CENTERS FOR MEDICARE & MEDICAID SERVICES

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Drug Diversion in the Medicaid Program

State Strategies for Reducing Prescription Drug Diversion in Medicaid

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Background

"Drug diversion" is best defined as the diversion of licit drugs for illicit purposes. It involves the diversion of drugs from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary. While drug diversion is not a new phenomenon, States are reporting a significant increase in the problem. In fact, according to the 2010 National Drug Threat Assessment report, "The threat posed by the diversion and abuse of controlled prescription drugs (CPDs), primarily pain relievers, is increasing, as evidenced by the sharp rise in the percentage (4.6 percent in 2007, 9.8 percent in 2009) of state and local law enforcement agencies reporting CPDs as the greatest drug threat in their area." Increased abuse of CPDs has led to elevated numbers of deaths related to prescription opioids, which increased 98 percent from 2002 to 2006.[1]

The National Drug Threat Assessment report further states that, "The most commonly diverted CPDs are opioid pain relievers, according to Drug Enforcement Administration (DEA) and the National Survey of Drug Use and Health (NSDUH) data."[2] Opioid pain relievers are popular among drug abusers because of the euphoria they induce. Opioid pain relievers include codeine, fentanyl (Duragesic, Actiq), hydromorphone (Dilaudid), meperidine (Demerol, which is prescribed less often because of its side effects), morphine (MS Contin), oxycodone (OxyContin), pentazocine (Talwin), dextropropoxyphene (Darvon), methadone (Dolophine), and hydrocodone combinations (Vicodin, Lortab, and Lorcet)."

In addition to opioids, it has been reported that significant diversion is occurring with high cost antipsychotic and mental health drugs, such as aripiprazole (Abilify), ziprasidone (Geodon), risperidone (Risperdal), quetiapine (Seroquel), and olanzapine (Zyprexa), as well as benzodiazepines such as alprazalam (Xanax), clonazepam (Klonopin) and lorazepam (Ativan).

The impact of drug diversion on the Medicaid program goes beyond just the cost of the prescription drugs. There are also the costs associated with doctor's visits, emergency department (ED) treatment, rehabilitation centers, and other health care needs, not to mention the human toll. In 2008, the Drug Abuse Warning Network (DAWN), operated by the Substance Abuse and Mental Health Services Administration (SAMHSA), estimated that prescription or over-the-counter drugs used non-medically were involved

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[1] Figure 18 from the National Drug Threat Assessment- Number of Reported Unintentional Poisoning Deaths with Mention of Opioid Analgesics 5,547 (2002) 11,001 (2006) http://www.justice.gov/ndic/pubs38/38661/index.htm

[2] http://www.oas.samhsa.gov/nhsda.htm

in 1.0 million ED visits. Among the legal drugs, the most common drug categories involved were drugs acting on the central nervous system, especially opioid painkillers and psychotherapeutic drugs (especially sedatives and antidepressants). Opioid painkillers were associated with approximately 306,000 visits and benzodiazepines with 272,000 visits.[3] As entities jointly responsible for the Medicaid program, both CMS and State Medicaid Agencies (SMAs) must take action to make certain that the correct controls and safeguards are in place to ensure prescription drugs are used by their intended beneficiaries and purposes.

Federal Partnerships

The CMS and DEA have established key partnerships in the prevention of drug diversion. The mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. The DEA is responsible for the Controlled Substance Registration File which is a list of 1.3 million active registrants of all entities and provider types that prescribe, administer, procure, and dispense controlled substances. This file contains identifying information of each registrant. In December 12, 2010 CMS issued an Advisory to State Program Integrity Directors on Medicaid Prescription Drug Fraud and Abuse Prevention: Access to DEA Registration File. Further, information on the DEA can be found at the following link: http://www.deadiversion.usdoj.gov.

State Partnerships

On March 25, 2010 CMS and the DEA met with both local and State officials in Ohio to discuss the growing problem of drug diversion in that state. In response to these growing concerns, the CMS Medicaid Integrity Group and the State of Ohio agreed to work collaboratively to reduce improper payments for prescription drugs.

Additionally, CMS in close collaboration with States, is providing education resources through its Education Medicaid Integrity Contractor (Education MIC) to promote best practices and will focus on providers that have been identified as having the high potential aberrant prescribing patterns for five targeted therapeutic drug classes that have also been identified as having potentially high outlier payments. Materials will focus on the importance of prescribing drugs within the dosage guidelines approved by the FDA. Although this collaboration effort is initially being piloted in only 5 States, if the results are promising, plans are in place to expand the education campaign nationally. Also, the Education MIC is developing written materials to help educate providers on areas of drug diversion, including how to identify drug seeking behavior in beneficiaries and appropriate reporting of suspicious fraudulent behavior.

Strategies for Combating Controlled Prescription Drug Diversion in Medicaid

Previous laws enacted to help safeguard against drug diversion include tamper resistant prescription pads. Effective October 1, 2007, Federal law prohibits payments for covered outpatient drugs written on non tamper-resistant pad. As part of State efforts to

[3] http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf

combat drug diversion, States should ensure that this requirement is being enforced. For more information on the tamper resistant prescription pad requirements, including Frequently Asked Questions and a State Medicaid Director Letter, see the CMS website at the following link: http://www.cms.gov/FraudAbuseforProfs/15_TRP.asp#TopOfPage."

One of the first lines of prevention in drug diversion is the ability to identify and screen high risk providers that may facilitate drug diversion. The Affordable Care Act grants States significant new authority to fight fraud and abuse in the area of drug diversion, including the ability to:

- Establish enhanced oversight for new providers,
- Establish periods of enrollment moratoria or other limits on providers identified as being high risk for fraud and abuse,
- Establish enhanced provider screening, and
- Require States to suspend payment when there is a credible allegation of fraud which may include evidence of overprescribing by doctors, overutilization by recipients, or questionable medical necessity.

In addition to these provisions in the Affordable Care Act, there are other actions States can take to prevent and detect problems with drug diversion. Elements of a robust State controlled prescription drug program include:

- Identifying problematic CPD diversion issues within the retroactive Drug Utilization Review (DUR) process. The State of Kentucky's program integrity area has access to a database of all controlled substance prescriptions filled in Kentucky. Access to the system helps identify outliers and reduce the time and cost involved in drug diversion investigations.[4]

- Establishing effective pro-active DUR screenings, such as implementing a prior approval process for high CPD doses or quantities and regularly monitoring for overutilization. The Pennsylvania Medicaid Program, with the help of the DUR board, was able to identify anomalies in utilization as the basis for refining the Medicaid program's prior authorization criteria. A Pharmacy and Therapeutics Committee developed a preferred drug list (PDL) that limits the prescribing habits of physicians to appropriate drugs in each drug class. The PDL is updated twice a year and has proven cost effective. From SFY 2005 to SFY 2007, per member per month costs in Pennsylvania decreased from $95.84 to $76.90.[5]

- Monitoring pain management clinics for evidence of overprescribing opioids. Pain management clinics are often at the center of significant drug diversion activities and in some States are unregulated. Monitoring programs should not only review opioids dispensed at pharmacies, but also those opioids that might be

[4] http://www.cms.gov/FraudAbuseforProfs/Downloads/kyfy09comppireport.pdf
[5] http://www.cms.gov/FraudAbuseforProfs/Downloads/pafy08comppifinalreport.pdf

dispensed by the provider in the pain management clinic. Oklahoma and Florida have each enacted legislation increasing monitoring of pain management clinics. For more details, refer to the section "Examples of recent State Legislation affecting Drug Diversion" on page 5 of this bulletin.

- Looking across Federal programs to expose fraudulent activities. Drug diversion impacts both Medicaid and Medicare. CMS encourages States to become involved in the Medi-Medi program. Medi-Medi contractors analyze and link data from both the Medicaid and Medicare claims processing systems. They have an established track record of exposing fraudulent provider activity that otherwise may not have been revealed through the review of State Medicaid data alone.

- Collaborating with colleagues in State agencies, bordering States, and law enforcement. Drug diversion impacts the entire healthcare systems and can occur across State lines. SMAs should share information with other State agencies responsible for mental health, substance abuse, pharmacy and medical boards to plan special projects that deal with aberrant providers and beneficiaries. SMAs should share information with bordering States when confirmed diversion links have been established. We also encourage you to reach out to law enforcement, including Medicaid Fraud Control Units (MFCUs), and State and local police. The State of Louisiana program integrity staff teamed up with mental health rehabilitation (MHR) staff from a sister agency to conduct a 100 percent review of all MHR providers. The project involved the monitoring and auditing of approximately 131 MHR providers and resulted in a number of major findings of fraud or abuse. Louisiana saved $64,797,452 through cost avoidance and made 49 overpayment recoveries that netted $585,604.54. The project also resulted in 14 referrals to the Medicaid Fraud Control Unit (MFCU).[6]

- Implementing a prescription drug monitoring program (PDMP). Practitioners and pharmacists should be encouraged to enter data and routinely access PDMPs, where available, to view patient utilization records and identify potential abusers. As of July 31, 2009, 40 States have PMDP laws, and 33 States have operational programs.[7]

- Establishing or augmenting effective recipient "lock-in" programs per 42 CFR 431.54(e) for recipients who over utilize prescription drugs. If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met.

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[6] http://www.cms.gov/FraudAbuseforProfs/Downloads/lafy09comppirev.pdf

[7] "Prescription Drug Monitoring Program: A brief overview national alliance for model state drug laws. August 2009. http://www.namsdl.org/documents/PDMPsBriefOverview7-31-09.pdf

Many States have lock-in programs, but not all include a restriction requiring beneficiaries to obtain prescriptions from a single pharmacy. In an attempt to end pharmacy-hopping, some States are requiring high users of certain drugs, including OxyContin, Xanax and Valium, to use only one pharmacy and get prescriptions for controlled substances from only one medical office. This helps to improve monitoring of the entire processes from prescription to medication utilization. The State of Iowa has a robust lock-in program with an estimated cost savings of approximately $2 million annually. Recipients abusing the program are locked into a primary care physician, pharmacy, and hospital/emergency room. The lock-in program creates a safety net approach and limits the recipient's ability to obtain drugs. The program also identifies providers who may be engaging in unsound medical practices.[8]

- Encouraging beneficiary participation in the national prescription drug "Take-Back" campaign that offers more than 4,000 sites around the nation where the public can drop off expired, unused and unwanted prescription drugs. Unused medications in the household may contribute to growing rates of prescription drug abuse among Americans. The first ever National Prescription Drug Take Back Day on Saturday, September 25, 2010, collected 121 tons of pills. Information on the "Take-Back" campaign can be found at the following link: http://www.takebacknetwork.com.

- Encouraging providers and beneficiaries to safeguard their identities. Identifiers, such as National Provider Identification (NPI) numbers, Tax Identification Numbers (TIN), U.S. Drug Enforcement Administration (DEA) numbers, and Social Security numbers (SSN) have become extremely valuable commodities. When fraudulently obtained, these identifiers can be submitted on claims to receive payment for services or items never received by patients. This kind of identity theft can have grave personal, professional and legal consequences for providers and beneficiaries. Providers and beneficiaries should be educated on appropriate steps they can take to safeguard their identities. Information on medical identity theft can be found at the following link: http://www.oig.hhs.gov/fraud/idtheft/.

Additional Resources

Below are additional resources that may be helpful in combating drug diversion.

Government Accountability Office (GAO) Report

In September 2009, GAO issued a report entitled "Fraud and Abuse Related to Controlled Substances Identified in Selected States." This report highlights strategies some States employ to combat controlled substance fraud waste and abuse. These strategies include:

[8] http://www.cms.gov/FraudAbuseforProfs/Downloads/iacompfy08pireviewfinalreport.pdf

- Checking the List of Excluded Individuals/Entities (LEIE)[9] and the Excluded Parties List System (EPLS),[10] as routine procedures in screening prescribing providers and pharmacies.
- Verifying that the pharmacy and prescribing physician are registered with the DEA for controlled substances they are prescribing or dispensing. For further information, refer to CMS' December 12, 2010 Advisory on Medicaid Prescription Drug Fraud and Abuse Prevention: Access to DEA Registration File.
- Ensuring beneficiaries are not being enrolled multiple times through pre-enrollment checks.
- Checking Social Security Administration (SSA) master death files for deceased beneficiaries and providers, and preventing payment of claims that contain deceased beneficiary or deceased provider information.

CMS recommends that States implement the GAO strategies as part of an effective drug diversion prevention program. A copy of the full report can be found at the following link: http://www.gao.gov/new.items/d09957.pdf

Center for Disease Control and Prevention (CDC) Issue Brief

In July 2010, the CDC issued a poison-issue brief entitled "Unintentional Drug Poisoning in the United States." This brief summarizes the most recent information about deaths and emergency department (ED) visits resulting from drug poisoning. The brief indicates that drug overdose death rates have increased five-fold since 1990, largely because of prescription opioid painkillers. The brief also provides recommendations to healthcare providers, pharmacy benefit managers, and States on the use and monitoring of opioid prescriptions.

A copy of the full brief can be found at the following link:
http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf

Examples of recent State Legislation affecting Drug Diversion

- In April 2010, Oklahoma (OK) enacted legislation, the Oklahoma Interventional Pain Management and Treatment Act (SB 479), which makes it unlawful to practice or offer to practice interventional pain management unless the practitioner is a licensed Doctor of Medicine (MD) or Doctor of Osteopathic (DO) Medicine. This legislation does not prohibit a nurse anesthetist from administering a lumbar intra-laminar epidural steroid injection or peripheral nerve blocks if requested by and under the supervision of a physician (MD/DO) and under conditions in which timely on-site consultation by such physician is available. This legislation prohibits nurse anesthetists from operating a freestanding pain management

[9] Maintained by the U.S. Department of Health & Human Services-Office of Inspector General
[10] Maintained by the U.S. General Services Administration

facility without direct supervision of a physician who is board-certified in interventional pain management or its equivalent.

- In May 2010, Utah (UT) enacted legislation (HB28) aimed at greater enforcement of drug laws targeted at prescription drug abuse. The new law reduces the availability of prescription drugs for abuse; increases public awareness of the negative physical and psychological effects of prescription drug abuse; provides for the legal sanctions to prosecute those who abuse them; decreases tolerance of non-medical use of prescription drugs; adds the muscle-relaxer Soma to the State's controlled substance list; makes the penalty for selling fake versions of illegal drugs the same as that for selling the real drugs; and establishes a network for disposal of unwanted prescription drugs, among other changes.

- In June 2010, Florida (FL) enacted legislation (S 2272) that gives the State greater oversight of pain-management clinics. The new law increases State regulation of the clinics, stiffens penalties the State may impose upon them, limits anyone paying cash for the prescription narcotics to a 72-hour supply for dispensation, bans advertisements for specific treatments like the opiate oxycodone and requires specific training for doctors to practice pain management.

- In August 2010, health care officials in Massachusetts approved a new detection system designed to stop "doctor shopping'' by addicted patients who try to deceive doctors into prescribing narcotics. Expanding upon an older system that reported on a limited number of drugs and did not offer direct physician access, the new process and application will require pharmacists to report prescriptions they receive for a much broader roster of medications, including steroids. The system will receive weekly updates rather than monthly. Physicians will be able to review the prescription histories of patients and be able to identify those with a history of widespread abuse. Lastly, they will also receive public health reports on their patients who are flagged by the system.

Conclusion

The CMS Medicaid Integrity Group is actively working with States and law enforcement partners on drug diversion issues and looks forward to working with all States to reduce improper payments and diversion of prescription drugs. If you have any questions or would like more information on this topic, please contact Gretchen Kane, Medicaid Integrity Specialist, CMS Medicaid Integrity Group, at 415-744-3806 or Gretchen.Kane@cms.hhs.gov .