Public Policy Statement on Patient Review and Restriction (PRR) Programs

Background

Patient Review and Restriction (PRR) programs, also known as pharmacy "lock-in" programs, allow payers, including State Medicaid programs and commercial insurers, to curb a beneficiary's overutilization, and possible misuse, of physician services and/or prescription medications by restricting the patient to a single designated provider, pharmacy, or both.[1] The federal regulation that authorizes the establishment of these programs within Medicaid gives broad discretion to the states to determine whether and how they are implemented:

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.[2]

The only federal requirements are that Medicaid programs 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.[3] Since the authorizing federal legislation doesn't offer specific instructions regarding program design or the definition of excessive use of services, there is significant variation in scope and design among the programs that have been established to date.

As of 2018, 46 state Medicaid agencies[4] and 202 Medicaid Managed Care Organizations (MCOs)[5] operated PRR programs. Program design varies widely between states in terms of defining high-risk controlled substance use, the scope of restrictions, and length of program enrollment. For example, states use a wide variety of criteria to determine which Medicaid beneficiaries will be enrolled in their PRR programs, from simple numeric thresholds to extensive criteria lists that include a variety of behaviors indicative of overutilization. Most states define overutilization of controlled substances based on quantities of prescriptions filled, number of pharmacies visited, and/or number of controlled substance prescribers seen over a certain period of time. Many states use a combination of objective criteria and subjective assessment by PRR program staff to determine client enrollment. Moreover, while most Medicaid programs restrict enrollees to a single pharmacy and a single prescribing clinician, others restrict only pharmacy access or tier how enrollees are restricted based on the extent of their overutilization.

The Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Medicare Part D plan sponsors to establish drug management programs (DMPs) for beneficiaries at risk for misuse of "frequently abused drugs" (FADs) for plan years beginning in 2019. While most plan sponsors have already implemented DMPs, the SUPPORT for Patients and Communities Act of 2018 requires all Part D sponsors to have a DMP for plan years beginning

on or after January 1, 2022. DMP regulations require plan sponsors to engage in case management before instituting a coverage limitation, and CMS has stated that "significant reduction in opioid overutilization in the program has been due mostly to case management, and to a much lesser extent, because of coverage limitations."[6]

PRR programs have been instituted and studied primarily in State Medicaid programs and more recently in Medicare Part D plans, but several commercial insurers also employ them. However, publicly available information about commercial insurer programs is scarce. PRR programs have been proposed as a potential tool in the effort to reduce prescription drug misuse, diversion, and overdose deaths, both in state Medicaid programs and by commercial insurers. However, peer-reviewed research on the design and effectiveness of PRR programs is scarce.[7] Studies to date, which primarily stem from publicly accessible internal Medicaid program evaluations, have demonstrated PRR programs can reduce health plan expenditures,[8,9] use of controlled substances,[10,11] or both,[12,13] but none have linked PRR programs to lower diversion rates, lower rates of substance use disorders, increased engagement in substance use disorder treatment, or reduced overdose deaths among beneficiaries. Other studies have found that enrollment in a lock-in program is associated with increased controlled substance prescription fills and higher daily dosages of opioids obtained through Medicaid and non-Medicaid payment sources.[14,15] Accordingly, CDC has called for "more current and robust evaluations of PRR programs to examine impact on health-related outcomes such as hospitalizations and overdose deaths."[16]

Of concern, the Medicaid and CHIP Payment and Access Commission (MACPAC) highlighted in a report to Congress that pharmacy and provider lock-in programs may impede access to medications for addiction treatment such as buprenorphine.[17] It notes that prescribers may need to make several buprenorphine dosage adjustments in the early stages of treatment, increasing the likelihood that a beneficiary may get locked in because they are receiving multiple prescriptions within a certain time frame. Further, clinicians report that PRR programs can be particularly limiting and impede access to needed medications for people experiencing homelessness or who lack transportation, as well as those on a non-standard medication dosage.

Ultimately, the implementation of a PRR program relinquishes professional judgement regarding a patient's health in favor of a bureaucratic, one-size-fits-all approach, which may be influenced primarily by financial interests such as reduced health plan expenditures. The potential for unintended consequences to the patient's health is high if the circumstances of each unique patient's clinical needs are not assessed by a trained professional. Prevention and treatment are the best interventions to address the opioid addiction and overdose epidemic. There is no substitute for the professional judgement of a caring and educated clinician who has an existing therapeutic alliance with the patient.

Recommendations:

The American Society of Addiction Medicine recommends:

1. States and payers that have not yet implemented PRR programs refrain from doing so, given the scarce evidence that PRR programs are an effective mechanism to reduce prescription misuse, diversion and overdose deaths, and the evidence that they may impede access to addiction treatment.

2. As an alternative to PRR programs, policymakers and payers should increase support for existing programs known to be effective in reducing prescription misuse, diversion and overdose deaths, including increased use of state prescription drug monitoring programs (PDMP),[18] improved FDA regulations and monitoring,[19] ready access to naloxone,[20] and increased access to treatment for addiction.[21]

If policymakers or payers proceed with implementing PRR programs despite our recommendation otherwise, the American Society of Addiction Medicine strongly recommends the following:

3. Payers, including Medicaid, Medicare and commercial insurers, who choose to institute patient review and restriction (PRR) programs design them to encourage behavior change and support care and treatment rather than as punitive measures.
    a. A patient's prescriber should be alerted to the patient's possible prescription drug misuse and encouraged to perform a comprehensive screening and/or assessment of the patient for a possible substance use disorder.
    b. If indicated, the patient should be referred for follow-up treatment with a specialist pain and/or a substance use disorder treatment provider.

4. Criteria to identify patients for enrollment should be evidence-based and, given the paucity of evidence, results of these programs should be made publicly available to ensure appropriate use.
5. PRR programs should provide reasonable accommodations to patients to ensure program enrollment and de-enrollment is not overly burdensome, particularly for patients needing acute emergency services, and those who are experiencing homelessness, unemployment, lack of transportation, or other social stressors.
6. Payers should encourage their prescribers and pharmacists to check their state PDMP before prescribing or dispensing a controlled substance to any patient.
7. When possible, State Medicaid programs should work to integrate data between their PDMP and Medicaid claims to identify patients who may be circumventing the PRR program to obtain additional prescriptions by paying out of pocket. Such an interchange of information may help identify patients in need of substance use disorder education or referral to treatment.
8. Physicians and all other health professionals licensed to prescribe controlled medications should be required to complete training on treating and managing patients with substance use disorders.

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revised on a regular basis; therefore, those wishing to utilize this document must ensure that it is the most current position of ASAM on the topic addressed.

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[2] 42 CFR 431.54(e)

[3] 42 CFR 431.54(e)(1)–(3)

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