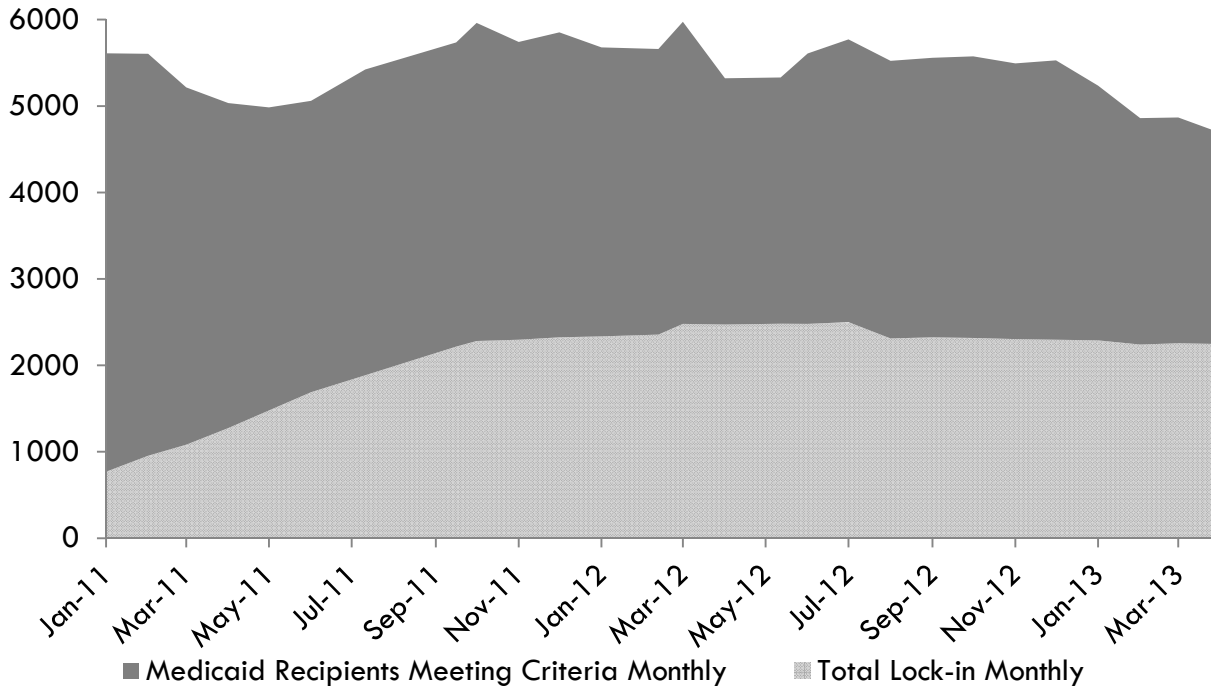
Xerox, the former contractor, had several responsibilities related to administration of the lock-in program including identifying enrollees who met lock-in criteria, notifying enrollees by certified mail of their selection for the program, providing support for administrative appeals, and providing phone support through a call center. Though DMA planned to transition the administration of the lock-in program to CSC in July 2013, the contract with CSC does not include specifications for the administration of the lock-in program. For example, there is no requirement in the CSC contract to send certified letters to lock-in enrollees notifying them of their selection for the program. In addition, there are no performance standards in the CSC contract for the administration of the lock-in program. Such specifications and standards were included in the former Xerox contract.

DMA was able to provide contract documents highlighting the technical requirements for the functionality of the program within NCTracks. However, DMA was not able to provide any documentation describing the process and timelines for the transition of the lock-in program to CSC administration, nor, more generally, could DMA provide any written procedures for the administration of the program. As a result, the Program Evaluation Division cannot conclude that technical problems with NCTracks are the only impediment to the lock-in program being operational and effective.

DMA failed to enroll all Medicaid beneficiaries who met program criteria, which limited the effectiveness of the Medicaid lock-in program and corresponding cost savings. When the lock-in program was operational, DMA contracted with its vendor to enroll 200 individuals per month rather than enrolling everyone who met program criteria. Enrolling 200 individuals per month meant that other individuals who met the program criteria were not enrolled in any given month and, thus, did not benefit from the program. In order to assess whether DMA was enrolling all individuals who met the criteria into the lock-in program, the Program Evaluation Division compared the number of individuals that DMA enrolled per month with the number of individuals identified as meeting the lock-in criteria by the contractor. Exhibit

18 shows thousands of Medicaid recipients meeting program enrollment criteria not being newly enrolled in the program each month.

Exhibit 18: Thousands of Medicaid Beneficiaries Meeting the Lock-in Program Enrollment Criteria Were Not Being Newly Enrolled in the Program Each Month



Source: Program Evaluation Division based on data from the Division of Medical Assistance.

The programmatic decision to only enroll an average of 200 individuals per month also meant that the program did not comply with state law. Session Law 2010-33 states that the DMA “shall lock Medicaid enrollees into a single pharmacy and provider when the Medicaid enrollee’s utilization of selected controlled substance medication meets the lock-in criteria...” The law does not contain a provision allowing DMA to select certain individuals to enroll in the program while not enrolling others who also meet program criteria.

When asked about this underenrollment, lock-in program administrators stated that the program exempted patients with terminal cancer or those requiring care from a skilled nurse. However, no policy or procedure exists directing or describing these exemptions. Furthermore, DMA did not conduct any analysis to determine if the underenrollment could be attributed to exemptions for terminal cancer or patients requiring a skilled nurse. Therefore, North Carolina lacks reasonable assurance the lock-in program was enrolling all Medicaid beneficiaries who should have been in the program.

Several changes would improve the effectiveness of the Medicaid lock-in program once it is again operational. When the lock-in program was operational, it was effective in reducing enrollee utilization of prescribed controlled substances—one evaluation found that new enrollees in the

program had on average 1.3 fewer prescriptions per month.²⁹ Still, the Program Evaluation Division identified several areas in which changes to the lock-in program would result in improved effectiveness and cost savings to the State.

Eligibility Expansion. North Carolina could improve its program effectiveness by modifying lock-in criteria to include certain stimulants. DMA's lock-in program criteria are based on a Medicaid enrollee's utilization of opioids, benzodiazepines, and certain anti-anxiety medications. However, commonly-abused stimulants such as Adderall and Ritalin are not included in the criteria for lock-in. It is unclear why the lock-in program does not include the stimulant class of controlled substances, which, like other controlled substances, has the potential for abuse and the ability to create psychological or physical dependence. The Program Evaluation Division identified three adjacent states in the southeast with lock-in programs: Kentucky, South Carolina, and Tennessee. All three states' lock-in programs include stimulants as part of their criteria for lock-in.

Data Coordination. Another change that could improve lock-in program effectiveness involves the use of data from the CSRS. The Medicaid program already has claims data on its enrollees' utilization of controlled substances that are paid for by the program. This data is used by DMA to identify lock-in program enrollees. However, a drug seeker could evade detection by paying for some or all controlled substance prescriptions with cash, which would prevent the prescription drugs from showing up in Medicaid claims data. Joining Medicaid and CSRS data is considered a best practice. By joining Medicaid enrollee claims data with data from the CSRS, DMA could identify individuals in the lock-in program who are paying cash for controlled substances. DMA also could identify additional Medicaid enrollees who meet lock-in criteria when the controlled substances they obtain through Medicaid and those they purchase with cash are viewed together.

Communication. The Program Evaluation Division identified program communication as another area where DMA could improve its effectiveness. DMA notifies beneficiaries that have been selected to enroll in the lock-in program. Prescribers and pharmacies selected by patients are sent a letter notifying them that they are the lock-in providers. Notices are then sent to all recipients about program changes and targeted notices are sent to those individuals selected for the lock-in program. The lock-in program also maintains a call center that was operated by the previous contractor, sends messages to providers through its management information system, and communicates through the Community Care of North Carolina network. These communication efforts could be bolstered by having a website devoted to the lock-in program; no site currently exists. For comparison, the State of Washington has a website devoted to its program and has developed a series of frequently asked questions for different program stakeholders, including enrollees, pharmacists, prescribers, primary care physicians, and hospital emergency departments. Washington has also developed a series of fliers about the program, which are available on its website.

²⁹ Mercer, Inc. (2013). *Beneficiary Management Lock-In Program Analysis: State of North Carolina*. Phoenix, AZ: Marsh & McLennan Companies.

Internal Audits. DMA policy stated that as part of lock-in process oversight, “Program Integrity will conduct audits to ensure compliance with this policy.”³⁰ Despite having this policy in place, DMA’s Program Integrity Section has never conducted an audit of the lock-in program. Audits of the lock-in program would help ensure program restrictions are functioning properly, determine whether there is a need to change any program policies, and determine whether there is any potential need for improved provider education. When the Program Evaluation Division inquired about the lack of audits of the lock-in program, DMA officials stated they expect to complete an audit of the program in the first quarter of 2014.

The State of Washington has had success with integrating its Medicaid claims data with its controlled substances reporting system. Each month, Washington sends its controlled substances reporting system vendor a list of all Medicaid enrollees, and the vendor matches those clients with data from Washington’s controlled substances reporting system. These data allow Washington to have a more complete picture of Medicaid enrollees’ use of controlled substances, and Washington uses this information in detecting aberrant or fraudulent prescribing by some medical providers. As an example of how this information is used, Washington found that over a six-month period, 478 of its Medicaid enrollees filled prescriptions less than 10 days apart for the same drug by having Medicaid pay for one and using cash for the other. Washington also uses this information to monitor the compliance of enrollees in its lock-in program in order to determine whether they should be released from the program.

Increasing the duration of Medicaid lock-in participation would result in greater program benefits. State lock-in programs save Medicaid programs money by reducing controlled substance utilization and also reducing the use of medical services. In North Carolina, the lock-in program was estimated to have a net savings to the Medicaid program of \$8 million during a 12-month period in 2011–12, \$2.8 million of which are savings realized by the State, with the remainder of savings realized by the federal government.³¹

The majority of the cost of administering a lock-in program involves actual enrollment into the program. Once an individual is in the program, the Medicaid claims system does the work of preventing payments to anyone other than the one prescriber and pharmacy. North Carolina’s lock-in period lasts for one year, at which time enrollees are released from the program, though they can be re-enrolled if they meet criteria. Because enrollment is the major cost of the lock-in program, keeping enrollees in the program for a second year would involve little additional cost, but would continue to yield benefits in improved coordination of care and cost savings. In fact, other states do have longer lock-in periods—Washington and Kentucky both lock in enrollees for a period of two years. Even after the two-year period ends, Washington retains 28% of its enrollees in their lock-in program because these individuals continue to meet the program criteria. Analysis of the State

³⁰ NC Division of Medical Assistance (2013, July). *Outpatient Pharmacy, Clinical Coverage Policy No: 9*. Retrieved from <http://www.ncdhhs.gov/dma/mp/9pharmacy.pdf>.

³¹ Because the federal government and State share the cost of Medicaid, the State only realized 34.7% of the total program cost savings in 2012.

of Washington's program found even larger savings through its lock-in program than were found in North Carolina.³²

Increasing lock-in duration to two years would double the number of enrollees in North Carolina's program. For example, if DMA continued to enroll only 200 new individuals per month, but increased the lock-in duration to two years, total enrollment would reach 4,800 individuals in one year. Assuming the cost savings per lock-in enrollee remains constant as enrollment grows, this change would yield an additional \$2.8 million in savings per year to DMA at very little additional cost.

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.

Because the Controlled Substances Reporting System (CSRS) is a complex information system, North Carolina contracts with a private contractor to provide this service. The Department of Health and Human Services (DHHS) holds a contract with Health Information Designs, LLC (HID) for the operation of the CSRS. HID provides this same service to 19 other states. DHHS pays an annual rate of \$220,785 under a contract that began in January 2012 and is effective through December 2014.

The CSRS user interface is a web-based program that is accessible to registered health care providers and pharmacists. Underpinning the web-based program is an information system with many components. The system collects data from pharmacies, verifies the accuracy of that data, matches new data received from pharmacies to existing records, facilitates access to the system for authorized users, and provides tools for analysis and reporting of the data. Optimal system performance is dependent on proper specification of the information system during the procurement process. For this reason, the contract DHHS holds with HID is an important component of the State's system for monitoring the abuse of prescribed controlled substances.

In order to analyze the effectiveness and value of the contract, the Program Evaluation Division compared DHHS' procurement documents with those of the State of Washington, which were obtained through a public records disclosure request.³³ Compared to the State of Washington, the Program Evaluation Division's review of the North Carolina contract found it lacks several important features related to user access controls, data security, and advanced analytics.

DHHS's contract fails to incorporate important internal controls for managing CSRS user access to ensure security of protected medical information. Internal controls are broadly defined as a process or set of processes designed to ensure

³² Washington estimated that its patient review and coordination program saved the Washington's Medicaid program \$18.1 million in 2009 based on a caseload of 3,087 program enrollees.

³³ The Program Evaluation Division selected Washington because both states hold contracts with HID and subject matter experts highlighted Washington as a state engaged in many best practices for data sharing, all of which are implemented through its contract with HID.

- the effectiveness and efficiency of operations;
- the reliability of financial reporting; and/or
- compliance with applicable laws and regulations.

Important components of internal controls are the control activities. Control activities are the policies and procedures that help ensure necessary actions are taken to address risks to achieving objectives. Control activities occur throughout the organization and include approvals, authorizations, verifications, reconciliations, reviews of operating performance, security of assets, and segregation of duties.

Registration for the CSRS is conducted online through the health care oversight boards, and paper applications can also be submitted to the Controlled Substances Regulatory Branch (CSRBR) within the Division of Mental Health, Developmental Disabilities and Substance Abuse Services. Among other items, registrants are required to provide their state board license number, Drug Enforcement Agency (DEA) registration number, and a system access password.

While the CSRBR has established procedures to control who can register to use the CSRS, it lacks procedures to guide deactivation of user accounts or removal of users from the system. Once someone successfully registers for the system, there are no procedures in place to ensure that a user has continued to meet the requirements to have an account. The CSRBR stated it has removed account access for some individuals in the past but those removals were the result of complaints the CSRBR received.

The State of Washington has addressed the issue of user account controls through its contract with HID. Washington requires HID to implement a feature which forces users to update their account once a year based on the account creation date. If the account is not updated or confirmed within 45 days, the account is deactivated and can only be reinstated by contacting the Washington helpdesk. Washington also requires HID to check the DEA number submitted by users against a file of valid DEA numbers to ensure that there is a match. Finally, Washington specifies that HID ensure a user cannot create duplicate accounts within the system.

Unlike the State of Washington, DHHS did not incorporate user account controls into its contract with HID. As a result, North Carolina lacks assurance that all individuals who are currently registered to access the CSRS should continue to have access to the system. In order to test whether certain users should no longer have access to the system, the Program Evaluation Division cross-referenced the list of prescribers and dispensers registered to access the CSRS with an up-to-date list of prescribers and dispensers with valid DEA numbers in North Carolina. The analysis shows an estimated 11% (n=1,067) of individuals with active CSRS accounts who are registered to use the CSRS with a DEA number that is not presently valid.

To further examine who may have improper access to the CSRS, the Program Evaluation Division reviewed data on prescribers who no longer hold a license to practice medicine in North Carolina due to an adverse action of the North Carolina Medical Board. The Program Evaluation Division reviewed individuals who either had their license revoked by the Medical Board or voluntarily surrendered their license in the years 2010–2012. By comparing

this list with CSRS registered users, the Program Evaluation Division identified 13 individuals with access to the CSRS who should not have had access because their medical licenses were no longer valid.

Of the 13 individuals the Program Evaluation Division identified who should not have had access to the CSRS, two individuals have since had their license to practice reinstated. DHHS has subsequently closed 11 accounts and has also determined that one of the individuals has continued to access the CSRS since the loss of licensure. According to Session Law 2013-152, a person who intentionally, knowingly, or negligently releases, obtains, or attempts to obtain information from the CSRS in violation of the Controlled Substances Reporting System Act shall be assessed a civil penalty by DHHS not to exceed \$10,000 per violation.

DHHS did not adequately specify certain data security requirements in the CSRS contract. The CSRS contains personal data on anyone who filled a prescription for a controlled substance within the last six years. This data includes patient name, address, controlled substance drug type, quantity of the dispensed drug, and estimated days of supply. DHHS contract language related to data security lacks specificity.

One weakness in the DHHS contract is that it does not specify password management standards. Password management is the process of defining, implementing, and maintaining password policies throughout an enterprise. Passwords authenticate a user's identity and are required as a means to protect data, systems, and networks. The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) Guide to Enterprise Password Management suggests a system might permit passwords between 8 and 20 characters long and require a combination of letters and digits. Providing a clear list of password requirements helps users to select strong passwords that meet criteria. The DHHS contract contains no specifications for password management, which represents a significant weakness for CSRS data security.

In contrast to the DHHS contract requirements, Washington's contract includes references to specific internet privacy and security standards. The Washington contract requires that security controls meet or exceed those described by the Federal Information Processing Standards (FIPS) established by NIST for information security. NIST protocols specify that organizations should conduct security control assessments. NIST also makes recommendations for enterprise password management. The incorporation of these additional security standards increases the likelihood that access, storage, and use of prescribed controlled substance data is safe and secure from malicious intent.

DHHS's contract does not specify features that would allow for advanced analysis of CSRS data. CSRS data can be very useful in conducting analysis of the prescription drug abuse problem, understanding how the nature of the problem is changing, and evaluating the outcomes of various interventions designed to address prescription drug abuse. Two major groups of state researchers rely upon CSRS data:

- The Division of Public Health's Injury and Violence Prevention Branch uses data from the CSRS, emergency departments, medical

examiners, and other sources to monitor the problem and evaluate and inform public health policy and strategies.

- The University of North Carolina’s Injury Prevention Research Center uses CSRS data to conduct analyses such as evaluating outcomes of North Carolina’s Controlled Substances Reporting System, developing a tool to identify high-risk prescribers, and evaluating the impacts of the Medicaid lock-in program.

The DHHS contract with HID states that the actual database will reside on HID’s server and the database and the data shall belong to the State. Exhibit 19 shows the contract allows DHHS staff to use a web-based program to search, correlate, query, and match records on all variables contained in the records. However, more advanced data analysis must occur outside of the HID’s web-based program by exporting the data to an electronic format that can be used by researchers.

Exhibit 19

North Carolina’s Contract for the Controlled Substances Reporting System Lacks Important Features for Internal Controls, Security, and Data Analysis

Contract Feature	North Carolina	Washington
Internal Controls Features		
Specifies procedures to deactivate user accounts or remove users from system	X	✓
Verifies whether users have active DEA numbers	X	✓
Ensures users cannot create duplicate accounts	X	✓
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	X	✓
Requires security controls meet or exceed federal standards for information security	X	✓
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	X	✓
Allows batch reporting of files based on a list of clients	X	✓
Provides de-identified reports	X	✓
Provides ad-hoc reports that cannot be produced through the system online	X	✓

Notes: North Carolina and Washington use the same vendor, Health Information Designs, to implement each state’s prescription drug monitoring program. Federal standards for information security are set by Federal Information Processing Standards (FIPS) established by the National Institute of Standards and Technology (NIST).

Source: Program Evaluation Division based on a review of contract documents from the Department of Health and Human Services and the State of Washington.

Because the DHHS contract lacks specific requirements for data accessibility that would allow for advanced analytics, North Carolina researchers are forced to expend time and monetary resources to acquire and clean CSRS data, when the data are provided. Washington has dealt with this issue by requiring HID to securely transfer a copy of the system database to Washington's Department of Health (DOH). Under Washington's contract, HID is also required to provide up to five ad-hoc reports per month that DOH staff cannot produce through the web-based program. Washington has used this ad-hoc report feature of its contract to analyze Medicaid enrollees' use of prescribed controlled substances.

The DHHS contract has no requirement for the transfer of CSRS data to the State for advanced analytics. Greater contract specificity would allow the Division of Public Health and the University of North Carolina's Injury Prevention Research Center to have improved access to the data and would prevent these entities from wasting staff time and monetary resources to acquire needed data.

North Carolina spends \$43,346 more annually to procure its CSRS than the State of Washington even though North Carolina's system has less functionality. A comparison of North Carolina and Washington's contracts with HID shows North Carolina is paying \$121,146 more annually than the State of Washington when comparing similar services. The amount that North Carolina pays is more than twice what Washington pays for its equivalent level of service. However, the two systems do not have equal functionality—Washington's system incorporates many additional features that more closely align with best practices. For example, Washington has recognized the importance of interstate data sharing as a best practice and has built this capability into its contract. Similarly, Washington, through its contract with HID, has connected its system to the Washington Health Information Exchange. Even with all the additional functionality Washington receives through its contract with HID, it still pays \$43,346 less than North Carolina on an annual basis. Exhibit 20 compares the costs and functionality included in North Carolina and Washington's contracts and shows North Carolina pays more for less.

Exhibit 20: Annually, North Carolina Pays Over \$43,000 More than Washington for its Controlled Substances Reporting System While Receiving 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 ¹	—	\$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)
Subtotal		\$77,800	\$(77,800)
Total Cost	\$220,785	\$177,439	\$43,346

Notes: Health Information Designs (HID) is the vendor for the prescription drug monitoring programs in North Carolina and Washington. SiteKey authentication is a web-based security system that provides mutual authentication between a website and a user of that site.

Source: Program Evaluation Division based on a review of contract documents from North Carolina and Washington.

In summary, DHHS’ contract for the CSRS does not specify important features related to internal controls for user accounts and data security. The contract also does not require features that would improve the ability of researchers to conduct advanced analysis of CSRS data. Finally, DHHS pays more for the CSRS than the State of Washington and receives less functionality.

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

North Carolina lacks a strategic and holistic approach to the prescription drug abuse epidemic because the State does not have a single entity with the responsibility or authority to address this problem. As a result, the State lacks an overarching set of goals, a strategic plan, and a performance management system to track and monitor its efforts. Other states have created strategic plans by bringing together numerous agencies and stakeholders involved in addressing the problem.

As discussed earlier in this report, the State’s system for monitoring and preventing the abuse of prescribed controlled substances involves four mechanisms:

- oversight and regulation of prescribers and dispensers by state health care regulatory boards;
- operation of the Controlled Substances Reporting System (CSRS), the State’s prescription drug monitoring program;
- operation of the Medicaid lock-in program to review behavior of patients with high use of prescribed controlled substances; and

- enforcement of state laws for the misuse and diversion of controlled substances.

Exhibit 21 lists the state agencies, boards, and institutions currently involved in preventing the misuse of prescribed controlled substances. Outside of this group of state entities there are non-profit organizations, federal agencies, local governments, and businesses that participate as well.

Exhibit 21: State Entities Currently Involved in Preventing Prescription Drug Abuse

State Agencies, Boards, and Institutions	Division/Entity	Role(s)
Department of Health and Human Services	<ul style="list-style-type: none"> • Division of Mental Health, Developmental Disabilities and Substance Abuse Services <ul style="list-style-type: none"> ○ Controlled Substances Reporting Branch • Division of Public Health <ul style="list-style-type: none"> ○ Injury and Violence Prevention Branch • Division of Medical Assistance • Office of Rural Health and Community Care 	<ul style="list-style-type: none"> • Operates the CSRS • Monitors and reports injuries and deaths related to prescription drug misuse and abuse • Operates the Medicaid lock-in program • Provides grants to support efforts to prevent the misuse of prescribed controlled substances
Department of Justice	<ul style="list-style-type: none"> • Attorney General's Office <ul style="list-style-type: none"> ○ State Bureau of Investigation 	<ul style="list-style-type: none"> • Enforces state laws for the misuse and diversion of controlled substances
State Health Care Regulatory Boards	<ul style="list-style-type: none"> • NC Board of Dental Examiners • NC Board of Nursing • NC Board of Pharmacy • NC Board of Podiatry Examiners • NC Medical Board 	<ul style="list-style-type: none"> • Licenses, oversees, and monitors prescribers and dispensers of controlled substances
UNC System	<ul style="list-style-type: none"> • UNC Injury Prevention Research Center (UNC Chapel Hill) 	<ul style="list-style-type: none"> • Evaluates the effectiveness of the CSRS • Conducts research in support of the CSRS, law enforcement, and regulatory boards

Note: CSRS stands for the Controlled Substance Reporting System.

Source: Program Evaluation Division based on interviews and a review of documents.

Although several state entities participate in the system, North Carolina does not have a single entity responsible for developing a strategic and holistic approach to address the prescription drug abuse epidemic. Several state entities collaborate around aspects of preventing the misuse of prescribed controlled substances, but these collaborations generally focus on a single aspect of the State's system or program. For example, the CSRS has a multi-agency advisory committee tasked with providing advice on the operation of the system. Although this committee is informal, other state entities and nonprofit organizations such as the Division of Public Health, the North Carolina Medical Board, and the UNC Injury Prevention and Research Center regularly participate in meetings. However, the discussions and suggestions from this committee are limited to the improvement of the CSRS and do not address the prescription drug abuse epidemic from all sides. Likewise, the Division of Public Health's Injury and Violence Prevention Branch developed a strategic plan in 2012 that includes objectives related to unintentional poisonings.³⁴ However, action steps outlined in the plan are specific to what the branch can do,³⁵ the plan does not link all responsible

³⁴ Division of Public Health, Injury and Violence Prevention Branch. (2012, April). *Building for Strength: North Carolina's Strategic Plan for Preventing Injuries and Violence: Addendum to Update Objectives*. Raleigh, NC: Department of Health and Human Services.

³⁵ Objectives for the unintentional poisoning prevention goal team include serving as the state resource to facilitate collaboration, communication, research, and public health policy around poisonings; promoting best practices and evidence-based programs on

agencies and interested stakeholders involved to achieve a set of goals related to the prescription drug abuse problem.

Strategic planning is a process used to determine what the State wants to accomplish over a given time period, and how it plans to achieve those aims. This process includes setting clear goals and measurable objectives, assessing capacity, and developing strategies and action items that are assigned to a responsible party. Strategic plans can

- serve as communication documents that inform agency staff, stakeholder groups, and decision makers;
- advise management on how to link strategy with day-to-day operations; and
- be used for resource allocation, including budgetary decisions.

Without a strategic plan, it is difficult to hold state entities and other stakeholders accountable for their contributions to addressing the prescription drug abuse problem.

Strategic planning processes should identify and engage critical stakeholders in identifying and implementing strategies to achieve statewide goals. A 2012 survey by the National Association of State Alcohol and Drug Abuse Directors found that 29 states or territories had convened a state task force involving multiple state agencies and stakeholders to address prescription drug abuse. Taskforces in two states—Colorado and Oklahoma—have gone further by developing state-level plans that set measureable goals to address prescribed controlled substance abuse and outline several strategies to achieve these goals (see Exhibit 22).

Exhibit 22: Examples of State Plans for Addressing Prescribed Controlled Substance Abuse

State	Description	Measurable Goal	Strategy Areas
Colorado	The Colorado Plan to Reduce Prescription Drug Abuse arose out of an effort led by the Colorado governor and included representatives from human services, public health, public safety, information technology, the attorney general's office, and the governor's policy office.	Reduce the prevalence of non-medical use of prescription pain medications in Colorado by 3.5% (92,000 Coloradans) by 2016	<ul style="list-style-type: none"> • Provider and prescriber education • Prescription drug monitoring program • Disposal • Public awareness • Data and analysis
Oklahoma	The Reducing Prescription Drug Abuse in Oklahoma state plan was developed by a 37-member workgroup co-chaired by leaders of the state's mental health and public health agencies.	Reduce the number of unintentional overdose deaths involving opioids in Oklahoma from 11.0 per 100,000 to 9.4 per 100,000 by 2017	<ul style="list-style-type: none"> • Community/public education • Provider/prescriber education • Disposal/storage for the public • Disposal/storage for providers • Tracking and monitoring • Regulatory/enforcement • Treatment/interventions

Source: Program Evaluation Division based on a review of documents.

With a strategic plan in place, North Carolina could implement a performance management system to measure, monitor, and report on statewide efforts to reduce prescription drug abuse. Previous Program Evaluation Division reports have emphasized the importance of strategic

unintentional poisonings to prescribers, consumers, and public policy makers; supporting law enforcement infrastructure to prevent illegal distribution and use of controlled medications; and increasing coordination between the unintentional poisoning prevention goal team and other strategic action committee teams.

planning and performance management systems to measure, monitor, and report progress toward achieving goals.³⁶ Strategic planning links management to operational activities by connecting the goals identified in the strategic plan to the operational objectives measured by a performance management system. Developing and implementing a formalized performance management system involves three components:

- setting operational objectives;
- monitoring progress towards achieving objectives; and
- taking remedial action when performance falls short.

A strategic planning process would allow the State to develop overarching strategic goals for addressing the prescription drug abuse problem, and each agency or stakeholder involved would align their operational objectives with those goals. A performance management system would then allow the State to monitor the results of activities, providing feedback about what is or is not working.

Beyond the four mechanisms discussed in this report, North Carolina's approach to reducing prescription drug misuse and abuse should include Operation Medicine Drop, the State's drug take-back program,³⁷ and substance abuse treatment centers and programs as well as public education campaigns. These strategies have been cited as important aspects of the national response to the prescription drug abuse problem.³⁸ The State also can coordinate with and support efforts at the local or regional level aimed at addressing this issue. For example, the Chronic Pain Initiative is a joint effort of Community Care of North Carolina and the non-profit organization Project Lazarus. This statewide initiative is based on the success of Project Lazarus, which reduced unintentional deaths in Wilkes County by 69% between 2009 and 2011. The Project Lazarus model has five components:

- community activation and coalition building;
- monitoring and epidemiologic surveillance;
- prevention of overdoses through medical education and other means;
- use of rescue medication to reverse overdoses by community members; and
- evaluation of project components.

The Department of Health and Human Services' Office of Rural Health and Community Care funds this state-level effort by using federal Medicaid funds to support three Chronic Pain Initiative grants totaling over \$1.3 million. The fact that the Office of Rural Health and Community Care provides grant funding to this initiative demonstrates how many different state agencies, divisions, offices, centers, or programs are involved in some fashion in addressing the prescription drug abuse problem.

³⁶ Program Evaluation Division (2011, April). North Carolina Should Weigh Continued Investment in the Global TransPark Authority and Consider How to Repay the Escheat Fund Loan. Report to the Joint Legislative Program Evaluation Oversight Committee. Raleigh, NC: General Assembly. Program Evaluation Division (2012, October). North Carolina Should Require NC Railroad Company to Pay an Annual Dividend and Strengthen Reporting. Report to the Joint Legislative Program Evaluation Oversight Committee. Raleigh, NC: General Assembly.

³⁷ Operation Medicine Drop is part of Safe Kids NC, which is operated by the North Carolina Department of Insurance.

³⁸ Office of National Drug Control Policy (2011). *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. Washington, DC: White House.

Recommendations

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

As discussed in Finding 1, opioid prescribing guidelines are important to educate health care providers and improve the care and safety of patients. Currently, North Carolina statewide opioid prescribing guidelines do not apply to all health care providers or meet the criteria for clinical practice guidelines. As a result, the General Assembly should require the following state officials and occupational licensing boards to jointly develop statewide opioid prescribing guidelines for health care providers:

- the State Health Director,
- the Director of Medical Assistance,
- the Director of the Division of Mental Health, Developmental Disabilities and Substance Abuse Services,
- the directors of medical, dental, and mental health services within the Department of Public Safety,
- North Carolina Board of Dental Examiners,
- North Carolina Board of Nursing,
- North Carolina Board of Podiatry Examiners , and
- North Carolina Medical Board.

The guidelines should be developed based on the criteria for clinical practice guidelines set forth by the Institute of Medicine of the National Academies and therefore should

- 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; and
- explain and assess the benefits and harms associated with options for alternative treatments.

Other state and federal prescribing guidelines mentioned in Finding 1 of this report should serve as models to develop and refine North Carolina's prescribing guidelines. The development of the guidelines should consider use of opioid dosage thresholds for physician consultation. The statewide prescribing guidelines should be completed by December 31, 2014, and the General Assembly should require the health care provider occupational licensing boards to adopt the opioid prescribing guidelines by no later than July 1, 2015.

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

Continuing education provides an opportunity for health care providers to stay up-to-date on proven medical advances. Currently, with the exception of dentists who have been found to have violated controlled substance prescribing and dispensing regulations, health care providers are not required to obtain continuing education on the abuse of prescribed controlled substances.

The General Assembly should direct the North Carolina Board of Dental Examiners, the North Carolina Board of Nursing, the North Carolina Medical Board, and the North Carolina Board of Podiatry Examiners to require continuing education on the abuse of prescribed controlled substances as a condition of licensure.

The boards should be directed to require that at least one hour of the total required continuing education hours consists of a course designed specifically to address prescribing practices. The course should include, but not be limited to, instruction on controlled substance prescribing practices and controlled substance prescribing for chronic pain management.

Recommendation 3. The General Assembly should amend N.C. Gen. Stat. § 90-113 to enable improved Controlled Substances Reporting System access and utilization.

As discussed in Finding 2, the Controlled Substances Reporting System (CSRS) appears underutilized, but several options exist to increase and remove barriers to its use. These options require statutory amendment. N.C. Gen. Stat. § 90-113.74 should be amended to implement the following options identified in this report.

- **Allow the CSRS to contribute data to the North Carolina Health Information Exchange (NC HIE).** Allowing the CSRS to contribute data to the NC HIE would streamline how health care providers are able to access the CSRS, making it less cumbersome. Contributing data to the NC HIE should occur through web service calls. The amendment should further stipulate that once CSRS data are contributed to the NC HIE, the data should be subject to the confidentiality provisions laid out in N.C. Gen. Stat. § 90-413.
- **Allow CSRS data to be released to officers within the Drug Enforcement Administration's Office of Diversion Control.** Granting federal law enforcement agents the ability to directly request information from the CSRS would improve efficiencies and increase the caseload capacity for federal and state law enforcement agencies.

Amending statute to increase and remove barriers to use of the CSRS would establish the legal authorization for the Department of Health and Human Services (DHHS) to amend its contract with the CSRS vendor in order to provide greater access to data for the investigation and enforcement of controlled substance law. The General Assembly should direct DHHS to develop the appropriate policies and procedures documenting and supporting this additional functionality and expanded access.

Recommendation 4. The General Assembly should direct the Department of Health and Human Services (DHHS) to modify the contract for the Controlled Substances Reporting System (CSRS) to improve performance, establish user access controls, establish data security protocols, and ensure availability of data for advanced analytics.

As discussed in Finding 4 of this report, the contract for operation of the CSRS extends through December 2014. Before exercising the renewal option the General Assembly should require DHHS to modify the contract to improve performance, establish user access controls, establish data security protocols, and ensure availability of data for advanced analytics.

To improve CSRS performance, establish user access controls and data security protocols, and ensure availability of data for advanced analytics, the contract should include the following features:

- **Health Information Exchange connection.** This contract modification requires additional resources; \$5,100 for one-time connection and \$15,000 in annual service fees. The General Assembly should direct DHHS to utilize existing state and federal resources to cover the cost of this modification.
- **Interstate connectivity.** This contract modification would require additional resources. The Program Evaluation Division estimates this enhanced capability would cost \$40,035 for a one-time connection to RxCheck Hub and \$10,000 annually for service fees. The cost for the one time connection fee can be covered through the use of federal grant funding, already being received by DHHS through the Harold Rogers Prescription Drug Monitoring Program grant. However, the General Assembly should direct DHHS to utilize existing state and federal resources to pay for the cost of the annual service fees. To enable interstate data sharing, DHHS should establish an interstate data sharing compact and pilot interstate data sharing with South Carolina, Tennessee, and Virginia.
- **Account updates.** The contract should include a system feature requiring users to update account information annually.
- **Prescriber number validation.** The contract should include a requirement that the contractor cross-reference CSRS users with DEA numbers to ensure access is limited to users with valid, up-to-date information.
- **Data security protocols.** The contract should include a requirement that the contractor meet Federal Information Processing Standards (FIPS) established by the National Institute of Standards and Technology (NIST).
- **Data transfer.** The contract should require the contractor to transfer a copy of the CSRS database to DHHS on a quarterly basis. Transferred data should be encrypted, include identified and de-identified cases, and be conducted through standard file transfer protocol.
- **Ad-hoc reporting.** The contract also should require the contractor to provide up to five ad-hoc reports per month that DHHS staff cannot produce through the online system.

The General Assembly should direct DHHS to develop the appropriate policies and procedures documenting and supporting the functionality enabled by the contract modifications.

Modifications to the contract should be completed by December 2014. The General Assembly should require DHHS to report to the Joint Legislative Program Evaluation Oversight Committee and the Joint Legislative Oversight Committee on Health and Human Services regarding modifications to the contract by November 2014.

Recommendation 5. The General Assembly should direct the Controlled Substances Reporting Branch to expand monitoring capacity by establishing data use agreements with the Prescription Behavior Surveillance System.

Participating in the Prescription Behavior Surveillance System (PBSS) enhances the State's monitoring capacity without the commitment of additional state resources. To participate in the PBSS, the branch should be directed to establish a data use agreement with the Center of Excellence at Brandeis University. The data use agreement should be executed by January 2015. PBSS reports should be provided on a biannual basis to the Joint Legislative Oversight Committee on Health and Human Services and the Joint Legislative Oversight Committee on Justice and Public Safety beginning in June 2015.

Recommendation 6. The General Assembly should direct the Division of Medical Assistance to improve the effectiveness and efficiency of the Medicaid lock-in program.

As discussed in Finding 3, the lock-in program is currently non-operational due to technical problems with NCTracks. With the program non-operational, the Division of Medical Assistance (DMA) has an opportunity to plan for and address several programmatic issues before the program becomes operational once again. The General Assembly should direct DMA to

- **Establish written procedures for the operation of the lock-in program, including specifying the responsibilities of DMA and the contractor.** DMA does not have any written procedures for the administration of the lock-in program. DMA should establish a set of written procedures that clearly enumerates DMA's responsibilities and the contractor's responsibilities throughout the entire lock-in process. Having written procedures would allow DMA staff and contractor staff to have clear direction on their roles in administering the program.
- **Establish procedures for the sharing of bulk data with the Controlled Substances Regulatory Branch.** As part of lock-in program procedures, DMA should develop procedures for sharing data with the Controlled Substances Regulatory Branch so that DMA can systematically identify Medicaid enrollees who are circumventing the lock-in program through the use of cash payments for prescribed controlled substances. The State of Washington has already implemented a model DMA can follow.

- **Extend lock-in duration to two years.** DMA can ensure lock-in enrollees benefit from the program for a longer duration by extending the required participation time to two years. The State also will realize greater Medicaid cost savings by extending the duration of the lock-in program.
- **Revise program eligibility criteria through consultation with the Physicians Advisory Group.** The Physicians Advisory Group is a non-profit organization created for the purpose of advising the Department of Health and Human Services. State law directs DMA to utilize lock-in criteria approved by the Physicians Advisory Group. DMA should consult with the Physicians Advisory Group to revise the lock-in criteria, including considering the addition of stimulants to lock-in eligibility criteria. DMA also should seek formal approval for undocumented criteria. These criteria allow for anyone with a recent terminal cancer diagnosis or anyone in a skilled care nursing facility to be exempt from the lock-in program. Expanding eligibility will result in additional cost savings. However, until the edits to the lock-in program are integrated into NCTracks, the savings cannot be calculated. As a result, the General Assembly should direct DMA to submit a report estimating the projected annual cost savings to the Joint Legislative Program Evaluation Oversight Committee and the Joint Legislative Oversight Committee on Health and Human Services within one year of the lock-in program again becoming operational.
- **Develop a website and communication materials to inform lock-in enrollees, prescribers, pharmacists, and emergency room health care providers about the program.** All stakeholders would benefit from improved information about the program.
- **Increase program capacity to ensure that all individuals who meet program criteria are locked-in.** DMA should increase enrollment capacity above the 200 individuals per month that it had been enrolling. Bolstering enrollment each month will allow DMA to ensure that every individual meeting criteria each month is enrolled into the program. Because each lock-in enrollee saves the State money, the cost of increasing program enrollment capacity would be offset by savings to the State from the program.
- **Conduct an audit of the lock-in program by May 30, 2014.** Once the program becomes operational, Program Integrity should conduct an audit to address the effectiveness of program restrictions in preventing overutilization of controlled substances. The audit also should identify any program vulnerabilities and address whether there is evidence of any fraud or abuse within the program.

The General Assembly should direct the Division of Medical Assistance to report to the Joint Legislative Program Evaluation Oversight Committee by September 30, 2014, on the progress of implementing all items included in this recommendation.

Recommendation 7. The General Assembly should 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.

As discussed in Finding 5, North Carolina lacks a coordinated strategy and performance management system to monitor prescription drug abuse. The Department of Health and Human Services (DHHS) should lead the effort to develop a statewide strategic plan because it is the state agency with the primary responsibility for operating two key components of North Carolina's system to monitor prescription drug abuse: the Controlled Substances Reporting System (CSRS) and the Medicaid lock-in program. In addition, two other DHHS divisions play a role in monitoring and preventing prescription drug abuse: the Division of Public Health tracks unintentional poisonings due to prescription drugs and other substances and the Office of Rural Health and Community Care provides funding to support statewide implementation of the Chronic Pain Initiative.

To support this strategic planning effort, the General Assembly should direct DHHS to form the Prescription Drug Abuse Strategic Planning Committee consisting of DHHS divisions and other state entities, non-profit organizations, federal agencies, local governments, and businesses currently involved in preventing prescription drug abuse. At minimum, this committee should include representatives from

- Division of Medical Assistance;
- Division of Mental Health, Developmental Disabilities and Substance Abuse;
- Division of Public Health;
- Office of Rural Health and Community Care;
- Department of Justice (State Bureau of Investigation and Attorney General's office);
- health care regulatory boards with oversight of prescribers and dispensers of prescription drugs (North Carolina Board of Dental Examiners, North Carolina Board of Nursing, North Carolina Board of Pharmacy, and North Carolina Medical Board);
- the UNC Injury Prevention Research Center;
- the substance abuse treatment community; and
- Project Lazarus.

In addition to engaging these critical stakeholders, DHHS should complete the following steps in the strategic planning process:

- identify a mission and vision for North Carolina's system to reduce and prevent prescription drug abuse;
- scan the internal and external environment for the system's strengths, weaknesses, opportunities, and challenges (commonly referred to as a SWOC analysis);
- compare threats and opportunities to the system's ability to meet challenges and seize opportunities (commonly referred to as a GAP analysis);
- identify strategic issues based on SWOC and GAP analyses; and
- formulate strategies and resources for addressing these issues.

The strategic plan for reducing prescription drug abuse should include three to five strategic goals that are outcome-oriented and measurable. Each goal should be connected with objectives supported by the four mechanisms of the system:

- oversight and regulation of prescribers and dispensers by state health care regulatory boards;
- operation of the CSRS, the State's prescription drug monitoring program;
- operation of the Medicaid lock-in program to review behavior of patients with high use of prescribed controlled substances; and
- enforcement of state laws for the misuse and diversion of controlled substances.

In addition, the General Assembly should direct DHHS, with the consultation of the Prescription Drug Abuse Strategic Planning Committee, to develop and implement a formalized performance management system that connects the goals and objectives identified in its strategic plan to operations of the CSRS and Medicaid lock-in program, law enforcement activities, and oversight of prescribers and dispensers. The performance management system should be designed to monitor progress towards achieving goals and objectives and should recommend actions to be taken when performance falls short. Developing and implementing a performance management system will allow North Carolina to determine the effectiveness of its system for monitoring prescribed controlled substances and reducing prescription drug abuse.

Going forward, the General Assembly should direct DHHS to establish a Prescription Drug Abuse Advisory Committee to be the steering committee to monitor achievement of strategic objectives and receive regular reports on progress made toward reducing prescription drug abuse in North Carolina. At a minimum, representatives of this committee should include entities that participated in the development of the strategic plan.

Lastly, the General Assembly should require DHHS to submit annual reports on the performance of North Carolina's system for monitoring prescription drug abuse to the Joint Legislative Oversight Committee on Health and Human Services and the Joint Legislative Oversight Committee on Justice and Public Safety starting December 1, 2015.

Appendix

Appendix A: List of Acronyms

Agency Response

A draft of this report was submitted to the Department of Health and Human Services for review. Its response is provided along with this report.

Program Evaluation Division Contact and Acknowledgements

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

Staff members who made key contributions to this report include Jeff Grimes and Pamela L. Taylor. John W. Turcotte is the director of the Program Evaluation Division.

Appendix A: List of Acronyms

Acronym	Name
AMA:	American Medical Association
ASAM:	American Society of Addiction Medicine
CCNC:	Community Care of North Carolina
CDC:	Centers for Disease Control
CSC:	Computer Sciences Corporation
CSRB:	Controlled Substances Reporting Branch
CSRS:	Controlled Substances Reporting System
DEA:	Drug Enforcement Administration
DECU:	Diversion and Environmental Crimes Unit
DHHS:	Department of Health and Human Services
DMA:	Division of Medical Assistance
DOH:	Department of Health (State of Washington)
FDA:	Food and Drug Administration
FIPS:	Federal Information Processing Standards
GAO:	Government Accountability Office
HID:	Health Information Designs, LLC
HIE:	Health Information Exchange
KASPER:	Kentucky All Schedule Prescription Electronic Reporting System
NAMSDL:	National Alliance for Model State Drug Laws
NC HIE:	North Carolina Health Information Exchange
NIST:	National Institute of Standards and Technology
PBSS:	Prescription Behavior Surveillance System
PDMP:	Prescription Drug Monitoring Program
SBI:	State Bureau of Investigation
VA:	Department of Veterans Affairs
VHA:	Veterans Health Administration



North Carolina Department of Health and Human Services

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Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Robin Gary Cummings, M.D.
Deputy Secretary for Health Services and Medicaid Transformation
Acting State Health Director

April 17, 2014

John W. Turcotte, Director
Program Evaluation Division
North Carolina General Assembly
Legislative Office Building, Suite 100
300 N. Salisbury Street
Raleigh, NC 27603-5925

Dear Mr. Turcotte,

DHHS staff is thankful for your Division's evaluation of North Carolina's system for monitoring the abuse of prescribed controlled substances, and is pleased to offer its observations and responses to the recommendations found in your April 7 report.

Ensuring the health, safety, and well being of all North Carolinians is the top priority for the Department, and it takes all of the recommendations from the Program Evaluation Division very seriously. DHHS is charged with monitoring and minimizing prescription drug abuse in the state, and operates both the Controlled Substances Reporting System (CSRS) and the Medicaid lock-in program with oversight provided by two of the Department's largest Divisions.

The Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMHDDSAS) has worked for forty-five years to protect the health and safety of the people of North Carolina through the prevention of misuse and criminal activity related to controlled substances. Pursuant to General Statute 90-101, the Drug Control Unit under DMHDDSAS is tasked with preventing the diversion of controlled substances through the registration and inspection of any person who manufactures, distributes, dispenses or conducts research with any controlled substances within the state. After many years of Drug Control Unit inspectors conducting investigations manually, in 1985 DMHDDSAS began requesting legislative authority to establish the NC Controlled Substances Reporting System. This authority was granted in 2005, and automating the collection of prescription information has helped the state improve its ability to identify controlled substance abusers and to stop the diversion of prescription drugs in a more efficient and cost effective manner.

Secondly, the Division of Medical Assistance is charged with the enormous task of reducing fraud, abuse, and waste in state Medicaid. One of the challenges this Division faces is the population of Medicaid patients who struggle with pain and often seek multiple prescriptions from multiple doctors, which leads to dramatically higher costs and the potential for abuse and overuse. To address this problem, the Medicaid lock-in program launched in October 2010.

Technology identifies Medicaid recipients with multiple prescriptions for opiate pain relievers or sedative/anti-anxiety medicines, and the Division of Medical Assistance “locks in” those recipients to using a single physician and pharmacy. Locking patients in to one doctor and one pharmacy ensures that they receive the medications and care they truly need while providing an additional level of oversight that can prevent abuse and overuse.

The lock-in program has been well received by the provider community. Additionally, DMA has received positive feedback from CCNC regarding how the lock-in program has assisted in the management of complex patients. DHHS is proud that this program enables beneficiaries who have uncontrolled pain to connect with a sole provider who will address this medical issue and improve the beneficiary’s quality of life for the long-term rather than simply providing a quick fix.

Attached you will find comments on your report findings and the feasibility of your recommendations. DHHS is in agreement that it should implement many of these recommendations, and some have already been integrated into the current system of monitoring prescription drug abuse in this State. It is my hope that, with Program Evaluation’s input, DHHS can utilize its dedicated staff to improve upon the current system for monitoring and preventing the abuse of prescribed controlled substances.

The Department is grateful to the staff of the Program Evaluation Division of the General Assembly for its professionalism and proficiency throughout the entirety of this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Robin Gary Cummings". The signature is fluid and cursive, with a large loop at the end.

Robin Gary Cummings, M.D.

Attachment

Addendum to Official Response

Recommendation 1. The General Assembly should direct state health officials, in consultation with the health care provider occupational licensing boards, to develop statewide opioid prescribing guidelines and direct health care provider occupational licensing boards to adopt those statewide guidelines.

DHHS has no problem with this recommendation. The Department's Division of Mental Health, Developmental Disabilities, and Substance Abuse Services agrees to assist in the development of these guidelines. The Division of Medical Assistance is not directly affected by this recommendation, but could provide support from a clinical perspective.

Recommendation 3. The General Assembly should amend N.C. Gen. Stat. § 90-113 enabling improved CSRS access and utilization.

- **Allow the CSRS to contribute data to the North Carolina Health Information Exchange (NCHIE).**

DHHS agrees with this recommendation. The Department will require other funding for ongoing operations while the Harold Rogers PDMP grant funds may be used for the one-time enhancement.

- **Allow CSRS data to be released to officers within the Drug Enforcement Agency's Office of Diversion Control.**

DHHS agrees with this recommendation.

Recommendation 4. The General Assembly should direct the Department of Health and Human Services (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.

- **NC Health Information Exchange connection.**

DHHS agrees with this recommendation, and the Department will require other funding for ongoing operations while Harold Rogers PDMP grant funds may be used for the one-time enhancement. CSRS has only received a one-time state appropriation of \$54,000 for a recurring cost for this program.

- **Interstate Connectivity.**

DHHS agrees with this recommendation. The two options for joining a national hub for interoperability – NABP PMP InterConnect and RxCheck offered through the Integrated Justice Information Systems (IJIS) Institute - are currently being reviewed.

- **Account updates** – DHHS agrees.
- **Prescriber number validation** – DHHS agrees.
- **Data security protocols** – DHHS agrees.
- **Data transfer** – DHHS agrees.
- **Ad-hoc reporting** – DHHS agrees.

Recommendation 5. The General Assembly should direct the Controlled Substances Reporting Branch to expand monitoring capacity by establishing data use agreements with the Prescription Behavior Surveillance System.

DHHS agrees with this recommendation.

Recommendation 6. The General Assembly should direct the Division of Medical Assistance to improve the effectiveness and efficiency of the Medicaid lock-in program.

- **Establish written procedures for the operation of the lock-in program, including specifying the responsibilities of DMA and the contractor.**

DHHS agrees with this recommendation and is currently documenting the procedures required by DMA and its contractor.

- **Establish procedures for the sharing of bulk data with the Controlled Substances Regulatory Branch.**

DHHS, with input from the Attorney General's Office, will research capabilities to share data with the Medicaid lock-in program. In December of 2013 the Department registered a staff person at the Division of Medical Assistance to review the CSRS data against the lock-in data. Enlisting guidance from the Attorney General's Office will ensure that DMA's procedures for sharing data with the Controlled Substances Regulatory Branch will be in compliance with federal and state laws.

- **Extend lock-in duration to two years.**

DHHS agrees to review the current criteria for duration of lock-in with the Narcotic Task Force and the N.C. Physicians Advisory Group for clinical appropriateness of extending the duration to two years, and will make revisions according to the recommendations it receives.

- **Revise program eligibility criteria through consultation with the Physicians Advisory Group.**

DHHS agrees to review current inclusion criteria with the Narcotic Task Force and the N.C. Physicians Advisory Group for inclusion of other drug classes. DHHS agrees to report annual savings to the Joint Program Evaluation Legislative Oversight Committee within one year of re-implementation.

- **Develop a website and communication materials to inform lock-in enrollees, prescribers, pharmacists and emergency room healthcare providers about the program.**

DHHS agrees to have a webpage linked from the outpatient pharmacy program webpage to lock-in program information, and already provides the communication materials requested.

- **Increase program capacity to ensure that all individuals who meet program criteria are locked-in.**

DHHS agrees to work with Human Resources to expand current staffing in order to support increased enrollment into the program. DHHS also agrees to discuss staffing

needs with the Office of Administrative Hearings and the Attorney General Office to support additional mediations and hearings related to increased enrollees.

- **Conduct an audit of the lock-in program by May 30, 2014.**

DHHS agrees to conduct an audit once the program becomes operational again but cannot commit to the May 30, 2014 date because the exact operational date is unknown at this time.

Computer Sciences Corporation (CSC) has not formally defined the implementation date for the Recipient Lock In bundle. CSC must deliver the preliminary design document (PDD) to the State by May 15th. Once the State approves the PDD, CSC will receive it back on approximately June 1st. At that time CSC would be able to provide an estimated implementation date.

In the meantime, Program Integrity is working on an audit of the pharmacy lock-in program. Data analyses in progress include but may not be limited to: the number of emergency fills per beneficiary, the frequency and reasons beneficiaries changed authorized prescribing or dispensing providers, and location patterns of providers. Findings of these and other indicators as identified will be included in the final audit report.

Recommendation 7. The General Assembly should 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.

DHHS agrees with this recommendation, and DMHDDSAS is prepared to lead this strategic planning effort.