DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

CMCS Informational Bulletin

DATE: January 28, 2016

FROM: Vikki Wachino
Director
Center for Medicaid and CHIP Services

SUBJECT: Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction

The Centers for Medicare & Medicaid Services (CMS) has issued a series of Informational Bulletins on effective practices to identify and treat mental health and substance use disorders covered under Medicaid.[1] The purpose of this Bulletin is to highlight emerging Medicaid strategies for preventing opioid-related harms. The epidemic of opioid overdose, misuse and addiction is a critical public health issue that affects the lives of millions of Americans, including those who are enrolled in the Medicaid program. This Informational Bulletin provides background information on overdose deaths involving prescription opioids, describes several Medicaid pharmacy benefit management strategies for mitigating prescription drug abuse and discusses strategies to increase the provision of naloxone to reverse opioid overdose, thereby reducing opioid-related overdose deaths. Wherever possible, the bulletin provides examples of methods states can use to target the prescribing of methadone for pain relief, given the disproportionate share of opioid-related overdose deaths associated with methadone when used as a pain reliever.

Background

Opioid misuse, overdose and addiction occurs in only a subset of individuals prescribed opioid medications for pain relief. However, because many individuals take opioids, the number of Americans affected is significant. According to the Centers for Disease Control and Prevention (CDC), deaths due to prescription opioid pain medication overdose in the United States have more than quadrupled from 1999 to 2011.[2] Of the 43,982 drug overdose deaths in 2013, 37 percent were associated with prescription opioid analgesics (e.g., oxycodone, hydrocodone and methadone).[3] A primary driver of the rapid rise in opioid overdose deaths was the increased

[1] Additional Informational Bulletins on behavioral health can be found at: http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/mental-health-services.html.
[2] Chen LH, Hedegaard H, Warner M. Drug-poisoning deaths involving opioid analgesics: United States, 1999–2011. NCHS data brief, no 166. Hyattsville, MD: National Center for Health Statistics. 2014.
[3] Hedegaard H, Chen LH, Warner M. Drug-poisoning deaths involving heroin: United States, 2000–2013. NCHS data brief, no. 190. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics. 2015. Available at http://www.cdc.gov/nchs/data/databriefs/db190.htm.

number of prescriptions for opioid pain medications, especially prescriptions associated with high doses, longer course of treatment and in conjunction with benzodiazepine use.[4,5] This increased prescribing was driven by concerns about insufficient treatment of pain and lack of accurate information about the potential for addiction.[6]

In addition to the increase in drug-related deaths, the rise in opioid prescribing has led to increases in the prevalence of opioid use disorder[7]. Inappropriate opioid prescribing can also result in costly medical complications such as nonfatal overdoses, falls and fractures, drug-drug interactions and neonatal conditions. These complications result in costly, preventable healthcare expenditures and cause an incalculable amount of emotional suffering.

Combatting the epidemic of opioid misuse, overdoses and addiction is the focus of a Department of Health and Human Services multipronged initiative. The initiative involves actions to improve opioid prescribing and risk mitigation strategies, increase the dissemination of overdose prevention education and expand use of naloxone (a prescription drug that reverses opioid overdoses) as well as access to substance use disorder (SUD) treatment, including medication assisted treatment for opioid use disorders.

Research shows the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid beneficiaries are prescribed painkillers at twice the rate of non-Medicaid patients and are at three-to-six times the risk of prescription painkillers overdose. [8,9] North Carolina found that while the Medicaid population represented approximately 20 percent of the overall state population, it accounted for one-third of drug overdose deaths, the majority of which were caused by prescription opioids.[10] One study from the state of Washington found that 45 percent of people who died from prescription opioid overdoses were Medicaid enrollees.[11]

Though all prescription opioids can contribute to unintentional overdose and death, methadone in particular accounts for a disproportionate share of opioid-related overdoses and deaths. To address this, many state drug utilization review programs already incorporate utilization management criteria addressing the use of methadone. In order to reduce prescription opioid-related harms, states are encouraged to consider additional steps to reduce the use of methadone

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[4] Imtiaz S, Shield KD, Fischer B, Rehm J. Harms of prescription opioid use in the United States. *Subst Abuse Treat Prev Policy.* 2014;9:43.

[5] Baumlatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796-801.

[6] Meier B. A World of Hurt: Fixing Pain Medicine's Biggest Mistake. New York: New York Times e-book; 2013.

[7] Paulozzi LJ, Jones CM, Mack KA, Rudd RA. Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999—2008. MMWR 60(43); 1487-1492.

[8] Sharp MJ, Melnik TA. Poisoning deaths involving opioid analgesics-New York State, 2003-2012. *Morb Mortal Wkly Rep* 2015; 64:377-380.

[9] Coolen P, Lima A, Savel J, et al. Overdose deaths involving prescription opioids among Medicaid enrollees—Washington, 2004-2007. *Morb Mortal Wkly Rep.* 2009; 58:1171-1175.

[10] Whitemire JT, Adams, GW. Unintentional overdose deaths in the North Carolina Medicaid population: prevalence, prescription drug use, and medical care services. *State Center for Health Studies*. August 2010(162):1-11.

[11] Coolen P, Lima A, Savel J, et al. Overdose deaths involving prescription opioids among Medicaid enrollees—Washington, 2004-2007. *Morb Mortal Wkly Rep.* 2009; 58:1171-1175.

prescribed for pain relief. For decades, methadone has been safely and effectively used in medication assisted treatment for opioid use disorder. Under appropriate circumstances, methadone can also be an effective pain medication.[12] However, methadone's pharmacokinetics and pharmacodynamics make it a complex medication to prescribe for pain relief.[13] As methadone's use for pain relief has increased, so has the number of methadone related overdoses.[14,15] While methadone represented less than 5 percent of opioid prescriptions dispensed between 2002 and 2008, it was implicated in one-third of opioid-related deaths during that time period.[16] Between 2004 and 2006, the rate for methadone-related emergency department visits was approximately 23 times greater than for hydrocodone, and six times greater than for oxycodone.[17] The CDC estimates that 30 percent of prescription opioid-related drug overdose deaths in 2009 involved methadone prescriptions for pain.[18]

The increased risk of morbidity and mortality associated with methadone is evident in the Medicaid population. Between 2006 and 2010, the rate of methadone overdose was 10 times greater than that for other prescription opioids among the Washington Medicaid population. Further, overdoses involving methadone were more than twice as fatal as overdoses involving other prescription opioids.[19] Tennessee found that the risk of out-of-hospital death in non-cancer Medicaid patients receiving methadone was 46 percent greater than that for those receiving morphine.[20] Given the disproportionate share of opioid-related overdose deaths associated with methadone prescribed for pain relief purposes, states may consider options to reduce the use of methadone prescribed as a pain reliever as part of their efforts to reduce opioid-related harms.

Given the high impact on the program, Medicaid plays an important role in curbing the epidemic of deaths and injuries from opioid medications. Medicaid programs can encourage the use of safer, effective alternatives to opioid pain medications—in particular, alternatives to methadone prescribed for pain relief—by working collaboratively with other state agencies to educate Medicaid providers about opioid prescribing and dispensing practices. Medicaid programs can consider pharmacy benefit management strategies such as reassessing preferred drug list (PDL) placement, introducing clinical criteria, prior authorization, step therapy, quantity limits, and

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[12] Chou R., et al. Methadone safety: a clinical practice guideline from the American Pain Society and College on Problems of Drug Dependence, in collaboration with the Heart Rhythm Society. *J Pain.* 2014 Apr;15(4):321-37.
[13] U.S. Food and Drug Administration. Information for Healthcare Professionals Methadone Hydrochloride. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm142841.htm. Accessed September 17, 2015.
[14] Ibid.
[15] Ray WA, Chung CP, Murray KT, Cooper WO, Hall K, Stein CM. Out-of-hospital mortality among patients receiving methadone for noncancer pain. *JAMA Intern Med.* 2015; 175(3):420-7. doi: 10.1001/jamainternmed.2014.6294. PubMed PMID: 25599329; PubMed Central PMCID: PMC4346542.
[16] Webster, L, et al. An analysis of the root causes for opioid-related overdose deaths in the United States. *Pain Medicine* 2011; 12:S26-S35.
[17] Ibid.
[18] Paulozzi LJ, Jones, CM, Mack KA. . Vital signs: risk for overdose from methadone used for pain relief–United States, 1999-2010. *Morb Mortal Wkly Rep.* 2012;61,493-7. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm.
[19] Fulton-Kehoe D, et al. Opioid poisonings in Washington state Medicaid: trends, dosing, and guidelines. *Medical Care* 2015; 53(8):679-685.
[20] Ray, W, et al. Out-of-hospital mortality among patients receiving methadone for noncancer pain. *JAMA Intern Med.* 2015; 175(32):420-427.

implementing drug utilization review (DUR) processes. These strategies should be revisited continually as the nature of the opioid epidemic evolves and new information emerges. States can also work to increase access to (and use of) Prescription Drug Monitoring Programs (PDMPs) to monitor opioid prescribing. Importantly, as part of a comprehensive strategy to address opioid use disorder and reduce opioid-related overdose deaths, states can consider strategies to increase the provision of naloxone and medically necessary substance use disorder treatment services. CMS initiatives and opportunities regarding substance use disorder are discussed at the end of this Bulletin.

Effective Medicaid Pharmacy Benefit Management Strategies

Opioid pain medication is one of many options to address pain relief; however, it is associated with significant risks such as sedation, cardiac arrhythmias, increased risk of falls and the development of substance use disorders.[21] Reinforcing provider awareness about the appropriate use of opioid pain medications, as well as non-opioid analgesic options, is crucial to decreasing inappropriate opioid prescribing. Studies show limited evidence of long-term beneficial effects of long-term opioid therapy in improving chronic pain and functioning.[22,23] In addition to patients' clinical morbidities, the risks associated with opioid use vary depending on numerous factors including the dose, type, prescribed quantity, duration of treatment and the potential for drug-drug interactions including those precipitated by the concomitant use with other central nervous system depressants or sedatives (e.g. benzodiazepines) that increase the risk of respiratory depression.[24] There is no formula for predicting which individuals who are prescribed opioid medications for pain will develop a substance use disorder (a dependency or addiction) or suffer an overdose. However, states can assist in minimizing these risks by implementing the following approaches:

Provider Education

States can improve opioid medication prescribing and dispensing practices by (1) supporting training for health care professionals (e.g., pharmacists, nurses, other prescribers); (2) disseminating opioid prescribing guidelines which include protocols for safer prescribing of methadone; and (3) providing clinician feedback on prescribing. These tools can highlight the importance of a complete patient assessment prior to prescribing opioid medications that would include an evaluation of the underlying etiology of pain and a screening for risk factors (e.g., substance use disorders, contraindicated medications, mental health conditions as well as parameters that could indicate higher risk for cardiac, hepatic or pulmonary adverse events like respiratory depression) that are associated with a higher probability of opioid-related harms.

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[21] Chou R, Turner JA, Devine EB, et al. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health Pathways to Prevention workshop. *Ann Intern Med.* 2015; 162:276-286.
[22] Ibid.
[23] Agency for Healthcare Research and Quality. the effectiveness and risks of long-term opioid treatment of chronic pain. AHRQ Pub. No. 14-E005-1-EF http://effectivehealthcare.ahrq.gov/ehc/products/557/1988/chronic-pain-opioid-treatment-executive-141022.pdf. Published September 204. Accessed September 17, 2015.
[24] Roxane Laboratories, Inc. Dolophine® Hydrochloride CII (Methadone Hydrochloride Tablets, USP). http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/006134s028lbl.pdf. Accessed September 17, 2015.

These tools should also emphasize the need for ongoing patient monitoring. Educational materials can offer guidance on the decision to initiate opioid pain medications and, if appropriate, which type of medication to initiate. For instance, methadone, which is characterized by complicated and variable pharmacokinetics and pharmacodynamics, should be initiated and titrated cautiously only by clinicians who are familiar with its use and risks.[25] Recent guidelines provide monitoring recommendations for prescribing methadone to specific patients.[26]

Several state Medicaid agencies have been part of collaborative efforts to educate providers about opioid medication prescribing. For example, Washington State developed an opioid prescribing guideline in 2007 which has since been updated that uses an interagency state work group in collaboration with clinical experts.[27] As part of a comprehensive effort, overdose deaths and hospitalizations for prescription opioids in Washington have declined in recent years.[28]

Preferred Drug List

Medications are often designated as preferred or non-preferred drugs by the pharmacy and therapeutics committee (P&T) or DUR board of the state Medicaid agencies or contracted managed care organization. In most cases, providers are permitted to prescribe preferred drugs without seeking prior authorization. However, if a drug is listed as non-preferred on the PDL, the providers are usually required to obtain approval from the state Medicaid agency or managed care plan before the drug is paid for. States may subject a drug to such prior authorization consistent with the requirements of section 1927(d)(5) of the Act.

Given the significant evidence suggesting that the use of methadone contributes disproportionately to opioid overdose and deaths, the known complexities with appropriately prescribing this medication as well as the widespread availability of other medications to treat pain, we urge that states remove methadone for pain (outside of end of life care) from their preferred drug lists. This is consistent with the recommendation from the CDC that methadone should not be considered a drug of first choice by prescribers or insurers for chronic non-cancer pain.[29] States that provide a prescription drug benefit will still have to make the drug available to Medicaid patients who need it, as long as it is a covered outpatient drug. By removing the drug from preferred status, states have the option of limiting its use to only those patients for whom treatment with other pain medications is ineffective.

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[25] Chou R, Fanciullo GJ, Fine PG,et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain.* 2009:10(2):113-130.e22.

[26] Chou R, Cruciani RA, Fiellin DA, et al. Methadone safety: a clinical practice guideline from the American Pain Society and College on problems of drug dependence, in collaboration with the Heart Rhythm Society. *J Pain.* 2014; 15(4):321-337.

[27] Agency Medical Directors' Group. Interagency Guideline on Prescribing Opioids for Pain, 3rd edition. http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf. Published June 2015. Accessed September 17, 2015.

[28] Franklin G, Sabel J, Jones CM, et al. A comprehensive approach to address the prescription opioid epidemic in Washington State: milestones and lessons learned. Am J Public Health. 2015 Mar; 105(3):463-9. doi: 10.2105/AJPH.2014.302367. Epub 2015 Jan 20.

[29] Paulozzi LJ, Jones, CM, Mack KA. . Vital signs: risk for overdose from methadone used for pain relief–United States, 1999-2010. *Morb Mortal Wkly Rep.* 2012;61,493-7. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm.

Clinical Criteria

States may decide that methadone should remain a preferred drug while requiring edits that allow claims to be authorized for payment at the point-of-sale (POS) only when the recipients' claims and/or diagnosis history satisfy each of the clinical criteria established to ensure appropriate utilization of the drug. For example, when states process methadone claims, the automated review of the recipients' claim histories could confirm the presence or absence of any recent claims for benzodiazepines or long-acting opioids within a specified time period. The concomitant use of methadone with these medications could be precluded due to drug-drug interactions that increase the recipients' risk of respiratory depression and opioid overdose. Additionally, before methadone claims are paid, the automated review could ascertain chronic pain diagnosis in the recipients' diagnosis histories. When methadone claims do not satisfy these clinical criteria, payment would not be immediately authorized at the POS. Instead, the claims would be subject to the prior authorization process consistent with the requirements of the Act, which would require the provider to obtain approval from the state Medicaid agency or contracted managed care organization.

Step Therapy

A Medicaid program may require the trial of another agent prior to the use of a specific drug. For example, a state that has methadone on its PDL may require that, before authorizing payment, an examination of the recipient's claims history is performed to ensure that the recipient used another preferred, long-acting opioid for a specified duration before beginning methadone therapy.

The state of Vermont implemented prior authorization criteria which involves step therapy for methadone recently. Among other criteria, this state has a requirement that before initially being prescribed methadone for pain, patients must have documented side effects, allergies, or treatment failure to a preferred, long-acting opioid.

Prior Authorization

Prior authorization typically means that the Medicaid agency or the contracted managed care organization will not pay for Medicaid beneficiaries' medication unless the provider has obtained permission before prescribing the drug. The criteria for prior authorization often reflect evidence-based standards consistent with the compendia listed in 1927(g)(1)(B). For example, prior authorization can help ensure that prescriptions for pain in doses higher than 30 milligrams of methadone per day (the recommended maximum daily starting dose) are appropriate.

Virginia's Medicaid program is one of 19 states with prior authorization criteria for long-acting opioid pain medication. Before long-acting opioids can be approved for managing chronic, nonmalignant pain, providers must (1) document that there is treatment plan that includes a diagnosis, the goals of therapy as well as an assessment of addiction risk; and (2) attest that the Virginia Board of Pharmacy PDMP database has been recently reviewed. Patients must sign a pain management contract that addresses the consequences of unexplained loss or shortage of

medications as well as those associated with obtaining similar prescription medications from other prescribers. Patients must also sign an agreement to use only one pharmacy further described below in patient review and restriction programs.

Quantity Limits

A state Medicaid agency or contracted managed care organization may impose quantity limits on medications as a way to promote safe and appropriate use of a medication, ensuring that they are not overprescribed. For example, quantity limits may be useful in verifying that a methadone prescription for pain is prescribed only for a specified duration, so the prescriber can reassess the recipient periodically. A significant percentage of states apply quantity limits to opioid products prescribed for pain.

Drug Utilization Review

Retrospective and concurrent drug utilization review (DUR) measures can be used to identify potentially inappropriate prescribing practices. States are encouraged to exercise sound clinical judgment and utilize available resources to aid their DUR programs and P&T committees. We note the availability of the Pharmacy Quality Alliance's three measures of potential opioid misuse and abuse. These measures include receiving opioids (1) at high dosage, (2) from multiple prescribers and pharmacies, and (3) at high dosage and from multiple prescribers and pharmacies.[30] In order to optimize care while discouraging fraud, waste and abuse of prescribed opioids, states are encouraged to consider implementing programs that provide ancillary care for beneficiaries diagnosed with chronic pain who have been found to be receiving unusually high doses of opioids, seeing multiple prescribers or pharmacies.

Increase Access to and Use of State Prescription Drug Monitoring Programs

PDMPs collect data from pharmacies, outpatient hospital pharmacies, outpatient clinics and other data submitters on dispensed, controlled substance prescriptions. To oversee its PDMP, each state designates an agency which may include, but is not limited to health departments, pharmacy boards or a state law enforcement agency. Additionally, each state controls who will have access to the database and for what purpose. Authorized users can obtain these data through a secure and electronically-accessible database. PDMPs have been shown to be effective in preventing drug diversion.

CMS understands that many Medicaid agencies have reported barriers that hinder their ability to utilize the PDMP database in their state. These barriers include lack of funding to maintain operation of the PDMP, prescribers not accessing the database to obtain patient history, lag time in submission of prescription data to the database, administrative limitations denying real-time access and restrictions limiting Medicaid agency access to the database. Reasons for limiting Medicaid agency access to PDMPs include state laws prohibiting Medicaid agency access, Medicaid pharmacy staff being denied access because they are not directly delivering healthcare, database access being limited to law enforcement members or access allowed only for active

[30] Pharmacy Quality Alliance. PQA Measure Development. 2015. http://pqaalliance.org/measures/default.asp. Accessed September 17, 2015.

investigations. In addition, some states allow patients to opt out of having their prescriptions entered into the database. However, despite these barriers, some states allow Medicaid programs to access PDMP data so they can better identify potential inappropriate prescribing and use of controlled prescription drugs, such as opioids, and some Medicaid agencies require prescribers and pharmacies to access patient history in the PDMP database prior to prescribing and dispensing controlled substances, thereby enhancing states' DUR program oversight activities. There are several strategies states can pursue to increase PDMP adoption and functionality. For example, in states where Medicaid can access PDMP information, state Medicaid programs can consider including language into provider agreements and managed care contracts to require providers to access their state PDMP as a condition of provider agreement and payment, to the extent that such access is permissible under applicable Federal and state laws. Further, states can harness the benefits of their PDMP use by requiring mandatory electronic prescribing of controlled substances if consistent with applicable Federal and state laws. To enhance functionality, states could develop real-time data infrastructure between pharmacy POS systems and PDMPs to capture cash transactions. This would enable PDMP users to determine if beneficiaries are filling opioid prescriptions outside of the Medicaid benefit and/or are using multiple pharmacies. Such programs would be subject to applicable Federal laws as well as state privacy laws. In states where the Medicaid agency has limited access to the PDMP, state Medicaid directors could advocate directly with State Boards of Pharmacy and state legislators to promote access. Successful collaborative initiatives to reduce prescription opioid abuse in Oklahoma and Washington included promoting full access to PDMP data for monitoring and data research purposes.[31,32]

In 2013, New York required prescribers to check the state's PDMP before prescribing opioid pain medications. Since 2013, they reported a 75 percent drop in the number of patients who used multiple prescribers and pharmacies for controlled prescription drugs.[33] In concert with related policies targeting inappropriate opioid prescribing, Florida found that oxycodone-caused mortality declined 25 percent in the month immediately following implementation of Florida's PDMP.[34] Other states showed a decrease in controlled substance prescriptions and patients visiting multiple practitioners seeking opioid pain medications. In addition, states were able to identify patients in need of addiction or pain management support. Improvements in prescribing behaviors and decreases in adverse effects are expected to be even greater when the PDMP is part of a health information technology system. PDMPs are most effective when they are used by all clinicians, don't interfere with access to medicine for legitimate medical needs and protect sensitive personal and health information.[35]

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[31] State Medicaid interventions for preventing prescription drug abuse and overdose: a report for the National Association of Medicaid Directors. October 1, 2014. Available at: http://medicaiddirectors.org/node/1071.

[32] A state plan: reducing prescription drug abuse in Oklahoma. 2013. Available at: http://www.ok.gov/odmhsas/documents/Rx%20Abuse%20Prevention%20Plan.pdf.

[33] PDMP Center of Excellence at Brandeis University. Mandating PDMP participation by medical providers: current status and experience in selected states.2014. http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps. Accessed on September 17, 2015.

[34] Delcher C, Wagenaar AC, Goldberger BA, Cook RL, Maldonado-Molina MM. Abrupt decline in oxycodone-caused mortality after implementation of Florida's Prescription Drug Monitoring Program. *Drug Alcohol Depend.* 2015; 150:63-8. doi: 10.1016/j.drugalcdep.2015.02.010. Epub 2015 Feb 19.

[35] Islam MM, McRae IS. An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions. *BMC Pharmacol Toxicol.* 2014;15:46.

Patient Review and Restriction Programs

Most Medicaid programs have implemented Patient Review and Restriction programs (PRRs) to address possible patient overuse of opioid medications and other controlled prescription drugs. If a Medicaid agency finds that beneficiaries have used Medicaid services at a frequency or an amount that is not medically necessary, as determined in accordance with utilization guidelines established by the state, the agency may restrict those beneficiaries to obtain Medicaid services from designated providers for a reasonable period of time, Medicaid programs can only impose these restrictions if they (1) give patients notice and an opportunity for a hearing, (2) ensure that restricted patients still have reasonable access to Medicaid services, and (3) exclude emergency services from the restriction as described in 42 CFR 431.54(e). A number of state Medicaid programs including Louisiana, Washington, Oklahoma, Connecticut, Iowa, and North Carolina report that their PRRs have resulted in fewer narcotic analgesic pills prescribed and cost savings.[36]

While states may consider the aforementioned approaches to reduce the risk of prescription opioid-related harm, states should develop policies and strategies that are consistent with the Mental Health Parity and Addiction Equity Act which seeks to ensure that financial and treatment limitations for mental health and substance use disorders are applied no more restrictively than medical/surgical benefits.[37] This includes the use of prior authorization, step therapy and quantity limits which may be seen as treatment limitations that would be inconsistent with the application of the Mental Health Parity and Addiction Equity Act to the Medicaid program. CMS is available to provide technical assistance on these points.

Increasing the Use of Naloxone to Reverse Opioid Overdose

In addition to the pharmacy benefit management and monitoring strategies described above, states can also work to increase the provision of naloxone to reverse drug overdoses and reduce the number of opioid-related overdose deaths.
Naloxone is a drug indicated for the complete or partial reversal of narcotic depression, including respiratory depression induced by opioids including natural and synthetic narcotics, propoxyphene, methadone and certain narcotic-antagonist analgesics. It is also indicated for the diagnosis of suspected acute opioid overdose.[38] Naloxone prevents or reverses the potential life-threatening effects of opioids, including respiratory depression, sedation, and hypotension, thereby allowing an opioid overdose victim to resume normal breathing. Naloxone has not been

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[36] Roberts AW, Skinner AC. Assessing the present state and potential of Medicaid controlled substance lock-in programs. *J Manag Care Spec Pharm*. 2014;20:439-46c.
[37] See CMS State Health Official Letter # 13-001. Re: Application of the Mental Health Parity and Addiction Equity Act to Medicaid MCOs, CHIP, and Alternative Benefit (Benchmark) Plans. Available at http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-001.pdf.
[38] Naloxone hydrochloride FDA-approved drug label Information. Obtained from http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76f7eee1-d524-43a4-a868-ffa9f29638a6.

shown to produce tolerance or to cause physical or psychological dependence[39,40] and is not designated as a controlled substance by the Drug Enforcement Agency. In the absence of opioids or agonistic effects of other opioid antagonists, naloxone exhibits essentially no pharmacologic activity. However, in cases of opioid overdose emergency, naloxone is most effective with rapid onset of action and this requires it to be administered in a timely manner.[41]

In most states, naloxone is not available as an over-the-counter drug. Instead, it can be provided by prescription during the regular course of medical care. Depending on a state's laws, this medication can be provided by pharmacist-initiated collaborative practice agreements, pharmacist prescriptive authority, state authorizing legislation (which protects physicians who prescribe and citizens who administer take-home naloxone), or community-based overdose education and naloxone distribution programs.

To promote ease of access to this potentially life-saving treatment, some communities distribute naloxone kits (that may contain naloxone and syringes fitted with an atomizer for easier nasal administration as opposed to intravenously) and often provide training on the proper use of these products. The first FDA-approved naloxone nasal spray was approved in November of 2015. State Medicaid agencies vary in their coverage of take-home naloxone and the atomizer (i.e., a pump-driven device that sprays injectable naloxone into the nose) for its administration. Some states cover the cost of the drug only after preapproval or prior authorization on the basis of medical necessity. Some only cover the cost of the drug and not the atomizer. Others cover the cost of the drug (with or without the atomizer) only for selected Medicaid populations (e.g., individuals enrolled in managed care, fee-for-service, or an alternative benefit plan).[42] For example, New Mexico's Medicaid program reimburses for naloxone rescue kits for beneficiaries at risk for opioid overdose.[43]

State Medicaid programs, in coordination with other state organizations, have taken the following strategies to improve access to naloxone:

Include Naloxone on the Medicaid Preferred Drug List

Medicaid programs in a number of states such as California and New York include all injectable forms of naloxone including the auto-injectable form of naloxone on their Medicaid Preferred Drug Lists. States that provide a prescription drug benefit are reminded that the Fee-for-Service program and the managed care organization contractors must provide coverage for drugs that are

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[39] Naloxone hydrochloride FDA-approved drug label Information. Obtained from http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76f7eee1-d524-43a4-a868-ffa9f29638a6

[40] Kim D, Irwin K, Khoshnood K. Am J Public Health. 2009 March; 99(3): 402–407. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality.

[41] Naloxone hydrochloride FDA-approved drug label Information. Obtained from http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76f7eee1-d524-43a4-a868-ffa9f29638a6.

[42] Seiler N, Horton K, Malcarney M-B. Medicaid reimbursement for take-home naloxone: a toolkit for advocates. Milken Institute School of Public Health, The George Washington University. 2014. http://publichealth.gwu.edu/pdf/hp/naloxone_medicaid_report_gwu.pdf.

[43] New Mexico Department of Health. Coverage of naloxone under Medicaid announced: expansion of toolkit to help reduce overdose deaths. http://nmhealth.org/news/information/2014/6/?view=88. Published June 18, 2014. Accessed September 17, 2015.

covered outpatient drugs (that is, drugs from manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, unless specifically excluded from coverage by statute), such as the auto-injectable and intranasal formulations of naloxone, whether or not they are included on their Preferred Drug Lists.

Expand Community-Based Naloxone Distribution Programs

Providing naloxone kits to laypeople reduces overdose deaths while being safe and cost effective.[44,45,46] U.S. and international health organizations recommend providing naloxone kits to patients in substance use treatment programs, individuals leaving prison and jail and laypeople who might witness an opioid overdose.[47] As of 2014, the CDC reported that naloxone distributed to laypeople had resulted in more than 26,000 overdose reversals nationwide since 1996.[48] Since 2006, Massachusetts has implemented an overdose education and naloxone distribution program that significantly reduced overdose deaths in the 19 communities.[49]

Expand Access to Naloxone by Making It Available Without a Prescription

On July 16, 2015, Ohio's governor enacted emergency legislation that makes naloxone available without a prescription in the state. With this policy change, pharmacies can now offer naloxone over the counter to individuals cleared by a doctor or health official. Kentucky also enacted a similar approach in 2015 that allowed first responders or members of an opioid user's family to receive naloxone without a prescription.

Offer Training in Overdose Prevention and Response

States such as Rhode Island are expanding the training that they provide for overdose prevention and response. To reduce overdose deaths, this training is being offered to opioid users, their families and friends, addiction treatment program staff, community coalitions, human services providers, correctional staff, first responders, prescribers, and pharmacists.

State Laws That Have Been Enacted To Address Liability Concerns Related to Naloxone

A number of states have passed laws that address both bystander and physician concerns regarding the distribution and administration of take-home naloxone. These laws generally provide legal protection to the physicians who prescribe and to the bystanders ("Good

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[44] Doyon S, Aks SE, Schaeffer S. Expanding access to naloxone in the United States. *Clin Toxicol.* 2014;52:989-992.

[45] Walley A, Xuan Z, Hackman HH, et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ.* 2013;346:1-12.

[46] Coffin PO, Sullivan SD. Cost-effectiveness of distributing naloxone to heroin users for lay overdose reversal. *Ann Intern Med.* 2013;158:1-9.

[47] Opioid overdose prevention programs providing naloxone to laypersons–United States, 2014. *Morb Mortal Wkly Rep.* 2015;64:631-635.

[48] Opioid overdose prevention programs providing naloxone to laypersons–United States, 2014. *Morb Mortal Wkly Rep.* 2015;64:631-635.

[49] Walley A. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ.* 2013;346:fl74.

Samaritans") who possess or administer take-home naloxone. For example, state laws may provide immunity from civil or criminal liability by waiving criminal liability for possession of naloxone without a prescription, laypersons' administration of naloxone, or authorizing prescriptions to third parties other than those at risk of overdose.

Expanding Coverage and Access to Opioid Use Disorder Treatment

As part of a comprehensive strategy to address opioid use disorder, states can assess their Medicaid benefits coverage, delivery systems, payment mechanisms and provider networks for substance use disorder services to ensure that effective treatments are available to beneficiaries when medically appropriate. This Informational Bulletin is the latest in a series of actions CMS has taken to support state efforts to effectively design, deliver and pay for services to treat substance use disorder. CMS is available to assist states in determining how to incorporate additional services and providers into their Medicaid programs, as we believe ensuring access to a robust set of treatment models is critical to combatting opioid use disorder and its healthcare complications.

In July 2014, CMS launched the Medicaid Innovation Accelerator Program (IAP), a strategic support platform designed to support states' ongoing delivery system reforms.[50] Based on our work with states and stakeholders, CMS identified substance use disorder as the first focus area for IAP efforts. The IAP provides states with expert resources, coaching opportunities and hands-on program support to accelerate policy, program and payment reforms appropriate for a robust SUD system. The goal of the IAP initiative on SUD is to support participating states to better identify individuals with SUD, enhance provider capacity to effectively treat individuals with SUD, and expand coverage for promising and evidence-based SUD services, such as medication-assisted treatment.

CMS also recently issued several Informational Bulletins regarding Medicaid coverage for behavioral health conditions, including a joint publication with the Substance Abuse and Mental Health Services Administration, the Centers for Disease Control and Prevention, and the National Institute on Drug Abuse describing best practices, state-based initiatives and useful resources for the delivery of medication-assisted treatment.[51] In January 2015, CMS released an Informational Bulletin addressing early identification and treatment of adolescents with a SUD.[52] Earlier this year, CMS also proposed several rules that, if finalized, would strengthen states' ability to provide services to individuals with substance use disorder. In April 2015, CMS issued a proposed rule that would offer the protections of the Mental Health Parity and Addiction Equity Act to any beneficiary enrolled in a Medicaid or CHIP managed care organization. CMS is currently considering comments on the rule. In May 2015, CMS proposed a rule that would allow states to claim federal funds for managed care beneficiaries who receive crisis stabilization treatment in inpatient and sub-acute crisis facilities. This provision of the proposed managed care rule is designed to improve access to medically necessary short-term inpatient behavioral health services.

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[50] For more information, please visit http://www.medicaid.gov/state-resource-center/innovation-accelerator-program/innovation-accelerator-program.html.
[51] http://www.medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf.
[52] http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.

CMS recognizes the need to improve access to non-hospital based services as well. In July 2015, CMS issued guidance on a new opportunity under section 1115 demonstration authority to develop a full continuum of care for individuals with a SUD, including coverage for short-term residential treatment services not otherwise covered by Medicaid.[53] This new opportunity is geared to support states engaged in broad and deep SUD system transformation efforts, enabling them to provide a full continuum of care by introducing service, payment and delivery system reforms to improve the care for individuals with SUD.

Our efforts directly support the Department of Health and Human Services initiative on opioid abuse and the recent Presidential Memorandum addressing prescription drug abuse and heroin use. In March 2015, Secretary Burwell launched a multi-pronged initiative to decrease opioid overdoses, overdose mortality and the prevalence of opioid use disorder. [54] The Secretary's initiative targets three priority areas: opioid prescribing practices; expanded use and distribution of naloxone; and expansion of medication-assisted treatment (MAT). In October 2015, President Obama issued a memorandum with the goals of reducing prescription opioid and heroin deaths, promoting appropriate and effective pain medication prescribing and improving access to treatment.[55] The President's memorandum directs certain federal departments and agencies to take several actions, including training federal health care prescribers on the appropriate and effective prescribing of opioid pain medications, reviewing health benefit requirements and policies in order to identify any barriers individuals with opioid use disorder would encounter in accessing MAT, and identifying any current practices, such as the use of methadone as a preferred or first-line pain management drug that are inconsistent with the goals of reducing opioid use disorders and overdoses. This bulletin is part of CMS' ongoing effort to support these initiatives.

In addition to considering the pharmacy benefit management strategies described in this bulletin to mitigate the risk of prescription opioid-related harm, states may consider reviewing their benefits coverage, service utilization and other data to assess if Medicaid enrollees with opioid use disorder have sufficient access to MAT services. MAT is the use of FDA-approved medications in combination with behavioral therapies to provide a whole-patient approach to treating SUDs.[56] There is strong evidence that the use of MAT provides substantial cost savings and leads to improved quality of life and health outcomes for individuals with SUD, including opioid use disorder.[57] Buprenorphine, methadone and naltrexone are the three medications approved by the FDA for opioid dependence. Studies have shown that the most effective treatments for opioid use disorders are those that include a set of comprehensive medical, social,

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[53] http://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf.
[54] https://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths.
[55] https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin.
[56] https://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths.
[57] http://www.medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf.

psychological and rehabilitation services that address all the needs of the individual.[58]

Although MAT has significant evidence to support it as an effective treatment, it remains highly underutilized. Many Medicaid programs use benefit design requirements, such as prior authorization, that may reduce the use of and access to MAT. For example, as of 2013 prior authorization was required for the use of buprenorphine-naloxone in 48 Medicaid programs. A number of states also have total lifetime limits on the use of buprenorphine-naloxone, even though the scientific literature shows that opioid use disorder is a chronic disease.[59]
CMS is committed to assisting states in addressing opioid use disorder and providing effective treatment services for individuals with substance use disorder. CMS is available to provide technical support to states assessing access to MAT services for individuals with opioid use disorder.

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[58] Potter, J.S.; Marino, E.N.; Hillhouse, M.P., et al. Buprenorphine/naloxone and methadone maintenance treatment outcomes for opioid analgesic, heroin, and combined users: findings from Starting Treatment with Agonist Replacement Therapies (START). Journal of Studies on Alcohol and Drugs 74(4):605-613, 2013.
[59] Substance Abuse and Mental Health Services Administration. Medicaid coverage and financing of medications to treat alcohol and opioid use disorders. HHS Publication No. SMA-14-4854. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

Resources

Substance Abuse and Mental Health Services Administration. Opioid overdose prevention toolkit. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2014. Available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-474

U.S. National Library of Medicine. MedLine Plus. Prescription Drug Abuse. https://www.nlm.nih.gov/medlineplus/prescriptiondrugabuse.html

U.S. National Library of Medicine. MedLine Plus. Pain Relievers. https://www.nlm.nih.gov/medlineplus/painrelievers.html

Medicare Part D Opioid Drug Mapping Tool. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html

Additional information about the Centers for Medicare & Medicaid Services Medicare Part D opioid over utilization policy is available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

Additional information about Recent Medicaid Prescription Drug Laws and Strategies is available on the National Alliance for Model State Drug Laws is available at: http://www.namsdl.org/

Additional information about State Medicaid interventions for preventing prescription drug abuse and overdose is available in the following document: *Interventions For Preventing Prescription Drug Abuse And Overdose: A Report For The National Association Of Medicaid Directors. October 1, 2014*. Available at: http://medicaiddirectors.org/sites/medicaiddirectors.org/files/public/namd_rx_abuse_report_october_2014.pdf

Additional information about Prescription Drug Monitoring Programs (PDMP) Center of Excellence is available at: http://www.pdmpexcellence.org/

Additional information about the Washington State Agency Medical Directors Group's continuing medical education concerning opioid prescribing is available at: http://www.agencymeddirectors.wa.gov/quality.asp