Medicaid Integrity Institute (MII)

Compendium of Promising Practices

Developed from the Emerging Trends in Medicaid – Opioids Course

October 17-19, 2017, Columbia, SC

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Executive Summary

Opioid overdoses increased by roughly 30% across the US in just 14 months between 2016 and 2017, according to a new report by the US Centers for Disease Control and Prevention (CDC). A unique challenge of this epidemic is that it involves both legally obtained prescription drugs and illicit substances such as fentanyl and heroin, which share similar chemical properties and induce comparable physiological effects. Thus, a variety of approaches to policy, prescribing and dispensing practices, treatment, law enforcement, and public awareness campaigns is needed to change the direction of the alarming opioid misuse and overdose trends.

In response to this deadly epidemic, federal and state partners came together at the Medicaid Integrity Institute (MII) in Columbia, South Carolina to strategize and share perspectives to identify promising practices to help mitigate opioid abuse and misuse. Subject matter experts from five federal agencies and 39 states, plus the District of Columbia, identified and prioritized the most crucial opioid vulnerabilities shared among the states. Provider, beneficiary, and industry strategies and promising practices were discussed regarding opioid vulnerabilities, mitigation activities, and pertinent challenges. Mitigation activities and potential promising practices were outlined to address the vulnerabilities through policy, technical development, innovative payment models and programs, data analysis, outreach and partnerships, and fraud reduction. Gaps and challenges to implementing these promising practices have also been identified for this compendium.

Course participants identified the following four prescription opioid priority vulnerabilities:

- 1. Lack of standardized use of Prescription Drug Monitoring Programs (PDMP); Lack of Access to and Sharing of PDMP Data
- 2. Prescribing Practices and Policy Issues
- 3. Oversight Issues
- 4. Education Needs for Providers, Beneficiaries, and other entities

More than 70 promising practices to mitigate these vulnerabilities were identified. The following work describes the mitigation activities and the challenges faced when implementing these initiatives.

Introduction

¹ Glenza, J. (2018, March 06). Opioid crisis: Overdoses increased by a third across US in 14 months, says CDC. Retrieved from https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc

² National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2018, January 17). Prescription Opioids and Heroin. Retrieved from https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin

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The severity of the opioid epidemic in the United States is well documented. Following the promotion of opioids by pharmaceutical companies as a non-addictive method of pain treatment in the 1990s, prescribing practices increased dramatically.³ In the years following, as opioid overdose deaths from both prescription and illegal opioids began to climb, and it became evident that prescription opioids could be highly addictive and dangerous when used improperly.⁴ Illegal and prescription opioids caused the deaths of more than 42,000 Americans in 2016, the worst year on record with five times the number of deaths in 1999. So large was this rise in opioid deaths that life expectancy for a person in the United States actually *fell* for the second year in a row, more than negating the effect of medical advances..^{5, 6}

A unique challenge of this epidemic is that it involves both legally obtained prescription drugs and illicit substances such as fentanyl and heroin, which share similar chemical properties and induce comparable physiological effects.⁷ Thus, a variety of approaches to policy, prescribing and dispensing practices, treatment, law enforcement, and public awareness campaigns are needed to change the direction of the alarming opioid misuse and overdose trends. Communities and all levels of government are working on creative solutions to have a meaningful impact on this complex crisis.

As part of this effort, in October 2017, CMS held a three day course at the Medicaid Integrity Institute (MII)⁸ to bring the expertise of various stakeholders to bear on the opioid crisis. Course faculty presenters included staff from the Centers for Medicare Services' (CMS) Center for Program Integrity (CPI) and Center for Medicaid and CHIP (Children's Health Insurance Program) Services (CMCS); Centers for Disease Control (CDC); Substance Abuse and Mental Health Services Administration (SAMHSA); Health Resources and Services Administration (HRSA); representative(s) from the states of Arizona, Minnesota, Missouri, Ohio, Oklahoma, Pennsylvania, South Carolina, and Washington; and the Health and Human Services (HHS) Office of Inspector General (OIG).

National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services. (2016, November). Effective Treatments for Opioid Addiction. Retrieved from <a href="https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-tr

⁵ Kochanek, K. D., MA, Murphy, S. L., BS, Xu, J., MD, & Arias, E., PhD. National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2017, December). Mortality in the United States. Retrieved from https://www.cdc.gov/nchs/data/databriefs/db293.pdf

⁶ Stein, R., NPR. (2017, December 21). Life Expectancy Drops Again As Opioid Deaths Surge In U.S. Retrieved from https://www.npr.org/sections/health-shots/2017/12/21/572080314/life-expectancy-drops-again-as-opioid-deaths-surge-in-u-s

⁷ National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2018, January 17). Prescription Opioids and Heroin. Retrieved from https://www.drugabuse.gov/publications/research-reports/prescription-opioids-heroin

⁸ Medicaid Integrity Institute. (n.d.). Retrieved from https://www.justice.gov/mii

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Representatives from 39 of the 50 states and Washington, DC, attended the course on behalf of state Medicaid, Program Integrity, and Law Enforcement agencies. Attendees brought a range of perspectives, drawn from clinical, program administration, and law enforcement experience. They shared their respective organizations' responses to the opioid crisis, highlighting practices that were particularly effective, as well as lessons learned. CMS developed this Compendium of Promising Practices from discussions that took place throughout the three day course. We hope that states will use the mitigations presented in this document to build on and enhance their current activities and achieve the comprehensive and robust response needed from all stakeholders to end the opioid crisis.

Notes:

- This compendium is not intended to be construed as a comprehensive representation of each state's efforts to address the opioid epidemic. The information presented in this compendium highlights <u>some</u> of the activities that states have employed and/or hope to initiate to address the opioid epidemic as discussed during the MII course.
- States shared practices which appeared promising based on early or available results. At the time of the conference, detailed data and outcomes were not readily available or shared; however, states can be contacted for further detail (see Appendix A).
- Prior to distribution, representative states were given an opportunity to review the information for accuracy and provide feedback.
- The information shared in this document should not be construed as an official commitment from the federal government or any state.

Emerging Trends in Medicaid – Opioids: Course Description and Structure

Presentations and open discussions were structured for this course to enable a high level overview of federal strategies and perspectives from CDC, CMS, HRSA, and SAMHSA. Additionally, state subject matter experts presented on opioid vulnerabilities, mitigation activities, and challenges pertinent to their state Medicaid, Program Integrity, and law enforcement agencies as a basis for a large group discussion (see Appendix A for participant information) on identifying both common and unique vulnerabilities and contributing factors to address the opioid epidemic. Through discussion, attendee consensus identified four high priority vulnerabilities felt to have the greatest impact on the opioid crisis. Small group breakout sessions were then held to give each group the opportunity to discuss the identified vulnerabilities, as well as mitigation activities, challenges and concerns their states had upon implementing these strategies. These breakout sessions also provided a venue for attendees to share ideas on potential solutions that could be put into practice and their projects currently in various stages of implementation. Following the conclusion of these breakout sessions, attendees reconvened as a large group to share and discuss breakout session outcomes, coordinate findings and identify promising practices.

Organization of the Compendium

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This compendium is presented from a program integrity perspective. The document initially discusses vulnerabilities identified during our large group discussion with emphasis on the four vulnerabilities that attendees identified as high priority. Mitigation activities to address the top four vulnerabilities are then presented and further subcategorized under: (1) Policy, (2) Technical Development, (3) Innovative Payment Models and Programs, (4) Data Analysis, (5) Outreach and Partnerships, (6) Fraud Reduction, and (7) Other. These subcategories appear under each vulnerability for which states had a mitigation activity applicable to that subcategory. Challenges and concerns shared throughout discussions of vulnerability mitigation activities and projects are also expressed throughout.. Additionally, state suggestions in which CMS and/or other federal entities can assist in addressing and/or implementing a mitigation strategy and addressing any potential barriers to implement an identified mitigation activity are captured. Furthermore, this compendium presents activities that states are currently considering to address and other suggestions that could be considered in the future. Finally, this compendium concludes with multiple appendices to inform the reader of all vulnerability discussions that occurred throughout the MII opioids course and state point of contacts and available resources. It is our hope that this compendium will be reviewed by and helpful to various audiences, including, but not limited to, State Program Integrity Staff, Medicaid Medical Directors, and Pharmacy Professionals.

Vulnerabilities

Definition of Vulnerability

A Vulnerability is a specific weakness in the program or a gap in protection efforts that can be exploited by potential program abusers, resulting in the risk of potential harm or loss being realized.⁹ Harm can include damages to a Medicaid agency's or beneficiary's finances or resources, or injury to a beneficiary's health. Such harm can also have secondary impacts on programs and individuals beyond the immediate scope of the vulnerability.

VULNERABILITY

A specific weakness in the program or a gap in protection efforts that can be exploited by potential program abusers, resulting in the risk of potential harm or loss being realized.

Results of Large Group Vulnerability Discussion

CMS facilitated a large group discussion to identify Medicaid program vulnerabilities in the landscape of the opioid crisis. In this section, all of the vulnerabilities that were identified during the discussion are discussed briefly with examples and additional detail provided as applicable for clarity.

⁹ Center for Program Integrity, Centers for Medicare and Medicaid Services (2018, February). Vulnerabilities and Mitigation Strategies in Medicaid Personal Care Services. Retrieved from https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/Downloads/vulnerabilities-mitigation-strategies.pdf

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➤ Lack of Access to Medication-Assisted Treatment (MAT)

SAMHSA defines MAT as, "The use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders (SUD)." The medications, such as methadone, buprenorphine, and naltrexone, serve to alleviate withdrawal symptoms and psychological cravings, and in combination with behavioral therapy, have been shown to reduce opioid use, deaths from opioid overdose, criminal activity, and transmission of infectious disease, while improving retention in treatment. 11,12

Despite the evidence demonstrating the effectiveness of MAT, it is still an underused form of treatment.¹³ Because of its proven efficacy, lack of access to MAT can be contributing to the harm of beneficiaries.

There are a number of issues that contribute to lack of MAT access:

- o Limits on the number of patients that clinicians can treat: After qualifying for a SAMHSA Data 2000 waiver that permits prescribing of buprenorphine in an outpatient setting, clinicians may only treat a maximum of 30 patients during the first year. After one year, they may apply to treat up to 100 patients; after one year of prescribing to 100 patients, they may apply to increase their patient limit to 275. 14,15
- Limited incentives to provide MAT: Some policies, regulations, and payment mechanisms can limit MAT implementation such as the inability of Medicare to pay for methadone dispensed on Opioid Treatment Programs.¹⁶

¹⁰ Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2015, July 21). Medication-Assisted Treatment (MAT). Retrieved from https://www.samhsa.gov/medication-assisted-treatment

National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services.
 (2016, November). Effective Treatments for Opioid Addiction. Retrieved from <a href="https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction

¹³ Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2015, June 15). Medication and Counseling Treatment. Retrieved from <a href="https://www.samhsa.gov/medication-assisted-treatment/treat

¹⁴ Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2015, June 22). Apply to Increase Patient Limits. Retrieved from https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/increase-patient-limits

¹⁵ Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2018, May 15). CARA Act Update. Retrieved from https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/qualify-np-pa-waivers

¹⁶ U.S. Department of Health and Human Services, Office of the Surgeon General. (2016, November). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, 2016. Retrieved from https://www.surgeongeneral.gov/library/2016alcoholdrugshealth/index.html

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o Bias against MAT: Belief that MAT is not treating the underlying causes of addiction and is simply trading one drug for another. ^{17, 18}

As a result, it is difficult for people with opioid use disorder (OUD) to find a treatment facility or clinicians who can provide MAT in an outpatient setting, particularly in rural areas.¹⁹

> Complex implications and variability in access to and use of naloxone

Naloxone is a rescue medication that is indicated for the emergency treatment of a known or suspected opioid overdose and the reversal of consequent slowing or cessation of breathing that can lead to death.²⁰ With the rise of the opioid epidemic, there have been efforts to increase the availability of naloxone to address these emergency situations. On April 5, 2018, the Surgeon General of the United States launched a Surgeon General Advisory on Naloxone and Opioid Overdose²¹. With the advisory, he urges more individuals, especially family, friends and those who are personally at risk for an opioid overdose to keep naloxone on hand.

While this increased availability has saved lives, course attendees noted that it has complicated implications, one of which is the recurring use of naloxone on the same people who appear to have no intention to treat their OUD. Naloxone administration to repeat users is being interpreted as an abuse of community resources, but it is impossible to ignore the harm to a victim of an overdose if the rescue drug is withheld. Moreover, there is concern about whether it is appropriate to continue to use rescue drug resources in light of the increased need, rising price of the drug, and limited funding for first responders. ^{22, 23}

¹⁷ Shallow, G. (2018, April 20). In Philly's recovery community, a bias against those taking medication to treat opioid addiction. Retrieved from https://generocity.org/philly/2018/04/17/philadelphia-recovery-community-bias-against-medication-assisted-treatment-opioid-addiction/

¹⁸ U.S. Department of Health and Human Services, Office of the Surgeon General. (2016, November). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, 2016. Retrieved from https://www.surgeongeneral.gov/library/2016alcoholdrugshealth/index.html

¹⁹ Governor Chris Christie, Governor Charlie Baker, Governor Roy Cooper, Congressman Patrick J. Kennedy, Professor Bertha Madras, PhD, & Florida Attorney General Pam Bondi. (2017, November). The President's Commission on Combating Addiction and the Opioid Crisis. Retrieved from https://www.whitehouse.gov/sites/whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

²⁰ National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services (April 2018). Overdose Reversal with Naloxone (Narcan, Evzio). Accessed from https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio

²¹ General, S. (April 5, 2018). Surgeon General's Advisory on Naloxone and Opioid Overdose. Retrieved from https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html

²² Gupta, R., Shah, N. D., & Ross, J. S. (2016). <u>The Rising Price of Naloxone Risks to Efforts to Stem Overdose Deaths</u>. New England Journal of Medicine, 375(23), 2213-2215.

²³ Craig, T., Lewis, N. (2017, July 15). As opioid overdoses exact a higher price, communities ponder who should be saved. The Washington Post. Retrieved from https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-

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Another facet of the naloxone vulnerability is the variation in state laws governing access to the medication. A majority of states have broadened access to the rescue drug, though approaches differ and fall generally into one of two categories: (1) third-party prescriptions and (2) non-patient-specific prescriptions. ²⁴ Currently, 45 states and Washington, DC permit third-party prescriptions, which allow clinicians to prescribe naloxone to those who are not at risk of overdose for use on someone else. In some states, these third parties are required to complete a training before they can obtain the naloxone. A drawback of this type of prescription is that a visit to a clinician is still required, so those who are most at risk are still unlikely to obtain the drug. ²⁵ Non-patient-specific prescriptions are even more flexible: in states with these laws, anyone at risk for an opioid overdose or a third party who may be in a position to administer the drug in the event of an overdose may obtain naloxone from a pharmacy without first having to visit a clinician. Standing orders are perhaps the most well-known type of non-patient-specific prescriptions and show great promise in expanding naloxone access, but they are not available in every state. ²⁶

> Lack of covered or promoted alternative treatments for pain

For severe pain, opioids can be a necessary component of treatment, but they are often over utilized, particularly in the Medicaid population. The Medicaid and CHIP Payment and Access Commission (MACPAC)²⁷ notes Medicaid beneficiaries are prescribed opioids at a disproportionately higher rate than non-Medicaid populations, thus, are more likely to experience an overdose and have a higher rate of OUD than the non-Medicaid populations.

According to a report from the National Academy for State Health Policy (NASHP), states have the optional authority in Medicaid to cover non-pharmacological alternative treatments for pain. The Social Security Act specifically authorizes coverage of physical therapy, and provides the flexibility to cover such alternative services as acupuncture,

higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf story.html?utm term=.14477f198a04.

²⁴ Center for the Application of Prevention Technologies, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2018, January 20). Naloxone Access Laws Tool-samhsa.gov. Retrieved from https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf.

²⁵ Center for the Application of Prevention Technologies, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2018, January 20). Naloxone Access Laws Tool-samhsa.gov. Retrieved from https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf

²⁶ Center for the Application of Prevention Technologies, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. (2018, January 20). Naloxone Access Laws Tool-samhsa.gov. Retrieved from https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf

²⁷ MACPAC. (n.d.). Retrieved from https://www.macpac.gov/

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massage therapy, and cognitive-behavioral therapy.²⁸ Per the same report, of the 51 Medicaid agencies surveyed, 39 reimbursed for physical therapy, 38 reimbursed for psychologist services, 36 covered occupational therapy services, and 27 covered chiropractic treatment. The report acknowledges that states have budget limitations and that the evidence base may not be conclusive enough to warrant coverage for alternative therapies. However, as evidence bases and coverage for alternative therapies expand, there are opportunities to improve the range of covered services and nonpharmacological care, which will help reduce the risks that can arise from opioid use or misuse.²⁹

> Scope of opioid epidemic unknown

Awareness and treatment of OUD is on the rise, but the disorder remains underdiagnosed. It can be challenging to distinguish legitimate pain treatment needs from drug-seeking behavior, and some clinicians may be reluctant to document the disorder. 30,31 There is also a gap between rates of diagnosis and treatment as reported by MACPAC in 2017, "Many Medicaid enrollees with an opioid use disorder are still not receiving treatment ... [due to] individuals not perceiving the need for treatment or fearing the stigma of having a SUD." The complexities of diagnosing and treating opioid use disorder are illustrated by the fact that only an estimated 32 percent of Medicaid enrollees with an opioid use disorder are receiving treatment. 32

Without an understanding of the full scope of affected individuals, beneficiaries with OUD will not be identified and referred to treatment, and will remain at risk. Medicaid resources may also be used inappropriately or disproportionately as a result. For example, a beneficiary with OUD will likely continue to seek prescription medications and may consider illicit drug options because they can be acquired cheaper and are often more potent. Use of illicit drugs places those individuals at increased risk for exposure to diseases such as Hepatitis C, Human Immunodeficiency Virus (HIV) and secondary infections. All of these factors can translate to an increase in associated medical costs.³³

²⁸ Dorr, H., & Townley, C. (2016, September 05). Chronic Pain Management Therapies in Medicaid: Policy Considerations for Non-Pharmacological Alternatives to Opioids. Retrieved from https://nashp.org/chronic-pain-management-therapies-medicaid-policy-considerations-non-pharmacological-alternatives-opioids/

²⁹ JAMA Network Open. 2018;1(6):e183044. doi:10.1001/jamanetworkopen.2018.3044

³⁰ Bryan N. Cochran, Annesa Flentje, Nicholas C. Heck, Jill Van Den Bos, Dan Perlman, Jorge Torres, Robert Valuck, Jean Carter. (2014, March 11). Factors predicting development of opioid use disorders among individuals who receive an initial opioid prescription: Mathematical modeling using a database of commercially-insured individuals. Retrieved from https://www.sciencedirect.com/science/article/pii/S0376871614007716

³¹ Lembke, A., MD, & Chen, J. H., MD, PhD. (2016, September 01). Use of Opioid Agonist Therapy for Medicare Patients in 2013. Retrieved from https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238

³² Report to Congress on Medicaid and CHIP, Medicaid and CHIP Payment and Access Commission. (2017, June). Medicaid and the Opioid Epidemic. Retrieved from https://www.macpac.gov/publication/medicaid-and-the-opioid-epidemic/

³³ Fogoros, R. N. (2018, January 10). What Are the Economic Costs of Drug Use to Society? Retrieved from https://www.verywellmind.com/what-are-the-costs-of-drug-abuse-to-society-63037

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Priority Vulnerabilities

Course attendees reached consensus that addressing the four vulnerabilities described below would have the greatest impact on the opioid crisis. For that reason, during smaller group breakout sessions, attendees discussed mitigation strategies that are currently being employed or could be utilized in the future to address these priority vulnerabilities. These mitigation activities are presented in subsequent sections of the compendium.

> Priority Vulnerability 1: Lack of standardized use of Prescription Drug Monitoring Programs (PDMP); Lack of Access to and Sharing of PDMP Data

A PDMP is an electronic database run by each state that is used to capture all dispensed controlled substance prescriptions in their state. Clinicians are able to check the PDMP "to obtain prescription history information on patients under their care." PDMP data can help clinicians identify patterns of potentially inappropriate and dangerous use of opioids that may indicate OUD or an elevated risk for overdose, such as doctor or pharmacy shopping and frequent prescription use. With PDMP information, a clinician can evaluate whether a different prescription or treatment may be appropriate, or whether the patient should be screened for OUD and referred to treatment if he/she is positive.

The CDC considers PDMPs to be "... among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk...," but they remain an area of vulnerability in combating the opioid epidemic.³⁸ For example, standard requirements across states governing who is required to check and update the PDMP (clinician only; pharmacist only; both) and when (with every prescription; only with new prescriptions; every 180 days; only upon dispensing; etc...) do not exist. Another complication is that some PDMPs capture data only within their state, or share only with their immediate geographic neighbors, leaving healthcare providers and pharmacists with no insight to their patients' controlled substances obtained across some state lines. The lack of interoperability between state PDMP systems complicates the ability to share data across state lines. Further, there are limitations to how PDMP data can be utilized. Although this

³⁴ Hildebran, C., Cohen, D. J., Irvine, J. M., Foley, C., O'Kane, N., Beran, T., & Deyo, R. A. (2014, July). How Clinicians Use Prescription Drug Monitoring Programs: A Qualitative Inquiry. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4180422/

³⁵ Substance Abuse and Mental Health Services Administration. (2017, Winter). Prescription Drug Monitoring Programs: A Guide for Healthcare Providers. Retrieved from https://store.samhsa.gov/shin/content/SMA16-4997/SMA16-4997.pdf

³⁶ Haller, D. L., & Acosta, M. C. (2010). Characteristics of Pain Patients with Opioid-Use Disorder. Psychosomatics, 51(3), 257-266. Retrieved from https://www.sciencedirect.com/science/article/pii/S0033318210706939

³⁷ The Pew Charitable Trust, Research & Analysis. (2018, May). Improvements to Prescription Drug Monitoring Programs Can Inform Prescribing. Retrieved from http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/05/improvements-to-prescription-drug-monitoring-programs-can-inform-prescribing

³⁸ Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2017, October 03). Opioid Overdose: What States Need to Know about PDMPs. Retrieved from https://www.cdc.gov/drugoverdose/pdmp/states.html

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data could be used to identify beneficiaries who are doctor shopping, some states do not permit PDMP data to be used for potentially punitive purposes. In other words, the PDMP may only be accessed by clinical staff, and not Medicaid or Program Integrity staff.

> Priority Vulnerability 2: Prescribing Practices and Policy Issues

Policies designed to impact prescribing practices must be considered carefully. Federal and state governments have an important role in designing clear policy and providing helpful tools to support providers and encourage safe behaviors. Policymakers make every effort to draft policies clearly and evaluate them within the context of other policies to avoid the creation of inconsistencies and unintended consequences; however, even with the best of intentions, such issues are inevitable. MII course attendees provided the following example issues to address as part of this vulnerability:

- o Inconsistent policies across Medicaid fee-for-service (FFS) vs. Managed Care Organizations (MCO): Some states noted that there were different rules governing Medicaid, depending on whether FFS or administered by a MCO. In particular, the varying policies created challenges during coverage appeals because similar situations could not be handled consistently.
- o Medicaid-enrolled providers who accept cash payment from Medicaid beneficiaries: Cash payment prevents creation of a claim, so Medicaid is not made aware of services rendered. Therefore, information is not captured that may be used by permitted entities to identify opioid misuse, abuse or overprescribing practices.
- O Unintended consequences: The structure of FFS or MCO capitation rate payment models could encourage a provider to see greater numbers of patients rather than focusing on their clinical outcomes. The payment structures could create an incentive to treat patients quickly, such as prescribing a pill for pain rather than spending time discussing a range of treatment options, and to avoid more time-consuming patients who have multiple complex chronic conditions such as OUD.
- O Confusing or limited resources on best practices for pain treatment: The aggressive opioid prescribing practices utilized by pharmaceutical companies in the 1990s are now known to be harmful, but altering "accepted" habits is a challenge, especially with limited pain treatment and medication prescribing guidance and the lack of "covered" alternative treatments that are known to be effective.

Resolving this vulnerability requires striking an appropriate balance between policies that regulate Medicaid care and the need to preserve the relationship between autonomous health care providers and beneficiaries.

> Priority Vulnerability 3: Oversight Issues

Monitoring of provider, beneficiary, and other entity behaviors to identify potential program misuse and abusers is a critical element of protecting beneficiary health and Medicaid resources. States cited a number of issues pertaining to their current oversight

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efforts that remain vulnerable and discussed a number of mitigation activities. The vulnerable issues discussed include:

- O Prescriber Enrollment and Screening: Providers are required to enroll with the state's Medicaid agency to treat Medicaid and CHIP beneficiaries. Provider enrollment allows state Medicaid agencies to conduct screening of all Medicaid providers to protect beneficiary safety and reduce fraud risk. However, some states expressed concern about providers having the option to forfeit licensure in a state, in lieu of license revocation due to a violation. That practice makes it difficult for other states to identify problematic providers through their screening processes.
- o Insufficient communication across and within federal/state agencies and with MCOs: Without ongoing communication and information sharing, identified aberrant prescribers, at-risk beneficiaries, and diversion schemes may "slip through the cracks" and remain unaddressed.

> Priority Vulnerability 4: Education Needs for Providers, Beneficiaries, and Other Entities

Even if all other vulnerability areas are addressed, their impact would remain limited without attention to educational needs. Policy changes and community resources, for example, are only effective when targeted providers and beneficiaries are aware of them.

Identifying and implementing effective methods to spread information to different audiences can present a unique challenge, and its importance is sometimes overlooked. States identified educational needs as a priority vulnerability, emphasizing the need to improve this area of work. With successful education initiatives, risk for harm and/or exploitation by potential program abusers can be reduced across all vulnerabilities.

Mitigation Activities

Threats to the well-being of beneficiaries and programs cannot be eliminated, but by working

together and examining vulnerabilities carefully, CMS and states can strengthen Medicaid programs and close the problematic gaps. Attendees of the *Emerging Trends – Opioids* course discussed activities that are currently being used to mitigate the identified priority vulnerabilities in their states.

MITIGATION

An action or activity that reduces risk or improves a problem by helping to resolve a vulnerability or limit its impact.

These mitigation activities are presented in this section along with recommendations/promising practices on successful elements, weaknesses identified, challenges encountered, and how the federal government may be able to support these activities.

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$\begin{tabular}{ll} Vulnerability 1-Issues with Prescription Drug Monitoring Programs (PDMP)-Access to and Sharing of PDMP Data \end{tabular}$

This section explores mitigation activities that states have used to address PDMP issues.

Category: Policy

PDMP Access, Enforcement, and Data Sharing Across State Lines **Background**

PDMPs are only effective when they function efficiently and are used consistently. When PDMPs have incomplete data, are not accessed at critical points of care (such as when prescriptions are written or dispensed), or are not used to their full potential, at-risk beneficiaries are not identified and can continue to exploit controlled substance prescribing and dispensing. During the MII course, states shared the promising practices that they have implemented or are considering implementing to make their state PDMPs as comprehensive and effective as possible.

Promising Practices and Recommendations

Many states require clinicians to check the PDMP for beneficiary activity that suggests misuse, abuse, or diversion, but requirements vary based on the clinician type and or timing of the check. Connecticut requires a prescribing practitioner to check the PDMP prior to prescribing greater than a 72 hour supply of any controlled substance (Schedule II-V). In Maine, New Jersey, New York, North Dakota³⁹, and Oklahoma, for example, clinicians are required to check the PDMP both before writing and filling a prescription for new Schedule II controlled substances. Texas will be implementing the same requirement beginning in 2019. In Florida, daily reporting to the PDMP is required. The law also requires prescribers and dispensers of controlled substances to check the PDMP before writing or dispensing controlled substances in Schedules II-IV & V if opiate. Prescribers/Pharmacists who do not check the PDMP may get a non-disciplinary citation.⁴⁰

In Maine and Connecticut, a follow up check is required every 90 days for as long as that prescription is renewed. In Oklahoma, requirements are similar; however, the timeline for a follow up check is required after 180 days have elapsed since the clinician initially prescribed any of the

³⁹ In North Dakota, clinicians must register with the PDMP if they have a DEA registration number. Clinicians must check the PDMP if reported drugs will be prescribed to a patient for a period to exceed 12 weeks or when patient exhibits signs associated with diversion or abuse, and at minimum, semi-annually thereafter. This does not apply to reported drugs prescribed to patients in a controlled setting where drugs are locked and administered to a patient such as hospice, group homes, or long-term care facilities. PDMP rules for clinicians may be found at http://www.legis.nd.gov/information/acdata/pdf/50-05-02.pdf. PDMP rules for pharmacists may be found at http://www.legis.nd.gov/information/acdata/pdf/61-12-01.pdf

⁴⁰ Florida's Controlled Substance Bill new laws effective July 1, 2018 http://flsenate.gov/Session/Bill/2018/21/BillText/er/PDF

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following commonly abused medications: opioids, benzodiazepines or carisoprodol (except for hospice patients or patients residing in a nursing facility). In Ohio and Tennessee, when potential behavioral red flags are identified, other providers, including pharmacists, must review a beneficiary's PDMP report that covers at least a one year time period in order to gain a comprehensive understanding of the beneficiary's behavior.⁴¹

In Idaho and Ohio, pharmacists can be fined if they do not comply with the requirement to check the PDMP. They can also be fined if they dispense a refill early. A number of states also specifically stipulate that prescriptions paid for in cash must be entered to the PDMP which can help identify beneficiaries trying to circumvent Medicaid prescription limitations and/or the production of claim records.

Promising Practices:
PDMP Access, Enforcement,
and Data Sharing Across State Lines

⁴¹ Situations in which Ohio pharmacists are required to perform a PDMP check over a one year period: When a new controlled substance is prescribed; when a PDMP report has not been reviewed for the preceding 12 months; when a prescriber is located outside pharmacy geographic area; when a patient is from outside the usual pharmacy geographic area; when a pharmacist has reason to believe the patient has received prescriptions for controlled substances from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location (i.e. same group practice); or when the patient is exhibiting signs of potential abuse or diversion.

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To assist with adherence to PDMP check requirements, several states grant the ability to delegate access to the PDMP to support staff including Louisiana, Georgia, New York, Florida and Ohio (scope and responsibility of support staff varies between states). In New Jersey, for example, the delegation authorities are quite broad and extend to include medical or dental residents in a teaching facility, medical assistants authorized by a practitioner, and registered dental assistants. Maryland extends its access beyond physicians: Maryland's PDMP data on prescription opioids and other controlled dangerous substances can be made available to healthcare providers, patients, researchers. health pharmacists, occupations licensing boards, and public health and safety agencies.

In order to improve the strength and score of their databases, states have begun to share their PDMP data with or grant access to some other states, typically their immediate geographic neighbors. This sharing broadens the data set and helps to reduce "blind spots," such as when a doctor or pharmacy shopper crosses state lines to obtain and fill prescriptions, knowing that their state PDMP is not interoperable. Some states, such as New Hampshire, participate in an interstate data exchange network that allows them to share PDMP data/access on controlled substances with neighboring states. Connecticut shares its PDMP

- ➤ Require clinicians to check the PDMP both before writing and filling a prescription for new Schedule II controlled substances.
- ➤ PDMP follow up check with each refill or every 90-180 days.
- ➤ Require clinicians to check PDMP for concurrent opioid, benzodiazepine, and carisoprodol prescriptions.
- ➤ Require a one year look back period during PDMP checks.
- Establish fines against clinicians who do not comply with requirements to check/update the PDMP.
- Establish flags or fines against pharmacists who dispense a refill early.
- ➤ Require that all prescriptions, including those paid in cash, be entered to PDMP.
- ➤ Allow clinicians to delegate PDMP access to support staff.
- ➤ Share PDMP data with other states (at a minimum, with all neighboring states).
- ➤ Allow PDMP access to healthcare providers, pharmacists, patients, researchers, health occupations licensing boards, and public health and safety agencies.
- ➤ To the extent state law permits, perform regular analyses of PDMP data for PI purposes. As appropriate, make referrals to law enforcement, MCOs, CMS, state Patient Review and Restriction (PRR) program, etc.

data with thirty states. Tennessee shares its PDMP data with five of its eight neighboring states; Pennsylvania shares data with 16 other states and Washington, D.C. Michigan has PDMP sharing agreements with 22 states.

States agree that participation in an interstate PDMP data exchange network is an important component of an effective PDMP. A number of private companies facilitate this cross-state data sharing, though some states report that the costs associated with such companies can be prohibitive.

In addition to having clinician's access PDMP data, a number of states have instituted the practice of reviewing PDMP information specifically to identify and investigate aberrant provider and beneficiary behavior. In some states, PI staff are able to access the PDMP data for this purpose directly; in others, PI staff are permitted varying levels of access, such as to limited PDMP data,

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reports generated from the PDMP, or information on specific beneficiaries. Louisiana Medicaid staff, for instance, does not have direct access to MCO claims, but can use the PDMP to gain insight into whether an MCO paid for services or prescriptions for a beneficiary, or whether there are any cash payments. North Dakota runs queries on individual beneficiaries when requests for early refills and other exceptions for controlled substances are received. The North Dakota State Medicaid Agency (SMA) also reviews for cash payments by Medicaid recipients on a monthly basis.

In contrast, Maine's PI staff cannot access the PDMP directly, but they request and receive reports on a regular basis to review for patterns indicating possible fraud, waste, and abuse. They also meet with the PMDP's coordinator as needed to review those reports and make referrals to law enforcement. In Arkansas and Mississippi, in addition to other limited parties per state law, law enforcement agencies are permitted to access the PDMP for the purpose of researching behavior of parties under active investigation. Mississippi's SMA also reviews PDMP data on beneficiaries that are identified in their reports as receiving opioid prescriptions that meet certain criteria, as well as data for beneficiaries about whom they have received complaints about selling prescription medications or illicit drugs. If the beneficiary has been accused of selling drugs and they have filled a prescription for controlled substances, the Mississippi SMA refers that information to the state's Bureau of Narcotics prior to taking any other action on the complaint. If the beneficiary is enrolled in a MCO, the Mississippi SMA refers the complaint to that MCO. If the beneficiary is dually eligible for Medicare, the complaint is referred to CMS. If the beneficiary meets the criteria for the Mississippi PRR program, the beneficiary is referred for lock-in.

Some states are also using PDMP information for other PI purposes. The Minnesota Department of Human Services, for example, has authorization under statute to access the PDMP for two specific reasons: (1) to identify and manage recipients of the lock-in program; and (2) as part of their work to implement a system to identify when clients in a licensed opioid treatment program have also been prescribed or dispensed controlled substances in addition to those administered by treatment program.

Weaknesses and Challenges

The state of New Hampshire discussed very specific challenges with respect to accessing PDMP data. New Hampshire's PDMP, overseen by the New Hampshire Board of Pharmacy, does not currently share data with the SMA. The New Hampshire PDMP does share aggregate data with the two border states of Maine and Vermont. If New Hampshire Medicaid can get access to the PDMP data, it would need to be at the individual person level, not aggregate. This is because the interventions which New Hampshire Medicaid currently uses (beneficiary patient review and restriction program and provider education) target individuals. Thus, New Hampshire's SMA has the dual challenge of access to data and data detail.

Another weakness discussed was a lack of universal sharing of PDMP data among all states. States also cited having a PDMP, but no requirements (either in statute or as required by the licensing board) to check or enter information as another key weakness. For example, Minnesota law does

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not require clinicians or pharmacists to check the PDMP. The law only requires clinicians and pharmacists licensed by Minnesota to register and maintain an account with the PDMP. Some states also do not permit delegation of the PDMP check to support staff, requiring the clinician and/or pharmacist to perform the check. Lastly, some states do not permit PI or fraud control staff to access PDMP data. In some cases, such access is never permitted; in other states, such as New Jersey and Connecticut, it can only be accessed in the case of an active investigation.

Category: Technical Development

Improvements and system changes for PDMPs

Background

In addition to developing policies that make PDMPs more efficient and effective, states are also implementing improvements to the systems themselves.

Promising Practices and Recommendations

Louisiana is currently developing alerts that flag beneficiaries who demonstrate patterns that indicate potential opioid abuse. The alerts will make it simpler for clinicians and pharmacists who check the PDMP to become aware of and make a clinical judgment on whether to take action to address potentially problematic behavior.

Several states are also working to address the challenge of interpreting equivalencies across different opioid medications. Ohio now includes morphine milligram equivalent (MME)

calculations for a number of common opioid medications to make it easier for clinicians to evaluate their patients. Similarly, Louisiana is building MME programming into their state PDMP to help with enforcing new policy that limits beneficiaries to a maximum daily dose of 90 MME.

Weaknesses and Challenges

Clinicians continue to report that it is time

consuming to access the PDMP as part of the patient encounter. Network connection speeds and computer hardware capabilities are one element of that challenge, but states are aware of the need to streamline some systems' designs to reduce the issue of "too many clicks" to complete a PDMP check and entry.

Promising Practices: Improvements and System Changes for PDMPs

- Develop alerts that automatically flag beneficiaries who demonstrate potential doctor shopping or opioid abuse.
- Include morphine milligram equivalent (MME) calculations for common opioid medications.
- Display beneficiaries' daily MME calculations.

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Federal Government Opportunities to Support States

States proposed a number of approaches that the federal government could use to address PDMP issues. The first suggestion was for the federal government to support and promote development of a national PDMP that requires state participation, ensures state interoperability, and grants authority to use the data across state lines. As part of the national PDMP development, states recommended that the federal government research ways to control data quality, such as determining which data fields to require at a minimum, and establish a corresponding data warehouse that makes the data available to states for analysis. Alternatively, states suggested that the federal government develop federal standards for PDMPs in order to eliminate inconsistencies in data collection and sharing across states. States recommended that CMS promote adherence to federal standards for PDMPs in order to receive federal matching funds for Medicaid programs.

Vulnerability 2 – Prescribing Practices and Policy Issues

This section explores mitigation activities that states have used to address prescribing practices and policy issues.

Category: Policy

Patient Review and Restriction (PRR)/Lock-in programs

Background

PRR programs are one mitigation activity that Medicaid and other health care plans use to prevent abuse of dangerous controlled substances, drug diversion, and overdose. These tools are used in situations where a beneficiary has been identified as being "at risk," often because of a pattern of receiving multiple prescriptions from various clinicians and/or filling them at different pharmacies (a practice known as "doctor/pharmacy shopping" that can be a sign of illicit drug diversion or OUD). 42, 43 PRR programs are more commonly known as "lock-in" programs because they limit a beneficiary to the use of one pharmacy, primary care physician, and/or hospital to ensure safe coordination of care and better transparency regarding prescription drug treatments. Almost all states have implemented lock-in programs, but characteristics of the programs vary. 44 During the MII course, representatives discussed aspects of their PRR programs that were particularly successful or presented challenges.

⁴² Simeone, R. (2017, April 11). Doctor Shopping Behavior and the Diversion of Prescription Opioids. Retrieved from http://journals.sagepub.com/doi/abs/10.1177/1178221817696077

⁴³ Sansome, R., MD, & Sansome, L., MD. (2012, November/December). Doctor Shopping: A Phenomenon of Many Themes. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3552465/

⁴⁴ Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. (2017, October). Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2016 Annual Report: Prescription Drug Fee-For-Service Programs. Retrieved from

 $[\]frac{https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dursummary-report.pdf}{}$

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Promising Practices and Recommendations

To improve success of a PRR program, Pennsylvania and South Carolina recommended having consistent policies across Medicaid FFS and MCO programs. This uniformity makes understanding and enforcement of rules and processes, handling appeals, and sharing information with providers easier to manage. South Carolina emphasized the importance of having well-defined lock-in criteria and strong

Promising Practices: Patient Review and Restriction (PRR)/Lock-in programs

- Make PRR criteria and policies consistent across FFS and MCOs
- Define lock-in criteria clearly

algorithms in which PI staff found reduced complaints and streamlined program function. One such criterion involves members who pay cash for prescriptions. In Minnesota and Virginia's⁴⁵ PRR programs, it is practice to lock in beneficiaries who misrepresent their status as a Medicaid beneficiary (i.e., state that they do not have insurance) in order to pay cash for prescriptions. Oklahoma is also considering expanding the PRR program to include other drugs, such as gabapentin, which recent studies have found can increase the risk of opioid-related death when used in combination with opioids.⁴⁶ Finally, Oklahoma and Pennsylvania advocated for designing IT systems that push lock-in information on beneficiaries to eligibility verification screens. This is visible to providers so they can see immediately that the recipient is locked in and to which provider and pharmacy before rendering a service.

Several states disseminate information on regular basis to improve provider and beneficiary awareness of criteria and PRR program requirements. Washington, DC also uses the lock-in program to educate beneficiaries and support them with Medication Therapy Management.

States typically evaluate their lock-in programs for cost savings and improvements in member behaviors. For instance, over the course of two cost studies on their program, Washington State determined a savings of \$500 per client per month after lock-in. Tennessee reported approximate overall savings of \$109,000 during FY2016. Nevada produces a monthly lock-in savings report, which calculates the savings for each individual recipient in the program.

Changes in member behavior seemed somewhat more difficult to evaluate, though many states are making efforts to do so. New Hampshire MCOs, for example, report encounter data from before, during, and after lock-in to evaluate behavior changes. In their FFS program, Connecticut performs a twelve month post-intervention evaluation to determine if recipients placed in the lock-in program are adhering to its terms. Utah and Washington, DC measure outcomes after restriction

⁴⁵ CMM L/I Criteria: Misuse of Medicaid Card/12-VAC-130-810E. #17. "One or more documented occurrences of paying cash for controlled substances, analgesic drugs, or psychotropic drugs in addition to the use of the eligibility card to obtain similar or duplicative controlled substances."

⁴⁶ Gomes, T., Juurlink, D. N., Antoniou, T., Mamdani, M. M., Paterson, J. M., & Brink, W. V. (2017, October 3). Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case–control study. Retrieved from http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002396

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and at the end of the lock-in period, respectively, assessing whether beneficiaries would still meet the criteria for referral to the PRR program. Georgia also checks for beneficiaries who are referred to the lock-in program repeatedly.

Weaknesses and Challenges

PRR programs may be a helpful tool to fight the opioid epidemic, but they have limitations. A number of states, including Michigan, Pennsylvania, and Vermont cited concerns that the PRR program does not address the OUD that may be the root cause of beneficiaries' problematic behaviors, and are considering creating a system to refer the locked in beneficiary to behavioral health/OUD treatment services. Further, some health care providers find that the process to verify whether a beneficiary is in a lock-in program is time consuming. In Vermont, in situations where clinicians do not perform the verification check, the state has limited mechanisms to sanction those clinicians, as well as the members who seek to circumvent the lock-in by paying for services and prescriptions in cash. More generally, several states noted that it is difficult to enforce lock-in terms.

New Jersey noted that without a centralized lock-in program, recipients can circumvent the restrictions by switching MCOs. In Texas, the lack of continuous beneficiary eligibility and the inability to track cash purchases are also a problem.

Some states' lock in methods are manually intensive and cumbersome, making the program costly and difficult to administer effectively. Other challenges include handling recipient phone calls effectively, and ensuring that MCOs are also appropriately responsive to members.

Alignment with CDC Guidelines for Prescribing Opioids for Chronic Pain

Background

The CDC reports that an estimated 11% of American adults experience pain on a daily basis. When pain is severe, clinicians often prescribe prescription opioids, despite self-reports that they have

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insufficient training in opioid prescribing. ^{47,48,49,50} Medical schools and physician training programs nationwide have been enhancing content on pain and addiction in an effort to educate practitioners on the risks of the old practice of controlling pain more aggressively and using opioids liberally. ⁵¹ Although research supports a multidisciplinary approach for treatment of chronic pain, opioids can play an important role for some patients, and clinicians need suitable education to evaluate patients and manage opioid treatment. Beyond what was required by medical schools, however, there was limited opioid prescribing training or guidance available.

In recent years, a number of state and federal agencies and professional organizations began to address this gap area.⁵² However, there was significant variability in the recommendations developed by these groups which the CDC sought to address with release of its Guidelines for Prescribing Opioids for Chronic Pain, aimed at primary care providers, in 2016.⁵³ States have since taken steps to promote and align with the CDC guidelines in Medicaid through various policy levers. A number of states have established policies on quantity limits and prior authorization (including step therapy⁵⁴) that mirror the recommendations in the CDC Guidelines.

Promising Practices and Recommendations

To reduce the risk of addiction and diversion of unused pain medication, many states have placed limits on days' supply, MME, or both for initial prescriptions of opioids used to treat new/acute pain. Policies that closely mirror the CDC guidelines have limits ranging from three to seven days' supply or 90 MME for new prescriptions. Idaho's SMA, as an example, instituted 90 MME limits.

⁴⁷ Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2016, March 18). Morbidity and Mortality Weekly Report (MMWR): CDC Guideline for Prescribing Opioids for Chronic Pain. Retrieved from https://www.cdc.gov/mmwr/volumes/65/tr/pdfs/rr6501e1er.pdf

⁴⁸ Anderson, P. (2016, April). HHS Releases National Pain Strategy. Retrieved from https://www.medscape.com/viewarticle/861626

⁴⁹ HHS Office, & Assistant Secretary for Health. (2018, May 21). Pain Management Best Practices Inter-Agency Task Force. Retrieved from https://www.hhs.gov/ash/advisory-committees/pain/index.html

⁵⁰ Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. (2011). Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/22553896

⁵¹ Breining, G. (2017, February 21). Stemming the Opioid Epidemic. Retrieved from https://news.aamc.org/patient-care/article/stemming-opioid-epidemic/

⁵² Throckmorton, D. C., MD, & U.S. Food and Drug Administration, U.S. Department of Health and Human Services. (2016, March 1). FDA Policies and Actions Related to the Development and Use of Opioids to Treat Pain. Retrieved from

 $[\]frac{https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM489206.pdf$

⁵³ Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2016, March 18). Morbidity and Mortality Weekly Report (MMWR): CDC Guideline for Prescribing Opioids for Chronic Pain. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf

⁵⁴ Step therapy is a type of Prior Authorization that requires trial of a medication on a state Medicaid agency's preferred drug list before a non-preferred medication in the same drug class and indication will be approved for use.

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In order to justify increasing the dose over that limit, prior authorization is required along with documentation of patient function and other non-pharmacological therapies or non-narcotic therapies that have been utilized or that are used concurrently. Since implementation of this policy, Idaho has not approved any requests for exceptions to increase doses over 90 MME because providers have not been able to provide satisfactory justification.

In Maryland, state law instructs all providers to prescribe the lowest effective dose of an opioid for a quantity that is not greater than that needed for the expected duration of pain. Statute also imposes a 30 day quantity limit for all opioid prescriptions. For courses of pain treatment with long-acting opioids or a total daily dose that exceeds 90 MEDs, prior authorization is required every six months, along with the following ⁵⁵:

- Attestation of a patient-provider agreement;
- Medical justification for the high dose and/or long-acting opioid prescription;
- Attestation of random drug screenings before and during treatment; and
- Attestation that a naloxone prescription was given or offered to the patient.

MCOs are permitted to implement limitations or requirements in addition to or beyond Maryland's state policy.

In-line with the CDC recommendation to begin opioid treatment with immediate-release formulations, some states, such as Florida, require that beneficiaries be prescribed immediate-release formulations of opioids for pain before prescribing extended-release formulations. Florida's law recently established a 3 day supply limit of Schedule II opioids for 'acute' pain, with an exception up to 7 days if criteria is met and notation is provided on the prescription. In Louisiana, prior authorization is required for all extended-release formulations of opioids. Connecticut requires prior authorization for extended-release opioid formulations unless the prescribing provider has a taxonomy pertaining to Hematology or Oncology. Further, the Louisiana SMA requires that prescribers use a standardized *Opioid Analgesic Treatment Worksheet* to request overrides and prior authorizations for medically necessary quantities of

Promising Practices: Alignment with CDC Guidelines for Prescribing Opioids for Chronic Pain

- Establish limits on days' supply, MME, or both for initial prescriptions of opioids:
 - o 3 to 7 day supply maximum
 - o 90 daily MME maximum.
- Require prior authorization over quantity limits and documentation of other nonpharmacologic and non-opioid therapies utilized or used concurrently.
- Require a prescription for immediaterelease opioid formulations before extended release formulations.
- Require prescribers to use a standardized Opioid Analgesic Treatment Worksheet to request overrides and prior authorizations for medically necessary quantities of opioids in excess of dose and quantity limits.
- Track utilization trends and financial savings and compare to volume and type of complaints received about policies from members and clinicians.

⁵⁵ Maryland Medicaid excludes patients with sickle cell anemia or those in hospice from the prior authorization process, but recommends the lowest effective dose and shortest duration of treatment possible for safety.

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opioids in excess of the prescribed dose and quantity limits for beneficiaries in both Medicaid FFS and MCO programs. Although there was strong resistance to this *Worksheet* from MCOs (whom requested to use their own criteria), having a single form ensured alignment of the FFS and MCO programs and helped limit clinician resistance because of this simplified process.

States are still in the process of determining the success of quantity limits and prior authorization requirements, but some are seeing promising results in the financial savings that are being achieved. From 2014-2017, Oklahoma has been tracking utilization trends – including amount paid, quantity dispensed, number of claims, and number of Medicaid beneficiaries – for immediate-release formulation opioids. All four parameters have demonstrated a linear decline since implementation of the quantity limit, and the number of monthly prescribers of short-acting opioid analgesic has decreased by 16% over this period. New Hampshire has also compared the savings achieved to the volume and type of complaints that are received about the policies from members and prescribers.

Weaknesses and Challenges

States faced a range of challenges when implementing quantity limits and prior authorization requirements, but perhaps the greatest challenges come from chronic pain patients whose long term pain is complex and often already treated, in many instances effectively, with high MMEs.⁵⁶ Idaho began providing case management for chronic pain patients already receiving doses over 90 MME, and, to date, has not approved dose increases over what patients were already receiving. Idaho continues to work with clinicians to consider tapering doses as appropriate, but reports that prescribers do not often move to taper their patients' doses.

States provided a number of suggestions to manage the myriad of challenges associated with implementing quantity limit and prior authorization policies. Several states identified communication with stakeholders as a top priority. Quantity limit and prior authorization policies were not initially well-supported in Maine, but support was improved through individual, group and statewide educational opportunities. Oklahoma emphasized the need for a clear communication plan for providers and involving clinicians and MCOs in the planning process. Oklahoma recommended establishing criteria and associated exceptions, and validating that MCO systems can accommodate the edits prior to moving forward with implementation. Oklahoma also recommended an increase in staffing during implementation to handle increased calls from members and clinicians, a recommendation echoed by Ohio. In general, rural areas face the challenges of limited numbers of clinicians and availability of alternative treatments making it difficult to shift pain treatment away from high doses of opioids without alternatives.

⁵⁶ Note: CMS and states are aware of anecdotal reports that some efforts to address the opioid crisis have created challenges for hospice or cancer patients to access opioid medications. Treatment of cancer and hospice patients requires medical supervision based on therapeutic goals, ethical considerations, and the balance of risks and benefits of opioid therapy. CMS encourages states to monitor for and address such unintended consequences in their policies.

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A critical weakness of quantity limits and prior authorization requirements is the lack of a clear link to positive medical outcomes. Further complicating this issue involves large and increasing percentages of some states Medicaid populations managed by MCOs. Many SMAs have limited access to MCO information and each MCO have different criteria for the policies.

Provider Enrollment and Screening

Background

According to Federal regulations, clinicians that wish to order, refer, and prescribe services, supplies, and/or medications for Medicaid recipients are required to enroll with SMAs. Clinicians must enroll in each state for which they would like to provide services to that state's eligible Medicaid and CHIP recipients. According to the Medicaid Provider Enrollment Compendium, examples of ordering and referring for beneficiaries include:

- Prescribing medications;
- Ordering laboratory testing;
- Ordering imaging services;
- Ordering durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS);
- Referring a beneficiary to another provider or facility for covered services; and
- Determining or certifying a beneficiary's need for a covered item or service (e.g., outpatient drug counseling).

The goal of enrollment requirements is to enable screening of all Medicaid providers to protect beneficiary safety and reduce fraud risk. Since the Patient Protection and Affordable Care Act (PPACA)⁵⁷, States have been required to perform enhanced screenings of Medicaid providers according to their risk for fraud, waste, and abuse, using procedures such as fingerprint-based criminal background checks and site visits.⁵⁸

As of March 2016, States were also required to complete the first cycle of a revalidation of enrollment for all providers, which is required to be conducted every five years. However, based on a 2016 OIG⁵⁹ report, many States struggle to implement the enhanced screenings and revalidation processes and requested guidance from CMS. To date, States have made progress, but are in the early stages of implementation and had limited recommendations to share at MII.

⁵⁷ HealthCare.gov. (2010, March). Patient Protection and Affordable Care Act - HealthCare.gov Glossary. Retrieved from https://www.healthcare.gov/glossary/affordable-care-act/

⁵⁸ Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. (2017, June 23). Medicaid Provider Enrollment Compendium (MPEC). Retrieved from https://www.medicaid.gov/affordable-care-act/downloads/program-integrity/mpec-6232017.pdf

⁵⁹ Levinson, D. R., Inspector General. (2016, May). Department of Health and Human Services: Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented. Retrieved from https://oig.hhs.gov/oei/reports/oei-05-13-00520.pdf

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Promising Practices and Recommendations

Mississippi recommended that other states implement a practice similar to what they have found to be successful: configuring their payment system to automatically deny claims for prescribers without a Mississippi Medicaid provider number. Automating the process made for easy and effective enforcement of the requirement.

Many states expressed concern regarding providers who migrate from one state to another and do not disclose actions taken against them by the state medical board in their prior state. States discussed the need for SMAs to encourage boards to cease

Promising Practices: Provider Enrollment and Screening

- Configure payment system to automatically deny claims for prescribers without a Medicaid provider number.
- Require state medical boards to cease the practice of allowing problematic providers to rescind their licenses in order to avoid disciplinary action, as that makes it difficult for other states to identify problems with the provider's history.

the practice of allowing problematic providers to rescind their licenses in order to avoid disciplinary action, as that makes it difficult for other states to identify problems with the provider's history.

Weaknesses and Challenges

Resistance from stakeholders was cited by states as a major challenge to implementing the above promising practices. In Mississippi, for example, the Bureau of Pharmacy received a lot of resistance from stakeholders after the requirement for pharmacist enrollment went into effect, despite providing notice through various media (e.g. Provider Bulletins, Late Breaking News, Medicaid workshops, and Pharmacy Board notifications) over several months prior to the change taking place. Michigan's SMA has also experienced resistance from advocacy groups and individual clinicians, who have called the increased oversight unnecessary and potentially burdensome. New Hampshire is currently implementing the enrollment process.

Continuing Education on Opioids

Background

Many clinicians self-report that they have insufficient training in opioid prescribing which may have been a contributing factor to the rise of the opioid epidemic. In an effort to make healthcare safer for beneficiaries by ensuring broad and consistent knowledge of safe and current opioid prescribing practices, states have begun to establish continuing education requirements on opioids. For individual clinicians, states are requiring documentation of continuing education for clinicians to renew their licenses. Additionally, some states have also established extensive requirements,

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including continuing education, for facilities that wish to operate as Pain Management Clinics in response to the link between these clinics and "pill mills". ⁶⁰

Promising Practices and Recommendations

State requirements vary by provider type and the number of hours of required education. In Nevada, for example, each person registered by the State Board of Pharmacy must complete annual training on the misuse and abuse of controlled substances, otherwise the state may suspend or revoke a registration. In Florida, the state requires two hours of board-approved continuing education on the Validation of Prescriptions for Controlled Substances for pharmacists to renew their licenses. Prescribing practitioners are also required to complete a board-approved 2-hour continuing education on prescribing controlled substances as part of biennial license renewal. Connecticut's law requires physicians, advanced practice registered nurses (e.g. nurse practitioners), physician assistants and dentists to complete, at a minimum, one hour of continuing education on risk

Promising Practices: Continuing Education on Opioids

- Require training on pain management and the misuse and abuse of controlled substances on an annual basis or with each license renewal.
- Link CME requirements to licensure to make requirements easy to track and enforce.
- Authorize suspension or revocation of a registration for failure to complete such training.
- Establish additional continuing education requirements for any pain management clinic staff or specialty.
- Establish criteria and plan to evaluate success of the education requirements.

management, including, but not limited to, prescribing controlled substances and pain management every two years. The State of Maryland mandated one continuing education credit hour on opioid prescribing for doctors to renew licensure and developed a list of approved courses from which to choose.

Tennessee is an example of one state that has established continuing education requirements for pain management clinic staff. The clinic's Medical Director (or supervising physician of an advanced practice registered nurse or physician assistant) must, "...Meet the statutory requirements to be a pain management specialist, and shall complete the requisite continuing education to maintain that status..." Furthermore, Tennessee regulations state that, "...Each health care provider providing pain management services at a clinic shall complete ten (10) hours in continuing education courses during each health care provider's licensure renewal cycle...The ten (10) continuing education hours shall address at least one or more of the following topics related to pain medicine: (a) Prescribing controlled substances; (b) Drug screening or testing; (c) Pharmacological and non-pharmacological pain management; (d) Completing a pain management focused history and physical examination and maintaining appropriate progress notes; (e)

⁶⁰ Rigg, K. K., March, S. J., & Inciardi, J. A. (2010). Prescription Drug Abuse & Diversion: Role of the Pain Clinic. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3030470/

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Comorbidities with pain syndromes; and (f) Substance abuse and misuse including diversion, prevention of same, and risk assessment for abuse.". ⁶¹

For most states, requiring opioid-related continuing education for renewing medical licensure is a relatively new initiative. The states represented at the MII reported that more time and data are needed in order to assess outcomes and successes, but practices did show promise. Using continuing education credits and linking requirements to licensure make the requirements easy to "...track and enforce...", as cited by the Department of Justice representative at MII. Continuing education requirements vary by discipline, but requirements are generally limited to only 1-2 Continuing Education Units (CEUs) every two years.

Weaknesses and Challenges

Balancing the need for patient safety and OUD prevention with the many demands on clinician time is an ongoing challenge. Representatives from many SMAs support continuing education on opioid prescribing and pain management. It is hoped that by including continuing education on opioid prescribing and pain management into the current requirements for licensure and renewal, there would not be additional burden placed on prescribers.

Category: Innovative Payment Models and Programs

Initiatives for Certain At-Risk Populations

Background

States are testing a number of initiatives aimed at identifying beneficiaries in need of OUD treatment and developing better and more comprehensive treatment methods. Some of these initiatives, such as the Addiction and Recovery Treatment Services (ARTS) in Virginia, are coordinated via a Section 1115 waiver demonstration. New Hampshire is looking to expand its PRR program and use it to identify beneficiaries with OUD in order to address the core issue for the lock-in program rather than just restricting their pharmacy and/or health care provider access.

⁶¹ Tennessee Department of Health, Division of Health. (2017, November). Rules of the Department of Health Division of Pain Management Clinics, Chapter 1200-34-01 Pain Management Clinics. Retrieved from http://publications.tnsosfiles.com/rules/1200/1200-34/1200-34-01.20171126.pdf

⁶² Medicaid.gov. Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. (n.d.). About Section 1115 Demonstrations. Retrieved from https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html

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Promising Practices and Recommendations

Ohio is beginning care management and coordination initiatives for beneficiaries with severe mental illness and chronic conditions. They are looking to examine social determinants of health while improving health outcomes and the Healthcare Effectiveness Data and Information Set (HEDIS). Ohio is building care management metrics into MCO plans to make it easier to assess outcome measures while improving SMA-MCO collaboration and data sharing. This program will begin July 1, 2018, therefore, detailed recommendations are not yet available, but there is hope that improved data and a focus on populations with complex physical and mental health problems will lead to improved processes and outcomes.

Virginia's ARTS program, implemented in April of 2017 via a Section 1115 waiver demonstration, provides access to a full continuum of SUD treatment services, covering both physical and behavioral treatments that are based on American Society of Addiction Medicine criteria (ASAM). ⁶³ The ARTS program expanded short-term SUD inpatient detoxification and residential treatment access, increased payment rates for existing SUD treatment services, added Peer Support services, required SUD Care Coordinators at all MCO⁶⁴ and organized provider education, training, and recruitment activities. An independent evaluation of the first quarter of the ARTS program by Virginia Commonwealth University found:

- A 50% increase in treatment rates among Medicaid beneficiaries with SUD;
- A 30% increase in the number of beneficiaries with OUD receiving pharmacologic treatment; and
- That the number of practitioners providing outpatient counseling to Medicaid beneficiaries with SUD more than doubled. 65, 66

Promising Practices: Initiatives for Certain At-Risk Populations

⁶³ Department of Medical Assistance Services, Virginia Medicaid Program. (2017, April 1). Addiction and Recovery Treatment Services (ARTS). Retrieved from http://www.dmas.virginia.gov/Content_Pgs/bh-home.aspx

⁶⁴ Commonwealth of Virginia Department of Medical Assistance Services. (n.d.). Retrieved from http://www.dmas.virginia.gov/files/links/910/CCC Plus MCO Contract January 2018.pdf

⁶⁵ Health Behavior and Policy | Virginia Commonwealth University. (2017, September). Addiction and Recovery Treatment Services - ARTS Evaluation Update. Retrieved from http://www.dmas.virginia.gov/Content_atchs/bh/HBP_ARTS Issue 01_092017.pdf

⁶⁶ Katherine Neuhausen, M. M. (2017, August 30). Update On Virginia Medicaid Addiction and Recovery Treatment Services (ARTS) Program. Retrieved from Virginia Department of Medical Assistance Services. http://www.dmas.virginia.gov/Content-atchs/bh/Medicaid%20Addiction%20and%20Recovery%20Treatment%20Services%20Update%20-%20August%202017.pdf

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Another innovative initiative from New Hampshire's SMA includes collaboration with the State's Bureau of Drug and Alcohol Services and the SMA's Program Integrity component to perform pre-screens of potential providers who apply to enroll as inpatient OUD treatment organizations. The SMA Program Integrity component sends both nurse reviewers and provider enrollment specialists for a site visit. Among other tasks, these nurse reviewers evaluate and continuing education. When a beneficiary with OUD is screened and meets the requirement for residential treatment, the Bureau of Drug and Alcohol Services then conducts "Pay for Performance" measurements in two areas:

- 1) If that member is admitted within 24 hours of referral, the Bureau pays the provider \$50; and
- residential treatment, if the member does not re-enter treatment within 90 days, the Bureau pays the provider \$75.
- 2) When a member is discharged from

- the completeness of medical records, security of any medications, and the program design relative to treatment regimens. The provider enrollment specialists evaluate the facility for safety and cleanliness, as well as employee records for evidence of credentials, federal database checks,
- Build care management metrics into Managed Care Plans to make it easier to assess outcome measures.
- Provide access to a full continuum of SUD treatment services, covering both physical and behavioral treatments.
- Expand short-term SUD inpatient detoxification and residential treatment access, increase payment rates for existing SUD treatment services, add Peer Support services, require SUD Care Coordinators at all MCOs, and organize provider education, training, and recruitment activities.
- Perform pre-screens of potential providers who apply to enroll as inpatient OUD treatment organizations.
- Institute "Pay for Performance" measures for inpatient OUD treatment centers that recognize efficient admission for and successful outcomes of treatment.

Establish a system to refer beneficiaries identified as being "at risk" through their

lock-in program to behavioral health/OUD treatment services.

The state of Pennsylvania has discussed establishing a system to refer beneficiaries identified as being "at risk" through their lock-in program to behavioral health/OUD treatment services. Such a program would aim to address the root of the problem, OUD, and not simply limit their pharmacy or health care providers. Although new Medicaid regulations to include behavioral health services have been proposed in Pennsylvania over a number of budget years, they have not yet received state legislative approval.

The first measure recognizes an efficient admission for treatment, while the second recognizes the success of that treatment. The New Hampshire SMA is beginning to see positive outcomes, particularly with pregnant women. Note: Pay for Performance measures can create unintended and adverse consequences, so it is important to monitor the integrity of programs for such

Weaknesses and Challenges

developments.

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The Ohio SMA initially encountered some challenges with buy-in from the behavioral health community when making changes to care management and coordination for beneficiaries with severe mental illness and chronic conditions. They addressed the resistance by engaging early with stakeholders and being transparent about the policies under consideration and plans for implementation. By involving the stakeholders, the SMA made sure that their concerns were addressed throughout the process and reflected in the result.

New Hampshire has had difficulty evaluating the costs associated with their screening program because the state's Bureau of Drug and Alcohol Services funds some services using grant money which has complicated the creation of accurate cost reports. New Hampshire also reported challenges with monitoring for proper enrollment and billing by SUD providers because they tend to have multiple programs in various locations.

Category: Outreach and Partnership

Creative Cooperation

Background

Addressing the opioid crisis successfully will require a multidisciplinary, holistic approach with cooperation and collaboration among a variety of stakeholders. Recognizing this, states reported a variety of partnerships and creative solutions that are being implemented. Partnerships ranged from collaboration among government agencies and state professional boards to discussions with beneficiaries in recovery from OUD.

Promising Practices and Recommendations

Promising Practices: Creative Cooperation

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SMAs across the country are working with government agencies, health care professionals and their state boards, and private sector companies involved in health care (such as plan sponsors and pharmacy benefit managers (PBM)) to implement prescribing practices and policy that will help to address the opioid crisis.

In Mississippi, the Governor appointed an Opioid and Heroin Task Force to make recommendations to address the crisis. That Task Force presented forty-one recommendations to the Governor in August 2017, covering health care provider, law enforcement and prosecution work, and enhanced education, prevention and treatment efforts. Among the holistic recommendations were the following regarding prescribing practices and policy:

- Requirements to report prescriptions for scheduled medications to the PDMP daily;
- Checking the PDMP at each patient encounter where a prescription for an opioid and/or benzodiazepine is written;
- Limits of 7 days' supply of opioids for acute non-cancer pain;
- Point of service drug testing at each prescription for chronic, non-cancer pain;
- Increased access to and funding for treatment facilities, programs, and medically assisted treatments for opioid and/or benzodiazepine addiction. Exploration of all options for federal funding, grants, etc.⁶⁷

The Task Force is currently holding open forum discussions with stakeholders to discuss implementation and challenge resolution.

Minnesota convened an Opioid Prescribing Work Group tasked with, "Developing statewide guidelines on appropriate opioid prescribing for acute pain, post-acute pain and chronic pain; developing educational resources for providers for communicating to patients about pain; and implementing an opioid prescribing quality improvement program among Minnesota Health Care Program-enrolled providers whose prescribing behaviors are found to be outside of community

- Form a task force to develop recommendations that address the crisis
- Develop statewide guidelines on appropriate opioid prescribing for chronic pain (consistent with CDC *Guideline*), acute pain, and post-acute pain
- Develop educational resources for providers for communicating to patients about pain
- Implement an opioid prescribing quality improvement program among Medicaid providers whose prescribing behaviors are found to be outside of community standards
- Convene regular meetings with stakeholders to share information on new policies and discuss issues relevant to health care practice
- Interview people with OUD to gain insights into their experiences, needs, and behaviors
- Have program integrity staff participate in policy making in order to balance competing priorities of program integrity staff and policy makers

⁶⁷ Department of Public Safety, Mississippi Bureau of Narcotics, State of Mississippi. (2017, August 2). Governor's Opioid and Heroin Study Task Force - Mississippi. Retrieved from http://www.mbp.ms.gov/Documents/Gov Task Force Recs 2017.pdf

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standards."⁶⁸ The Minnesota Opioid Prescribing Work Group membership is set forth in statute and requires representation across a variety of stakeholder groups, including health care providers, mental health experts, pharmacists, law enforcement, health professionals, health plan representatives, consumers and state representatives. All work group meetings are open to the public for comment in person and via webcast. The work group completed development of the opioid prescribing guidelines in spring of 2017. The guidelines are described as consistent with the *CDC Guideline for Prescribing Opioids for Chronic Pain*, but with additional information. It was reported that it was a significant challenge to create prescribing protocols that address all phases of the opioid prescribing cycle, but the work group successfully released the recommendations to the public for comment and is currently reviewing the feedback that was received. Clinician educational resources and quality improvement program measures are currently under development. As part of final rollout, informational hearings and many other education efforts are planned.

The District of Columbia pharmacy program, in collaboration with the PBM, holds quarterly Pharmacy Forum meetings with Medicaid, PBM, and pharmacy provider representatives to exchange information on new policies and discuss and address issues relevant to pharmacy practice. To make the meetings convenient for pharmacists, the District schedules two (2) sessions per quarter at different dates and times. Providers also have multiple options to join the meeting in person, by teleconference, or via webinar. Although the District of Columbia SMA is not tracking outcomes quantitatively, qualitative feedback reflects that pharmacy providers are better informed and aware of available policies, requirements, manuals and the preferred drug list. They have found the meetings to be helpful in identifying challenges and barriers, as well as ways to address problem areas. The District of Columbia has also observed a reduction in complaints and phone calls/e-mail requests for information from pharmacy providers who attended the forum versus those who do not attend.

Utah's SMA took the creative approach of inviting a beneficiary in recovery from OUD to speak at a conference. This person gave insight into Medicaid program weaknesses and health care system gaps by sharing methods used to obtain opioids for non-medical use. One example shared by the speaker was the tendency to seek prescriptions from dentists because they were considered a "weak link." The speaker described the practice of calling the dentist in the evening to report pain, which would often achieve the desired result of the dentist calling in a prescription to a pharmacy. The speaker also reported the practice of going to a pharmacy late in the evening with a "rush" prescription, purposely seeking out pharmacies with long lines. In many cases, pharmacies have the control practice of calling a doctor to verify a prescription for a controlled substance. However, in the evening, most doctors' offices are not staffed, making it impossible to verify the prescription until the following business day. With a long line of customers, pharmacy staff are less likely to attempt to verify a prescription at all, or invite a confrontation with a customer who is not willing to wait until the next business day for their prescription to be filled.

⁶⁸ Office of the MHCP Medical Director, Minnesota Department of Human Services. (2016, March). Opioid Prescribing Improvement Program - Minnesota. Retrieved from https://mn.gov/dhs/assets/Opioid Initiative Legislative Report tcm1053-202705.pdf

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The Utah SMA was able to share these insights with health care providers and pharmacies in an effort to close the exploited gaps.

There is also a desire to have PI staff participate in policy making in an effort to balance the competing priorities of PI staff and policy makers. Pennsylvania has monthly meetings between PI and policy staff to discuss new policy, challenges, and clarification needs, but a challenge with this collaboration is that there is a long approval process. This issue was echoed by Mississippi PI staff, who draft policy recommendations to share with their Bureau of Policy; however, depending on workload and competing priorities of the Bureau, the timeframe for implementation of those recommendations is inconsistent.

Weaknesses and Challenges

The District of Columbia SMA had difficulty attracting a wide range of pharmacy representatives to attend the quarterly Pharmacy Forum meetings. Invitations were extended to every pharmacy provider whether corporate or independent, but in most cases, attendees were representatives from independent pharmacies.

Category: Fraud Reduction

Fraud Reduction Practices

Background

In assessing SMA PI, many states have identified areas of beneficiary care that are particularly susceptible to fraud or that may be demonstrating trends of potential abuse and misuse. Among these are paper prescriptions, lack of identification requirements, and medically unnecessary laboratory tests. States have implemented or are considering implementing procedures surrounding these areas to protect beneficiaries and Medicaid funds.

Promising Practices and Recommendations

In addition to patient safety issues such as errors of drug name, dose, frequency of dosing, and route, paper prescriptions are also associated with high rates of fraud. Over the past several years, electronic prescriptions, defined as, "A prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care," have become key to resolving these issues. CMS has called e-prescribing, "An important element in improving the quality of patient care...." The majority of states now require use of electronic prescriptions for controlled substances, including opioids. New York state reports seeing, "A

⁶⁹ Samadbeik, M. M., Ahmadi, M., & Asanjan, S. (2013, October). A Theoretical Approach to Electronic Prescription System ... Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3950788/

⁷⁰ Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. (2014, February 26). E-Prescribing. Retrieved from https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html

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drastic reduction in forged paper prescriptions for controlled substances due to electronic prescribing."

Although it has not yet been implemented, several states recommended or are considering requirement for photo identification with services and prescription acquisition (for tracking purposes, identification review similar to dextromethorphan products). An exception is Florida, in which a law requiring pharmacist verification of a patient's identity becomes effective July 1, 2018. In addition to non-opioid related fraud, such as when another person uses an enrollee's Medicaid card for medical treatment, the requirement could also reduce drug diversion from fraudulent prescriptions. In Mississippi, the practice of requiring photo identification was recommended, though not yet approved or However, the Mississippi Board of required. Pharmacy verified that a large pharmacy chain does require photo identification to pick up a prescription for a controlled substance, indicating that private businesses may begin to embrace the idea. New Hampshire PI has proposed (to the state DHHS) on-site pharmacy desk-audits to validate the pharmacy opioid dispensing process; no decision has been made for a start date.

Another fraud, waste, and abuse issue facing many states is excessive billing by laboratory companies for medically unnecessary lab tests related to opioids. Medically unnecessary tests can include running both basic (sometimes called qualitative)

Promising Practices: Fraud Reduction Practices

- Require electronic prescriptions for controlled substances.
- Consider a requirement to present photo identification to access services or pick up prescriptions (for tracking purposes, similar to identification review for dextromethorphan products).
- For laboratory testing:
 - Require basic, qualitative test before Medicaid will cover the more expensive quantitative screen.
 - Implement a quantity limit of five qualitative and quantitative tests per quarter.
 - o Only cover services at participating labs.
- Perform claim audits and analyses to identify laboratory and ordering provider outliers and refer suspicious activity to Medicaid Fraud Control Units (MFCU) or law enforcement for investigation.
- Do not permit Medicaid beneficiaries to fill prescriptions out of state, except in border states, or require prior authorization for out of state prescriptions:
 - Combine with eligibility checks to confirm beneficiary still resides in state.

and confirmation (known as quantitative) urine tests, even if the basic test result is negative for opioids. Some laboratories have also continued to conduct tests at a high frequency, even when a patient has been testing negative for opioids consistently, indicating a reduced need for testing.⁷¹ To address the problem, some states have instituted policy changes that require the basic, qualitative test before Medicaid will cover the more expensive quantitative screen. Ohio has found it effective to implement a quantity limit of five qualitative and quantitative tests per quarter, and to only cover services at participating labs. Some states, such as Connecticut and Pennsylvania, perform claim audits and analyses to identify laboratory and ordering provider outliers and will

⁷¹ Segal, D. (2017, December 27). In Pursuit of Liquid Gold. New York Times. Retrieved from https://www.nytimes.com/interactive/2017/12/27/business/urine-test-cost.html

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refer suspicious activity to their MFCUs and/or law enforcement for investigation. New Hampshire PI has identified lab test ordering patterns with a significant number of outliers. For example, when doing an analysis of pain clinic providers (using paid laboratory claims) it was found that one provider, during one 12 month period, ordered both a qualitative and quantitative test for 100% of their lab orders (70 of 70). This data is preliminary; the state will be validating that the tests were actually ordered and that the laboratory was not billing for tests not performed.

In another effort to reduce the risk of fraudulent prescriptions, North Dakota has stopped allowing Medicaid beneficiaries to fill prescriptions out of state, except in border-states⁷². The North Dakota SMA implemented an edit that flags all out-of-state prescriptions so that they require prior authorization before filling. By allowing prescriptions to be filled in immediate neighboring states, North Dakota reports that criticism of the policy is rare. They did, however, recommend that states implementing a similar policy combine the policy with eligibility checks to ensure that patients are still living in their state. They report that pharmacy claims are often seen long before any other claim type; therefore, to protect Medicaid funds, states should first confirm that the beneficiary remains enrolled.

Weaknesses and Challenges

Many provider advocacy groups resisted the implementation of e-prescribing citing the cost of implementation and risk to care quality as key concerns. Several states recommended being prepared for these challenges from providers and engaging them early in discussions to address concerns.

In identifying medically unnecessary laboratory testing, states reported difficulty evaluating laboratories that were owned by the ordering health care provider.

Federal Government Opportunities to Support States

A number of states requested that the federal government issue more guidance on lock-in programs. It has been challenging for some states to compel MCOs to fully implement PRRs in their plans, and further guidance or minimum standards for lock-in programs from the federal government could help. Texas suggested that clinician lock-in programs would be useful in Medicare as many high utilizers are dually eligible for Medicare and Medicaid.⁷³

⁷² North Dakota Department of Human Services Provider Manual for Pharmacies (March 2018). Referenced from http://www.nd.gov/dhs/services/medicalserv/medicaid/docs/pharmacy-manual.pdf

⁷³ Comprehensive Addiction Recovery Act (CARA) is being implemented as of January 1, 2019: Comprehensive Addiction Recovery Act. 22 July 2016. Retrieved from https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf

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Further, there is great variation across states in the timeframes that beneficiaries are locked in. In Vermont, for example, the lock-in is permanent; in South Carolina the lock-in period is two years. Pennsylvania's lock-in period is a standard five years as previously approved by CMS (HCFA) in 1985. Consistent guidelines or recommendations regarding most effective lock-in periods could improve the variation, but more research is needed to support the impact of these programs and identify the most effective lock-in duration period.⁷⁴

States requested varying levels of guidance from the federal government regarding quantity limits and prior authorization requirements. One suggestion was for CMS to lead by example, such as was done in the 2019 call letter. In that call letter, CMS mirrored the CDC *Guidelines* in its quantity limit and prior authorization requirements.⁷⁵ Another suggestion was to implement regulations related to prescribing controlled substances so that all states have the same requirements and have clear limits for Medicaid reimbursement. Similarly, states proposed that CMS facilitate FFS policy alignment across states. It was also requested that CMS develop standard rules regarding beneficiaries paying cash for Medicaid-covered services and penalties for the beneficiary and/or provider for accepting. It is important to note that if no claim is submitted to Medicaid, these types of transactions are outside of Medicaid's payment system and scope.

States made two general suggestions regarding innovative payment models and programs. They requested that the federal government increase flexibility for states to determine their own solutions for OUD, possibly via grant funding. Another request was for CMS to explore additional alternative payment methods to encourage integrated systems for pain management.

States requested CMS's assistance with educating providers on the benefits of e-prescribing. States also requested that CMS issue standardized guidelines for ordering and billing of opioid-related laboratory tests, to help providers, plans, and other stakeholders to address the excessive laboratory testing problem.

Generally, states also requested that the federal government facilitate information sharing across states, a goal that this course and compendium begin to address. Most attendees were interested to learn what was occurring in each state Medicaid program, what kind of policies were being developed and implemented in response to the opioid crisis, and the resources states were using to develop those programs and policies (e.g., state Agency Medical Directors Groups, Bree Collaborative ⁷⁶). States suggested that the federal government compile and disseminate state

⁷⁴ Centers for Disease Control and Prevention. (2012, December). Approaches to Drug Overdose Prevention Analytical Tool (ADOPT): Evaluating Cost and Health Impacts of a Medicaid Patient Review & Restriction Program. Retrieved from

http://www.ucdmc.ucdavis.edu/iphi/Programs/OOD/resources/CDC%20Opioid%20Project Final%20Report.pdf

75 Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Retrieved on August 6, 2018 from:

https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

76 The Dr. Robert Bree Collaborative was established so that public and private health care stakeholders would have the opportunity to identify specific ways to improve health care quality, outcomes, and affordability in Washington State (http://www.breecollaborative.org/about/)

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information, highlighting innovative ideas, effective strategies and processes, and outcomes, including metrics that states found most useful for trend analysis.

Vulnerability 3 – Oversight Issues

This section explores mitigation activities that states have used to address oversight issues.

Category: Policy

Payment Under the Medicaid Provider Enrollment Agreement

Background

States agree that providers accepting cash payments in lieu of submitting a claim for services provided to Medicaid beneficiaries is problematic because of the potential for fraud and abuse in the absence of a claim submitted to the state Medicaid plan. In cases where cash payments have been identified, enforcement of sanctions or removal of the enrolled provider from the Medicaid program could be considered.

Promising Practices and Recommendations

In some states, when a provider enrolls in the Medicaid program, they agree to accept payment under the Medicaid program as payment in full for services rendered. Unfortunately, in the absence of laws or policy requiring that providers submit claims for all services rendered to Medicaid beneficiaries, there are providers who will accept cash payment instead of or in addition to the Medicaid payment. Several states have considered or implemented a policy making this a

Promising Practices:
Payment Under the Medicaid Provider Enrollment
Agreement

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violation of the Medicaid provider agreement to accept cash payment from a Medicaid beneficiary in lieu of submitting a claim to Medicaid. In Tennessee, when a provider has been identified as accepting cash from a Medicaid beneficiary for services rendered, Medicaid notifies the provider that it is a violation of Medicaid policy to do so, and informs them that data will be rerun in six months to check their compliance. Some states have discussed taking this policy a step further and removing providers from Medicaid if they accept cash payments for services. Michigan is considering having pharmacists enroll as rendering providers; at this time, only pharmacies (rather than individual pharmacists), are required to enroll.

- Consider policy that makes it a violation of the Medicaid provider agreement to accept cash payment from a beneficiary in lieu of submitting a claim to Medicaid:
 - O When a provider has been identified as violating this policy, issue a warning.
 - o Consider removing those providers from Medicaid if the behavior continues.
 - O Consider enrolling and including pharmacists under this policy.
- Use PDMP data to identify beneficiaries paying cash for prescriptions.
- When the PDMP is not accessible to SMA/PI staff, consider asking pharmacies to notify Medicaid when they receive cash payments from beneficiaries.

With respect to pharmacies, states have used PDMP data (when the PDMP is accessible to the SMA) to identify beneficiaries paying cash for their prescriptions. When access to the PDMP is not permitted, states may ask pharmacies to notify Medicaid when they receive cash payments. Medicaid can then count that prescription fill against the beneficiary's daily dose limit for opioids.

Category: Data Analysis

Clinician and Beneficiary Activity

Background

Evaluating both clinician and beneficiary activity is necessary to identify problematic practices. States employ various data tools to identify potential aberrant prescribers and high risk beneficiaries who can then be referred to law enforcement or other appropriate entities for further action.

Promising Practices and Recommendations

Proactive data review is essential to identifying potential program abusers, misuse and opportunities for intervention. States use any number of algorithms when reviewing beneficiary and clinician habits. In an effort to not overlook populations that may have in the past been exempt from review, states may choose to include all diagnosis codes. For example, beneficiaries with a previous diagnosis of cancer may be reviewed; these patients may be in remission from cancer,

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yet have continued to use high doses of opioids and may have developed OUD.⁷⁷ For these reasons, Louisiana is reevaluating its current practice of excluding cancer patients from their analyses. Evaluating exemption criteria and reviewing claims to see if individuals are still receiving cancer treatment (though this may be a challenge) will help determine if the SMA should continue to exempt those recipients.

Some state Medicaid programs work in collaboration with other state agencies to identify aberrant activities. Tennessee receives a monthly feed from the state Office of Inspector General on Medicaid recipients arrested on a drug related charge. The state then sends the list to the PBM, which in turn provides the state with information on those beneficiaries' clinicians, pharmacies that filled their prescriptions, the medications, and the dates prescribed and filled. An alert is also sent to the provider about their patient with a recommendation to review.

Through the state's Holy Trinity Project⁷⁸, Illinois reviews Medicaid data from most recent 18

months. This has led to the referral of 30-40 providers to the state's MFCU and the identification of a major pill mill.

States such as Minnesota, New Jersey and Pennsylvania have identified dentists as a source of problematic prescribing. Actions taken by each state to address the issue vary, but one state is working with the Board of Dentistry to educate dentists about the problem. They are conducting provider outreach with presentations on outlier prescribing practices or are referring the dentist to the State Board of Dentistry and the DEA for further action.

Connecticut's data analytics contractor has developed algorithms focusing on opioid utilization patterns. These algorithms allows the user to identify recipients who may be at risk due to potential opioid abuse and addiction; identify prescribers, recipients, and

Promising Practices: Clinician and Beneficiary Activity

- Include all diagnosis codes in analyses; do not exclude beneficiaries with a previous diagnosis of cancer or Sickle Cell Disease.
- Collaborate with other state agencies to identify aberrant activities, e.g. review data from OIG or law enforcement on Medicaid recipients arrested on a drug-related charge; follow up with PBM, SMA, and providers as appropriate.
- Review data regularly on prior 18 months to identify and address shifting trends and make referrals to MFCU and law enforcement.
- Promote opioid epidemic awareness and prescribing education campaigns for dentists, a group that has been identified as problem prescribers in many states.

pharmacies involved in possible drug diversion; and identifier outliers amongst opioid prescribers and pharmacies.

⁷⁷ Identifying and assessing the risk of opioid abuse in patients with cancer: an integrative review (2016). Substance Abuse and Rehabilitation. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4898427/

⁷⁸ "Holy Trinity" is a trio combination drug regimen that includes a drug in each of the following classes: (1) opioid, (2) benzodiazepine, and (3) skeletal muscle relaxer (e.g. carisoprodol).

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Weaknesses and Challenges

States expressed varied issues with data review depending on the state's activities. For example, Louisiana has difficulty determining the reason that a beneficiary is no longer receiving cancer treatment. Treatment cessation could indicate remission and potentially a reduced need for continued opioid use, or it may indicate a transition to hospice and therefore a need for comfort care, including opioids. The reason for ceasing treatment is important to determine whether or not they should include the individual in their data analyses.

Tennessee's initiative, which sends providers an informational letter regarding beneficiaries arrested on a drug charge, has resulted in some confusion from providers. The providers are often concerned that they have done something in violation of their contract with the MCO and SMA. To alleviate the provider's concerns, the state stresses to them that the letter is for informational purposes only.

Category: Outreach and Partnership

Collaboration among State Agencies and Boards

Background

Information sharing through collaboration between state stakeholders is necessary to address opioid misuse and abuse from all perspectives. This collaboration will ensure information is used productively and all parties informed of current and future outcomes to make informed decisions.

Promising Practices and Recommendations

Ohio program integrity staff meet regularly with their partners in the Prescription Drug Integrity Group where Medicaid paid claims data and PDMP data are used to identify aberrant prescribing behavior. They also meet with law enforcement and other regulatory partners in "Pill Mill

Promising Practices: Collaboration among State Agencies and Boards

- Identify aberrant behavior and share information with PI partners and law enforcement; coordinate enforcement activities via regular meetings.
- Recommend Medicaid policy changes based on information learned from criminal investigations.

Coordination" meetings to coordinate enforcement activities. Based on this review, some providers may be referred to the Ohio MFCU for a criminal investigation; to the Ohio surveillance and utilization review subsystem (SURS) for audit; and/or for review by the appropriate board for licensing issues. Success is measured by the number of aberrant providers identified and referred for criminal investigation. Additionally, Ohio measures success by their ability to recommend policy changes to the SMA based on information learned from criminal investigations. The collaborative efforts have proven a positive initiative,

and Ohio recommends that other states considering such practices do what they can to collaborate

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and create process efficiencies that maximize the capabilities of each group. Ohio recommends meeting regularly, making sure that all parties are well represented, and holding staff accountable on follow up assignments.

Weaknesses and Challenges

The main challenge experienced by Ohio with their "Pill Mill Coordination" Meetings was understanding each agency's role and responsibility, and recognizing the value they could add to the process. Once this occurred, each state agency remained engaged. An additional challenge had been obtaining data sharing agreements between their agencies, often a slow process.

Category: Fraud Reduction

Communication with MCOs

Background

There are two payment models that states employ to manage their beneficiaries. In a FFS model, providers are reimbursed directly by the SMA for each service (e.g., a personal care service, respite, supported employment) based on a unit established for the delivery of that service (e.g., 15-minutes, per hour, per visit, per day). States also have the option to utilize a managed care model. Medicaid managed care provides for the delivery of Medicaid health benefits and additional services through contracted arrangements between state Medicaid agencies and MCOs that accept a capitation payment for these services, per member, per month. Some states are implementing a range of initiatives to coordinate and integrate care beyond traditional managed care. These initiatives are focused on improving care for populations with chronic and complex conditions, aligning payment incentives with performance goals, and building in accountability for high quality care. Participating states discussed how they partner with their MCOs to identify and address fraudulent behaviors on the part of providers.

Promising Practices and Recommendations

⁷⁹ Medicaid.gov, Centers for Medicare and Medicaid Services. (2017). Pay-for-Performance Rate Methodologies in a HCBS FFS. Retrieved from https://www.medicaid.gov/medicaid/hcbs/downloads/training/pay-for-performance.pdf

⁸⁰ Capitation payments are payments agreed upon in a capitated contract by a health insurance company and a medical provider. They are fixed, pre-arranged monthly payments received by a physician, clinic or hospital per patient enrolled in a health plan, or per capita. Monthly payment is calculated one year in advance and remains fixed for that year, regardless of how often the patient needs services.

⁸¹ Medicaid.gov, Centers for Medicare and Medicaid Services. (2017). Managed Care. Retrieved from https://www.medicaid.gov/medicaid/managed-care/index.html

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A number of states share an exclusion list, termination list, and/or suspension list of providers with their MCOs. South Carolina, for example, utilizes a SharePoint site to communicate provider exclusions and terminations with the MCOs. Each time a provider is entered who was terminated

for Cause, Suspension, or Exclusion, each MCO must confirm that they took action to verify that the provider is not in their system. The MCO must also document the date and upload a copy of their letter to the provider. South Carolina's SMA also generates SUR reports showing each MCO that pays providers after sanctions are imposed. Finally, the state's Excluded Providers List is released to the public via the South Carolina Medicaid website. South Carolina reports that it has been invaluable having designated staff that works closely with the MCOs and keeps the SMA informed of issues.

In Ohio, their Managed Care PI Group shares information on bad actor providers with MCOs so that all MCOs exclude them from their networks. These MCO contracts also allow MCOs to block DEA numbers, which is helpful with providers who are out of state. Ohio's success rate is measured by ensuring that the managed care plans

Promising Practices: Communication with MCOs

- Share exclusion list, termination list, and/or suspension list of providers with MCOs:
 - Confirm that each MCO took similar action or verify that the provider is not in their system.
- Release excluded providers list to public.
- When resources allow, designate staff to work closely with MCOs and keep SMA informed.
- If MCO contracts allow, review for Drug Enforcement Agency (DEA) numbers that are blocked by MCOs (especially for out of state providers).
- Meet regularly with MCOs and consider ways to incentivize the plans to identify and report fraud, waste, and abuse in a timely fashion.

remove bad actor providers and cease making payments to them. For states looking to implement similar practices, Ohio recommends meeting regularly with the state MCOs and considering ways to incentivize the plans to identify and report fraud, waste, and abuse in a timely fashion.

Weaknesses and Challenges

South Carolina identified several challenges in its review of providers. There has been confusion between participating and non-participating providers and placing an action against a provider in the event they enroll with the MCO.

Ohio's greatest challenge has been making sure to avoid conflict with the plans. Ohio holds weekly calls with MCOs to ensure they are not interfering with one another's investigations. Another challenge Ohio was faced with involves staff turnover which can lead to confusion and disruption in processes. Ohio attempts to handle this challenge with adequate training and clear lines of communication.

Federal Government Opportunities to Support States

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States would like for CMS to encourage single state Medicaid agencies to have regular program integrity meetings with their MCOs (if applicable) and MFCUs. The states feel this would facilitate collaboration among all parties and better identification and consistent action against high risk beneficiaries or aberrant prescribers.

Vulnerability 4 – Educational Needs

This section explores mitigation activities that states have used to address educational needs of providers and beneficiaries.

Category: Outreach and Partnership

Educational Efforts for Providers

Background

States discussed a number of approaches to educating and communicating with enrolled providers about opioids. Methods included the development of resource toolkits, mass communications, presentations and discussions with provider groups, and targeted communications based on clinicians' opioid prescribing habits.

Promising Practices and Recommendations

California's SMA reported that in November 2014, the state medical board distributed an educational toolkit for Medicaid clinicians titled *Guidelines for Prescribing Controlled Substances for Pain.*⁸² The toolkit focused on how to manage patient needs and discuss opioid medication issues with pain patients. Although metrics were not available at the time this document was prepared, California's SMA recommended the distribution of a similar resource by other states to all providers who prescribe opioids.

Promising Practices: Educational Efforts for Providers

⁸² Medical Board of California. (2014, November). Guidelines for Prescribing Controlled Substances for Pain. Retrieved from https://www.mbc.ca.gov/Licensees/Prescribing/Pain Guidelines.pdf

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States have also used mass communication methods to reach providers for education purposes. For example, New Hampshire has used "fax blasts" in the past to send notices to 300 pharmacies communicating updates to rules and preferred drug lists. This method is not currently being used for opioid communications, but they received positive feedback about the method and may consider it for opioid messaging.

Similarly, North Dakota sends emails⁸³ to pharmacies and posts the same information to the state website, which saves the state money by eliminating paper mail costs. Through this media, North Dakota is also able to track how many emails are opened.

States have also invited clinicians to discussions to understand their prescribing habits and provide an opportunity for intervention. In the District of Columbia, for example, the Drug Utilization Review (DUR) board invites prolific prescribers of opioids to its regular monthly meetings to explain their prescribing habits. The DUR board also invites subject matter experts (SMEs) to share their knowledge with the board and top prescribers. The

- Develop and distribute educational toolkit to Medicaid clinicians titled Guidelines for Prescribing Controlled Substances for Pain.
- Send communications about opioids via email and posts to Medicaid website, which can track how many emails are opened and website visits received.
- Hold regular DUR board meetings with top outlier prescribers to explain prescribing behaviors; use meetings for targeted educational efforts and to encourage providers to be part of the opioid epidemic solution.
- Send individualized letters to clinicians to alert them to potentially problematic prescribing practices and enclosing CDC Guideline for Prescribing Opioids for Chronic Pain.
- Provide quarterly "report cards" to highest prescribers of opioids, ranking clinicians by mean and standard deviations over the mean for multiple measures.
- Inform pharmacy staff of mechanisms available to them to report possible fraud.

District of Columbia SMA reports qualitative indicators of success. For example, in 2017, the DUR board invited a SME to discuss underutilization of hydroxyurea⁸⁴, a medication for sickle cell anemia patients, which has been linked to possible overutilization of opioids as a result. After the meeting, the SME became very engaged with the District of Columbia DUR and expanded work on interventions that promote awareness of the link between opioid overutilization and underutilization of the hydroxyurea treatment that can reduce the incidence of painful sickle cell episodes. Anecdotal reports from the PBM indicate slight increases in the use of hydroxyurea for sickle cell patients, which may lead to a reduction in the frequency of opioid utilization. The District of Columbia SMA suggested that such an initiative could be an effective interventional

⁸³ North Dakota Pharmacists Email Campaign Archive accessed from https://us11.campaign-archive.com/home/?u=851a362b85cd6e8791c6a5384&id=420498c9d9

 ⁸⁴ U.S. Food and Drug Administration, U.S. Department of Health and Human Services. (n.d.). Hydroxyurea - FDA prescribing information, side effects and uses. Retrieved from https://www.drugs.com/pro/hydroxyurea.html
 ⁸⁵ Agrawal, R. K., Kantilal Patel, R., Varsha shah, L. N., National Center for Biotechnology Information, U.S. National Library of Medicine. (2014, June 30). Hydroxyurea in Sickle Cell Disease: Drug Review. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4022916/

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tool for other states as well, as it establishes collaborative practices and encourages providers to be part of the solution.

Many states have implemented sending individualized letters to clinicians to alert them to potentially problematic prescribing practices. The District of Columbia DUR board, for example, identifies providers to receive a letter when there is a potential drug-drug/disease interaction; contraindication; polypharmacy; overutilization; inappropriate indication, dosing, frequency and/or duration; and/or failure to perform necessary monitoring and testing. Each member of the DUR board reviews about 50 individual patient profiles each month and makes their recommendations either to send or not to send a letter to providers based on their professional judgment. The letter typically advises the provider to review and reconsider the appropriateness of the patient's current treatment plan and make modifications to meet their patient's medical needs. Because there are no established systematic and quantitative measures at this time, it is difficult to determine the effectiveness or the impact of the intervention, but there has been some general positive feedback from providers who receive the letters.

Idaho's SMA identifies and sends educational letters with the CDC Guideline for Prescribing Opioids for Chronic Pain to the prescribers of the 150 patients with the highest MME/day in the state. Prescribers represent a mix of specialties, though many are pain management providers. Idaho has evaluated the impact of these letters and has noted a decrease in average daily MME after a six month follow up. However, not all providers have responded to the letters, so the Idaho SMA has instituted the practice of denying prior authorizations for high dose opioids until a response to the letter is received. Idaho recommends that states considering similar mailings be prepared to consistently and repeatedly remind providers who prescribe high doses of opioids to review the CDC Guidelines and inform them of risks associated with such practices.

The Oklahoma SMA also sends educational letters, targeting clinicians who have patients that appear to be "doctor shopping" (those with four doctors and four pharmacies in a 90 day period). These letters, along with other initiatives, has resulted in a decrease in the number of multiple clinician episodes in this population by approximately 50%.

Similarly, Tennessee provides quarterly "report cards" to their highest prescribers of opioids. Outcomes for this activity have been difficult to measure as each report lists different clinicians, but after conversations with many of the providers, the Tennessee SMA reports that many have changed their prescribing habits due to the report card. Tennessee elected to include multiple measures (called "hot buttons") in the report to improve the scope of information, including, percentage of short-acting vs. long-acting opioids; use of pure vs. combination opioids; benzodiazepine and carisoprodol denials; average MMEs; use of methadone for pain; and concurrent prescription with a hypnotic or stimulant. The report ranked clinicians by mean and standard deviations over the mean for each measure. Tennessee recommended strongly that such a report card initially be used as an educational intervention, with clinicians who continue to be outliers in future rounds to be referred for investigation. Their report card contains the following paragraph: "We consider this retrospective review to be educational. However, if comparing your

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prescribing patterns show that you are an outlier compared to others, our goal is that you will consider making adjustments in those particular areas.....Clinicians who continue to be outliers compared with their peers may be referred by the DUR Board to TennCare's Provider Review Committee for their consideration."

New Hampshire Program Integrity is working to bring together stakeholders in a collaborative education effort. This effort would cross many entities and would need input from the following: PDMP to use data to validate the need; New Hampshire Boards of Medicine, Pharmacy and Licensure, perhaps to request that "opioid prescribing and alternatives" education be a licensure or CEU requirement; collaboration of the Bureau of Drug and Alcohol Abuse Services, which reviews clinical practices at SUD/OUD providers; Medicaid Office of Business and Policy and its subset Pharmacy Program for their policy input; and OUD/SUD providers, pharmacies and constituent groups. This list may not be all inclusive as likely others would be needed to come to a consensus on how to educate multiple population, what to use for materials, and how wide an audience to target.

Lastly, Utah is working on informing pharmacy staff about mechanisms available to them to report potential fraud. In a partnership between the Utah SMA and OIG, Utah is conducting annual provider trainings in this area and is working to produce correspondence targeting pharmacies to help train them on fraud reporting.

Weaknesses and Challenges

Limited resources and funding for development and mass distribution of educational materials for providers and beneficiaries is a shared challenge for states, and was reported to be a common barrier to SMAs developing their own educational materials.

A lack of funding for state DUR board work also limits its ability to effectively conduct and expand its interventional efforts and initiatives.

Letters to clinicians based on prescribing behavior was another source of challenges cited by states. Oklahoma reported that identification of providers through data analysis, as well as generation of the letters themselves, can be a time consuming and resource-intensive process. Tennessee cautioned that it is very difficult to calculate true MMEs and claims for benzodiazepines, carisoprodol, and methadone, because of the frequency with which beneficiaries will pay in cash instead of allowing a claim to be submitted to Medicaid. This makes identification of clinicians difficult to accomplish accurately.

SMAs are also limited in their ability to sanction clinicians and beneficiaries unlike in other government-run benefit programs such as the federal Supplemental Nutrition Assistance Program. Sanctioning providers and beneficiaries from the Medicaid can be difficult without defined policy and regulations.

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Obstacles surrounding mass communication is also a gap, particularly those sent via email where the primary challenge cited was the messages being filtered out as spam, and thus never viewed by the intended recipient.

Educational Efforts for Beneficiaries

Background

Work focused on beneficiary education is a critical element of any initiative combating the opioid epidemic. Without a focus on education, many initiatives may be at risk of falling short of their goals. In addition to commonly known educational channels such as social media, Medicaid websites that provide information and resources for beneficiaries, and public health campaigns on recovery and addiction help, states discussed some other promising practices to educate beneficiaries on opioid initiatives.

Promising Practices and Recommendations

States are working to improve proactive counseling by providers when an opioid is prescribed as well as beneficiary acknowledgment of receiving information on use and risks of opioids. In the state of Pennsylvania, some Medicaid clinicians require patients to sign a pain management agreement. It includes full disclosure of all medication and restriction to only treat with a single practitioner for pain needs. In Texas, chronic pain management clinicians must include in the medical record that they provided education to the patient and that the patient entered into a written pain management agreement.

States have also made efforts to improve education on specific opioid related projects. For example, Louisiana issues standardized letters to

Promising Practices: Educational Efforts for Beneficiaries

- Implement pain management agreements with full disclosure of all medication information and restriction to only treat with a single practitioner for pain needs.
- Issue standardized letters to beneficiaries explaining various initiatives (e.g., lock-in program, case management) and how the initiatives will help them to better utilize Medicaid benefits.
- Through flyer campaigns in provider offices, educate beneficiaries on what constitutes fraud and when and how to report it.

beneficiaries explaining how their lock-in program will help them better utilize Medicaid benefits. Illinois and Mississippi are taking a similar approach and emphasizing the positive aspects of access to better care through case management.

New York State's Office of Aging for Medicare and Medicaid developed an educational outreach program pilot that stresses the importance of protecting Medicaid cards, bills, and prescription medications. They found the initiative to be effective and expanded it statewide.

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Lastly, South Carolina's Medicaid Recipient Fraud Unit organized a campaign that issued flyers to be posted in clinicians' offices. The flyers educated beneficiaries on what constitutes fraud (for example, if they suspect that someone is selling their medications or using another person's Medicaid card) and when and how to report it.

Federal Government Opportunities to Support States

States made a variety of suggestions on how CMS and other federal agencies could help support provider and beneficiary educational efforts:

- California would like the federal government to assist in provider educational work in several ways, including to work closer with medical boards around the nation to increase communication and education for providers, assist states with increasing access to medication-assisted treatment, and provide more education regarding naloxone.
- California and Michigan suggested that the federal government encourage standardization of Continuing Medical Education (CME) requirements or recommendations on opioid prescribing, patient pain management, and OUD.
- Idaho would like the federal government to develop messaging for providers that increasing narcotic doses is not the only option to treat chronic non-cancer pain.
- The District of Columbia would like the federal government to help fund DUR board interventional efforts and provide clarification on the Health Insurance Portability and Accountability Act (HIPAA)⁸⁶ regulations regarding sharing information among different health care professionals and PBMs.
- Several States requested that CMS develop a centralized location or toolkit that pulls together government educational resources (e.g., from CDC, SAMHSA, HRSA, etc...) for different audiences for states to access and disseminate.
- Several states would like the federal government to develop standardized dosing criteria for acute and chronic pain. Ohio and Pennsylvania suggested that the federal government develop a Surgeon General warning, similar to cigarettes, to ensure that all those receiving opioid prescriptions are aware of the associated risks.

Conclusion

The information contained in this compendium was produced as a result of interactive discussion between state and federal partners. Over 70 promising practices for implementing mitigation activities and programs have been identified for the top four vulnerabilities: (1) Prescription Drug Monitoring Programs; (2) Prescribing Practices and Policy Issues; (3) Oversight Issues; and (4)

⁸⁶ HHS Office of the Secretary, Office for Civil Rights, & OCR. (2013, July 26). Summary of the HIPAA Security Rule. Retrieved from https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html

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Educational Needs for Providers and Beneficiaries. Perspectives were shared that address potential challenges to develop consistent promising practices to ensure optimal and efficient implementation of mitigation strategies that address these vulnerabilities. Discussion focused on using policy, technical development, innovative payment models and programs, data analysis, outreach and partnerships, and fraud reduction approaches to address the prioritized vulnerabilities.

The federal government and states' missions to address the opioid epidemic are far from complete. CMS hopes that this *Compendium of Promising Practices* will provide states and other stakeholders with a useful tool to reference when implementing opioid mitigation activities and programs. CMS also hopes that sharing the document publicly will encourage constructive comments and the development of additional promising practices. CMS envisions developing additional MII opioid courses that continue and expand on these discussions, and that include federal agencies and states that were unable to attend this course. Additional seminars and conferences may also allow for discussion of the larger number of vulnerabilities identified in this MII course beyond the four that were prioritized and discussed. The goal of releasing this compendium is to promote discussion and consideration of various opioid mitigation activities that may ultimately decrease opioid related deaths from both prescription and illegal opioids throughout the United States.

Appendix A - MII Faculty and Participants

*Denotes Faculty

State/Organization	Last Name	First Name	Title
Alaska	Brown	Timothy	Mental Health Clinician III
Arizona	Abdulhai- Mollahosseini	Chaza	Program Integrity Auditor

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Florida	Rubin	Kelly	Senior Pharmacist
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Indiana	Flynn	Kelly	Director, Policy & Program Development
Indiana	Ross	John	Pharmacy Clinical Programs Manager
Indiana	Selig	Becky	Investigation & Coordination Manager
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Kentucky	Douglass	Charles	Assistant Director of Policy and Operations
Kentucky	Jones	Chandra	Branch Manager
Louisiana	Knecht	Paul	Pharmacist 4
Maine	Osgood	Denise	Program Manager
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Michigan	Giering	Matthew	Lead Investigative Analyst

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Mississippi	Reno	Laura	DOM-Medicaid Nurse Bureau Director
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*Missouri	Valley	Michael	Investigator II
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New Hampshire	Chavanelle	Marylynne	Program Specialist 4
New Hampshire	Cioffi	Mark	Analyst
New Jersey	Jacquish	Brenda	Medicaid Review Analyst
New Jersey	Jaskir	Vira	Medicaid Fraud Investigator
New Jersey	Lasher	Ekta	Investigator
New Mexico	Medina-Lujan	Lisa	Program Administrator
New Mexico	Roybal	Max	MA-O
New York	Gilbert	William	Investigative Spec 4

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North Carolina	Thompson	John	Director
North Dakota	Murphy	Alexi	Assistant Administrator, Pharmacy Services
North Dakota	Joyce	Brendan	Administrator, Pharmacy Services
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*Office of Inspector General	Krause	Kathy	Special Agent/Operations Officer
Ohio	Early	Lloyd	Special Agent in Charge, MFCU
Ohio	Barger	Michelle	Pharmacologist
Ohio	Hayes	Tracy	Medicaid Health Systems Administrator
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*Pennsylvania	Mailey	Pamela	Division Director
South Carolina	Fowler	Richard	Program Coordinator
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*South Carolina	Overbaugh	Larry	Health Care Fraud Investigator
*Substance Abuse and Mental Health Services Administration	Fan	Jennifer	Public Health Advisor

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Tennessee	Mayo	Ronda	Project Manager
Texas	Coney	Catherine	Chief Pharmacy Officer
*United States Attorney's Office	Falkinburg	Thomas	Assistant Director
*United States Attorney's Office	Wilson	Karen	Program Manager/Training Specialist
Utah	Cottrell	Gene	Inspector General
Utah	Facer	William	Investigator
Vermont	Short	Steve	Associate Director of Beneficiary Fraud
Virginia	McQueen	Jeanette	Health Care Compliance Analyst
*Washington State	Best	Scott	Clinical Review Unit Manager

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Appendix B – Promising Practice Summary

Promising Practices

PDMP Access, Enforcement and Data Sharing Across State Lines

- Require clinicians to check the PDMP both before writing and filling a prescription for new Schedule II controlled substances.
- > PDMP follow up check with each refill or every 90-180 days.
- ➤ Require clinicians to check PDMP for concurrent opioid, benzodiazepine, and carisoprodol prescriptions.
- Require a one year look back period during PDMP checks.
- Establish fines against clinicians who do not comply with requirements to check/update the PDMP.
- Establish flags or fines against pharmacists who dispense a refill early.
- Require that all prescriptions, including those paid in cash, be entered to PDMP.
- ➤ Allow clinicians to delegate PDMP access to support staff.
- Share PDMP data with other states (at a minimum, with all neighboring states).
- Allow PDMP access to healthcare providers, pharmacists, patients, researchers, health occupations licensing boards, and public health and safety agencies.
- ➤ To the extent state law permits, perform regular analyses of PDMP data for PI purposes. As appropriate, make referrals to law enforcement, MCOs, CMS, state Patient Review and Restriction (PRR) program, etc.

Improvements and System Changes for PDMPs

- Develop alerts that automatically flag beneficiaries who demonstrate potential doctor shopping or opioid abuse.
- Include morphine milligram equivalent (MME) calculations for common opioid medications.
- Display beneficiaries' daily MME calculations.

Patient Review and Restriction (PRR)/Lock-in Programs

- Make PRR criteria and policies consistent across FFS and MCOs
- Define lock-in criteria clearly

Alignment with CDC Guidelines for Prescribing Opioids for Chronic Pain

- Establish limits on days' supply, MME, or both for initial prescriptions of opioids:
 - o 3 to 7 day supply maximum
 - o 90 daily MME maximum.
- Require prior authorization over quantity limits and documentation of other nonpharmacologic and non-opioid therapies utilized or used concurrently.

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- Require a prescription for immediate release opioid formulations before extended release formulations.
- Require prescribers to use a standardized Opioid Analgesic Treatment Worksheet to request overrides and prior authorizations for medically necessary quantities of opioids in excess of dose and quantity limits.
- Track utilization trends and financial savings and compare to volume and type of complaints received about policies from members and clinicians.

Provider Enrollment and Screening

- Configure payment system to automatically deny claims for prescribers without a Medicaid provider number.
- Require state medical boards to cease the practice of allowing problematic providers to rescind their licenses in order to avoid disciplinary action, as that makes it difficult for other states to identify problems with the provider's history.

Continuing Education on Opioids

- Require training on pain management and the misuse and abuse of controlled substances on an annual basis or with each license renewal.
- Link CME requirements to licensure to make requirements easy to track and enforce.
- Authorize suspension or revocation of a registration for failure to complete such training.
- Establish additional continuing education requirements for any pain management clinic staff or specialty.
- Establish criteria and plan to evaluate success of the education requirements.

Initiatives for Certain At-Risk Populations

- ➤ Build care management metrics into Managed Care Plans to make it easier to assess outcome measures.
- ➤ Provide access to a full continuum of SUD treatment services, covering both physical and behavioral treatments.
- Expand short-term SUD inpatient detoxification and residential treatment access, increase payment rates for existing SUD treatment services, add Peer Support services, require SUD Care Coordinators at all MCOs, and organize provider education, training, and recruitment activities.
- Perform pre-screens of potential providers who apply to enroll as inpatient OUD treatment organizations.
- > Institute "Pay for Performance" measures for inpatient OUD treatment centers that recognize efficient admission for and successful outcomes of treatment.
- Establish a system to refer beneficiaries identified as being "at risk" through their lock-in program to behavioral health/OUD treatment services.

Creative Cooperation

- Under direction of the Governor, form a task force to develop recommendations address the crisis
- Develop statewide guidelines on appropriate opioid prescribing for chronic pain (consistent with CDC *Guideline*), acute pain, and post-acute pain Develop educational resources for providers for communicating to patients about pain
- Implement an opioid prescribing quality improvement program among Medicaid providers whose prescribing behaviors are found to be outside of community standards
- Convene regular meetings with stakeholders to share information on new policies and discuss issues relevant to health care practice

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- Interview people with OUD to gain insights into their experiences, needs, and behaviors
- Have program integrity staff participate in policy making in order to balance competing priorities of program integrity staff and policy makers

Fraud Reduction Practices

- Require electronic prescriptions for controlled substances.
- Consider a requirement to present photo identification to access services or pick up prescriptions.
- For laboratory testing:
 - o Require basic, qualitative test before Medicaid will cover the more expensive quantitative screen.
 - o Implement a quantity limit of five qualitative and quantitative tests per quarter.
 - o Only cover services at participating labs.
- Perform claim audits and analyses to identify laboratory and ordering provider outliers and refer suspicious activity to Medicaid Fraud Control Units (MFCU) or law enforcement for investigation.
- Do not permit Medicaid beneficiaries to fill prescriptions out of state, except in border states, or require prior authorization for out of state prescriptions:
 - o Combine with eligibility checks to confirm beneficiary still resides in state.

Payment Under the Medicaid Provider Enrollment Agreement

- Consider policy that makes it a violation of the Medicaid provider agreement to accept cash payment from a beneficiary in lieu of submitting a claim to Medicaid:
 - o When a provider has been identified as violating this policy, issue a warning.
 - o Consider removing those providers from Medicaid if the behavior continues.
 - o Consider enrolling and including pharmacists under this policy.
- Use PDMP data to identify beneficiaries paying cash for prescriptions.
- When the PDMP is not accessible to SMA/PI staff, consider asking pharmacies to notify Medicaid when they receive cash payments from beneficiaries.

Clinician and Beneficiary Activity

- Include all diagnosis codes in analyses; do not exclude beneficiaries with a previous diagnosis of cancer or Sickle Cell Disease.
- Collaborate with other state agencies to identify aberrant activities, e.g. review data from OIG
 or law enforcement on Medicaid recipients arrested on a drug-related charge; follow up with
 PBM, SMA, and providers as appropriate.
- Review data regularly on prior 18 months to identify and address shifting trends and make referrals to MFCU and law enforcement.
- Promote opioid epidemic awareness and prescribing education campaigns for dentists, a group that has been identified as problem prescribers in many states.

Collaboration among State Agencies and Boards

- Identify aberrant behavior and share information with PI partners and law enforcement; coordinate enforcement activities via regular meetings.
- Recommend Medicaid policy changes based on information learned from criminal investigations.

Communication with MCOs

• Share exclusion list, termination list, and/or suspension list of providers with MCOs:

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- O Confirm that each MCO took similar action or verify that the provider is not in their system.
- Release excluded providers list to public.
- When resources allow, designate staff to work closely with MCOs and keep SMA informed.
- If MCO contracts allow, review for Drug Enforcement Agency (DEA) numbers that are blocked by MCOs (especially for out of state providers).
- Meet regularly with MCOs and consider ways to incentivize the plans to identify and report fraud, waste, and abuse in a timely fashion.

Educational Efforts for Providers

- Develop and distribute educational toolkit to Medicaid clinicians titled Guidelines for Prescribing Controlled Substances for Pain.
- Send communications about opioids via email and posts to Medicaid website, which can track how many emails are opened and website visits received.
- Hold regular DUR board meetings with top outlier prescribers to explain prescribing behaviors; use meetings for targeted educational efforts and to encourage providers to be part of the opioid epidemic solution.
- Send individualized letters to clinicians to alert them to potentially problematic prescribing practices and enclosing CDC Guideline for Prescribing Opioids for Chronic Pain.
- Provide quarterly "report cards" to highest prescribers of opioids, ranking clinicians by mean and standard deviations over the mean for multiple measures.
- Inform pharmacy staff of mechanisms available to them to report possible fraud.

Educational Efforts for Beneficiaries

- Implement pain management agreements with full disclosure of all medication information and restriction to only treat with a single practitioner for pain needs.
- Issue standardized letters to beneficiaries explaining various initiatives (e.g., lock-in program, case management) and how the initiatives will help them to better utilize Medicaid benefits.
- Through flyer campaigns in provider offices, educate beneficiaries on what constitutes fraud and when and how to report it.