

OFFICE OF INSPECTOR GENERAL

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

OPIOID DRUG UTILIZATION INSPECTION

*Texas Medicaid Efforts to Reduce
Prescription Opioid Abuse and Overutilization*



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WHY THE IG CONDUCTED THIS INSPECTION

In 2015 Texas Medicaid paid over \$33.3 million to fill opioid prescriptions for more than 426,000 Medicaid patients. Opioids are controlled substances commonly prescribed for the relief of pain. Their use, however, comes with significant risk. An inspection was conducted to answer the following questions:

- Has the Texas Medicaid program implemented effective procedures to identify and reduce prescription opioid abuse?
- Are there alternative or additional programs that have been proven effective at reducing opioid abuse that can be adopted by the Texas Medicaid program?

WHAT THE IG RECOMMENDS

The HHSC Medicaid and CHIP Services Department should:

- Collaborate with MCOs to develop and implement edits consistent with CDC recommendations.
- Identify VDP edits that correspond to CDC guidelines for managing opioid use and consider requiring MCOs to incorporate those edits.
- Require PMP registration for all prescribers of controlled substances to treat chronic pain and consider requiring it for all prescribers of opioids.
- Ensure that MCOs employ a quality assurance review of prescriber records to confirm adherence to 22 Texas Administrative Code § 170.3(1)(C).

The IG should:

- Identify the issue of limited PMP access to the Texas Legislature for consideration.

WHAT THE IG FOUND

The inspection consisted of a review of Centers for Disease Control (CDC) recommendations, Texas Administrative Code, and Medicaid prescription claims data. Inspections Division conducted interviews with representatives from managed care organizations (MCOs), Medicaid and CHIP Services Division Vendor Drug Program (VDP), IG Lock-in Program, and State Board of Pharmacy (Pharmacy Board). In addition, inspectors evaluated information from the Prescription Monitoring Program (PMP) database administered by the Pharmacy Board.

The PMP collects and monitors data on controlled substance prescriptions dispensed in Texas or to Texas residents. The PMP is available to pharmacies and prescribers and provides a way to monitor a patient's history of controlled substance prescriptions. Texas Administrative Code requires physicians to consider use of PMP data under certain circumstances.

The IG Inspections Division identified the following issues:

- CDC recommendations should be incorporated in VDP edits.
- Texas Medicaid prescribers could better utilize the PMP.
- IG needs direct access to the PMP database.

Current VDP pharmacy point-of-sale edits do not incorporate all opioid related CDC recommendations such as: (a) use of extended release and long acting opioids, (b) daily dosages, (c) number of days opioids are initially prescribed, and (d) prescriptions written with more than three months of refills. Further, not all MCOs incorporate all VDP pharmacy point-of-sale edits.

There is evidence that the PMP is not used consistently by prescribers. PMP data was provided by the Pharmacy Board for Medicaid patients who received and for prescribers of opioid pain medication in 2015. The data showed that 55 of 100 prescribers reviewed did not access the PMP database that year. Thirty-eight of those 55 were not registered to use the database. PMP patient data confirmed that over 50 percent of the patients reviewed used cash to obtain controlled substances in addition to prescriptions covered by Medicaid. It is essential that prescribers review information in the PMP prior to prescribing controlled substances.

Access to information in the PMP database is governed by Texas Health and Safety Code § 481.076, which limits IG access to purposes related to law enforcement. As part of its responsibility to detect abuse in the Texas Medicaid program, access to the PMP database will enable the IG to identify patterns of patient behavior that suggest abuse of Medicaid benefits and notify appropriate agencies and organizations.

The management response indicates that the Vendor Drug Program (VDP) generally agrees with each recommendation related to HHSC Medicaid and CHIP Services Department.

TABLE OF CONTENTS

INTRODUCTION	1
Background.....	1
Inspection Standards.....	3
ISSUES AND RECOMMENDATIONS	4
Objective 1: Has the Texas Medicaid Program Implemented Effective Processes to Identify and Reduce Prescription Opioid Abuse?	4
Issue 1.1 CDC Recommendations Should be Incorporated in VDP and UM Edits	5
Recommendations 1.1.1 - 1.1.2 Incorporate CDC Recommendations	6
Objective 2: Are There Alternative or Additional Programs Proven Effective at Reducing Opioid Abuse That Can Be Adopted by Texas Medicaid?	8
Issue 2.1 Texas Medicaid Prescribers Could Better Utilize the PMP	8
Recommendations 2.1.1 - 2.1.3 PMP Registration and Quality Assurance Review	10
Issue 2.2 IG Needs Access to the PMP Database.....	11
Recommendation 2.2.1: Identify Limited PMP Access to Texas Legislature for Consideration.....	11
CONCLUSION	12
APPENDICES.....	13
Appendix A: Objective, Scope, and Methodology	13
Appendix B: Texas Health and Safety Code § 481.076	16
Appendix C: Report Team and Report Distribution.....	18
Appendix D: IG Mission and Contact Information	19

INTRODUCTION

The Texas Health and Human Services Commission (HHSC) Inspector General (IG) conducted an inspection of Texas Medicaid programs and procedures designed to reduce prescription opioid abuse and overutilization. The purpose of the inspection was to assess the effectiveness of the Texas Medicaid program at reducing prescription opioid abuse and to determine whether there are alternative programs that may further reduce opioid abuse.

Objective

The objectives of the inspection were to answer the following questions:

- Has the Texas Medicaid program implemented effective processes to identify and reduce prescription opioid abuse?
- Are there alternative or additional programs proven effective at reducing opioid abuse that can be adopted by Texas Medicaid?

Background

In 2015 the Texas Medicaid program paid over \$33.3 million to fill opioid pain medication prescriptions for more than 426,000 Medicaid patients.

Issues related to the treatment of acute and chronic pain are complex and challenging. Opioids are controlled substances commonly prescribed for the relief of pain. Their use, however, comes with significant risk. The Centers for Disease Control and Prevention (CDC)¹ reports that from 1999 to 2014, more than 165,000 people died from overdose related to opioid pain medication in the United States, and in 2013 an estimated 1.9 million people abused or were dependent on prescription opioid pain medication. According to the CDC, "Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder..." Nationally the death rate associated with opioid pain medication usage has increased markedly in the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially.²

According to the Centers for Medicare and Medicaid Services (CMS), Center for Medicaid and CHIP Services (CMCS)³, "Medicaid beneficiaries are prescribed painkillers at twice the rate of non-Medicaid patients and are at three to six times the risk

¹ The Centers for Disease Control and Prevention, under the Department of Health and Human Services, is recognized as the leading health promotion, research, prevention, and preparedness agency in the United States.

² Centers for Disease Control (CDC), Recommendations and Reports (March 18, 2016), "*Guideline for Prescribing Opioids for Chronic Pain.*"

³ CMCS serves as focal point for the formulation, coordination, integration, implementation, and evaluation of national program policies and operations relating to Medicaid and Children's Health Insurance Program (CHIP). CMCS works in partnership with states to improve the quality of their implementation of Medicaid and CHIP programs.

of prescription painkillers overdose.”⁴ Risk of overdose and death is further increased when certain classes of medications are combined with opioids. For example, benzodiazepines, often used to treat anxiety, when used with opioids can increase the euphoric effects of the opioids and may be sought out for this purpose. This combination increases the risk of over-sedation, depressed respiratory functioning, and death. The CDC recommends that clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

The HHSC Medicaid and CHIP Services Department Vendor Drug Program (VDP) and the IG Lock-In Program are two program areas that seek to identify and reduce potential prescription opioid abuse by Medicaid patients. Additionally, the Texas Prescription Monitoring Program (PMP), administered through the Texas State Board of Pharmacy (Pharmacy Board), collects and monitors prescription data for controlled substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state. Though not part of the Texas Medicaid program, the PMP database is available to pharmacies and prescribers and provides a venue for monitoring a patient's history of controlled substance prescriptions.

The IG Inspections Division surveyed all contracted managed care organizations (MCOs) and conducted onsite visits and interviews with selected MCOs. Staff also conducted interviews with representatives of VDP, IG Lock-In Program, IG Fraud Detection Investigative Strategy directorate (FDIS), the Pharmacy Board, Texas Department of Public Safety (DPS), Texas Department of State Health Services (DSHS), Medicaid Eligibility and Health Information System (MEHIS), and the Texas Pain Society. The Pharmacy Board provided aggregate data from the PMP database and FDIS provided Texas Medicaid prescriber and patient data using 2015 prescription claims information. See Appendix A for additional information.

The following resources provided guidance for this inspection and recommendations:

- Centers for Medicare and Medicaid Services, Center for Medicaid and CHIP Services (CMCS), Informational Bulletin (January 28, 2016), "*Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction*" (CMCS Bulletin)
- Centers for Disease Control (CDC), Recommendations and Reports (March 18, 2016), "*Guideline for Prescribing Opioids for Chronic Pain*" (CDC Report)

In this report, the term "prescription opioid abuse" is an inclusive term that refers to the non-therapeutic use of prescribed opioid medications, as well as use that places the Medicaid patient at increased risk of harm that is not outweighed by potential benefits. This includes, but is not limited to:

⁴ Centers for Medicare and Medicaid Services, Center for Medicaid and CHIP Services (CMCS), Informational Bulletin (January 28, 2016), "*Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction*."

- Inappropriate patient behaviors, such as "pharmacy shopping," which is using multiple pharmacies to fill prescriptions from multiple prescribers in an attempt to conceal efforts to obtain additional medications
- Prescriber behaviors that are outside of medically accepted best practices, such as prescribing high daily doses of opioids or dangerous combinations of opioids with other drugs

The term "chronic pain" is used in a manner consistent with the CDC Report and refers to pain that typically lasts more than three months or past the time of normal tissue healing.

Inspection Standards

The IG Inspections Division conducts inspections of Texas Health and Human Services programs, systems, or functions. Inspections are designed to be expeditious, targeted examinations into specific programmatic areas to identify systemic trends of fraud, waste, and abuse. Inspections typically use a smaller sample, a snapshot in time, and make recommendations to strengthen effectiveness and efficiency. The IG Inspections Division conducted the inspection in accordance with Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

ISSUES AND RECOMMENDATIONS

Objective 1: HAS THE TEXAS MEDICAID PROGRAM IMPLEMENTED EFFECTIVE PROCESSES TO IDENTIFY AND REDUCE PRESCRIPTION OPIOID ABUSE?

The VDP and the IG Lock-in Program are two Texas Medicaid program areas involved in efforts to reduce prescription opioid abuse by Medicaid patients through the identification of potentially duplicative, excessive, contraindicated, conflicting, or fraudulent opioid medication use. This inspection identified several factors that limit the potential effectiveness of the efforts of these program areas.

The VDP recommends and develops automated point-of-sale claims processing safeguards, known as clinical prior authorization edits (VDP edits), that are approved by the Drug Utilization Review Board (DUR).⁵ VDP edits are designed to minimize risk of patient harm by alerting pharmacies of potentially dangerous drug dosages or combinations. Generally MCOs, in conjunction with their Pharmacy Benefits Managers (PBMs)⁶, implement most VDP edits. In addition, many develop utilization management (UM) edits which do not require prior authorization.⁷

When a Medicaid patient presents a prescription to a pharmacy, VDP edits implemented by the MCO check the patient's Medicaid medical and drug claims history to determine whether the information on file matches the edit criteria for dispensing the prescribed drug. If the patient's medical record is not consistent with the clinical edit criteria, a prescriber authorization is required by the PBM before the medication can be processed and dispensed by the pharmacist.⁸

An example of a VDP edit is the "opiate overutilization edit." This edit first determines whether the Medicaid patient had a cancer diagnosis in the previous two years. It then reviews Medicaid claims history during the previous 60 days to count the number of (a) opioid medications prescribed, (b) pharmacies used to fill these prescriptions, (c) opioid claims processed through Medicaid, (d) prescribers, and (e) days supply of opioids dispensed. Based on this information, the system either approves the prescription claim for payment and dispensing by the pharmacist or notifies the pharmacist to obtain authorization from the prescriber.

Only Medicaid prescription claims are subject to the VDP edits. Prescriptions purchased with cash are not subject to the VDP edits. As a result, patients may obtain quantities of controlled substances that exceed clinical justification. When this is suspected, the MCO is expected to make a referral to the IG Lock-In Program for review. Patients who meet

⁵ The DUR is an advisory board consisting of HHSC appointed physicians and pharmacists.

⁶ A PBM is a third-party administrator of prescription drug benefits for MCOs.

⁷ Edits developed and implemented by MCOs and their PBMs cannot be more restrictive than those approved by the DUR.

⁸ Once obtained, the authorization remains in place for up to a year, depending on the particular edit.

criteria designed to identify potential excessive use or misuse of prescription medications are placed on "lock-in" status, thereby restricting their use of Medicaid benefits to a single designated pharmacy. This is intended to reduce the risk of abuse and harm to the patient and reduce unnecessary healthcare costs.

Initially, a MCO must submit supporting documentation and request IG Lock-In Program approval to place a patient on lock-in status. MCOs that meet the program's standards are authorized to place patients on lock-in status without prior approval. More than two-thirds of the MCOs have met the program standards and may "lock-in" patients without prior approval.

Several factors limit the ability of VDP, the IG Lock-In Program, and the MCOs to effectively manage opioid utilization:

- The programs initiate interventions by considering the number of opioid prescriptions a patient receives in a given time period, but potentially harmful individual prescription dosages do not trigger a response.
- CDC recommendations, noted in the CDC Report, have not been fully incorporated in the VDP edits.
- Information available is limited to Medicaid data sources. When a Medicaid patient pays cash for a controlled substance prescription, this information is not available to VDP, the IG Lock-In Program, or MCOs.

Issue: 1.1 CDC Recommendations Should be Incorporated in VDP and UM Edits

The CDC Report was used to assess practices of the Texas Medicaid program. This report is based on "a clinical systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain" and input from "experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee." There are 12 CDC recommendations⁹ for prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The recommendations most relevant to this issue are:

1. **"When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids."** The CDC Report notes that in 2014, the Food and Drug Administration modified the labeling for ER/LA opioids to recommend that they be reserved for the management of pain "severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom other treatment options are ineffective." The CDC Report also notes that the consensus among experts is that ER/LA opioids should only be initiated with patients already receiving opioids and should not be prescribed for intermittent use.
2. **"When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any**

⁹ Centers for Disease Control (CDC), Recommendations and Reports (March 18, 2016), "*Guideline for Prescribing Opioids for Chronic Pain.*"

dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day." The MME methodology establishes conversion factors for commonly prescribed opioids and allows different medications to be compared by relative strength. Dosages of 50 or more MME/day increase overdose risk without necessarily adding benefits for pain control or function.

3. **"Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."** This recommendation is intended to minimize unnecessary risks of long-term opioid use.
4. **"Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently."** Individual risks and benefits of opioid therapy can change over time and should be reassessed regularly. Limiting refills to three months, unless otherwise pre-authorized, promotes more frequent assessment of risks and benefits to the patient.

Current VDP edits do not incorporate CDC recommendations regarding:

- ER/LA use or histories
- Daily MMEs
- Numbers of days for which initial opioid prescriptions are dispensed
- Opioid prescriptions written with more than three months of refills

Consensus among MCOs interviewed during the inspection supports incorporating these CDC recommendations into the point-of-sale prior authorization edits. Several MCOs currently employ UM edits that do not require prior authorization but alert pharmacies when high daily MMEs are prescribed. Not all MCOs apply all currently available opioid-related edits. During interviews, MCOs explained that some VDP edits are difficult to incorporate due to technical issues with data systems.

Recommendation: 1.1.1 – 1.1.2 Incorporate CDC Recommendations

To minimize risk of overdose and prescription opioid abuse, the HHSC Medicaid and CHIP Services Department should:

- 1.1.1 Collaborate with MCOs to develop and implement VDP or UM edits consistent with CDC recommendations, for:
 - a. More than a 90-day supply of opioids that results in 50 MME/day or more
 - b. Opioids that result in a total of 90 MME/day or more

And the following edits to require prior authorization when the patient has no opioid prescriptions filled in the past 90 days:

- c. ER/LA opioids
 - d. More than a seven-day supply of opioids
 - e. Opioids totaling 50 or more MME/day
- 1.1.2 Identify the VDP prior authorization edits that correspond to CDC guidelines for managing opioid use and consider requiring MCOs to incorporate these specific edits to reduce opioid overutilization.

Management Response:

1.1.1 The Vendor Drug Program (VDP) generally agrees with the recommendation

- *The Vendor Drug Program (VDP) will collaborate with managed care organizations (MCOs) to ensure morphine milligram equivalent (MME) per day limits are implemented as quantity limits for opioids.*
- *VDP has a robust program of clinical prior authorizations designed to curb opioid misuse and protect patients from overdose. This includes both drug-specific and general opioid edits, as well as edits that check for certain combinations of concern such as opiates filled in proximity to benzodiazepines and/or muscle relaxants. Staff will evaluate current clinical prior authorization criteria and utilization management edits and will modify as appropriate.*

1.1.2 The Vendor Drug Program (VDP) generally agrees with the recommendation

VDP will identify all clinical prior authorizations that correspond to the CDC guidelines for managing opioid use and will consider requiring MCOs to incorporate these specific edits by 7/1/2017.

Objective 2: ARE THERE ALTERNATIVE OR ADDITIONAL PROGRAMS PROVEN EFFECTIVE AT REDUCING OPIOID ABUSE THAT CAN BE ADOPTED BY TEXAS MEDICAID?

Prescription monitoring programs (PMPs) are operational in 49 states, including Texas, and in one U.S. territory. The PMP databases collect and analyze controlled substance prescription information submitted by pharmacies. They are powerful tools, and when used appropriately, have a real impact on efforts to reduce prescription opioid abuse. In Texas, access to the data is essentially limited to prescribers, pharmacists, and law enforcement.

Texas Health and Safety Code § 481.075(i) (2016) mandates that pharmacies submit required information no later than the seventh day after the controlled substance prescription is completely filled. Information submitted includes: (a) dates that the prescription is issued and dispensed; (b) name, quantity, and intended use of the medication; (c) prescriber's name; and (d) name, address, and date of birth or age of the person for whom the controlled substance is prescribed.

Information in the PMP database can help detect and prevent prescription opioid abuse. It is available to practitioners who prescribe or are considering prescribing opioid pain medications. A physician is able to view patient history of prescribed controlled substances, regardless of payment source or prescriber, and make clinical decisions based on this information. Review of the PMP allows prescribers to identify pharmacy or doctor "shopping" and other inappropriate patient behaviors characteristic of substance use disorders. The PMP database captures all controlled substances dispensed, even when cash is used for the purchase.

Patients can purchase medications with cash without detection by the Medicaid program. Cash payment information is only available through the PMP and is easily accessible by physicians. Prescribers need to review the PMP in an effort to reduce prescription opioid abuse and make clinically sound decisions for their patients. The IG Lock-In Program, VDP clinical prior authorization edits, and MCOs do not have information available regarding cash payments for controlled substances; therefore, it is essential that prescribers review information in the PMP prior to prescribing controlled substances.

Issue: 2.1 Texas Medicaid Prescribers Could Better Utilize the PMP

A rule of the Texas Medical Board¹⁰ states:

(C) Prior to prescribing dangerous drugs or controlled substances for the treatment of chronic pain, a physician must consider reviewing prescription data and history related to the patient, if any, contained in the Prescription Drug Monitoring Program described by §§481.075, 481.076, and 481.0761 of the Texas Health and Safety Code and consider obtaining at a minimum a baseline

¹⁰ Title 22 Tex. Admin. Code § 170.3(1) (2016)

toxicology drug screen to determine the presence of drugs in a patient, if any. If a physician determines that such steps are not necessary prior to prescribing dangerous drugs or controlled substances to the patient, the physician must document in the medical record his or her rationale for not completing such steps.

The IG Inspections Division requested PMP data from the Pharmacy Board for 100 prescribers who prescribed opioid pain medication to Texas Medicaid patients in 2015. Twenty-five prescribers were selected from each of the following categories: (a) high numbers of opioid prescriptions written; (b) high prescription to patient ratios; and (c) high dollar amount prescribed. An additional 25 were selected at random.

PMP data provided by the Pharmacy Board showed that 55 of the 100 prescribers did not access the PMP database that year. Of the 55, 38 were not even registered to use the database. Analysis of Medicaid prescriber data and information from the PMP database showed that seven prescribers, who were responsible for a total of over 19,000 opioid pain medication prescriptions in 2015, did not access the PMP database that year.

Failure to use the PMP database prior to prescribing opioids is a significant concern (see Table 1) because analysis confirms that patients use cash to purchase controlled substances. The Pharmacy Board was provided a list of 25 Medicaid MCO patients for each of the following categories:

- On lock-in status for the entire year (unable to use Medicaid for prescriptions anywhere other than their one designated pharmacy)
- Received opioids totaling ≥ 90 MME/day for at least 9 months in 2015
- Received low doses of opioids for at least 9 months in 2015 (MME/day never exceeded 50)
- Received both opioids and benzodiazepines during at least 3 months in 2015

The PMP data¹¹ provided by the Pharmacy Board showed the number of patients in each group who paid cash for controlled substances at pharmacies as indicated in Table 1.

Over 50 percent of the patients sampled purchased additional controlled substances with cash. These purchases were not detected by VDP edits or by the IG Lock-In Program. Limitations on access to the PMP database prevent these program areas from detecting cash purchases. However, a prescriber's review of the PMP data would have detected these purchases. Physicians who fail to check readily available information regarding a Medicaid patient's prescription history in the PMP may place the patient at an elevated risk of prescription abuse, which may lead to addiction and possibly death.

¹¹ Per statute (Appendix B), the Pharmacy Board can only provide aggregate data for this purpose.

Table 1: Medicaid Patients Obtain Additional Controlled Substance Prescriptions with Cash

Groups who Received Opioid Prescription Pain Medication through Medicaid	Paid Cash for Additional Opioid Pain Medication		Paid Cash for Benzodiazepines		Paid Cash for Both Opioids and Benzodiazepines		Total who Paid Cash for Additional Controlled Substances	
	#	%	#	%	#	%	#	%
25 patients on lock-in status for the entire year	8	32%	3	12%	5	20%	16	64%
25 patients received opioids ≥ 90 MME/day for at least 9 months in 2015	8	32%	1	4%	1	4%	10	40%
25 patients received low doses of opioids for at least 9 months in 2015 (MME/day never exceeded 50)	8	32%	0	0%	4	16%	12	48%
25 patients received both opioids and benzodiazepines during at least 3 months in 2015	9	36%	3	12%	3	12%	15	60%

Source: Data from Texas State Board of Pharmacy, Prescription Monitoring Program

Recommendation: 2.1.1 – 2.1.3 PMP Registration and Quality Assurance Review

The HHSC Medicaid and CHIP Services Department should:

- 2.1.1 Require PMP registration for all prescribers of controlled substances to treat chronic pain.
- 2.1.2 Consider requiring PMP registration of all prescribers of opioids.
- 2.1.3 Ensure that MCOs employ a quality assurance review of prescriber records to confirm adherence to 22 Tex. Admin. Code § 170.3(1)(C).

Management Response:

2.1.1 The Vendor Drug Program (VDP) generally agrees with the recommendation
VDP agrees Texas Prescription Monitoring Program (PMP) registration should be required for all prescribers of controlled substances. Staff will work with Policy Development to determine the most appropriate way to implement this requirement for prescribers, VDP staff will develop a timeline outlining the steps and timeframe for determining the best avenue for implementing this recommendation by 07/01/2017.

2.1.2 The Vendor Drug Program (VDP) generally agrees with the recommendation
VDP agrees PMP registration should be required for all prescribers of opioids. Staff will work with Policy Development to determine the most appropriate way to implement this requirement for prescribers by 07/01/2017.

2.1.3 The Vendor Drug Program (VDP) generally agrees with the recommendation
VDP will create a workgroup by 8/1/2017 to make recommendations to HHSC leadership on an approach to require this in managed care while taking into consideration provider abrasion and MCO administrative burden. The timeline for implementation is dependent on the outcomes of activities performed for Recommendations 2.1.1 and 2.1.2.

Issue: 2.2 IG Needs Direct Access to the PMP Database

The IG's enabling legislation, in Tex. Gov't. Code § 531.102(a) (2015), states:

The commission's office of inspector general is responsible for the prevention, detection, audit, inspection, review, and investigation of fraud, waste, and abuse in the provision and delivery of all health and human services in the state, including services through any state-administered health or human services program that is wholly or partly federally funded, and the enforcement of state law relating to the provision of those services.

Access to information contained in the PMP database is governed by Texas Health and Safety Code § 481.076 (Appendix B), which limits IG access to purposes related to law enforcement.¹² Specific patient and prescriber information for prevention, detection, inspection, and review of waste and abuse required for healthcare oversight is not available to the IG. Therefore, during the course of this inspection, only aggregate data was provided by the Pharmacy Board.

As part of its responsibility to detect possible abuse in the Texas Medicaid program, access to the PMP database will enable the IG to identify patterns of patient behavior that suggest abuse of Medicaid benefits and notify appropriate agencies and organizations that a patient may be involved in potentially harmful or wasteful activities. For example, Tennessee law allows the Inspector General to access PMP as a part of its duties and responsibilities related to the state's health care program, TennCare.

PMP data could also be used to identify prescribing habits by physicians that suggest unnecessary use or overuse of dangerous drugs. Access to PMP data would allow the IG to provide information to appropriate agencies and organizations to better equip them to provide oversight and educate prescribers on best practices and legal requirements in prescribing opioids to treat chronic pain. This would reduce risk of harm to Medicaid patients and potential costs to the Medicaid program.

Recommendation: 2.2.1 Identify Limited PMP Access to Texas Legislature for Consideration

2.2.1 The IG should identify this issue to the Texas Legislature for consideration. The IG needs direct access to the PMP to fulfill its oversight functions and responsibilities related to opioid abuse and overutilization in the Texas Medicaid program.

¹² For law enforcement purposes, IG must request PMP information from the Texas Department of Public Safety.

CONCLUSION

The IG Inspections Division completed an inspection to assess the effectiveness of the VDP and the IG Lock-in Program at reducing prescription opioid abuse and to determine whether there are alternative programs that may further reduce prescription opioid abuse and overutilization. The inspection consisted of questionnaires completed by contracted MCOs, and onsite visits and interviews in October and November 2016.

The inspection identified the following issues:

- Specific CDC recommendations should be incorporated in VDP and UM edits.
- Texas Medicaid prescribers could better utilize the PMP.
- IG needs direct access to the PMP database to fulfill its oversight mission related to opioid abuse and overutilization in the Texas Medicaid program.

To address these issues and minimize risk of prescription opioid abuse and overdose to Medicaid patients, the IG Inspections Division recommends the HHSC Medicaid and CHIP Services Department should:

- Collaborate with MCOs to develop and implement VDP or UM edits consistent with CDC recommendations.
- Identify the VDP prior authorization edits that correspond to CDC guidelines for managing opioid use and consider requiring MCOs to incorporate these specific edits to reduce opioid overutilization.
- Require PMP registration for all prescribers of controlled substances for the treatment of chronic pain and consider requiring registration for all prescribers of opioids.
- Ensure that MCOs employ a quality assurance review of prescriber records to confirm adherence to 22 Tex. Admin. Code § 170.3(1)(C).

The IG needs direct access to the PMP to fulfill its oversight functions and responsibilities related to opioid abuse and overutilization in the Texas Medicaid program. The IG Inspections Division recommends that the IG identify this issue to the Texas Legislature for consideration. If implemented, these recommendations will potentially result in reduced risk of patient harm as well as cost savings and will help identify and reduce prescription opioid abuse and overutilization.

The IG Inspections Division thanks management and staff at the inspected entities for their cooperation and assistance during this inspection.

APPENDICES

Appendix A: Objective, Scope, and Methodology

Objectives

The objectives of the inspection were to answer the following questions:

- Has the Texas Medicaid program implemented effective processes to identify and reduce prescription opioid abuse?
- Are there alternative or additional programs proven effective at reducing opioid abuse that can be adopted by Texas Medicaid program?

Scope

The scope of the inspection focused on: (a) review of Medicaid prescription claims data from calendar year 2015, (b) assessment of relevant Texas practices at the time of the inspection, (c) review of generally recognized best practices, and (d) interviews conducted through fieldwork in October and November 2016. The IG Inspections Division sought to assess the effectiveness of the VDP and the IG Lock-In Program at reducing prescription opioid abuse and determine whether there are alternative programs that may further reduce opioid abuse and overutilization.

Methodology

Inspectors obtained and analyzed prescription opioid pain medication prescriber data to assess the following opioid pain medication information for each prescriber:

- Specific drugs prescribed
- Number of prescriptions filled for each specific drug
- Number of unique patients receiving each drug
- Total Medicaid allowable reimbursement to pharmacies for each prescription

The analysis was used to identify lists of 25 prescribers in each of the following categories: (a) high numbers of opioid prescriptions written; (b) high opioid pain medication prescription to patient ratios; and (c) high dollar amounts of opioid prescriptions. An additional 25 opioid pain medication prescribers were identified at random. The lists were submitted to the Pharmacy Board with a request for information related to PMP registration and access history for the prescribers during 2015.

Inspectors also obtained prescription data for Medicaid patients to identify all Medicaid opioid pain prescriptions for calendar year 2015. The data included the: (a) patient ID, (b) medication information, (c) MCO, and (d) IG Lock-In Program start date, if applicable.

In addition to providing statewide aggregate information, this data was used to identify MCOs with high and low lock-in rates among patients receiving opioid pain medications. The data was also organized by MCO to identify the number of unique patients who received prescriptions for opioid pain medications in 2015 and the number of patients in the IG Lock-In Program. Calculations for each MCO were made to determine the percent of patients who received opioid pain medications and were also in the IG Lock-In Program. Totals were calculated taking into account that some patients may have switched between various MCOs.

The MCOs were ranked from lowest to highest IG Lock-In Program utilization rates. The two highest and two lowest utilization rates of MCOs with at least 10,000 patients receiving opioid pain medications were identified and selected for in-depth interviews including onsite visits. The four selected MCOs collectively served a total of 152,629 unique patients who received at least one prescribed opioid pain medication.

Data was also analyzed and used to calculate daily MMEs for prescriptions filled through the four selected MCOs, using the conversion factors as listed in the CDC Report. Patient data was narrowed down and compiled into four categories.^{13,14} From each category the names of 25 patients were provided to the Pharmacy Board. The Pharmacy Board provided aggregate data identifying how many patients in each category paid cash for additional opioids or benzodiazepines. The categories were:

- On lock-in status for the entire year
- Received opioids ≥ 90 MME/day for at least 9 months in 2015
- Received low doses of opioids for at least 9 months in 2015 (MME/day never exceeded 50)
- Received both opioids and benzodiazepines during at least 3 months in 2015

The IG Inspections Division sent an email notification letter and a questionnaire to all MCOs on October 14, 2016, to communicate information regarding the inspection process and request participation. Onsite interviews were scheduled for October and November 2016 with the four selected MCOs: (a) Cigna-HealthSpring, (b) Texas Children's Health Plan, (c) Superior Health Plan, and (d) Parkland Health Plan. While onsite, the IG Inspections Division interviewed appropriate personnel from the MCOs, including clinical staff and representatives of special investigations units and pharmacy benefits managers.

In addition to the four MCOs, interviews were also conducted with representatives of the VDP, the IG Lock-In Program, FDIS, the Pharmacy Board, DPS, DSHS, MEHIS, and Texas Pain Society. The IG Inspections Division conducted the inspection in accordance

¹³ Patients were not included if available date indicated they received cancer medication or were treated by an oncologist in 2015. The CDC recommendations do not apply to patients receiving active cancer treatment.

¹⁴ Patients were not included if they did not receive Medicaid covered prescriptions in both January and December 2015, as this may indicate they were not eligible for Medicaid during part of the year and therefore were justified in paying cash for prescriptions.

with Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency. Those standards require that due professional judgment be used in planning and performing inspections and in reporting the results, and that evidence supporting inspection observations, conclusions, and recommendations be sufficient, competent, and relevant and lead a reasonable person to sustain the observations, conclusions, and recommendations.

The IG Inspections Division believes that the evidence obtained provides a reasonable basis for the issues and recommendations based on inspection objectives.

Appendix B: Texas Health and Safety Code § 481.076

TITLE 6	FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES
SUBTITLE C	SUBSTANCE ABUSE REGULATION AND CRIMES
CHAPTER 481	TEXAS CONTROLLED SUBSTANCES ACT
SUBCHAPTER C	REGULATION OF MANUFACTURE, DISTRIBUTION, AND DISPENSATION OF CONTROLLED SUBSTANCES, CHEMICAL PRECURSORS, AND CHEMICAL LABORATORY APPARATUS

OFFICIAL PRESCRIPTION INFORMATION; DUTIES OF TEXAS STATE BOARD OF PHARMACY. Effective: September 1, 2016

(a) The board may not permit any person to have access to information submitted to the board under Section 481.074(q) or 481.075 except:

- (1) an investigator for the board, the Texas Medical Board, the Texas State Board of Podiatric Medical Examiners, the State Board of Dental Examiners, the State Board of Veterinary Medical Examiners, the Texas Board of Nursing, or the Texas Optometry Board;
- (2) an authorized officer or member of the department or authorized employee of the board engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;
- (3) the department on behalf of a law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;
- (4) a medical examiner conducting an investigation;
- (5) a pharmacist or a pharmacy technician, as defined by Section 551.003, Occupations Code, acting at the direction of a pharmacist or a practitioner who is a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse or is a physician assistant described by Section 481.002(39)(D) or an employee or other agent of a practitioner acting at the direction of a practitioner and is inquiring about a recent Schedule II, III, IV, or V prescription history of a particular patient of the practitioner, provided that the person accessing the information is authorized to do so under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and rules adopted under that Act;
- (6) a pharmacist or practitioner who is inquiring about the person's own dispensing or prescribing activity; or
- (7) one or more states or an association of states with which the board has an interoperability agreement, as provided by Subsection (j).

(a-1) A person authorized to receive information under Subsection (a)(4), (5), or (6) may access that information through a health information exchange, subject to proper security measures to ensure against disclosure to unauthorized persons.

(a-2) A person authorized to receive information under Subsection (a)(5) may include that information in any form in the medical or pharmacy record of the patient who is the subject of the information. Any information included in a patient's medical or pharmacy record under this subsection is subject to any applicable state or federal confidentiality or privacy laws.

(a-3) The board shall ensure that the department has unrestricted access at all times to information submitted to the board under Sections 481.074(q) and 481.075. The department's access to the information shall be provided through a secure electronic portal under the exclusive control of the department. The department shall pay all expenses associated with the electronic portal.

(a-4) A law enforcement or prosecutorial official described by Subsection (a)(3) may obtain information submitted to the board under Section 481.074(q) or 481.075 only if the official submits a request to the department. If the department finds that the official has shown proper need for the information, the department shall provide access to the relevant information.

(a-5) Records relating to the access of information by the department or by the department on behalf of a

law enforcement agency are confidential, including any information concerning the identities of the investigating agents or agencies. The board may not track or monitor the department's access to information.

(b) This section does not prohibit the board from creating, using, or disclosing statistical data about information submitted to the board under this section if the board removes any information reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information.

(c) The board by rule shall design and implement a system for submission of information to the board by electronic or other means and for retrieval of information submitted to the board under this section and Sections 481.074 and 481.075. The board shall use automated information security techniques and devices to preclude improper access to the information. The board shall submit the system design to the director and the Texas Medical Board for review and comment a reasonable time before implementation of the system and shall comply with the comments of those agencies unless it is unreasonable to do so.

(d) Information submitted to the board under this section may be used only for:

(1) the administration, investigation, or enforcement of this chapter or another law governing illicit drugs in this state or another state;

(2) investigatory or evidentiary purposes in connection with the functions of an agency listed in Subsection (a)(1); or

(3) dissemination by the board to the public in the form of a statistical tabulation or report if all information reasonably likely to reveal the identity of each patient, practitioner, or other person who is a subject of the information has been removed.

(e) The board shall remove from the information retrieval system, destroy, and make irretrievable the record of the identity of a patient submitted under this section to the board not later than the end of the 36th calendar month after the month in which the identity is entered into the system. However, the board may retain a patient identity that is necessary for use in a specific ongoing investigation conducted in accordance with this section until the 30th day after the end of the month in which the necessity for retention of the identity ends.

(f) If the director permits access to information under Subsection (a)(2) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the director shall notify and cooperate with that agency regarding the disposition of the matter before taking action against the person, unless the director determines that notification is reasonably likely to interfere with an administrative or criminal investigation or prosecution.

(g) If the director permits access to information under Subsection (a)(3) relating to a person licensed or regulated by an agency listed in Subsection (a)(1), the director shall notify that agency of the disclosure of the information not later than the 10th working day after the date the information is disclosed.

(h) If the director withholds notification to an agency under Subsection (f), the director shall notify the agency of the disclosure of the information and the reason for withholding notification when the director determines that notification is no longer likely to interfere with an administrative or criminal investigation or prosecution.

(i) Information submitted to the board under Section 481.074(q) or 481.075 is confidential and remains confidential regardless of whether the board permits access to the information under this section.

(j) The board may enter into an interoperability agreement with one or more states or an association of states authorizing the board to access prescription monitoring information maintained or collected by the other state or states or the association, including information maintained on a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect. Pursuant to an interoperability agreement, the board may authorize the prescription monitoring program of one or more states or an association of states to access information submitted to the board under Sections 481.074(q) and 481.075, including by submitting or sharing information through a central database such as the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect.

(k) A person authorized to access information under Subsection (a)(4) who is registered with the board for electronic access to the information is entitled to directly access the information available from other states pursuant to an interoperability agreement described by Subsection (j).

Appendix C: Report Team and Report Distribution

Report Team

The IG staff members who contributed to this Inspections Division report include:

- Lisa Pietrzyk, CFE, CGAP, Director of Inspections
- Troy Neisen, CPA, Inspections Manager
- Michael Greer, Inspection Team Lead
- Pat Krempin, Inspector
- Amelia Lay, RN, Inspector
- Liviah Manning, PhD, Research Specialist
- Dawn Rehbein, Program Specialist

Report Distribution

Health and Human Services

- Charles Smith, Executive Commissioner
- Cecile Erwin Young, Chief Deputy Executive Commissioner
- Kara Crawford, Chief of Staff
- Heather Griffith Peterson, Chief Operating Officer
- Gary Jessee, Deputy Executive Commissioner for Medical and Social Services
- Jami Snyder, Associate Commissioner, Medicaid and CHIP Services Department
- Emily Zalkovsky, Deputy Associate Commissioner, Policy and Program, Medicaid and CHIP Services Department
- Katherine Scheib, Deputy Associate Commissioner, Operations, Medicaid and CHIP Services Department
- Tony Owens, Deputy Associate Commissioner, Health Plan Monitoring and Contract Services, Medicaid and CHIP Services Department
- Grace Windbigler, Director, Health Plan Management, Medicaid and CHIP Services Department
- Gina Marie Muniz, Director, Office of Health Information Services and Quality, Interim Director, Vendor Drug Program, Medicaid and CHIP Services Department
- Priscilla Parrilla, Interim Director, Pharmacy Operations and Contract Oversight
- Arshad Qureshi, Director, Drug Utilization Review and Formulary Management
- Karin Hill, Director, Internal Audit

Appendix D: IG Mission and Contact Information

Inspector General Mission

The mission of the IG is to prevent, detect, and deter fraud, waste, and abuse through the audit, investigation, and inspection of federal and state taxpayer dollars used in the provision and delivery of health and human services in Texas. The senior leadership guiding the fulfillment of IG's mission and statutory responsibility includes:

- Sylvia Hernandez Kauffman, Principal Deputy IG
- Christine Maldonado, Chief of Staff and Deputy IG for Operations
- Olga Rodriguez, Senior Advisor and Director of Policy and Publications
- Roland Luna, Deputy IG for Investigations
- David Griffith, Deputy IG for Audit
- Quinton Arnold, Deputy IG for Inspections
- Alan Scantlen, Deputy IG for Data and Technology
- Deborah Weems, Deputy IG for Medical Services
- Anita D'Souza, Deputy IG Chief Counsel

To Obtain Copies of IG Reports

- IG website: <https://oig.hhsc.texas.gov/>

To Report Fraud, Waste, and Abuse in Texas HHS Programs

- Online: <https://oig.hhsc.texas.gov/report-fraud>
- Phone: 1-800-436-6184

To Contact the Inspector General

- Email: OIGCommunications@hhsc.state.tx.us
- Mail: Texas Health and Human Services Commission
Inspector General
P.O. Box 85200
Austin, Texas 78708-5200
- Phone: (512) 491-2000