

**Psychiatric Medication Practices  
for Adult Civil Patients  
Colorado Mental Health Institutes  
Department of Human Services**

**Performance Audit  
May 2011**



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May 12, 2011

Members of the Legislative Audit Committee:

This report contains the results of a performance audit of psychiatric medication practices for adult civil patients at the Colorado Mental Health Institutes at Fort Logan and Pueblo. Both Institutes are within the Department of Human Services. The audit was conducted pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government. The report presents our findings, conclusions, and recommendations, and the responses of the Department of Human Services.

*Sally Symanski*



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## *Glossary of Terms and Abbreviations*

**Department** – Colorado Department of Human Services. A principal department in Colorado state government responsible for administering and overseeing the Colorado Mental Health Institutes at Fort Logan and Pueblo.

**Division** – Mental Health Institute Division. The administrative unit within the Colorado Department of Human Services that directly administers, manages, and oversees the Colorado Mental Health Institutes at Fort Logan and Pueblo.

**Fort Logan Institute** – Colorado Mental Health Institute at Fort Logan. One of two State-run mental health institutes that provide inpatient psychiatric treatment for individuals with the most serious mental illnesses.

**HMA Team** – Health Management Associates, Inc. A four-member, multidisciplinary review team under contract with the Colorado Office of the State Auditor to provide the necessary clinical expertise for this audit engagement.

**PRN** – Representing the Latin phrase *pro re nata*, PRN is commonly used in medical prescriptions to mean “as needed” or “as the situation arises.” The dosage of the prescribed medication is not scheduled; instead, administration is left to the caregiver’s or the patient’s prerogative.

**Psychiatric medications** – Medications used in the treatment of mental illness, including antipsychotics, antidepressants, mood stabilizers, anxiolytics, and stimulants.

**Pueblo Institute** – Colorado Mental Health Institute at Pueblo. One of two State-run mental health institutes that provide inpatient psychiatric treatment for individuals with the most serious mental illnesses.

**The Joint Commission** – An independent, nonprofit organization that sets health care quality and accreditation standards for hospitals in the United States.



**Psychiatric Medication Practices for Adult Civil Patients**  
**Department of Human Services**  
**Performance Audit**  
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## **Purpose and Scope**

The purpose of this audit was to determine whether the Department of Human Services (the Department) and the Colorado Mental Health Institutes at Fort Logan and Pueblo (the Institutes) provide adult civil patients, including patients under involuntary medication orders, with adequate safeguards against adverse side effects and other risks associated with psychiatric medications. We conducted this performance audit in response to a legislative request. We contracted with Health Management Associates, Inc. (the HMA Team), based in Lansing, Michigan, to provide the necessary clinical expertise for this audit engagement. Audit work was performed from August 2010 through May 2011. We acknowledge the cooperation and assistance provided by Department and Institute management and staff.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## **Overview**

*Mental illness* is a term that refers collectively to all diagnosable mental disorders, which are medical conditions that disrupt a person's thinking, feeling, mood, ability to relate to others, and daily functioning. Psychiatric medications are an integral part of treating mental illness. Commonly used psychiatric medications include antipsychotics, antidepressants, mood stabilizers, anxiolytics, and stimulants. When used correctly, psychiatric medications can be very effective at treating the symptoms of a mental illness. However, many psychiatric medications have negative side effects requiring patients to be routinely monitored and their medications to be carefully managed throughout treatment.

The State's two mental health institutes—the Colorado Mental Health Institute at Fort Logan (the Fort Logan Institute) and the Colorado Mental Health Institute at Pueblo (the Pueblo Institute)—are part of the continuum of mental health care, providing inpatient psychiatric treatment to those Coloradans with the most serious mental illnesses. In Fiscal Year 2010, the Institutes had a total of about 2,245 inpatient admissions.

The Mental Health Institute Division within the Department provides a certain level of direct administrative oversight regarding Institute operations, finance and budgeting, information

management, quality management, contract management, and regulatory compliance. In Fiscal Year 2010, the Fort Logan and Pueblo Institutes had expenditures of about \$26.9 million and \$78.4 million, respectively (about \$105.3 million total). The Institutes' primary revenue source is the State General Fund—comprising approximately 85 percent of the Institutes' total revenues in Fiscal Year 2010—with the remaining revenues coming from other sources, such as patient payments, Medicare, Medicaid, and third-party insurers.

## Key Findings

Strong medication management and monitoring practices that safeguard against adverse side effects and other risks associated with psychiatric medications are an essential component of providing quality patient care. Overall, the HMA Team found no overt or systemic problems with medication monitoring or management practices warranting immediate intervention. Nonetheless, the HMA Team found that the Department and the Institutes need to strengthen the clinical framework for using, managing, and monitoring psychiatric medications. Specifically, the HMA Team found that, in several key areas, the Department and the Institutes have not actively engaged in the design and implementation of common clinical practices and coordinated monitoring and oversight mechanisms that align with medical best practices and apply to both Institutes.

- **Emergency and Involuntary Medication Orders.** Seven patient files lacked sufficient clinical documentation to substantiate that a psychiatric emergency existed warranting an emergency medication order. Additionally, charts for six patients who were on emergency medication orders for more than 72 hours lacked clear documentation of a concurring opinion from another psychiatrist and/or a written request for a court hearing, as required by state rule. Finally, 19 patient files lacked sufficient clinical documentation to substantiate that conditions existed warranting a petition for or continued use of a court-ordered involuntary medication order. For example, four patients were under involuntary medication orders even though the medical charts appeared to indicate that the patient would accept or authorize the medications voluntarily. Clear and sufficient documentation of the clinical basis for emergency and involuntary medication orders is important because the medications are being administered without the patient's consent.
- **Antipsychotic Medications.** Medical charts for three patients on clozapine—an antipsychotic medication that has a potentially life-threatening side effect—did not provide a clear reference to the timing and results of prior trials of standard therapy (i.e., less risky treatments) documenting that the patients were thoroughly evaluated on other less risky antipsychotic medications. Additionally, practices at both Institutes may have unintentionally resulted in more than one antipsychotic medication being simultaneously prescribed to a patient. Specifically, eight patients' current medications were not discontinued upon initiation of an involuntary medication order, which means that the patients had two sets of medication orders in effect simultaneously. Further, there were cases in which the psychiatrist ordered two or three psychiatric medications, including

antipsychotics, on an as-needed basis for the same condition without sufficient documentation substantiating the need for multiple medications.

- **Medication Monitoring Guidelines.** Metabolic monitoring was not ordered for 17 patients who were prescribed second-generation antipsychotics. The American Diabetes Association and the American Psychiatric Association recommend metabolic monitoring of all patients on second-generation antipsychotics. Additionally, the Institutes do not have a uniform or consistent approach regarding medications that are designated as high-risk, or high-risk medications that have additional clinical guidelines and monitoring protocols. For example, the Fort Logan Institute has specific clinical guidelines and monitoring protocols for lithium, whereas the Pueblo Institute only designates lithium as a high-risk medication. Even where both Institutes have developed clinical guidelines and monitoring protocols for the same high-risk medications, each Institute allows different dosing specifications and requires different monitoring practices. Finally, established clozapine guidelines were not followed for two patients at the Pueblo Institute.
- **Medication Administration.** The Institutes' average medication error rates in Calendar Year 2010 were higher than the average medication error rate for a comparable peer group of facilities. Specifically, the Fort Logan and Pueblo Institutes averaged about 4.50 and 4.93 medication errors per 100 episodes of care, respectively. By comparison, facilities in the peer group averaged about 2.71 medication errors per 100 episodes of care. The Institutes' higher average medication error rates were within a statistically acceptable range of variation. Additionally, the HMA Team observed three medication passes at each Institute and identified medication errors occurring for four patients. The HMA Team also observed several conditions, such as frequent staff interruptions and inconsistent hand sanitizing practices, that increase the risk of medication errors or other problems occurring.
- **Electronic Health Record and Pharmacy Systems.** Currently, the Institutes utilize a paper-based medical record. A common criticism of paper-based records is the potential for fragmentation of patients' clinical data. The Institutes' migration to an electronic health record could hold significant benefits for patient care, including increased access to and integration of patient information, increased decision support for clinicians, and increased efficiencies in documentation practices. Additionally, the information system used by both Institutes' pharmacies is an aging legacy system that does not have sufficient functionality to facilitate the clinical and consultative services that pharmacies are increasingly being expected to provide. For example, the system cannot produce automated reports of patients' active medications, track Institute-wide and physician-specific prescription practices, or report on aggregate factors, such as the number of patients on a specific drug or the prescription drugs most commonly used at each Institute.

Our recommendations and the responses from the Department of Human Services can be found in the Recommendation Locator and in the body of this report.

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## RECOMMENDATION LOCATOR

**Agency Addressed: Department of Human Services**

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Rec. No.	Page No.	Recommendation Summary	Agency Response	Implementation Date
1	23	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to ensure that emergency and involuntary medication orders have a solid clinical basis in accordance with medical best practices. At a minimum, the Department should work with the Institutes to: (a) develop a common policy and procedures as a foundation for the clinical use of emergency and involuntary medication orders, including associated documentation requirements, when treating civil patients; and (b) routinely monitor and review the use of emergency and involuntary medication orders for appropriateness on an ongoing basis.	Agree	a. August 2011 b. October 2011
2	25	The Department of Human Services (the Department) should provide more clarity to mental health practitioners and better mirror medical best practices by working with the State Board of Human Services, affected facilities, advisory committees, and other stakeholders to revise the state rules governing the use of emergency and involuntary psychiatric medications, as appropriate.	Agree	January 2012

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## RECOMMENDATION LOCATOR

**Agency Addressed: Department of Human Services**

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Rec. No.	Page No.	Recommendation Summary	Agency Response	Implementation Date
3	28	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to minimize the unnecessary and/or unintended risks to patients when prescribing antipsychotic medications. Specifically, the Department and the Institutes should: (a) modify clozapine guidelines to require that physicians' orders reference prior treatment efforts and their results when clozapine is prescribed and provide instruction for how recently the two trials of standard therapy must have occurred prior to starting clozapine therapy; (b) establish a process to review patient chart documentation and verify that clozapine is clearly indicated prior to starting treatment; (c) ensure that all current medication orders are reviewed and medications discontinued, as appropriate, when an involuntary medication order is initiated; (d) reevaluate and limit, if not discontinued entirely, the practice of ordering multiple antipsychotic medications PRN (i.e., on an as-needed basis); and (e) actively identify and monitor all antipsychotic polypharmacy cases on a routine basis to ensure their continued appropriateness for patient treatment.	Agree	a. August 2011 b. September 2011 c. September 2011 d. September 2011 e. September 2011

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## RECOMMENDATION LOCATOR

**Agency Addressed: Department of Human Services**

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Rec. No.	Page No.	Recommendation Summary	Agency Response	Implementation Date
4	34	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to develop and implement a common high-risk medication policy and related procedures to ensure that adverse side effects patients may experience from the use of psychiatric medications are identified, managed, and/or mitigated uniformly and in accordance with medical best practices. At a minimum, the common policy and related procedures should: (a) designate a uniform list of high-risk medications for those drugs used by both Institutes, as well as uniform stand-alone clinical guidelines and monitoring protocols for those high-risk medications in common that warrant clinical, pharmacy, and laboratory monitoring; (b) require metabolic monitoring for all patients on second-generation antipsychotics; and (c) include routine reviews for compliance with common policies and procedures established for high-risk medications as part of both Institutes' quality improvement processes.	Agree	September 2011
5	40	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to strengthen medication administration programs and minimize the risk of medication errors occurring by: (a) requiring nursing supervisors from a different unit and/or pharmacists to perform routine, unscheduled observations of medication passes; and (b) exploring options to provide staff with more routine, targeted training opportunities regarding established medication administration policies and procedures, emerging best practices, certain administration techniques, and other identified problem areas.	Agree	July 2011

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## RECOMMENDATION LOCATOR

**Agency Addressed: Department of Human Services**

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Rec. No.	Page No.	Recommendation Summary	Agency Response	Implementation Date
6	44	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to achieve a more standardized level of information and organization in the medical charts. Specifically, the Department and the Institutes should: (a) ensure that psychiatrists record progress notes that clearly document the basis for all orders and changes in a patient's treatment plan; (b) consider implementing one or more behavioral management tracking tools, especially for use in assessing treatment response and medication management; and (c) develop a single form that tracks all court processes, steps, and scheduled events for the use of emergency and involuntary medication orders, as well as a means of ensuring that patients' current lists of active medications and current lists of problems are readily identifiable and accessible in the medical record.	Agree	a. September 2011 b. November 2011 c. November 2011
7	47	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes), the Governor's Office, and relevant legislative committees to pursue the eventual adoption of an electronic health record system.	Agree	July 2012
8	50	The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to maximize the use of pharmacy staff and pharmacy systems in support of medical staff and patient care. Specifically, the Department and the Institutes should: (a) include clinical monitoring and consultative services as part of the pharmacy department's primary responsibilities at each Institute, including conducting routine drug regimen reviews; (b) pursue the eventual replacement of the Institutes' legacy pharmacy system; and (c) develop interim solutions to improve upon tracking and reporting capabilities of the current pharmacy system in the most critical areas until the system can be replaced.	Agree	a. July 2011 b. December 2011 c. November 2011

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# Overview

## Chapter 1

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*Mental illness* is a term that refers collectively to all diagnosable mental disorders, which are medical conditions that disrupt a person's thinking, feeling, mood, ability to relate to others, and daily functioning. Just as diabetes is a disorder of the pancreas that, without treatment, can limit an individual's ability to function normally, mental illness is also a medical condition that, without treatment, can result in an individual's diminished capacity for coping with the ordinary demands of life. Mental illness affects persons of any age, race, religion, or income. According to the National Institute of Mental Health, an estimated 26 percent of Americans aged 18 and older suffer from a mental illness in a given year. Mental illness falls along a continuum of severity. About 6 percent of Americans aged 18 and older, or roughly 1 in 17 adults, suffers from a serious mental illness (e.g., major depression, schizophrenia, bipolar disorder, obsessive compulsive disorder, panic disorder, post traumatic stress disorder, and borderline personality disorder). The diagnosis, duration, and resulting disability of a serious mental illness can require more extensive and/or intensive treatment (e.g., inpatient hospitalization) than what is required with other less severe forms of mental illness.

The consequences of an untreated mental illness can often be significant, including disability, unemployment, substance abuse, homelessness, suicide, crime, and an overall diminished quality of life. However, many individuals with mental illness live an improved quality of life with the help of treatments such as medication. Medications cannot cure mental illness; however, they can be very effective at treating the symptoms and are often an integral part of any treatment plan. For example, according to data from the federal Substance Abuse and Mental Health Services Administration, in 2008, prescription medication was used during treatment for about 53 percent of adults in the United States with a serious mental illness.

## Mental Health Institutes

The General Assembly established the Mental Health Institute at Pueblo (the Pueblo Institute) in October 1879 and the Mental Health Institute at Fort Logan (the Fort Logan Institute) in July 1961. These two State-run mental health institutes (the Institutes) are a part of the continuum of mental health care for Colorado citizens. In Fiscal Year 2010, the Institutes had a total of about 2,245 inpatient admissions. Together, the Institutes provide inpatient psychiatric treatment for patients aged 12 and older with the most serious mental illnesses

such that they cannot function in society and/or be treated in their local community. The Institutes treat two categories of patients with mental illness: civil patients and forensic patients. Civil patients are individuals with serious mental illness who have sought treatment voluntarily or who have been committed involuntarily by a court. Civil patients are generally referred to the Institutes through local Community Mental Health Centers, which provide or arrange for certain core mental health services to individuals residing in designated geographic service areas of the state. Forensic patients are adults who are accused of a crime and found by the courts to be Not Guilty by Reason of Insanity or Incompetent to Proceed (i.e., defendants unable to assist in their defense). Forensic patients may also include individuals referred by the state courts for evaluation of competency to stand trial. Only the Pueblo Institute treats forensic patients.

This audit focused on the adult civil population, including geriatric patients (i.e., patients aged 60 and older). The adolescent civil population (i.e., patients under the age of 18) and all forensic patients were excluded from review. Statistics on the number of beds available and the average length of stay for adult civil patients, including geriatric patients, are as follows:

**Fort Logan Institute.** Currently, the Fort Logan Institute has 94 (82 percent) of its 114 beds allocated for adult civil patients. Effective January 1, 2010, the Fort Logan Institute closed its geriatric inpatient treatment unit; however, some geriatric patients remained at the Fort Logan Institute subsequent to this date pending final placement in other facilities. For Fiscal Year 2010, the Fort Logan Institute had an average adult and geriatric civil patient daily census of about 96 patients. The average length of stay was about 47 days for adult civil patients and 466 days for geriatric patients.

**Pueblo Institute.** Currently, the Pueblo Institute has 104 (72 percent) of its 144 civil beds allocated for adult and geriatric civil patients. For Fiscal Year 2010, the Pueblo Institute had an average adult and geriatric civil patient daily census of about 92 patients. The average length of stay was about 53 days for adult civil patients and 166 days for geriatric patients.

## Fiscal Overview

The State's two mental health institutes receive revenues from various sources to pay for the cost of patient care. As shown in the following table, the Institutes' primary revenue source is the State General Fund. Other revenue sources include patient payments (e.g., fee-for-service), Medicare, Medicaid, third-party insurers, counties, school districts, other state departments (e.g., Department of Corrections and Department of Education), and the Judicial Branch. Specifically, in Fiscal Year 2010, the Institutes' revenues totaled approximately \$105.3 million, of

which about \$89.5 million (85 percent) was from the State General Fund and about \$15.8 million (15 percent) was from other sources.

<b>Colorado Mental Health Institutes at Fort Logan and Pueblo</b>			
<b>Revenue Data</b>			
<b>Fiscal Year 2010</b>			
<b>(Dollars in Millions)</b>			
<b>Revenue Source</b>	<b>Fort Logan Institute</b>	<b>Pueblo Institute</b>	<b>Total</b>
General Fund	\$23.2	\$66.3	\$89.5
Other Sources <sup>1</sup>	\$3.7	\$12.1	\$15.8
<b>Total Revenues</b>	<b>\$26.9</b>	<b>\$78.4</b>	<b>\$105.3</b>
<b>Source:</b> Department of Human Services.			
<sup>1</sup> Includes revenues from patient payments (e.g., fee-for-service), Medicare, Medicaid, third-party insurers, counties, school districts, other state departments (e.g., Department of Corrections and Department of Education), the Judicial Branch, and other miscellaneous sources.			

State general funds are used to fill the difference between the Institutes' total spending authority and the total revenues from all other sources. Federal law generally does not allow federal Medicaid matching funds for services provided by the Institutes to individuals aged 21 through 64. This is a primary reason why the state general funds compose such a significant portion of the Institutes' total revenues. However, Medicaid is a primary payer of mental health services in community settings, and most patients become eligible for Medicaid once they are discharged from the Institutes.

In Fiscal Year 2010, the Fort Logan and Pueblo Institutes had expenditures of about \$26.9 million and \$78.4 million, respectively (about \$105.3 million total). The majority of expenditures are for personal services, which include salary, wages, and benefits for about 252 full-time-equivalent positions at the Fort Logan Institute and about 923 full-time-equivalent positions at the Pueblo Institute.

## Regulatory Oversight

State statute [Section 27-90-104(1), C.R.S.] vests the Colorado Department of Human Services (the Department) with the responsibility for managing, supervising, and controlling the Institutes. The Mental Health Institute Division (the Division) within the Department provides a certain level of direct administrative oversight regarding Institute operations, finance and budgeting, information management, quality management, contract management, and regulatory compliance. However, according to Department staff, the Institutes generally operate as separate entities. For example, both Institutes are licensed, accredited, and certified as separate psychiatric hospitals. Additionally, each Institute has different historical roots, receives referrals from and discharges

patients to different community providers, and has a different mix of patients and clinical staff.

Several other entities oversee and/or monitor the quality of care at the Institutes, as follows:

**The Division of Behavioral Health** is another division within the Department that monitors treatment provided by the two Institutes and 53 other mental health facilities under Title 27, Article 65, C.R.S. The Division of Behavioral Health approves these so-called “27-65 facilities” on an annual basis to provide rights-restricted procedures (e.g., 72-hour holds and evaluations, short- and long-term certifications, involuntary medications, and seclusion and restraint) to persons with mental illness.

**The Centers for Medicare and Medicaid Services** is the federal agency responsible for setting standards and overseeing the Medicare and Medicaid programs. The Institutes must comply with federal minimum health and safety standards for hospitals and psychiatric hospitals as a condition of receiving Medicare and Medicaid funding for qualifying patients.

**The Joint Commission**, formerly known as the Joint Commission on Accreditation of Healthcare Organizations, is an independent, nonprofit organization that sets health care quality and accreditation standards for hospitals in the United States. The Institutes are Joint Commission-accredited organizations. The federal Centers for Medicare and Medicaid Services has given the Joint Commission the authority to certify whether or not hospitals, including the Institutes, meet certain Medicare and Medicaid program requirements.

**The Department of Public Health and Environment** is the state agency responsible for ensuring that health care facilities in the state comply with applicable health and safety standards, including state licensure standards and federal standards for those facilities serving Medicare and/or Medicaid beneficiaries. The federal Centers for Medicare and Medicaid Services contracts with the Department of Public Health and Environment to conduct certification surveys and complaint surveys to ensure that hospitals, including the Institutes, comply with Medicare and Medicaid program requirements. The Department of Public Health and Environment also conducts occurrence investigations (e.g., patient abuse, assaults, unexplained deaths, medication diversions, and escapes/elopements) at health facilities as provided for under state law.

**The Department of Health Care Policy and Financing** is the state Medicaid agency responsible for overseeing and paying the costs of mental health services provided to Medicaid clients, including those

Medicaid-eligible individuals under age 21 or over age 64 who are served by the Institutes.

**The Department of Regulatory Agencies** is the state agency responsible for licensing health care professionals employed by the Institutes (e.g., psychiatrists, psychotherapists, psychologists, nurses, professional counselors, and social workers) and conducting inspections and investigating complaints related to pharmacies, including those located at the Institutes.

## Psychiatric Medications

Psychiatric medications, sometimes called psychotropic medications, are an integral part of treating mental illness. Commonly used psychiatric medications include antipsychotics, antidepressants, mood stabilizers, anxiolytics, and stimulants. Medications work differently for each individual and are taken for various lengths of time. For example, a person with mild depression may feel better after taking a medication for a few months and may never need it again. People with disorders such as schizophrenia or bipolar disorder, or people who have long-term or severe depression or anxiety, may need to take medication for a much longer period of time. Additionally, a number of factors can affect how medications work, including: the type of mental disorder being treated; age, sex, and body size; the presence of other physical illnesses; habits such as smoking and drinking; liver and kidney function; diet; other medications being taken; and adherence to the prescribed dosage and/or administration schedule.

Although psychiatric medications can be very effective at treating the symptoms of a mental illness, many medications also have side effects or contraindications that must be regularly monitored and managed. For example, certain antipsychotic medications can cause weight gain and changes in metabolism, which can increase the chances of a person developing diabetes and high cholesterol. Thus, a person's weight, glucose levels, and lipid levels should be monitored regularly. As another example, use of the mood stabilizer lithium can cause side effects, including loss of coordination; excessive thirst; frequent urination; blackouts; seizures; slurred speech; changes in heartbeat and vision; and swelling of the face, throat, hands, and lower legs. Persons treated with lithium should be monitored regularly to check the levels of lithium in the blood and ensure normal kidney and thyroid function. When multiple psychiatric medications are used in treatment, patients should also be monitored for potential drug interactions. Certain demographic groups may require more active monitoring when medication is used to treat a mental illness. For example, older adults often have more medical problems and tend to take more medications than younger people. As a result, older adults tend to have a higher risk of experiencing negative drug interactions, missing doses, or overdosing. Women who are pregnant or who may become

pregnant are another group that should be watched closely when medication is used to treat a mental illness due to possible effects on the developing fetus.

The Institutes use a multidisciplinary approach in which psychiatrists, pharmacists, nurses, and other staff all have roles to play in the process of administering and monitoring medication. The process begins with the psychiatrist, who assesses the patient's condition and discusses treatment options with the patient, including the use of medication and its potential side effects. The psychiatrist then prescribes the medication or medications. A prescription order is written into the patient chart and is communicated to pharmacy staff. Each Institute has its own pharmacy that is responsible for assembling the patient medications for each patient unit. Medications are generally delivered to each unit's medication room by pharmacy staff. Once medications are in the patient unit medication room, they are distributed by the nursing staff to patients on a regular basis during what is called a "medication pass." During the medication pass, nursing staff and psychiatric technicians administer topical, oral, or injectable medications. Patients taking certain oral medications are permitted to self-administer under the supervision of nursing staff. Following administration of the medication, all staff including physicians, physicians' assistants, nurses, technicians, and therapists monitor patients for any symptoms of an adverse drug reaction or other medication side effects. Additionally, each Institute has identified a list of high-risk medications, some of which have additional medication-specific protocols that set forth specific administration and monitoring requirements for patients who are prescribed these medications.

## **Audit Scope**

We conducted this performance audit in response to a legislative request that was precipitated by the death of a patient shortly after being discharged from the Pueblo Institute. Our audit focused on determining whether the Department and the Institutes provide adult civil patients, including patients under involuntary medication orders, with adequate safeguards against adverse side effects and other risks associated with psychiatric medications used in the treatment of mental illness.

We contracted with Health Management Associates, Inc. (the HMA Team), based in Lansing, Michigan, to provide the necessary clinical expertise for this audit engagement. The HMA Team comprised a four-member, multidisciplinary review team with expertise in forensic psychiatry, community psychiatry for adults with serious mental illness, clinical pharmacology with emphasis on psychotropic medications, psychiatric nursing, institutional practices for the mentally ill, and legal issues related to involuntary interventions (e.g., court orders for patients to receive medication without their consent).

The HMA Team conducted an onsite review of medical records for a nonstatistical sample of 60 adult civil patients (30 patients at each Institute) receiving inpatient mental health treatment from April 2010 through January 2011. The sample was not selected to be representative of the Institutes' entire patient populations. Rather, patients were sampled to provide sufficient coverage of those areas—such as patients under involuntary medication orders or patients prescribed certain high-risk medications—that were significant to the objectives of this audit. The HMA Team also observed three separate medication passes at each Institute, analyzed the Institutes' policies and procedures, and interviewed Department and Institute management and staff. Finally, the HMA Team provided general information and insight regarding the Institutes' practices in comparison with accepted professional standards of care and medical best practices.

During this audit, the HMA Team relied on accepted professional standards of care and medical best practices to assess and identify areas for improving the Institutes' use, management, and monitoring of psychiatric medications. As discussed previously, other entities bear regulatory responsibility for identifying and citing deficient practices under state licensure, federal certification, and other accreditation standards. We did not re-perform this work as part of our audit. The audit scope was limited to the adult civil patient population, including geriatric patients; therefore, civil patients under the age of 18 and all forensic patients were excluded from review. The audit also did not evaluate treatments, services, or other activities not specifically related to the administration and monitoring of psychiatric medications used in the treatment of patients' diagnosed mental illnesses. The audit included a specific review of medication monitoring for patients under involuntary medication orders; however, the audit did not examine the role of the courts in determining the necessity of involuntary medication orders.

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# Use, Management, and Monitoring of Psychiatric Medications

## Chapter 2

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The State’s two mental health institutes (the Institutes)—the Colorado Mental Health Institute at Fort Logan (the Fort Logan Institute) and the Colorado Mental Health Institute at Pueblo (the Pueblo Institute)—are part of the continuum of mental health care, providing inpatient psychiatric treatment to those Coloradans with the most serious mental illnesses. Typically, patients admitted to the Institutes are in the midst of significant psychiatric crisis. The Institutes’ mission is to provide “quality services that assist patients in achieving their mental health and health care goals.”

Psychiatric medications are an integral part of treating mental illness, and patients treated at the Institutes are no exception to this rule. Commonly used psychiatric medications include antipsychotics, antidepressants, mood stabilizers, anxiolytics, and stimulants. When used correctly, psychiatric medications can be very effective at treating the symptoms of a mental illness. However, many psychiatric medications have negative side effects requiring patients to be routinely monitored and their medications to be carefully managed throughout treatment. Strong medication management and monitoring practices that safeguard against adverse side effects and other risks associated with psychiatric medications are an essential component of providing quality patient care.

Overall, Health Management Associates, Inc. (the HMA Team)—a four-member multidisciplinary review team working under contract with the Office of the State Auditor—found both Institutes to be highly proficient and professional at stabilizing and treating medically and socially complex patients. The HMA Team found no overt or systemic problems with medication monitoring or management practices warranting immediate intervention. Nonetheless, the HMA Team found that the Department of Human Services (the Department) and the Institutes need to strengthen the clinical framework for using, managing, and monitoring psychiatric medications. Specifically, the HMA Team found that, in several key areas, the Department and the Institutes have not actively engaged in the design and implementation of common clinical practices and coordinated monitoring and oversight mechanisms that align with medical best practices and apply to both Institutes. Key areas for improvement include: (1) use of emergency and involuntary medication orders, (2) use of antipsychotic medications, (3) designation of high-risk medications and development of medication-specific

clinical guidelines and monitoring protocols, (4) minimizing the occurrence of medication administration errors, (5) improving clinical documentation, (6) planning for transition to an electronic health records system, and (7) better utilization of pharmacy services. We discuss these issues in the remainder of this chapter.

## Emergency and Involuntary Medication Orders

Involuntary interventions involve providing treatment to patients without their consent, such as administering involuntary medications, using seclusion and restraint, placing an individual under a 72-hour hold, or committing the individual to a treatment facility. Involuntary interventions are often necessary when treating serious mental illness to help stabilize and return patients to a state in which they can make treatment decisions competently or no longer pose a threat to themselves or others. Because treatment occurs without the patient's consent, additional safeguards are needed to ensure that involuntary interventions are used only when medically necessary. At the federal level, the Civil Rights of Institutionalized Persons Act of 1980 was passed to help protect the constitutional and federal statutory rights of persons confined in institutions owned or operated by state or local governments, including facilities for individuals who have mental illness. At the state level, Title 27, Article 65, C.R.S., provides the due process protections to ensure, among other things, the General Assembly's intent that a person be deprived of his or her liberty "for purposes of [mental health] treatment or care only when less restrictive alternatives are unavailable and only when his or her safety or the safety of others is endangered."

Under state rules [2 CCR 502-1, Section 19.421], there are two types of involuntary interventions with respect to the administration of psychiatric medications: emergency medication orders and involuntary medication orders.

**Emergency medication orders** are intended to be used as a short-term treatment solution when a psychiatrist determines that a psychiatric emergency exists. A psychiatric emergency condition exists if the person is determined to be in imminent danger of hurting himself or herself based on either of the following conditions:

- Symptoms which have in the past reliably predicted imminent dangerousness in that particular person.
- A recent overt act, including, but not limited to, a credible threat of bodily harm, an assault on another person, or self-destructive behavior.

Emergency medication orders must be reassessed every 24 hours. If the psychiatric emergency is expected to last for more than 72 hours, the psychiatrist must obtain and document a concurring consultation with another physician and petition the court for an involuntary medication order. Emergency medications cannot be used without the patient's consent for more than 10 days without a court order.

**Involuntary medication orders** are intended to be used in non-emergency settings or when a longer-term treatment solution is needed to stabilize a patient. Involuntary medication orders must be approved by a court prior to being administered, and each of the following conditions must exist:

- The patient is incompetent to effectively participate in the treatment decision.
- Treatment by psychiatric medication is necessary to prevent a significant and likely long-term deterioration in the patient's mental condition or to prevent the likelihood of the patient causing serious harm to himself or herself or others.
- A less intrusive appropriate treatment alternative is not available.
- The patient's need for treatment by psychiatric medication is sufficiently compelling to override any bona fide and legitimate interest of the person refusing treatment.

According to self-reported data, in Fiscal Year 2010, the Institutes issued a total of 485 involuntary medication interventions for their entire patient populations—236 (49 percent) emergency medication orders and 249 (51 percent) involuntary medication orders. The Fort Logan Institute issued approximately 84 percent of the 236 total emergency medication orders, and the Pueblo Institute issued approximately 86 percent of the 249 total involuntary medication orders.

The decision to use an involuntary intervention, such as an emergency or involuntary medication order, is not always straightforward and often requires a psychiatrist to employ considerable clinical experience and judgment. Because opinions can vary on what constitutes an appropriate use of an emergency or involuntary medication order, and because the patient's rights and safety are in balance when such interventions occur, the clinical basis for emergency and involuntary medication orders must be clearly and sufficiently documented in the patient's medical chart.

During this audit, the HMA Team reviewed medical charts for the 34 patients in our sample who were subject to an emergency medication order, an involuntary

medication order, or both while being treated at the Institutes from April 2010 through January 2011. The purpose of the review was to determine the clinical bases for using emergency and involuntary medication orders and assess the clarity and completeness of the supporting clinical documentation. As described in the following bullet points, the patient's medical chart lacked sufficient clinical documentation demonstrating the need for or continuation of emergency or involuntary medication orders in 22 of the 34 sampled cases (some cases had problems in more than one area). Consequently, the appropriateness of the involuntary intervention could not be fully substantiated.

- **Emergency medication orders.** The HMA team identified seven patient files (five at the Fort Logan Institute and two at the Pueblo Institute) that lacked sufficient clinical documentation to substantiate that a psychiatric emergency existed warranting an emergency medication order. For example, the emergency medication order for one patient was based on the patient's refusal to eat. However, the clinical documentation did not clearly demonstrate that, in this case, refusing to eat constituted an apparent imminent danger to the patient or others, thereby requiring an immediate intervention. In another case, documentation in the medical chart indicated that the patient agreed to take the medication voluntarily. This is a concern because the premise of an emergency medication order is that the patient needs medication immediately to address the patient's imminent dangerousness to himself or herself or others and is unable or unwilling to consent to treatment.

Additionally, charts for six patients who were on emergency medication orders for more than 72 hours lacked clear documentation of a concurring opinion from another psychiatrist and/or a written request for a court hearing. As noted previously, a concurring opinion and a written request for a court order must be completed to continue emergency medication orders beyond 72 hours. In general, there was also insufficient evidence in the patient files that alternatives to emergency medication, such as behavioral interventions, had been attempted before issuing the emergency medication order.

- **Involuntary medication orders.** The HMA team identified 19 patient files (12 at the Fort Logan Institute and seven at the Pueblo Institute) that lacked sufficient clinical documentation to substantiate that conditions existed warranting a petition for or continued use of a court-ordered involuntary medication order. For example, in one case, the clinical documentation did not clearly demonstrate that the involuntary medication was necessary to prevent the patient causing serious harm to himself or herself or others. In another case, a patient was administered involuntary medications via a nasogastric tube, which is a more invasive process, over a long period of time. However, there was no documentation in the

patient's chart that, during this time, alternative, less invasive means of medication administration had been periodically attempted and were proven unsuccessful. One criterion for involuntary medication orders is that a less intrusive appropriate treatment alternative is not available. Finally, the HMA Team noted four patients whose medical charts appeared to indicate that the patient would accept or authorize the medications voluntarily. The specific circumstances of each of these cases are unique, and involuntary medication orders may still have been appropriate. Nonetheless, it is concerning that involuntary medication orders were used or continued when there was some indication that the patients would accept their medications voluntarily. Currently, there is no requirement in state rule that involuntary medication orders must be reassessed or terminated on a set time frame or under certain conditions.

As with all involuntary interventions, the use of emergency and involuntary medication orders is a high-risk area of medical practice because patients are not in a position to advocate for themselves, and, thus, individual liberties are being compromised. Therefore, the Department and the Institutes must ensure that the use of emergency and involuntary medication orders is carefully and thoughtfully decided, documented, and monitored. Specifically, the Department and the Institutes need to take steps in several key areas to improve the use of emergency and involuntary medication orders.

First, the Department should work with the Institutes to develop a common policy and related procedures as a foundation for the clinical use of emergency and involuntary medication orders when treating civil patients. Currently, each Institute has its own individual policies, procedures, and practices. However, the same statutory and regulatory requirements apply to both Institutes, and both Institutes exist within the same state agency. Thus, the Department and the Institutes would be better positioned clinically and legally by ensuring a consistent clinical approach and documentation standards when using emergency and involuntary medication orders for patients, regardless of which Institute provides treatment. The Pueblo Institute may still need to maintain separate policies and procedures for forensic patients, whom the Fort Logan Institute does not treat.

Second, the use of emergency and involuntary medication orders should be specifically targeted for ongoing monitoring at both the Department and Institute levels. Currently, the Department does not directly monitor the Institutes' use of emergency and involuntary medication orders and related data, such as the status of court proceedings and time frames. The Institutes conduct internal reviews of medical practices that may periodically include involuntary interventions; however, there is no explicit ongoing review of emergency and involuntary medication orders within or between the Institutes. At the Department level, there should be detailed reporting and review of aggregate data regarding the Institutes'

use of emergency and involuntary medication orders, including a review of trends by each Institute and by specific physicians or units, and the statuses and outcomes of any court processes. Review of aggregate data by the Department would help to identify outliers, emerging trends, and changes in clinical practice that could be addressed through further review, training, corrective action, or other measures. At the Institute level, the Institutes should strengthen internal review processes, as well as engage in cross-Institute peer reviews on a routine basis, to ensure appropriate clinical use of emergency and involuntary medication orders and adherence to established policies and procedures. At a minimum, the reviews should specifically examine the clinical basis for using emergency and involuntary medication orders and the clarity and completeness of the related clinical documentation. Cross-Institute peer reviews would also promote the sharing of best practices between the two Institutes.

Finally, state rules need to be revised to provide more clarity to practitioners and better mirror medical best practices, thereby ensuring the appropriate use of emergency and involuntary medication orders. During its review, the HMA Team noted four areas where state rules do not provide adequate clarity to clinicians or align with medical best practices, as follows:

- State rules [2 CCR 502-1, Section 19.421.1] allow psychiatrists to use “symptoms which have in the past reliably predicted imminent dangerousness” as evidence of a psychiatric emergency. However, the rules provide no specificity regarding the types of symptoms or how recently these symptoms must have occurred to be considered when assessing imminent dangerousness. The HMA Team found that knowing these parameters could be beneficial, especially in those cases where the basis for the decision to use an emergency medication order is not always clear.
- State rules [2 CCR 502-1, Section 19.421.2] require that emergency medications be discontinued after 10 days until such time as a court order for involuntary medications is issued or, after a 24-hour period, the emergency situation returns. However, the HMA Team found this provision concerning because it can force the termination of an emergency medication order regardless of medical necessity, thereby disrupting the patient’s care and potentially compromising the patient’s condition. The HMA Team identified cases in which the emergency medication order was stopped for 24 hours and then restarted. Institute staff reported that this action is often necessary when the courts cannot hold a hearing on the petition for an involuntary medication order before the maximum allowable 10-day time frame for the emergency medication order expires. The rule should contain some provision allowing for the continuation of a medically necessary emergency medication order in those circumstances

when the courts cannot hold a hearing on the petition for an involuntary medication order within the maximum allowable 10-day time frame.

- State rules [2 CCR 502-1, Section 19.421.3] do not definitively address those conditions or circumstances when involuntary medication orders should be discontinued. The rules also contain no requirements that involuntary medication orders be periodically reassessed for their continued appropriateness. For example, as discussed previously, the HMA Team noted cases where patients remained under involuntary medication orders, even while agreeing to take the medications voluntarily. To ensure that patients' rights are being honored to the fullest extent possible, the rules should require documentation in the patient's chart substantiating a pattern of medication refusal adversely affecting treatment outcomes to justify continued use of an involuntary medication order when a patient voluntarily consents to treatment.
- State rules [2 CCR 502-1, Section 19.421.3] require the petition for an involuntary medication order to "specify what psychiatric medications are being recommended as potentially beneficial to the person," which, in practice, has been implemented by the Institutes as a requirement that the petition include specific names and dosages of medications. However, the HMA Team found this practice concerning because it places the courts in the position of having to rule on specific drug strengths or therapeutically equivalent drugs. The rules should require that petitions for involuntary medication orders identify only the class or classes of drugs being recommended for treatment.

The Department should work with the State Board of Human Services, affected facilities, advisory committees, and other stakeholders to consider revising state rules governing the use of emergency and involuntary psychiatric medications, as appropriate. The state rules governing involuntary psychiatric medications apply to all facilities, including the Institutes, that are approved by the Department to provide rights-restricted procedures (e.g., 72-hour holds and evaluations, short- and long-term certifications, involuntary medications, and seclusion and restraint). Although the scope of this audit was limited to the two Institutes, making these revisions to state rules could reduce the risk of inappropriate use of emergency and involuntary medication orders statewide.

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## **Recommendation No. 1:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to ensure that emergency and involuntary medication orders have a solid clinical basis in

accordance with medical best practices. At a minimum, the Department should work with the Institutes to:

- a. Develop a common policy and procedures as a foundation for the clinical use of emergency and involuntary medication orders, including associated documentation requirements, when treating civil patients.
- b. Routinely monitor and review the use of emergency and involuntary medication orders for appropriateness on an ongoing basis. The Department should review aggregate data regarding the Institutes' use of emergency and involuntary medication orders, including a review of trends by each Institute and by specific physicians or units, and the statuses and outcomes of any court processes. The Institutes should strengthen internal review processes, as well as engage in cross-Institute peer reviews on a routine basis, to specifically examine the clinical basis for using emergency and involuntary medication orders and the clarity and completeness of the related clinical documentation.

### **Department of Human Services Response:**

- a. Agree. Implementation date: August 2011.

Currently, each Institute has individual policies and procedures about the clinical use of emergency and involuntary medications. The Department will work with the Institutes to develop standardized policies and procedures about the clinical use of emergency and involuntary medication orders, including associated documentation requirements.

- b. Agree. Implementation date: October 2011.

The Department and the Institutes will increase monitoring of emergency and involuntary medication orders, including development of standardized reports to review aggregate data, trends by each Institute and by specific physicians or units, and the statuses and outcomes of any court processes. In addition, the Institutes will implement quarterly cross-Institute peer reviews where medical staff will examine the clinical basis used in emergency and involuntary medication orders and the clarity and completeness of the related clinical documentation.

## **Recommendation No. 2:**

The Department of Human Services (the Department) should provide more clarity to mental health practitioners and better mirror medical best practices by working with the State Board of Human Services, affected facilities, advisory committees, and other stakeholders to revise the state rules governing the use of emergency and involuntary psychiatric medications, as appropriate.

### **Department of Human Services Response:**

Agree. Implementation date: January 2012.

The Department is in the process of a rule revision for all programs, including a review of rules governing emergency and involuntary medications. The Division of Behavioral Health will revise these rules to provide more clarity to mental health practitioners and mirror medical best practices.

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## **Antipsychotic Medications**

Psychiatric medications can have dangerous side effects, thereby increasing the risk to patients when the medications are used to treat mental illness. Generally speaking, lower-risk medications should be tried and evaluated for effectiveness before higher-risk medications are prescribed. High-risk medications should be used only when absolutely necessary to stabilize a patient. Additionally, factors such as the risk of side effects and drug interactions, as well as cost, all increase when multiple medications are used simultaneously. This is particularly true of antipsychotic medications, which is a class of psychiatric medications commonly used at the Institutes.

The HMA team examined 60 patient charts and found that the Institutes do not consistently prescribe antipsychotic medications based on medical best practices, thereby introducing patients to unnecessary and/or unintended risks. Specifically, the HMA Team identified concerns with the Institutes' use of the antipsychotic medication clozapine, as well as the use of multiple antipsychotic medications simultaneously, known as polypharmacy.

### **Clozapine**

Clozapine is a powerful second-generation antipsychotic used to treat patients with schizophrenia. Clozapine differs from less aggressive medications in that it

does not cause certain undesirable side effects, such as involuntary muscle movement, repetitive movement, and speech problems. Despite these advantages, however, clozapine carries the risk of a unique side effect that must be closely monitored—agranulocytosis, in which the white blood cell count drops dramatically, rendering the patient extremely vulnerable to infections. Potentially fatal agranulocytosis occurs in 1 percent to 2 percent of patients on clozapine. Clozapine’s boxed warning states that:

“clozapine should be reserved for use in (1) the treatment of severely ill patients with schizophrenia who fail to show an acceptable response to adequate courses of standard antipsychotic drug treatment, or (2) for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at risk of reexperiencing suicidal behavior.”

Given the serious clinical risks associated with clozapine, both Institutes’ clozapine guidelines require that patients have two trials of an adequate dose and duration of standard therapy (i.e., less risky treatments) prior to starting clozapine therapy. The HMA Team reviewed medical charts for the 16 patients in our sample who were on clozapine and found that the physicians’ orders to start clozapine therapy for three patients at the Pueblo Institute did not provide a clear reference to the timing and results of prior trials documenting that the patients were thoroughly evaluated on other less risky antipsychotic medications. Additionally, at both Institutes, the HMA Team was concerned that clozapine was added as a medication or substituted for other antipsychotic medications before the full effects of the other medications would have been known.

The Department and the Institutes should take additional steps to ensure that psychiatrists prescribe clozapine only when other less risky treatment options have been fully explored and proven ineffective. Both Institutes’ clozapine guidelines require that patients have two trials of an adequate dose and duration of standard therapy prior to starting clozapine therapy. However, the Institutes’ clozapine guidelines should also require that physicians’ orders reference these prior treatment efforts and their results when clozapine is prescribed. Additionally, the Institutes’ clozapine guidelines should provide instruction for how recently the two trials of standard therapy must have occurred prior to starting a patient on clozapine therapy. Finally, each Institute should establish a process to review patient chart documentation and verify that clozapine is clearly indicated prior to starting treatment. We discuss issues related to having uniform medication monitoring guidelines in Recommendation No. 4.

## Polypharmacy

Antipsychotic polypharmacy is the practice of using multiple antipsychotic medications to treat the same condition. For example, some clinicians may use more than one antipsychotic medication in an attempt to more effectively or timely resolve a psychiatric crisis or manage a chronic psychiatric condition. Arriving at the optimal medication profile may also require that a patient be weaned from one antipsychotic medication as another is added.

The HMA Team reviewed the medical charts for the 60 sampled patients and identified instances in which more than one antipsychotic medication was simultaneously prescribed to a patient. Specifically, 28 of the 60 patients in the sample (16 patients at the Fort Logan Institute and 12 patients at the Pueblo Institute) were prescribed two or three antipsychotic medications at the same time, and 16 of the 60 patients in the sample (four patients at the Fort Logan Institute and 12 patients at the Pueblo Institute) were on four or five antipsychotic medications at the same time. The HMA Team did not conclude that the existence of polypharmacy was, on its face, problematic. However, using multiple simultaneous medications increases the risk of side effects and drug interactions and adds to the higher cost of patient care. Because of these concerns, polypharmacy should never occur unintentionally. During the audit, the HMA Team identified two scenarios occurring at both Institutes that may have unintentionally resulted in polypharmacy, as follows:

- **Involuntary medication orders.** The HMA Team observed eight patients (one patient at the Fort Logan Institute and seven patients at the Pueblo Institute) whose current medications (i.e., maintenance medications) were not discontinued upon initiation of an involuntary medication order. Because the involuntary medications were frequently different from the maintenance medications, these eight patients had two sets of medication orders in effect simultaneously. It was not always clear from the medical chart documentation that the psychiatrist intended the involuntary medications to be used in addition to, rather than used instead of, the maintenance medications. Although the HMA Team could not say with certainty that in each case the patient was overmedicated, the HMA Team concluded that failure to review and, if necessary, discontinue current medication orders when initiating an involuntary medication order creates a high risk of overmedication that should be addressed.
- **PRN orders.** The HMA Team identified instances of patients being prescribed psychiatric medications on an as-needed basis—referred to as a PRN order—for anxiety, agitation, and psychosis. However, there were cases in which two or three psychiatric medications, including antipsychotics, were ordered PRN for the same condition without

sufficient documentation from the psychiatrist substantiating the need for multiple medications. Additionally, the PRN orders were often written without clear guidance or instructions to nursing staff about when to administer the medications or for choosing between them. Although an extra dose of a single antipsychotic medication may be appropriate on an as-needed basis, the use of an *additional* antipsychotic medication on an as-needed basis is not a common medical practice and may unnecessarily expose patients to multiple antipsychotic medications simultaneously.

The Department and the Institutes should eliminate the risk of unintentional polypharmacy cases occurring by reviewing current medication orders and discontinuing medications, as appropriate, when issuing an involuntary medication order. The Institutes' practice of ordering multiple antipsychotic medications PRN should also be reevaluated and limited, if not discontinued entirely. If the practice is continued, the Department and the Institutes should ensure that physicians fully document the clinical conditions and patient circumstances when PRN medications should be administered and differentiate those circumstances when more than one PRN medication is ordered for the same condition.

Finally, the Institutes should actively identify and routinely monitor all antipsychotic polypharmacy cases to ensure their continued appropriateness for patient treatment.

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### **Recommendation No. 3:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to minimize the unnecessary and/or unintended risks to patients when prescribing antipsychotic medications. Specifically, the Department and the Institutes should:

- a. Modify clozapine guidelines to require that physicians' orders reference prior treatment efforts and their results when clozapine is prescribed and provide instruction for how recently the two trials of standard therapy must have occurred prior to starting a patient on clozapine therapy.
- b. Establish a process to review patient chart documentation and verify that clozapine is clearly indicated prior to starting treatment.
- c. Ensure that all current medication orders are reviewed and medications discontinued, as appropriate, when an involuntary medication order is initiated.

- d. Reevaluate and limit, if not discontinue entirely, the practice of ordering multiple antipsychotic medications PRN (i.e., on an as-needed basis). If the practice is continued, the Department and the Institutes should ensure that physicians fully document the clinical conditions and patient circumstances when PRN medications should be administered and differentiate those circumstances when more than one PRN medication is ordered for the same condition.
- e. Actively identify and monitor all antipsychotic polypharmacy cases on a routine basis to ensure their continued appropriateness for patient treatment.

### **Department of Human Services Response:**

- a. Agree. Implementation date: August 2011.

The Institutes currently require that the second-generation antipsychotic drug clozapine be used only when other less risky treatment options have been tried and failed. The Department will work with the Institutes to modify the clozapine guidelines to require that physician orders initiating clozapine reference at least two prior non-clozapine treatment efforts. In addition, clozapine guidelines will indicate how recently the two prior non-clozapine treatment efforts must have occurred.

- b. Agree. Implementation date: September 2011.

Periodic audits will be conducted to review patient chart documentation and verify that clozapine is clearly indicated prior to starting treatment. Audit results will be reviewed with medical staff to improve performance.

- c. Agree. Implementation date: September 2011.

Currently, medical staff at the Fort Logan Institute ensure that all current medication orders are reviewed and discontinued, as appropriate, when an involuntary medication order is initiated. This practice has now been implemented at the Pueblo Institute. In addition, the standardized involuntary medication policies and procedures identified in the response to Recommendation No. 1a will include the requirement that all current medication orders be reviewed and medications discontinued, as appropriate, when an involuntary medication order is initiated. In addition, periodic audits will be conducted to determine compliance with involuntary medication

policies and procedures. Audit results will be provided to staff to improve performance.

- d. Agree. Implementation date: September 2011.

The Department and the Institutes agree that the practice of ordering multiple PRN antipsychotic medications needs to be limited and, when performed, adequate documentation of rationale and clarity of use must be assured. Physicians will be instructed to fully document the clinical conditions and patient circumstances when PRN antipsychotic medications should be administered and differentiate those circumstances when more than one PRN medication is ordered for the same condition. Periodic audits will be conducted to determine physician compliance. Audit results will be provided to staff to improve performance.

- e. Agree. Implementation date: September 2011.

The Medical Directors at each Institute will periodically review each antipsychotic polypharmacy case involving more than two antipsychotics (including those administered PRN) for clinical appropriateness for patient treatment and supporting documentation. Findings will be provided to medical staff.

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## Medication Monitoring Guidelines

Accreditation standards promulgated by the Joint Commission require that hospitals “safely manage high-alert and hazardous medications.” Certain medications used by the Institutes carry with them significant risks of side effects. To ensure that Institute staff are aware of the potential risks to patients, the Institutes have each independently developed their own list of high-risk medications. Additionally, for a subset of these high-risk medications, the Institutes have each independently developed stand-alone clinical guidelines and monitoring protocols that address more specific issues such as maximum dosage, necessary lab testing, and monitoring for specific side effects. Each Institute has its own pharmacy and therapeutics committee that is responsible for determining which medications will be considered high-risk and which medications will have their own specific monitoring protocols.

The HMA Team reviewed the list of high-risk medications as well as the drug-specific medication guidelines and monitoring protocols in place at each Institute. As described in the following sections, (1) both Institutes’ protocols were inadequate when compared with medical best practices regarding second-

generation antipsychotics; (2) the Institutes do not have a uniform or consistent approach for designating high-risk medications and stand-alone, drug-specific clinical guidelines and monitoring protocols; and (3) Institute staff did not always follow established medication monitoring guidelines.

## **Second-Generation Antipsychotics**

Second-generation antipsychotics are a group of psychiatric medications used for the treatment of severe mental illnesses, such as schizophrenia, schizoaffective disorder, and mania. However, second-generation antipsychotics carry a high risk of diabetes, metabolic syndrome (i.e., a group of risk factors that can lead to heart disease and type 2 diabetes), and cardiovascular disease. Therefore, the American Diabetes Association and the American Psychiatric Association recommend metabolic monitoring of all patients on second-generation antipsychotics. Metabolic monitoring involves regular testing of weight, blood pressure, glucose levels, and lipid levels.

Currently, both Institutes allow psychiatrists to order metabolic monitoring when second-generation antipsychotics are used; however, neither Institute requires metabolic monitoring as a matter of policy. During its review of patient charts, the HMA Team identified 57 patients for whom second-generation antipsychotics had been prescribed during the review period. In 17 of these cases (11 at the Fort Logan Institute and six at the Pueblo Institute), metabolic monitoring was not ordered. In some of these cases, the patient exhibited clear signs of metabolic disturbance. For example, one patient had a fasting blood sugar of 190 milligrams per deciliter; the normal range is 70–120 milligrams per deciliter. Another patient had a 40-pound weight gain in one year. The HMA Team also noted patients on second-generation antipsychotics at both Institutes where appropriate lab work, weight, and/or body mass index analysis was carried out, but the results were scattered throughout the patient chart and not organized to illustrate the patient's comprehensive metabolic status. We discuss issues related to medical chart organization in Recommendation No. 6.

## **High-Risk Medications and Drug-Specific Protocols**

Generally speaking, psychiatric and other medications carry the same risk of adverse side effects regardless of whether the medications are prescribed to patients at the Fort Logan or the Pueblo Institutes. Thus, from a clinical perspective, the list of designated high-risk medications, as well as any drug-specific clinical guidelines and monitoring protocols, should be uniform and consistent between the two Institutes. The only case where a uniform approach should not be expected is when a drug is used by one Institute and not the other.

As shown in the following table, the HMA Team found that the Institutes do not have a uniform or consistent approach in terms of (1) those medications designated as high-risk, or (2) those high-risk medications with additional stand-alone, drug-specific clinical guidelines and monitoring protocols.

<b>Colorado Mental Health Institutes at Fort Logan and Pueblo Designated High-Risk Medications and High-Risk Medications with Specific Protocols</b>		
<b>Drug</b>	<b>Fort Logan Institute</b>	<b>Pueblo Institute</b>
Clozapine	✓*	✓*
Anticoagulants (i.e., Heparin and Warfarin)	✓*	✓*
Leuprolide	n/a	✓*
Depo-Provera	n/a	✓*
Lithium	✓*	✓
Carbamazapine	✓	✓
Phenytoin	✓	×
Digoxin	✓	×
Monoamine Oxidase Inhibitors	n/a	✓
Clopidogrel	×	✓
Concentrated Electrolytes	n/a	✓
Controlled Substances	✓	✓
Insulin	✓	✓
<b>Source:</b> Office of the State Auditor's analysis of policy and procedure documentation provided by the Department of Human Services.		
<b>Key:</b> n/a = Drug not used. × = Drug used but not designated as a high-risk medication. ✓ = Drug designated as a high-risk medication only. ✓* = Drug designated as a high-risk medication with additional stand-alone, drug-specific clinical guidelines and monitoring protocols.		

First, of the 13 designated high-risk medications between both Institutes, the Institutes have only six in common: clozapine, anticoagulants, lithium, carbamazapine, controlled substances, and insulin. The Fort Logan Institute considers two additional medications also used by the Pueblo Institute to be high risk while the Pueblo Institute does not: phenytoin and digoxin. Conversely, the Pueblo Institute considers one additional medication also used by the Fort Logan Institute to be high risk while the Fort Logan Institute does not: clopidogrel.

Second, both Institutes have developed additional drug-specific clinical guidelines and monitoring protocols for certain high-risk medications. Specifically, both Institutes have developed additional clinical guidelines and monitoring protocols for clozapine and anticoagulants. However, the Fort Logan Institute has

developed drug-specific medication monitoring guidelines for lithium, whereas the Pueblo Institute designates lithium as a high-risk medication only.

Finally, even in the two cases where both Institutes have developed specific clinical guidelines and monitoring protocols for the same high-risk medications—clozapine and anticoagulants—the guidelines and protocols are not uniform between the two Institutes. For example, different dosing specifications are allowed at each Institute and different monitoring practices are required. Specifically, for clozapine, the maximum allowable single dose at the Pueblo Institute is 500 milligrams, whereas a single dose of up to 600 milligrams is allowed at the Fort Logan Institute. The Fort Logan Institute’s guidelines require that a single dose of 12.5 milligrams be used when restarting a patient on clozapine who has been off the medication for more than two days. However, the Pueblo Institute requires only that the previous dosage be halved (up to 250 milligrams), even if the patient has been off the medication for up to one week. The Fort Logan Institute’s guidelines give specific time lines for certain medical testing, such as blood glucose testing for diabetes, for patients on clozapine. The Pueblo Institute’s guidelines provide no similar testing requirements.

## **Established Guidelines**

Institute staff should adhere to established clinical guidelines and monitoring protocols to help manage and/or mitigate any adverse effects and ensure patient safety. Overall, the HMA Team found that the Institutes were compliant with their respective drug-specific guidelines and protocols for 31 of the 33 patients in our sample who were prescribed one of these high-risk medications. The HMA Team found that established clozapine guidelines were not followed for two patients at the Pueblo Institute. Specifically, in one case, the required clozapine checklist was not in the chart. This checklist is used to document staff’s adherence to established clozapine guidelines. In the other case, the mandatory patient education about the drug’s therapeutic benefits and possible risk of side effects was not documented. On the surface, these types of missing items may seem inconsequential; however, they are part of ensuring proper monitoring for clozapine, which, as discussed earlier in this chapter, can have potentially life-threatening side effects.

As discussed previously, psychiatric medications carry the same risk of adverse side effects regardless of whether the medications are prescribed to patients at the Fort Logan or the Pueblo Institutes. Therefore, to address the concerns raised in this section, the Department should work with the Institutes to develop and implement a common high-risk medication policy and related procedures to ensure that adverse side effects patients may experience from the use of psychiatric medications are identified, managed, and/or mitigated uniformly and in accordance with medical best practices. The common policy should include a

uniform list of high-risk medications for those drugs used by both Institutes, as well as uniform stand-alone clinical guidelines and monitoring protocols for those high-risk medications in common that warrant clinical, pharmacy, and laboratory monitoring. Drugs used by only one Institute and not the other would not need to be included in the common policy. The common policy should also require metabolic monitoring for all patients on second-generation antipsychotics. Finally, quality improvement processes at both Institutes should include routine reviews for compliance with common policies and procedures established for high-risk medications.

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### **Recommendation No. 4:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to develop and implement a common high-risk medication policy and related procedures to ensure that adverse side effects patients may experience from the use of psychiatric medications are identified, managed, and/or mitigated uniformly and in accordance with medical best practices. At a minimum, the common policy and related procedures should:

- a. Designate a uniform list of high-risk medications for those drugs used by both Institutes, as well as uniform stand-alone clinical guidelines and monitoring protocols for those high-risk medications in common that warrant clinical, pharmacy, and laboratory monitoring.
- b. Require metabolic monitoring for all patients on second-generation antipsychotics.
- c. Include routine reviews for compliance with common policies and procedures established for high-risk medications as part of both Institutes' quality improvement processes.

### **Department of Human Services Response:**

- a. Agree. Implementation date: September 2011.

The Department will work with the Institutes to develop a uniform list of high-risk medications for those drugs used by both Institutes and uniform clinical practice guidelines and monitoring procedures for those high-risk medications in common that warrant clinical, pharmacy, and laboratory monitoring.

b. Agree. Implementation date: September 2011.

Currently, metabolic monitoring is left to the physician's discretion when second-generation antipsychotics are prescribed. Institute policies will be revised to require metabolic monitoring for all patients on second-generation antipsychotics. In addition, periodic audits will be conducted to determine compliance rates. Audit results will be provided to staff to improve performance.

c. Agree. Implementation date: September 2011.

The audit found that the Institutes were compliant with established drug-specific guidelines and protocols for 31 of 33 sampled cases. To ensure that this compliance rate continues to remain high, the Institutes will implement periodic reviews to monitor compliance with guidelines and protocols. Audit results will be provided to staff to improve performance.

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## Medication Administration

The correct and safe administration of medications to patients is a critical part of ensuring the quality of patient care. Medication administration, often referred to as a "medication pass," involves the process of physically preparing and administering medications to patients by following a uniform series of steps or controls intended to reduce the risk of errors from occurring. For example, strong medication administration practices help to ensure that the right dose of the right medication is given to the right patient at the right time, via the right delivery method (e.g., oral, intravenous). All hospitals seek to reduce medication errors as much as possible, and the Institutes are no exception. Each Institute has established policies and procedures governing the preparation and administration of medications to patients. These policies include non-punitive reporting requirements for medication errors. Reported medication errors are rated on their severity of impact to the patient. Medication error reports are reviewed by medication safety committees at the Fort Logan and Pueblo Institutes on a quarterly and monthly basis, respectively, for trends, and additional investigation or action, such as training, is initiated when appropriate. Finally, Department and Institute management receive monthly summary reports of medication errors.

As described in the following two sections, we obtained and reviewed data on medication error rates for the Institutes and found that the Institutes' average medication error rates in Calendar Year 2010 were higher than the average medication error rate for a peer group of facilities. Additionally, the HMA Team

observed three medication passes at each Institute and identified medication errors occurring as well as several conditions that increase the risk of medication errors or other problems occurring.

## Medication Error Rate

As mentioned in Chapter 1, both Institutes are accredited by the Joint Commission, whose mission is to continuously improve the safety and quality of care offered by health care organizations. The Joint Commission requires accredited psychiatric hospitals and other facilities that provide inpatient psychiatric treatment (e.g., acute care hospitals with a specialized inpatient psychiatric unit) to track and report data on several different standardized quality-of-care performance measures, thereby facilitating cross-facility comparisons. Some performance measures are required “core” measures, whereas others are optional and selected at the discretion of the facility. One optional quality-of-care measure that both Institutes track is the medication error rate, which is calculated as the number of medication error events occurring during the reporting period divided by the number of current and discharged patients during the reporting period (i.e., episodes of care).

The following table compares the Institutes’ average medication error rates for Calendar Year 2010 with one another and with the average medication error rate for a peer group of facilities. The peer group represents approximately 116 psychiatric hospitals, including the two Institutes, and other facilities providing inpatient psychiatric treatment that (1) participate as clients of the National Association of State Mental Health Program Directors Research Institute’s Behavioral Health Care Performance Measurement System, and (2) selected medication error rate as an optional performance measure.

Overall, in Calendar Year 2010, the average medication error rates at the State’s two mental health institutes were higher than the average medication error rate for the peer group. Specifically, the Fort Logan Institute averaged about 4.50 medication errors for every 100 episodes of care, and the Pueblo Institute averaged about 4.93 medication errors for every 100 episodes of care. By comparison, facilities in the peer group had a much lower average medication error rate—about 2.71 medication errors for every 100 episodes of care.

<b>Colorado Mental Health Institutes at Fort Logan and Pueblo Comparison of Medication Error Rates Calendar Year 2010</b>			
<b>Measure</b>	<b>Fort Logan Institute</b>	<b>Pueblo Institute</b>	<b>Peer Group Participant Average<sup>2</sup></b>
Medication Error Rate (per 100 episodes of care) <sup>1</sup>	4.50	4.93	2.71
<p><b>Source:</b> Office of the State Auditor's analysis of data provided by the Department of Human Services.</p> <p><sup>1</sup>The medication error rate is calculated as the total number of medication error events occurring during the reporting period divided by the number of current and discharged patients during the reporting period (i.e., episodes of care).</p> <p><sup>2</sup>Represents the average medication error rate for approximately 116 psychiatric hospitals or other facilities providing inpatient psychiatric treatment (e.g., acute care hospitals with a specialized inpatient psychiatric unit) that (1) participate as clients of the National Association of State Mental Health Program Directors Research Institute's Behavioral Health Care Performance Measurement System, and (2) selected medication error rate as an optional performance measure.</p>			

Although the Institutes' average medication error rates were higher than the peer group average, the difference in averages was within a statistically acceptable range of variation. When comparing medication error rates, it is also important to note that organizations, such as the Institutes, that promote error reporting in a non-punitive manner as a means of quality improvement will naturally have higher error rates than those organizations that tie medication errors to punitive sanctions, which can discourage error reporting. Additionally, 400 (99 percent) of the 403 medication error events occurring at the Institutes in Calendar Year 2010 were classified as having had a "minimal consequence" to the patient, meaning that the patient experienced no or minimal adverse consequences and no treatment or intervention other than monitoring or observation was required. The remaining three (1 percent) medication error events were classified as having had a "short-term consequence" to the patient, meaning that the patient experienced short-term, reversible adverse consequences, and treatment and/or intervention was required in addition to monitoring and observation. From a statistical perspective, the Institutes' higher average medication error rates are not "outliers" when compared with other peer facilities. Nonetheless, medication error rates are an accepted performance indicator, and this comparison provides important context and demonstrates that there is room for improvement.

## HMA Team Observations

During the audit, the HMA Team observed three medication passes (i.e., medication administration sessions) at each Institute to assess nursing staff's adherence to medication administration policies and procedures as well as best practices in medication administration. Each medication pass involved administering medications to numerous patients. Overall, based on these observations, Institute staff administering medication adhered to most of the

standards reviewed. For example, medication rooms and carts were locked, and medication administration records, which indicate the medications each patient should receive, were referenced before medications were prepared and administered. However, the HMA Team also observed medication errors occurring for four patients during the medication passes, as described below.

**Improper administration technique.** Following proper administration techniques is an important part of ensuring that the patient receives the intended dose of the prescribed medication. The HMA Team observed situations at each Institute where staff did not follow proper medication administration techniques. At the Pueblo Institute, staff administered medication to two patients via metered dose inhalers. However, the administration technique used was inadequate. Specifically, one of the patients appeared to be asleep, and the nurse simply puffed the inhaler in the patient's mouth. In the second case, the patient used the inhaler but was talking while doing so. These are both considered to be medication errors because Institute staff did not ensure that both patients inhaled and, therefore, received the full dose of their prescribed medications.

At the Fort Logan Institute, staff gave a third patient a medication cup containing numerous pills. However, both the nurse and the technician turned their backs as the patient ingested the pills. During the process, one tablet rolled down the patient's chest and onto the unit floor, unobserved by the Institute staff or the patient. A member of the HMA Team who observed this medication error brought it to the attention of the Institute staff. A new dose was prepared and administered, and the errant pill was found and destroyed. This is considered to be a medication error because, were it not for the intervention of the HMA Team, this patient would not have received the correct dose of the prescribed medication. Additionally, the errant pill, which was a narcotic, could possibly have been found and ingested by the same or another patient without Institute staff present.

**Improper administration time.** The timing of when a medication is administered can be an important part of maintaining the medication in the patient's system as well as managing and/or mitigating adverse effects. For example, some medications should be taken on an empty stomach, whereas others should be taken after a meal. The HMA Team observed a situation at the Pueblo Institute where staff did not adhere to the proper administration time for a fourth patient. The patient was supposed to be administered medication one-half hour prior to breakfast. The HMA Team observed staff administering the medication at 8:15 a.m.; however, according to Institute staff, breakfast occurred between 7:20 and 8 a.m. that day. This is considered to be a medication error because the patient's medication was administered at the wrong time.

During its site visits at the two Institutes, the HMA Team made several additional observations of conditions that increase the risk of medication errors or other

problems occurring during the medication administration process. Specifically, the staff administering medications:

- Were interrupted frequently by other staff or patients during two of the observations at the Pueblo Institute. Interruptions distract attention from important tasks that must be performed when preparing and/or administering medications.
- Segregated medication into medication cups prior to administration during one observation at the Fort Logan Institute. Although the medication cups were placed in each patient's drawer on the medication cart, the cups were not labeled with the medication name or dose. Preparation of medication in advance may provide for increased efficiencies; however, to reduce the risk of error, medication containers should be properly labeled when medications are prepared but not immediately dispensed.
- Did not always positively identify the patient during one of the observations at the Pueblo Institute. Positive patient identification is critical for ensuring that medications are administered to the correct patient.
- Did not always observe patients for immediate adverse reactions to medication during one of the observations at the Pueblo Institute. Recognizing immediate adverse reactions is an important step when administering medication in case the reactions need to be treated or indicate the development of harmful side effects.
- Did not initial the medication administration record as the medication was placed into the medication cup for administration during one of the observations at the Fort Logan Institute. Completing the medication administration record is important because it serves as the official record of medications administered to a patient.
- Did not routinely wash or sanitize their hands between patients during observations at both Institutes. For example, during one observation at the Fort Logan Institute, the staff person used hand sanitizer between each patient but not always at the proper point—that is, the staff person handled the next patient's medications prior to using the hand sanitizer. Proper hand washing or sanitation when administering medications to patients is important for avoiding the transmission of infections from staff to patient and vice versa.

The Institutes' medication error rates can never be reduced to zero; however, a strong medication administration program can effectively reduce the risk of

medication errors occurring. As discussed previously, the Institutes have processes for identifying, reporting, and reviewing medication errors. Strengthening the Institutes' medication administration programs to minimize the occurrence of medication errors must remain a focus area for ongoing quality improvement efforts. Specifically, the Department should work with the Institutes to require nursing supervisors from different units and/or pharmacists to perform routine, unscheduled observations of staff administering medications. Special attention should be given to geriatric patient units, where patients may need extra care to ensure that medications are correctly ingested or inhaled, and long-term patient units, where the staff's familiarity with the patients can reduce vigilance. Routine observation of medication passes would also allow nursing supervisors and/or pharmacists to identify those problems that need to be addressed through training or revisions to policies and procedures. Currently, nursing staff receive medication administration training upon hire and an annual competency review. However, the Department and the Institutes should also explore options to provide staff with more routine, targeted training opportunities regarding established medication administration policies and procedures, emerging best practices, certain administration techniques (e.g., inhalers), and identified problem areas.

Medication passes routinely take place multiple times a day at each Institute. As a result, it is easy for staff to become complacent and less vigilant in their adherence to established medication administration policies and procedures. This increases the potential for staff to administer the wrong medication; administer medications in the wrong dose, at the wrong time of day, or omit a dose; or administer medications to the wrong patient. Routine observation and ongoing training are important for maintaining staff awareness of the goals of a strong medication administration program and the potential negative effects on patients' safety and treatment outcomes when medication administration policies and procedures are not followed.

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### **Recommendation No. 5:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to strengthen medication administration programs and minimize the risk of medication errors occurring by:

- a. Requiring nursing supervisors from a different unit and/or pharmacists to perform routine, unscheduled observations of medication passes.
- b. Exploring options to provide staff with more routine, targeted training opportunities regarding established medication administration policies and

procedures, emerging best practices, certain administration techniques, and other identified problem areas.

### **Department of Human Services Response:**

- a. Agree. Implementation date: July 2011.

The Department will work with the Institutes to require nursing supervisors from a different unit to perform routine, unscheduled observations of medication passes. Pharmacy staff will not be used for these unscheduled observations.

- b. Agree. Implementation date: July 2011.

The Department and the Institutes will explore options, within available resources, to provide staff with more targeted training opportunities regarding medication administration policies and procedures, emerging best practices, certain administration techniques, and other identified problem areas.

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## **Clinical Documentation**

A medical chart comprises systematic documentation of a patient's individual medical history and care. The medical chart is a communication tool that ideally allows any member of the treatment team to quickly review and share pertinent information, such as a patient's conditions and diagnoses, treatment plan, current status, and active medications. Both Institutes have policies and procedures that contain requirements for clinical documentation. For example, the Pueblo Institute's policies address the need to document the medical necessity of treatment, patient progress, and response to treatment. The Fort Logan Institute's policies focus on the need for ongoing assessment of each patient and require that physicians document patients' responses to treatments on a weekly basis.

The HMA Team's scope of work did not explicitly call for an evaluation of medical chart organization and documentation; however, consideration of the adequacy of clinical documentation was inherent to the review of sampled patient charts to evaluate medication monitoring practices. As a result of this review, the HMA Team identified three particular areas of concern regarding medical chart documentation at the Institutes, as follows:

- **Psychiatric Documentation.** Psychiatrists should clearly document in the medical chart those observations and patient assessments that relate to

medication and other orders. In reviewing the sample patient files, however, the HMA Team found that both Institutes did not document treatment notes adequately. Specifically, at the Pueblo Institute, psychiatrists often did not substantiate their orders with a progress note explaining the need for the order, even in those cases where the order was for a new psychiatric medication. The Fort Logan Institute has a combined psychiatrist progress note and order form, which should make it more convenient for the psychiatrist to document a progress note next to each order. However, The HMA team found that the form was used correctly less than half the time, leading to orders for which the rationale and treatment goals were not substantiated by the physician.

- **Behavioral Management Documentation.** A patient's observed behavior is generally the basis for medication decisions, involuntary interventions, and other treatments. The tracking of symptoms or behaviors is a standard of practice in health care, and identification and tracking of the target symptoms of mental illness are pivotal in evaluating the effectiveness of psychiatric medication. During its review, the HMA Team noted extensive narrative documentation of patient behavior at both Institutes. For example, some patient charts had pages and pages of social work and nursing notes. Despite the amount of documentation present in many patient charts, however, a patient's clinical picture concerning behavior often remained unclear. Specifically, the Institutes do not use behavior tracking tools to help clinicians easily summarize and conclude upon patient behaviors in response to treatment. Such tools are commonly used in community psychiatry and in some mental health institutions to translate observational data into an easy-to-read visual representation. Behavior tracking tools are intended to make assessment practices more uniform within and across mental health disciplines and improve communication, which can be especially helpful when making clinical decisions regarding prescription of new drugs, dosage adjustments, administration of PRN medications, use of seclusion and restraint, and other interventions.
- **Medical Record Organization.** The medical records at each Institute are organized very differently, even though the Institutes' patients (with the exception of forensic patients at the Pueblo Institute) and treatment tools are largely the same. When reviewing the patient charts at both Institutes, the HMA Team found that there was no way to identify and review key aspects of patient care in an efficient and consolidated manner. For example, in cases of patients subject to involuntary medication orders, documentation regarding court proceedings was located in several places within the chart, making it difficult to track progress and determine the current status of any given intervention. In cases of patients on second-generation antipsychotics where metabolic monitoring is important,

documentation of lab results, patient weights, and family history data was located throughout the chart, making it difficult to determine whether the psychiatrist had considered all data elements when evaluating the patient's response to the medication. The HMA Team also noted that there is no easy way to identify a patient's current problem list, which is used by all clinicians to quickly identify the patient's active needs such as behavioral therapy or a special diet, or a patient's current active medications. For example, the medication administration record is located in the nursing station, and physician orders for medications are buried within the "orders" section of the patient medical chart. Both records must be reviewed to determine what medications were ordered and whether ordered medications were administered. The challenge of identifying a patient's current medications makes it more difficult to review and track medications when an involuntary medication order is put in place.

The medical records at the two Institutes need not be identical. However, a more standardized level of information and organization in the medical charts would offer additional support for patient care as well as efficiencies for quality improvement, peer review, and other regulatory oversight processes. The Department should work with the Institutes to improve clinical documentation in three key areas. First, the Institutes should ensure that psychiatrists record progress notes that clearly document the basis for all orders and changes in a patient's treatment plan. In other words, each physician order and change in treatment plan should be tied to a documented clinical observation. Quality improvement processes at both Institutes should include routine review of psychiatric documentation.

Second, the Department and the Institutes should consider implementing one or more behavioral management tracking tools, especially for use in assessing treatment response and medication management. The Institutes could pilot such tools on a single patient unit and assess their effectiveness before expanding implementation to other units.

Finally, the Department and the Institutes should work to achieve a more standardized level of information and organization in the medical charts. As a starting point, the Department should convene a group of clinical staff from both Institutes to review and compare medical charts and borrow from one another's strengths. At a minimum, the Institutes should develop a single form that tracks all court processes, steps, and scheduled events for the use of emergency and involuntary medication orders. The Institutes should also develop a means of ensuring that patients' current lists of active medications and current lists of problems are readily identifiable and accessible in the medical record.

## **Recommendation No. 6:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to achieve a more standardized level of information and organization in the medical charts. Specifically, the Department and the Institutes should:

- a. Ensure that psychiatrists record progress notes that clearly document the basis for all orders and changes in a patient's treatment plan. Quality improvement processes at both Institutes should include routine review of psychiatric documentation.
- b. Consider implementing one or more behavioral management tracking tools, especially for use in assessing treatment response and medication management.
- c. Develop a single form that tracks all court processes, steps, and scheduled events for the use of emergency and involuntary medication orders. The Institutes should also develop a means of ensuring that patients' current lists of active medications and current lists of problems are readily identifiable and accessible in the medical record.

## **Department of Human Services Response:**

- a. Agree. Implementation date: September 2011.

Periodic audits will be conducted to review a sample of medical staff progress notes to determine if the notes clearly document the basis for all orders and changes in a patient's treatment. Audit results will be provided to staff to improve performance.

- b. Agree. Implementation date: November 2011.

The Department and the Institutes will research options and the feasibility of implementing summary style behavior management tracking tools and consider implementing these tools within available resources. If implemented at the Institutes, these tools would likely involve significant manual processes. Many of these tools could be automated through an electronic health record.

- c. Agree. Implementation date: November 2011.

The Department and the Institutes will develop a single form that tracks all court processes, steps, and scheduled events for the use of emergency and involuntary medication orders. The Institutes will review the organization of the patient medical record, including a review of the list of patients' current medications and current problem list, and make changes to the record organization, if necessary, based on the review.

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## Electronic Health Records

The concept of an electronic health record is nothing new to the health care community. However, there has been a renewed push, spurred in part by passage of the federal American Recovery and Reinvestment Act of 2009 and the federal Affordable Care Act of 2010, toward adopting electronic health record systems and using them in ways to improve the safe and effective delivery of quality health care.

Currently, the Institutes utilize a paper-based medical record. During its review, the HMA Team noted that the Institutes' migration to an electronic health record could hold significant benefits for patient care, including helping to address many of the medication-related issues identified in this audit. The electronic health record is not a panacea; however, the benefits often associated with electronic health record systems include the following:

- **Increased access to and integration of patient information.** Improving access to patient data wherever and whenever clinical decisions are made is one of the key benefits of an electronic health record. Additionally, because patient data are brought together in one place, continuously updated, and immediately accessible to the treatment team, the electronic health record affords an integrated view of patient care that is often difficult to achieve via a paper-based record. For example, an electronic health record could help achieve better summaries of patients' current conditions, active medications, and legal proceedings for involuntary interventions, as well as enhanced and automated reporting on any number of clinical issues by patient, condition, provider, shift, or medication. The potential for fragmentation of clinical information is a common criticism of paper-based records.
- **Increased decision support.** An electronic health record can never take the place of clinical judgment and experience. However, an electronic

health record system can actively provide options and explanations that improve the clinician's efficiency and compliance with accepted practice guidelines. For example, electronic health record systems could prompt physicians to enter progress notes when medication orders are changed, provide alerts to potential drug interactions, remind physicians to order lab work for certain medications, and automatically recognize and flag abnormal lab results for followup.

- **Increased efficiencies.** Electronic health record systems are generally believed to increase efficiencies by reducing the time clinicians spend documenting patient care. For example, paper-based records often require duplicate data entry of the same patient information or observational data onto multiple forms. Electronic health records also solve the problem of illegible handwritten notes and physician orders. Electronic health record systems also provide for a more standardized organization of the patient's information, potentially yielding increased efficiencies for quality improvement and oversight processes, and are believed to contribute to quicker, more accurate billing processes.

The primary barrier to adopting electronic health records rests with the often significant up-front costs—the purchase of software and hardware, as well as an initial loss of productivity—that are inherent in the implementation of any new electronic information system. At a time when states and health care organizations are trying to reduce costs, allocating capital to new information systems presents a significant challenge for policymakers and administrators.

The Department and the Institutes reported reviewing several electronic health record systems in recent years to determine the feasibility of adopting electronic health records at the Institutes. Specifically, the Department evaluated a product available from its current health information system vendor, a system developed by the Utah State Hospital, and a system used by the U.S. Department of Veterans Affairs. The Department discontinued its evaluation efforts and further consideration of implementation strategies due to budget constraints.

We are concerned that the Institutes' ability to manage patient-centered care through a paper-based medical record will not continue to be feasible, given current trends and future demands on health care providers to routinely report on patient outcomes and established quality indicators in an integrated manner. Moreover, the potential for electronic health records to enhance the quality of patient care and safety at the Institutes warrants renewed attention and consideration. Therefore, the Department should work with the Institutes' leadership, the Governor's Office, and relevant legislative committees to pursue the eventual adoption of an electronic health record system at the Institutes. Although transitioning to an electronic health record system is not on the immediate horizon, continuing planning efforts will better position the State to

prepare for the day when the Institutes' use of electronic health records will be a minimum expectation to meet hospital accreditation, Medicare and Medicaid certification, and other quality of care standards.

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### **Recommendation No. 7:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes), the Governor's Office, and relevant legislative committees to pursue the eventual adoption of an electronic health record system at the Institutes.

#### **Department of Human Services Response:**

Agree. Implementation date: July 2012.

The Department agrees that implementation of an electronic health record system at the Institutes is needed and will continue to pursue implementation of these systems at each Institute. Department staff have reviewed four electronic health record systems over the last few years. However, the barrier to implementing an electronic health record is availability of state general funds to pay for the implementation, maintenance, and support. Federal funds for electronic health record implementation are available for acute care hospitals, but not for psychiatric hospitals. As the State's revenue situation improves, the Department will develop a request for funding to implement an electronic health record at the Institutes.

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## **Pharmacy Practices**

Traditionally, a hospital's pharmacy department has the primary responsibility for procurement, storage, and distribution of medications for all inpatients. Other roles or responsibilities often attributable to a pharmacy department include medication order review and evaluation, clinical monitoring, consultative and reporting services, distribution of medication information to facility staff, and medication education programs. Pharmacy staff have significant training and expertise in understanding the use of medications, possible adverse reactions and side effects, and potentially harmful drug interactions. To leverage this expertise, the use of pharmacists to provide clinical monitoring and consultative services has become the standard in other institutional settings. For example, federal regulations mandate pharmacist-performed drug regimen reviews in nursing facilities and intermediate care facilities for the mentally retarded. As part of the

patient treatment team, the Institutes' pharmacy staff should be able to support the medical staff regarding medication use and prescription through clinical monitoring and consultative services.

The HMA Team reviewed the pharmacy department at each Institute and discussed drug distribution processes and clinical services with the pharmacy staff. Both Institutes were found to comply with standards for drug purchasing, inventory control, and dispensing procedures. However, the HMA Team found that pharmacy clinical and consultative services were minimal at both facilities. For example, pharmacists perform only ad hoc medication history reviews of new or existing patients upon the request of the medical staff. Pharmacists do not perform routine drug regimen reviews or routine medication administration observations. Consequently, the Institutes and their patients are missing the opportunity to capture the positive effects that hands-on pharmacy services can have on patient care.

The HMA Team found that the current lack of pharmacy clinical support can be attributed to two primary causes. First, there has been no initiative to include clinical monitoring and consultative services as part of the pharmacy department's primary responsibilities at each Institute. For example, the Department and the Institutes have not developed and implemented a policy requiring pharmacy staff to conduct routine (e.g., quarterly) drug regimen reviews. We recognize that implementing drug regimen reviews could require additional pharmacy staff resources. However, current pharmacy staff may be able to absorb the workload by narrowing the drug regimen reviews to only patients who meet specific criteria, such as patients who have been at the Institute for a longer time period (e.g., more than three months), are taking three or more antipsychotics, or are on designated high-risk medications. As discussed in Recommendation No. 4, the pharmacy staff could add value by performing routine, unscheduled observations of medication passes to help identify and evaluate systemic problems that could lead to medication errors. As discussed in Recommendation No. 2, pharmacy staff could further assist with identifying and preventing unintended polypharmacy cases.

Second, the current information system, Opus/ISM, used by both pharmacies is an aging legacy system. In many ways, the Opus/ISM system is considered to be obsolete by current quality standards because it does not have sufficient functionality to facilitate the clinical and consultative services that pharmacies are increasingly being expected to provide in an inpatient treatment setting. For example, the system cannot produce automated reports of active medications for patients, track Institute-wide and physician-specific prescription practices, or report on aggregate factors, such as the number of patients on a specific drug or the prescription drugs most commonly used at each Institute. These types of reporting capabilities are necessary to adequately and efficiently support today's standards of patient care.

The HMA Team found that the Department and the Institutes could realize significant benefits from implementing a new automated pharmacy system. For example, automated functions found in more modern pharmacy systems include:

- Automated generation of reports, such as retrospective drug utilization reviews, physician drug order renewal lists, and other user-defined reports.
- Patient profiles that show drug-related lab results, patient diets, and non-drug treatments.
- Ability to interface with medication administration records in hard copy, electronic format, or both.

Automating reports could reduce the burden on pharmacy staff to produce these reports manually, thus freeing up pharmacy staff to provide additional clinical and consultative services, such as drug regimen reviews and medication pass observations. Another benefit of implementing a new pharmacy system is the possibility that the Institutes could save money on the use of particularly expensive medications. Specifically, a new pharmacy system could produce a report listing physician-specific prescription practices, which would help the Institutes identify physicians who use expensive versions of medications most frequently. By tracking medication use by physician, the Institutes could ensure that the most expensive medications are used only when necessary.

The Department should work with the Institutes to improve the pharmacy system, thereby enhancing the pharmacies' ability to provide clinical monitoring and consultative services. Both Institutes reported that they have been reviewing new pharmacy systems. The Department should work with the Institutes to pursue the eventual replacement of the Institutes' legacy pharmacy system. Until a new system becomes feasible, the Department should work with the Institutes to develop interim solutions wherever possible, given current system capabilities, that achieve better tracking and reporting of active medications for patients, patients on a specific drug or drugs, Institute-wide and physician-specific prescription practices, and the prescription drugs most commonly used at each Institute.

We recognize that replacing electronic information systems may not be feasible in the short term given the State's current budgetary environment. Nonetheless, psychiatric medications are an integral part of treating mental illness. It is important that the State recognize that the Institutes' aging and increasingly obsolete pharmacy system is a significant issue that will ultimately affect the Institutes' ability to provide meaningful progress in medication monitoring and other pharmacy functions that underpin the quality of patient care.

## **Recommendation No. 8:**

The Department of Human Services (the Department) should work with the Mental Health Institutes at Fort Logan and Pueblo (the Institutes) to maximize the use of pharmacy staff and pharmacy systems in support of medical staff and patient care. Specifically, the Department and the Institutes should:

- a. Include clinical monitoring and consultative services as part of the pharmacy department's primary responsibilities at each Institute. At a minimum, pharmacy staff should be required to conduct drug regimen reviews on a routine basis.
- b. Pursue the eventual replacement of the Institutes' legacy pharmacy system.
- c. Develop interim solutions to improve upon tracking and reporting capabilities of the current pharmacy system until it can be replaced. Efforts should be targeted toward tracking and reporting in the most critical areas, such as active medications for patients, patients on a specific drug or drugs, Institute-wide and physician-specific prescription practices, and the prescription drugs most commonly used at each Institute.

## **Department of Human Services Response:**

- a. Agree. Implementation date: July 2011.

Each Institute's pharmacy department currently provides clinical monitoring and consultative services within existing resources. For example, both Institute pharmacy departments currently monitor potential medication interactions, ensure that lab and other necessary monitoring occurs on schedule, and make recommendations about the timing and dosages of medications to maximize therapeutic effect in response to medical staff requests. The Institutes will also conduct periodic drug regimen reviews on a prioritized basis. Replacement of the existing legacy pharmacy system with a modern pharmacy system would increase pharmacist ability to provide increased clinical monitoring and consultative services and drug regimen reviews.

- b. Agree. Implementation date: December 2011.

The Department and the Institutes have evaluated several pharmacy systems to replace the existing legacy system currently in use. However, the barrier to implementing a new pharmacy system is

availability of state general funds to pay for the implementation, maintenance, and support. As the State's revenue situation improves, the Department will develop a request for funding to implement a new pharmacy system. The Department, with the involvement of the Governor's Office of Information and Technology, will determine which system best meets the needs of the Institutes and other direct care agencies in the Department that operate pharmacies (including the State Veterans Nursing Homes and the Grand Junction Regional Center).

- c. Agree. Implementation date: November 2011.

The Department will work to develop and implement interim solutions to improve upon tracking and reporting capabilities of the current pharmacy system until funding and resources are available to replace the system. These efforts will include improved management reporting about active medications for patients, patients on a specific drug or drugs, Institute-wide and physician-specific prescription practices, and the prescription drugs most commonly used at each Institute.

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