



**COLORADO**

Department of Human Services  
Reggie Bicha, Executive Director, CDHS

The Honorable John W Hickenlooper,  
Governor  
136 State Capitol  
Denver, CO 80203-1792

January 1, 2016

Re: Controlled Substance Diversion Prevention and Control Program Report

Dear Governor Hickenlooper:

Enclosed, please find a legislative report to the Governor, the President of the Senate and the Speaker of the House of Representatives from the Department of Human Services concerning the controlled substance diversion prevention and control program.

- *Section 18-18-308 C.R.S. (2015) requires the Department to submit an annual report on controlled substance diversion prevention and control program outcomes with respect to its effects on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances in this state.*

If you require further information or have additional questions, please contact the Department's Legislative Liaison, Lauren Lambert-Schreier, [lauren.schreier@state.co.us](mailto:lauren.schreier@state.co.us), or 303-866-3019.

Sincerely,

Reggie Bicha  
Executive Director

Enclosure

Cc: Molly Otto, Colorado Joint Legislative Library  
Debbi MacLeod, Colorado State Publications Library  
Nikki Hatch, Deputy Executive Director of Operations  
Alicia Caldwell, Deputy Executive Director of Legislative Affairs/Communication  
Julie Krow, MA, LPC, Deputy Executive Director, Community Partnerships  
Sarah L. Sills, MPA, MSTC, Director of Budget and Policy  
Nancy VanDeMark, Ph.D., Director, Office of Behavioral Health







**COLORADO**

**Office of Behavioral Health**

Department of Human Services

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# **Controlled Substance Diversion Prevention and Control Report C.R.S. §18-18-309 (2015)**

**Report to the Governor, the President of the  
Senate, and the Speaker of the House of  
Representatives**

January 1, 2016

## **Statement on the role of the Colorado Department of Human Services, Office of Behavioral Health related to Affordable Care Act and Expanded Medicaid Coverage**

The Colorado Department of Human Services, Office of Behavioral Health funds behavioral health treatment services for individuals who are “medically indigent” and for whom services are not funded through another payment source. Colorado Department of Human Services, Office of Behavioral Health defines “medically indigent” as those individuals that have mental health and/or substance use disorders and incomes below 300% of the Federal Poverty Level.

The Affordable Care Act improved behavioral health system accessibility and affordability for Coloradans through expanded Medicaid eligibility, minimum benefit package requirements, and financial assistance through the Colorado health insurance marketplace. As a result of these health policy changes, many people who were formerly served through the Colorado Department of Human Services, Office of Behavioral Health service system can now be served by Medicaid or other health insurance. Consequently, Colorado Department of Human Services, Office of Behavioral Health is projecting lower demand for behavioral health services from individuals who are uninsured and lower costs associated with clients who may be only briefly uninsured.

Due to the significant changes in behavioral health funding since the passage of the Affordable Care Act, Colorado Department of Human Services, Office of Behavioral Health continues to refine its approach to ensuring that essential services are available to individuals who have emergent service needs, lack insurance coverage, or where services are not covered by public or private health insurance. To date, Colorado Department of Human Services, Office of Behavioral Health has determined that while most individuals may be eligible for health insurance, important service gaps remain in the areas of 1) prevention/early intervention; 2) specific types of treatment services such as residential substance abuse treatment; 3) recovery support services such as housing and employment assistance; and 4) essential complementary services such as cross system care coordination and transition supports. Further, Colorado Department of Human Services, Office of Behavioral Health has identified emergent services such as crisis response and detoxification as areas where capacity must be available regardless of payer source in order to facilitate public and individual safety.

To ensure that Colorado Department of Human Services, Office of Behavioral Health invests its resources wisely and does not duplicate services that are funded by other sources, it has reoriented contracting to strategically address the gaps in insurance coverage. The Colorado Department of Human Services, Office of Behavioral Health has focused attention on defining and supporting essential capacity while encouraging contractors to recover costs from insurance plans for covered services. These changes are intended to ensure a safety net of behavioral health services for all Coloradans while minimizing the duplication of payment for services.

In support of behavioral health treatment services for Coloradans, the Colorado Department of Human Services, Office of Behavioral Health provides regulatory oversight for the use of controlled substances. The following is a report on controlled substance diversion prevention and control in Colorado for FY 2014-2015.

## Introduction

The Colorado Department of Human Services, Office of Behavioral Health submits this Controlled Substance Diversion Prevention and Control Report to the Governor, the President of the Senate, and the Speaker of the House of Representatives in compliance with:

§18-18-309 (4) C.R.S. 2015 Diversion Prevention and Control

“The department shall annually report to the governor and to the president of the senate and the speaker of the House of Representatives on the outcome of this program with respect to its effects on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances in this state.”

## Controlled Substance Diversion Prevention and Control Report

As required by C.R.S §18-18-309 (4), the Department of Human Services, Office of Behavioral Health is reporting on the controlled substance diversion prevention and control program.

The Department of Human Services, Office of Behavioral Health serves as the state authority for the Controlled Substances Act in Title 27, Article 80, Part 2. For the purposes of this report, “controlled substances” refers to: methadone, buprenorphine, lorazepam, chlordiazepoxide, alprazolam, and diazepam in licensed addiction programs that compound, administer, or dispense controlled substances to treat substance abuse and addiction. The Department of Human Services, Office of Behavioral Health regulates controlled substances dispensed by licensed controlled substance addiction treatment programs to prevent potential misuse and diversion of these medications by staff and patients.

### *Federal Regulation*

Controlled substances are under strict federal regulation. The federal Controlled Substances Act was created and implemented to require practitioners who prescribe, dispense, or administer controlled substances to register with the Drug Enforcement Agency. In 1974, the Narcotic Addiction Treatment Act (NATA) recognized the use of controlled substances to treat opioid dependence and defined long-term or maintenance treatment. The NATA also required separate registration of medical practitioners by the Drug Enforcement Agency (who use the controlled substances for opioid treatment). The federal executive branch ensures that the implementation of opioid medication assisted treatment includes the issuance of federal regulations found in the Federal Opioid Treatment Standards (United States Code of Federal Regulations 42 CFR 8.12).

Key elements for opioid medication treatment programs include:

- Practitioners must have federal certification and state approval to dispense methadone for addiction treatment.
- Practitioners must be certified by the Substance Abuse and Mental Health Administration.
- Practitioners must be registered with the Drug Enforcement Agency.
- Practitioners must be accredited by a Substance Abuse and Mental Health Administration-approved national accreditation organization.

- Physicians are not allowed to prescribe methadone for addiction treatment outside an approved opioid medication treatment program.
- Federal law does not preempt state's right to regulate.
- Substance Abuse and Mental Health Administration sets federal treatment standards and requires independent oversight with standards appropriate to the treatment.
- States monitor the same areas as federal agencies.
- States may have regulations that exceed federal regulation standards.
- All records are maintained in accordance with federal confidentiality rules governing drug and alcohol treatment records.

### *National Accreditation*

Opioid medication assisted treatment programs, in addition to federal and state oversight, are required to be accredited through a national independent accreditation organization. Accreditation is the process by which the Substance Abuse and Mental Health Administration approves national accreditation bodies that conduct periodic site visits to evaluate agencies compliance with accreditation standards, agency policies, procedures, and practices, and patient services regarding opioid medication assisted treatment programs. The Substance Abuse and Mental Health Administration approved the following three national accrediting bodies: The Joint Commission, The Commission on the Accreditation of Rehabilitation Facilities, and The Council on Accreditation.

### *State Regulation*

- Colorado first enacted laws regarding controlled substances in 1963 in the form of the State Narcotic Act.
- In 1968, Colorado enacted the Colorado Dangerous Drug Act.
- In 1981, the Colorado Dangerous Drug Act and the State Narcotic Act were combined into the Colorado Licensing of Controlled Substances Act (Act). The Act included disciplinary actions in the form of denial, revocation, or suspension of a license; the listing of unlawful acts; creation of definitions and penalties for procurement of controlled substances by fraud and deceit; and an inventory of Schedule I to V drugs. Additionally, recordkeeping requirements for licensees were delineated, along with authorization for inspections, investigations, and reports necessary to determine compliance.

The Colorado Department of Human Services, Office of Behavioral Health has established guidelines for the prevention of diversion of controlled substance medication from opioid medication assisted programs. The Colorado Department of Human Services, Office of Behavioral Health policies and procedures are written to protect the public from the loss, theft or misuse of controlled substances. Policy requires that licensed controlled substance addiction treatment programs that dispense controlled substances report directly to the Colorado Department of Human Services, Office of Behavioral Health Controlled Substances Administrator when a patient or staff person has lost, stolen or misused opioid medication. For example, licensed controlled substance addiction treatment programs are required to investigate when a patient may have misused the medication and as a result may adjust the quantity of the controlled substance that a patient is allowed to take outside the clinical facility ("take home doses"). The reported information from such events is compiled and reviewed by the Colorado Department of Human Services, Office of Behavioral Health

Controlled Substances Administrator for the purposes of understanding the scope of the problem and improving control and oversight through the provision of technical assistance.

In summary, substance use disorder treatment programs that utilize controlled substances for opioid medication assisted treatment are regulated by the federal government and state governments. Agency adherence to treatment standards is ensured through accreditation. For the protection and safety of all Colorado residents, multiple federal agencies combined with the Colorado Department of Human Services, Office of Behavioral Health provide regulatory oversight of the treatment of opioid dependence throughout the treatment continuum from onset of the substance use disorder to patient care and treatment.

Opioid medication assisted treatment programs must adhere to local ordinances, such as zoning laws, which strictly regulate operating locations. The Office of Behavioral Health provides ongoing support to these programs through various means including site visits, on-site trainings, and ongoing discussions at quarterly meetings. In addition to the identified critical incident trends, the most common issues associated with diversion are addressed through staff or patient education forums, meetings, and if necessary, formal policy changes.

### *Prescription Drug Monitoring Program*

All opioid medication assisted treatment programs are now required to adhere to the Prescription Drug Monitoring Program and implement policies and procedures to prevent the misuse of opioid medication and other substances. The Department of Regulatory Agencies has oversight and authority over the Prescription Drug Monitoring Program, which controls the prescribing of controlled substances for medical purposes not related to the treatment of addictions. The Colorado Department of Human Services, Office of Behavioral Health Controlled Substances Administrator works closely with the Department of Regulatory Agencies and the Prescription Drug Monitoring Program to coordinate and provide technical assistance between the two programs.

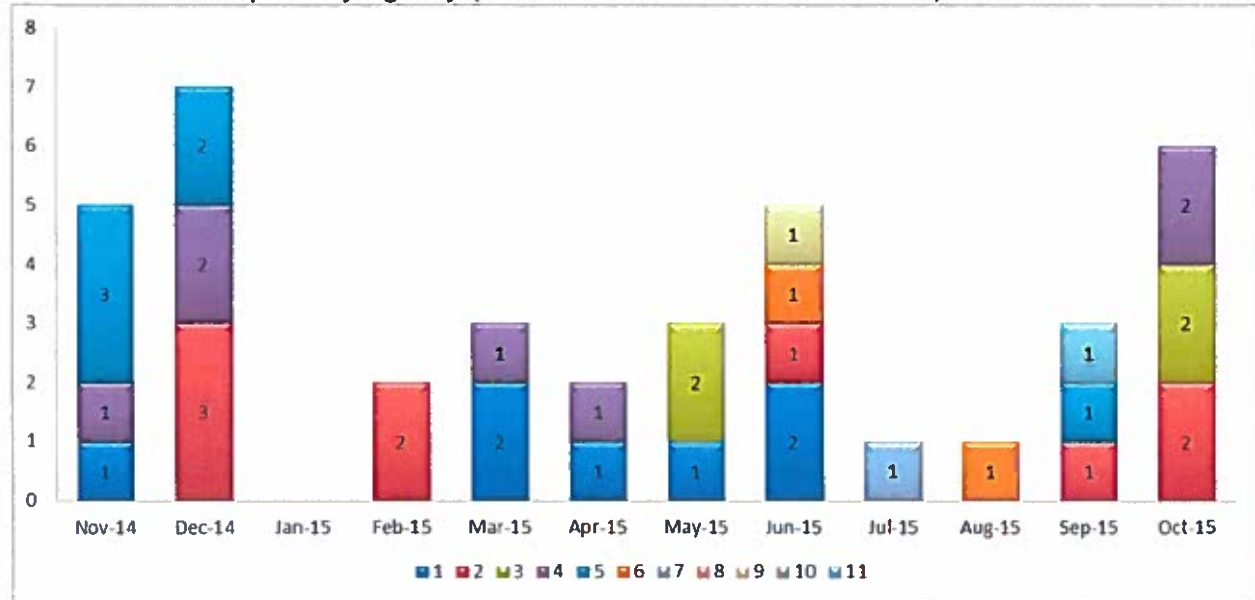
### **Outcomes**

From November 2014 to October 2015, the Colorado Department of Human Services, Office of Behavioral Health Controlled Substances Administrator identified a total of 38 instances at state licensed opioid medication assisted programs where medications were diverted. In these instances, the Colorado Department of Human Services, Office of Behavioral Health Controlled Substances Administrator:

- Assisted program staff in understanding the controlled substance protocol policy.
- Provided specific education to program staff and patients to reduce take-home doses to further reduce the likelihood of drug diversion or misuse.
- Sought program input into how diversion protocol policy can be improved and/or better operationalized within the agency itself.

Below is the graphical representation of reported instances of diversion for the sites reviewed by the Colorado Department of Human Services, Office of Behavioral Health (sites are not named, but are numbered one through eleven):

### Total Diversion Reports by Agency (November 2014 thru October 2015):



\*Legend: each color/number represents one of the eleven Colorado Department of Human Services, Office of Behavioral Health licensed opioid medication assisted treatment programs.

The State experienced an overall reduction of 34% (19) incidents reported to the State from the previous year. This reduction is notable and encouraging, given an increase of 800 patients in opioid medication assisted treatment programs and the establishment of three new opioid medication assisted treatment programs within the same time frame. The decrease in reported incidents of opioid drug diversion in programs may be indicative of two things:

1. The programs are experiencing an actual decreased number of diversion incidents from the previous year; or
2. Additional training may be needed for newer programs and counselors to properly identify and report instances of diversion. Actions to address this possibility are addressed below.

Through the implementation and use of the Prescription Drug Monitoring Program, there is now more frequent and enhanced collaboration with primary care physicians. This has allowed for the ability to proactively identify high-risk patients and scenarios, as well as address any further abuses of other controlled medications when patients are outside of the program's direct supervision and care.

#### Future Actions for controlled substance diversion:

1. New training for all programs on general controlled substance diversion.
2. New formal rules to increase the oversight of diversion issues that are expected to be completed by fall of 2016.
3. The Colorado Department of Human Services, Office of Behavioral Health has recommended further reducing the number of allowed take-home methadone doses as a means to reduce diversion.
4. Detailed review of patient charts at annual controlled substance licensing site visits to collect additional data on diversion issues. Reviewers will require plans of correction for

programs or individual counselors found to be associated with increased incidences of diversion.

