

Patient Review & Restriction Programs

Lessons learned from state Medicaid programs

CDC Expert Panel Meeting Report

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National Center for Injury Prevention and Control Division of Unintentional Injury Prevention

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About this Report

On August 27 and 28, 2012, the Centers for Disease Control and Prevention (CDC) convened the Medicaid Patient Review and Restriction (PRR) Expert Panel Meeting. Attendees represented state Medicaid agencies, managed care organizations, private insurers, and Federal agencies (see Appendix C for a list of panel members). The goal of the meeting, and this report, was to examine current practices of PRR programs, also called Medicaid "Lock-In" programs, and share insights about the operation of such programs to prevent prescription drug abuse, diversion, and overdose. Ultimately, the meeting sought to use the experiences of the people who run PRR programs to understand what these programs do and how they can do it better. The primary audience for this report is state Medicaid agencies and private insurers.

The suggestions in this report are based on promising practices or interventions and expert opinion. Additional research and evaluation is needed to understand the impact of these practices and interventions on reducing prescription drug abuse and diversion, as well as prescription drug overdoses, both fatal and nonfatal.

Introduction

Patient Review and Restriction programs (PRRs), also called "lock-in" programs, enable state Medicaid programs to rein in a Medicaid patient's overuse, and possible abuse, of physician services and prescription drugs without having to terminate Medicaid benefits altogether. They do this by allowing Medicaid programs to restrict patients suspected of over-utilization to a single designated provider, pharmacy, or both.

The federal regulation that authorizes PRRs is brief in its wording and broad in the discretion it affords state Medicaid programs:

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.¹

Medicaid programs may only impose restrictions if they give patients notice and an opportunity for a hearing, ensure that restricted patients still have reasonable access to Medicaid services, and exempt emergency services from the restriction.² Other than these basic requirements, states have broad discretion how, and whether, to implement PRRs. The Center for Medicare and Medicaid Services (CMS) has encouraged states to implement fraud and waste prevention efforts.³ Controlled substance abuse has been recognized as a problem by the National Association of State Medicaid Directors.⁴

PRRs existed long before the current U.S. epidemic of prescription drug overdoses; however, the intensity of this epidemic in the Medicaid population⁵ has prompted a need to maximize the impact of such programs in reducing the risk for people most at risk of overdose. CDC convened the August 2012 PRR Expert Panel Meeting to discuss current practices employed in these programs.

This report presents highlights from the meeting, including summaries of presentations on the scope of the problem, cost impact, selected states' experiences, and approaches to evaluating states' PRR programs. The main goal of this report is to examine the diverse practices of state PRR programs and identify practices that hold the most promise for reducing prescription drug abuse and overdose among the Medicaid population and the associated costs.

The Prescription Drug Abuse Epidemic and its Costs

An Epidemic of Overdoses

Len Paulozzi, MD, MPH, Centers for Disease Control and Prevention, presented information to the expert panel about prescription drug overdoses. In summary, prescription drug overdoses in the United States have reached epidemic levels, and overdoses of prescription opioid analgesics (painkillers like oxycodone, hydrocodone, and methadone) are the major drivers. More than 100,000 people have died in the last ten years from opioid overdoses, and the overdose death rate from these drugs has tripled since 1990. By 2010, these drugs accounted for more than 16,600 overdose deaths,⁶ more than double the number of deaths from cocaine and heroin combined. Drug poisoning has now surpassed motor vehicle crashes as the leading cause of injury death.⁷



While opioids have an important role in reducing pain among people with acute or chronic medical problems, the misuse and abuse of these drugs have increasingly become a serious public health and cost issue,⁸ especially among the Medicaid population. In Washington State, for example, the Medicaid population had a 5.7 times greater risk of dying from an opioid overdose than the non-Medicaid population. Despite being enrolled in the Washington PRR program (i.e., Medicaid patients with a troubling pattern of controlled substance use) PRR clients were at especially high risk of overdose; a staggering 1 in 170 died from an overdose of opioids each year.⁹

Medicaid patients also have a higher rate of hospitalizations for poisoning by opioids and related narcotics than people who have other forms of insurance or even the uninsured.¹⁰ Similarly, the rate of emergency department visits for drug poisoning is much higher for Medicaid patients than for people in other payer groups.¹¹

Overall, people on Medicaid are prescribed opioid prescriptions at more than twice the rate as people with private insurance.¹² Among Medicaid clients being treated for chronic pain, most of the prescriptions are consumed by the 10% of patients at the daily dosage of 100 morphine milligram equivalents or more, a level associated with greater risk of overdose.¹³

The Costs of Prescription Drug Misuse

William J Mahon, MAHON Consulting Group LLC, presented information to the expert panel on economic aspects of the problem. In summary, prescription drug abuse imposes a major financial burden on the healthcare system and insurance providers.¹⁴ Drug diversion, the "diverting" of drugs from their intended purpose to an illicit one, costs insurers as much as \$72.5 billion a year. But the costs related to prescription drug abuse include far more than simply the cost of the misused prescriptions.15 A study of pharmacy claims based on data from a two million-member database found that diagnosed opioid abusers had total health care costs eight times that of nonabusers. A large part of the excess costs are due to related medical claims, including physician office visits, diagnostic tests, ED care and exams, and conditions caused by prescription abuse, such as liver failure. Such non-drug costs in one study were 41 times the cost of prescriptions among patients with excessive numbers of prescriptions.¹⁶

Those involved in drug diversion include patients who are drug seeking/doctor shopping, corrupt prescribers and dispensers, and various perpetrators of illegal trade. These players find drug diversion worth the risk because of significant profits. For example, in 2009 a 40 mg tablet of Oxycontin® retailed for about \$5.66 and could be sold on the street for \$40.17



The enormity of the costs of diversion indicates that careful examination of prescribing patterns by insurers could yield major cost savings. For example, Wellpoint/Anthem identified 100 members with multiple prescriptions from five or more sources over a 90-day period. These members had total prescription claims of more than \$20,000 and total medical claims during that period of \$832,172. After a program to intervene and restrict pharmacies, the plan realized a savings of more than \$333,000 over a year.¹⁸

What We Know About PRRs

Chris Jones, PharmD, MPH, Centers for Disease Control and Prevention, presented findings from evaluations of PRR programs to the expert panel. In summary, PRR programs have the potential to reduce opioid usage to lower, safer levels, and thus save lives and lower health care costs. Although there is a major need for evaluations of PRR programs, existing studies and analyses suggest that PRRs have significant potential for reducing abuse and diversion among the Medicaid population, especially the subpopulation using large amounts of opioid analgesics.

Five published studies have illustrated that PRR programs can reduce expenditures, use of controlled substances, or both:

Missouri's PRR resulted in between \$1.8 to \$10.9 million in savings per year (approximately \$6.8 to \$41.3 million per year in 2012 dollars).¹⁹

- Between 1977 and 1983, Hawaii's Medicaid PRR restricted 270 patients with an estimated cost savings of \$900,000 (\$2 million in 2012 dollars). Of the patients counseled, warned, and voluntarily restricted between 1980 and 1983, 21% remained in compliance for one or more years with no further abuse, and in general the degree of abuse decreased for all enrollees.²⁰
- Louisiana's PRR program reduced polypharmacy (the use of more drugs than is medically necessary) among restricted patients and decreased the use of Schedule II narcotics, resulting in reduced pharmaceutical expenditures.²¹
- Those enrolled in the Oklahoma Medicaid PRR showed a decrease in the use of narcotic medications, multiple pharmacies and physicians, and emergency department visits. Interestingly, there was no association between changes in maintenance medication use among restricted patients, suggesting the PRR did not affect access to chronic disease medications.²²
- Ohio's Medicaid PRR demonstrated monthly dosage reductions of 40.8% for narcotic analgesics, 36.3% for sedatives, and 37.5% for nonnarcotic analgesics once patients were enrolled in the PRR.²³

Although not in the published literature, evaluations by Washington State provide valuable, and promising, information on PRRs. An initial evaluation showed a 37% decrease in physician visits, 33% decrease in ED visits, and a 24% decrease in number of prescriptions after patients were enrolled in the PRR. Among PRR enrollees in 2006, the average number of narcotic prescriptions decreased from 3.07 to 1.63 and total morphine milligram equivalents (MME) decreased from 312 MME/day to 185 MME/day. After one year, significant reductions were detected in hospital costs, ED visits for injuries from any cause, physician visits and costs, and narcotic prescriptions among PRR patients. No differences in mortality were seen between the two groups. Total savings of the PRR through 2012 are estimated at \$120 million. The calculated return on investment is at least \$12 for every \$1 invested in the program.24

Other state Medicaid programs have provided limited information on their PRRs. Florida reported 1,315 individuals had been placed into their Medicaid PRR between October 2002 and March 2005. During this time period, cumulative savings for medical and pharmaceutical expenses topped \$12.5 million.²⁵ Iowa has reported nearly \$2 million in savings as a result of their PRR.²⁶ Additional states have informally reported to CMS that their PRR programs have led to reductions in overutilization among enrolled patients.²⁷

Although the published literature demonstrates a positive impact on cost and some medical and pharmacy utilization measures, there is a clear need for more current and robust evaluations of PRR programs to examine impact on health-related outcomes such as hospitalizations and overdose deaths. Additional information related to evaluation needs is included in the **Promising PRR Practices Based on Program Experiences** below.

Promising PRR Practices Based on Program Experiences

PRR Expert Panel members provided a wide range of approaches for implementing their PRR programs. The diversity of these experiences provided a unique opportunity for participants to learn about different practices and identify those approaches that held the most promise for reducing abuse and diversion.

Participants identified the practices below through organized discussions and breakout sessions. While evaluation data are not available to make judgments about the effectiveness of these practices, the participants' suggestions provide a foundation for further study of how PRRs can best be leveraged to prevent prescription drug abuse, diversion, and overdose.

Client Selection Criteria

Determining which Medicaid patients should be enrolled in a PRR is a vitally important task; excessively rigid criteria could leave patients at-risk out of the program, while criteria that are too broad could needlessly burden Medicaid patients who are not overusing services and overwhelm PRR staff.

States employ a variety of selection criteria. (*Selection criteria employed by Massachusetts, Minnesota, North Carolina, and Washington are available in Appendix A*). The criteria vary from simple numeric thresholds to an extensive list of criteria that includes a wide variety of behaviors indicative of over-utilization or fraud.

States frequently make use of the judgments of their PRR staff regarding the medical necessity of past treatments as part of the selection process. PRR staff typically make exceptions to the selection criteria when clients have specific conditions such as cancer. Programs typically look at the past 90 days or during any 60-day period to count how many prescribers and pharmacies a Medicaid patient has seen.

Overall, participants agreed that PRR programs benefit from having both objective and subjective criteria and the criteria should be designed to reflect the needs of each state.

Panel members identified specific guiding principles for states to consider, including the following:

- Examine claims data and review current fraud prevention activities to determine which areas need to be augmented.
- Combine objective criteria with subjective review, based on clinical judgment.
- Focus efforts by deciding whether to emphasize improvements in patient care or detection of fraud.
- Refrain from standardizing client selection criteria at the federal level (e.g., selecting clients with 5+ different prescribers) because state regulations, priorities, and drug usage patterns vary.
- Include ongoing monitoring of changes in patient behaviors measured by the selection criteria.
- Choose criteria that complement other state programs, for example, the use of data from state prescription drug monitoring programs and the activities of the state board of pharmacy to reduce inappropriate prescribing.
- In developing patient selection criteria, consider including behaviors that have been shown to be a health risk to clients in terms of risk of abuse and/or overdose. The following are examples:
 - High daily opioid dosage in morphine milligram equivalents (MME), e.g., more than 100 or 120 MME per day
 - The number of prescriptions obtained by a patient during a given time period
 - The number of prescribers for a patient in a given time period
 - The number of pharmacies dispensing to a patient during a given time period.

Implementation

Developing and maintaining PRR programs can be a challenge. In general, the most difficult barriers seemed to be funding and staffing shortages rather than technical problems. (*See Appendix B for a more detailed list of barriers and potential strategies to overcome them.*) Despite the challenges to implementation, participants identified approaches in a number of areas that can help strengthen and sustain these programs.

General Implementation Concerns

- Pursue interstate data sharing if legally authorized.
- Ensure that the prescriber and pharmacy to which a patient is restricted operate in a way that is consistent with a program's "integrity," that is, assure that these providers are themselves not contributing to the problem.

Program Management

- Collaborate with law enforcement/drug diversion specialists in state/region.
- Leverage resources across departments, e.g., state health departments, Medicare programs, Boards of Pharmacy, state prescription drug monitoring programs, and professional associations.

Staffing

- Ensure that staffing numbers are adequate for a growing patient volume.
- Ensure that appropriate competencies are represented, including those with knowledge of pharmacy, clinical issues (e.g., drug interactions), case management/care coordination, administration (customer service), and analysis/evaluation.
- Seek a balanced investment in staffing and automation systems.

Program Recognition and Support

- Build multi-sector partnerships that emphasize common goals, e.g., encouraging people to be healthier, reducing fraud and related costs, and increasing patient safety.
- Engage with stakeholders (state professional associations, interest/stakeholder groups, agencies).
- Effectively communicate the successes of PRR programs.

Evaluation

Evaluation of PRR programs is vital to show that such programs can save money, make improvements in the health of Medicaid clients, and reduce the risk of overdoses. Although some evaluations have been published, most are not current, and there is no standard methodology for these evaluations.

The participants' discussion of promising practices for evaluation concluded that the ideal evaluation methodology should include the following:

- Consistent criteria for defining eligible patients.
- Consistent restriction actions.
- Robust data sources (including Medicaid claims, PDMP data, and mortality data).
- Measurement of pharmacy utilization, medical utilization, health outcomes, program costs, and cost benefit/cost-effectiveness of programs.
- Use of a comparison population with similar behavior patterns.
- Use of comparison, non-controlled drugs.

However, participants acknowledged that the "gold standard" evaluation carried out through academic-type research is likely to be more sophisticated than the more practical program evaluation that most states can do.

The group agreed that evaluations should address the following outcomes with available information:

- Health outcomes, including self-reported health, based on surveys.
- Changes in utilization, to include not only numbers of prescriptions, but also the dosage and numbers of days for prescriptions and the use of substance abuse and mental health services, which might increase after enrollment.
- Cost savings related to the medical and healthcare system, e.g., fewer ED visits and hospitalizations, as well as savings on drugs. As one state pointed out, the costs for medical services exceed the costs for prescription drugs by a factor of 100 to 1 among the Medicaid clients with the greatest overall usage of services.
- Comparison of changes in costs for controlled prescription drugs with changes in costs for maintenance medications or "market basket" medications (a sampling of commonly used drugs).

 Unintended consequences of PRRs, such as changes in the use of maintenance medications not prone to abuse or the switch to more expensive or less appropriate medications or illicit drugs.

Process measures are also helpful, e.g., the percentage of clients released for adherence after a specified enrollment period and the percentage of recidivism. The group recognized the need to have access to PDMP data, but acknowledged use of such data by PRR programs is currently not common.²⁸ If programs do not have evaluation experts on staff, they might profitably collaborate with academic centers, state health departments' epidemiology units, and other organizations that might offer such expertise.

Conclusion

The rate of drug overdose deaths in the U.S. has become so high that it has actually lowered the overall life expectancy of tens of millions of Americans, an alarming development in the public health of the nation. What we know about the prescription drug epidemic especially the high risk of overdose faced by Medicaid patients, those who take high dosages of opioids, and those who obtain drugs from multiple providers strongly points to the power of PRRs to reduce these unnecessary deaths.

The promising practices identified by the PRR Expert Panel attendees and detailed in this report are the beginning of a crucial discussion. The broad discretion afforded to state Medicaid programs to implement PRRs has created an opportunity to compare different programs' approaches to determine which work best for reducing prescription drug abuse, misuse, and overdose. Going forward, the efforts of PRRs must continue to be critically examined and robustly evaluated.

CDC Disclaimer

The findings and recommendations in this report are based on promising practices or interventions and expert opinion. Additional research is needed to understand the impact of these practices and interventions on reducing prescription drug abuse, diversion, and overdose. The conclusions of this report do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Appendix A

Selected States' Criteria for Restricting Access to Pharmacies and/or Providers

Massachusetts Criteria (pharmacy restriction only)

- 11 or more prescriptions, including original fill and refills of Schedule II, III, or IV controlled substances
- obtained from four or more prescribers OR
- filled by four or more pharmacies within 90 days.

Minnesota Criteria

Available at: www.revisor.mn.gov/rules/?id=9505.2165.

In the case of a recipient, the use of health services that results in unnecessary costs to the programs, or in reimbursements for services that are not medically necessary.

The following practices are deemed to be abuse by a recipient:

- 1. obtaining equipment, supplies, drugs, or health services that are in excess of program limitations or that are not medically necessary and that are paid for through a program;
- 2. obtaining duplicate or comparable services for the same health condition from a multiple number of vendors, such as going to multiple pharmacies or physicians. Duplicate or comparable services do not include an additional opinion that is medically necessary for the diagnosis, evaluation, or assessment of the recipient's condition or required under program rules, or a service provided by a school district as specified in the recipient's individualized education plan under Minnesota Statutes, section 256B.0625, subdivision 26;
- 3. continuing to engage in practices that are abusive of the program after receiving the department's written warning that the conduct must cease;
- 4. altering or duplicating the medical identification card for the purpose of obtaining additional health services billed to the program or aiding another person to obtain such services;
- 5. using a medical identification card that belongs to another person;
- 6. using the medical identification card to assist an unauthorized individual in obtaining a health service for which a program is billed;
- 7. duplicating or altering prescriptions;
- 8. misrepresenting material facts as to physical symptoms for the purpose of obtaining equipment, supplies, health services, or drugs;
- 9. furnishing incorrect eligibility status or information to a vendor;
- 10. furnishing false information to a vendor in connection with health services previously rendered to the recipient which were billed to a program;
- 11. obtaining health services by false pretenses;

- 12. repeatedly obtaining health services that are potentially harmful to the recipient;
- 13. repeatedly obtaining emergency room health services for nonemergency care;
- 14. repeatedly using medical transportation to obtain health services from providers located outside the local trade area when health services appropriate to the recipient's physical or mental health needs can be obtained inside the local trade area. For purposes of this sub-item, "local trade area" has the meaning given in part 9505.0175, subpart 22; or

15. repeatedly arranging for services and then canceling services in order to circumvent the spend-down requirement; and

In addition to the criteria in item B, the following practices are deemed to be abuse by a recipient enrolled in the restricted recipient program:

- 1. obtaining medical services from a physician without a referral from the recipient's designated primary care provider;
- 2. obtaining emergency room services for non-emergency care;
- 3. obtaining prescriptions from a pharmacy other than the designated pharmacy; or
- 4. obtaining health services from a non-designated provider when the recipient has been required to designate a provider.

North Carolina Criteria

Available at: http://www.ncdhhs.gov/dma/mp/9pharmacy.pdf (beginning on page 15)

- Benzodiazepines and certain anxiolytics: > 6 claims in 2 consecutive months, OR
- Opioids: > 6 claims in 2 consecutive months, OR
- Prescriptions for opiates and/or benzodiazepines and certain anxiolytics from > 3 prescribers in 2 consecutive months, OR
- Referral from a provider, the Division of Medical Assistance, or CCNC.

Washington Criteria

Available at: http://apps.leg.wa.gov/WAC/default.aspx?cite=182-501-0135

- Two or more of the following in a period of 90 consecutive days in the previous 12 months:
 - Received services from four or more different providers, including physicians, advanced registered nurse practitioners, and physician assistants;
 - Had prescriptions filled by four or more different pharmacies;
 - Received ten or more prescriptions;
 - Had prescriptions written by four or more different prescribers;
 - Received similar services from two or more providers in the same day; or
 - Had ten or more office visits.
- Any of the following within a period of 90 consecutive days in the previous twelve months:
 - Two or more emergency department visits;
 - Medical history that indicates "at-risk" utilization patterns;
 - Repeated and documented efforts to seek health care services that are not medically necessary; or
 - Has been counseled at least once by a health care provider, or a department or MCO staff member, with clinical oversight, about the appropriate use of health care services.
- The client received prescriptions for controlled substances from two or more different prescribers in any one month in a period of 90 consecutive days in the previous twelve months.
- The client's medical and/or billing history demonstrates a pattern of the following at any time in the previous twelve months:
 - · History of using health care services in a manner that is duplicative, excessive, or contraindicated; or
 - History of receiving conflicting health care services, drugs, or supplies that are not within acceptable medical practice

Appendix B

Barriers to Implementation and Suggested Strategies/Solutions Identified by the Panel

Barrier	Suggested Strategy/Solution
Difficult to break ties with problematic providers who appear repeatedly among providers prescribing to patients meeting PRR criteria	 Quantify claims for such providers to demonstrate that they are outside norms Compare their practice with established prescribing "limits," e.g., the limit on how much acetaminophen can be safely prescribed per day in combination with opioid products
Need to verify that single prescriber and single pharmacy chosen by the patient are themselves not contributing to the problem	 Review claims for providers and pharmacies Identify problematic providers or pharmacies and prohibit patients from selecting them
Cash purchases and denied claims not appearing in a patient's drug utilization history	Use state prescription drug monitoring programs (PDMPs)
Time demands on programs	Automate review process
Interstate prescriptions and interoperability of PDMP data	Continue current interoperability initiatives
Difficulty developing optimal criteria for client selection (both what works and what is allowed)	 Retain flexibility to match criteria to state's needs Retain flexibility to assess patients (more than just looking at numbers) Develop a "hybrid" approach: objective criteria to flag potential problem patients and subjective judgment that focuses on patient circumstances, care, and safety Enhance objective criteria, e.g., by including diagnostic codes Continue to evaluate to determine impacts
Patient privacy concerns	 Emphasize PRR's benefits to patients (not just a punitive practice) Educate providers about allowable uses of information. (Current statutes allow sharing of patient information among providers and Medicaid, except for patients seeking treatment for addiction) Engage in clear conversations with patients about privacy protection Ensure airtight data protection
Resistance from some retail pharmacies about being designated a "Medicaid pharmacy" (adding to workload, not being compensated for time/effort to verify patients, dealing with challenging patients)	 Limit burden of additional work to comply with restriction efforts Automate process as much as is possible
Staffing, e.g., case management, is very time-intensive; due process procedures are time-consuming	 Develop a business plan to analyze need, look at return on investment Continue to analyze and publicize cost savings over time Invest in high quality case management software Increase staff size in small increments, not all at once Automate process as much as possible
ED rules requiring ED to see all patients for any reason (therefore, allowing patients to shift to that setting)	 Coordinate with EDs to develop care plans for restricted clients Convey limits on use of ED services to patients

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Barriers to Implementation and Suggested Strategies/Solutions Identified by the Panel

Barrier	Suggested Strategy/Solution
Providers who do not want to accept PRR patients	 Develop relationship with providers 1:1; provide customer service benefits Offer provider education about issue
Challenges for the future as patients move from managed care to HC exchanges	 Study implications of this change
Lack of resources	 Build business case to demonstrate cost benefit of program Demonstrate improved care
Data availability (limited, lack of, not real time)	 Build business case to facilitate timely data access Compare data from other states
Ensuring inclusion of Medicare (disability) information	 Seek ability to share data with Medicare
Interstate prescriptions and interoperability of PDMP data	 Retain flexibility to match criteria to state's needs Retain flexibility to assess patients (more than just looking at numbers) Develop a "hybrid" approach: objective criteria to flag potential problem patients and subjective judgment that focuses on patient circumstances, care, and safety Enhance objective criteria, e.g., by including diagnostic codes Continue to evaluate to determine impacts
Demonstrating program's value	 Develop clear communication/education messages Develop return on investment data Publicize program results, including improved patient care and health outcomes as a result of PRR program Provide "success stories" Provide reimbursement incentives
Variation between programs	 Develop best practices Build evidence base Improve communication between states
Lack of PDMPs/authority or resources	 Provide access to PDMP data Build awareness of PDMP utility, improve knowledge about how to use PDMPs

Appendix C: Expert Panel Meeting Attendees

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