Issue Brief: Why Are Medicaid Lock-in Programs Used and How Can They Be Improved[1]

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The federal Medicaid Act includes various authorizations for states to require enrollees to obtain health services from designated providers. Mandatory managed care programs, for example, can require all beneficiaries in a state or defined geographic area to enroll in a managed care plan and obtain services from providers who participate in the plan's provider network.[2] States can also implement programs that require enrollees who are improperly using Medicaid services to obtain their care and/or services from a designated provider or providers. These types of restrictions are referred to as lock-in programs or patient review and restriction programs.

This Issue Brief provides background on states' use of beneficiary lock-in programs, highlighting states' renewed interest in using these programs to address the current prescription drug overdose epidemic. It then discusses legal requirements that state lock-in programs must meet. The Issue Brief concludes with recommendations to help ensure that lock-in programs are not being improperly applied to people who are high utilizers of care and services because they are living with disabling and chronic conditions.

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[2] See 42 U.S.C. § 1396u-2 (authorizing managed care through state plan amendment); *id.* § 1396n(b) (authorizing Secretary of Health and Human Services (HHS) to approve managed care waivers); *id.* § 1315 (authorizing HHS to approve demonstration projects). The choice of family planning services cannot be restricted. *Id.* § 1396a(a)(23).

Overview of Medicaid beneficiary lock-in programs[3]

Lock-in programs have been a state Medicaid option for quite some time. Properly functioning, they allow the lock-in provider to obtain a clear picture of a beneficiary's pattern and history of medical misuse, coordinate their care-seeking patterns, and avoid unnecessary expenditures. Lock-in programs can also be used in the effort to prevent prescription drug diversion (diverting licit drugs for illicit uses).

State interest in lock-in programs has exploded with the current prescription drug overdose epidemic. Opioid abuse is a particular problem. In 2011, opioids other than heroin represented approximately ten percent of all substance abuse treatment admissions, compared to only two percent in 2001.[4] Fully 29% of emergency department visits associated with prescription drug abuse involved nonmedical use of opioids.[5] Increased abuse of controlled prescription drugs (CPDs) led to elevated numbers of deaths related to prescription opioids, which increased 98 percent from 2002 to 2006.[6] Opioids are also subjected to diversion. Significant diversion is also associated with high cost antipsychotic and mental health drugs, such as aripiprazole (Abilify) and benzodiazepines, such as alprazalam (Xanax).[7]

Prescription drug overdose is particularly acute among the Medicaid population. Individuals enrolled in Medicaid are prescribed opioid prescriptions at more than twice the rate of the privately insured.[8] Medicaid beneficiaries in Washington State were found to have a 5.7 times greater risk of dying form an opioid overdose than the non-Medicaid population.[9] The Medicaid population also has a higher rate of hospitalization

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[3] States can also lock-out providers. States must exclude providers who have engaged in fraud. *Id.* § 1396a(a)(39). Using objective standards, agencies can exclude providers who are not qualified to provide services. *Id.* § 1396a(a)(23). States can lock-out providers who have been found to have provided services that were not medically necessary. *See* 42 C.F.R. § 431.54(e).

[4] *See* Thomas R.F. Dreyer et al., *Patient Outcomes in a Medicaid Managed Care Lock-In Program*, 20 J. OF MANAGED CARE & SPEC. PHARM. 1006 (Nov. 2015).
[5] *Id.*
[6] *See* CMS, *Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid* 1 (Jan. 2012), https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaidintegrityprogram/downloads/drugdiversion.pdf (last visited June 27, 2016).
[7] *See* A.W. Roberts & A.C. Skinner, *Assessing the present state and potential of Medicaid controlled substance lock-in programs*, 20 J. MAN. CARE SPEC. PHARM. 439 (May 2014) (hereafter *Assessing the present state*).
[8] *Id.*
[9] CDC National Center for Injury Prevention & Control, *Patient Review & Restriction Programs* 2 (2012), https://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf (last visited June 26, 2016).

for poisoning by opioids and similar narcotics than people with other forms of insurance or the uninsured.[10]

According to Andrew W. Roberts and his colleagues, 46 states are using some sort of prescription controlled substance lock-in program.[11] Most restrict beneficiaries to a single physician and a single pharmacy.[12] There are variations, however, as exemplified by Nebraska, which uses a five-tier system that restricts enrollees to additional providers depending on the degree to which controlled substances are being misused.[13] The duration of the lock-in period varies among states, typically ranging from six months to two years. Again, there are notable exceptions, including the State of New Jersey, which has a four year lock-in period.[14] States also use different criteria for deciding who will be enrolled in a lock-in program. Most states use quantitative benchmarks for deciding enrollment. For instance, Nevada triggers lock-in for individuals who fill any nine controlled substance prescriptions within a 60 day period. Virginia uses an intricate formula that defines overutilization with more than a dozen specific measures (*e.g.*, receiving two or more controlled substances from more than one pharmacy or more than one prescriber in at least a four-week period).[15]

Importantly, while quantitative benchmarks may serve to alert Medicaid to a misusing beneficiary, numbers alone may not tell the complete story. When care seeking habits trigger concern, the individual's health care conditions and needs must be considered; otherwise, a lock-in program can ensnare beneficiaries who have unusual care seeking characteristics due to medical necessity, access barriers, or other reasons not associated with intentional misuse of the Medicaid card.

Legal requirements for Medicaid enrollee lock-in

Properly implemented, lock-in processes can help to improve providers' prescribing practices and patients' appropriate use of services, including prescription medications. Congress, the Centers for Medicare & Medicaid Services (CMS), and courts have all addressed the features that must be included in a state Medicaid lock-in program.

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[10] *Id.*
[11] *See* A.W. Roberts & A.C. Skinner, *Assessing the present state, supra* n. 6 at 441 (finding all states except Arizona, California, New Mexico, and South Dakota has at least one lock-in program).
[12] *Id.*
[13] *Id.*
[14] *Id.* at 442.
[15] *See* A.W. Roberts & A.C. Skinner, *Assessing the present state*, *surpa* n.6, at 442.

The Medicaid Act generally authorizes states to use methods and procedures, as needed, to safeguard against unnecessary utilization of care and services.[16] In 1981, Congress amended the Medicaid Act specifically to authorize states to restrict the provider or providers from whom a beneficiary can receive items and services because of he or she is misusing the coverage.[17] The House Committee that reported the amendment intended that it apply "only to those recipients that clearly and without doubt overutilize services," labelled by the Committee as "chronic overutilizers."[18]

As enacted, 42 U.S.C. § 1396n(a)(2) allows states to restrict the provider or providers from which a beneficiary can receive care and services if the individual has been found to utilize items or services "at a frequency or amount not medically necessary."[19] The determination cannot be *ad hoc* but rather must be made in accordance with guidelines established by the state.[20] The restriction can last only for a "reasonable period of time."[21] The state's lock-in restrictions must also ensure that the affected beneficiary has reasonable access to services of adequate quality, taking into account geographic location and reasonable travel time.[22] Individuals must be provided notice and an opportunity for a hearing before being subjected to lock-in restrictions.[23]

Federal regulations further provide that the lock-in restrictions cannot apply to emergency services.[24] Legislative history also makes it clear that individuals who are subject to lock-in arrangements should be given "an opportunity to change the provider to be locked into periodically (in no case less frequently than every three months)." [25]

For these programs to function as the law intends, there needs to be a sufficient number and distribution of lock-in providers, including providers who do not have religious or non-medically based objections to providing the full range of services that the individual needs. Moreover, the providers with whom enrollees are locked in should be monitored to ensure they are not contributing to the problem.

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[16] *See* 42 U.S.C. § 1306a(a)(30)(A).
[17] *See* 42 U.S.C. § 1396n(a)(2); *see* 42 C.F.R. § 431.54; CMS, STATE MEDICAID MANUAL ¶ 2103.D (including lock-in as an exception to 42 U.S.C. § 1396a(a)(23),the Medicaid freedom of choice requirement). These federal requirements also apply to enrollees in Medicaid managed care programs.
[18] H.R. Rep. No. 158, 97th Cong., 1st Sess., Vol. II, 309 (1981).
[19] 42 U.S.C. § 1396n(a)(2)(A).
[20] *Id.*
[21] *Id.* § 1396n(a)(2).
[22] *Id.* § 1396n(a)(2)(B); 42 C.F.R. § 431.54(e)(2).
[23] 42 U.S.C. § 1396n(a)(2)(A).
[24] 42 C.F.R. § 431.54(e)(3). See also H.R. Rep. No. 158, 97th Cong., 1st Sess., Vol. II, 309 (1981) ("[I]n no event, should services from any certified provider be denied such recipient in the case of genuine emergency.").
[25]H.R. Rep. No. 158, 97th Cong., 1st Sess., Vol. II, 309 (1981).

An example illustrates some of the practical considerations that come into play when implementing a lock-in program. As noted above, states are interested in prescription drug lock-in programs. These programs must meet all of the requirements of federal law described above.[26] In addition, to ensure that the lock-in is actually based on misuse of services, the criteria for selection should determine whether the individual has a medical need for the medications due to some other reason, such as HIV/AIDS or another chronic disease or hospice care. There should be heightened scrutiny of selection that is triggered simply because the individual has exceeded a numerical threshold, for example using more than five different providers or taking more than seven prescriptions per month. Finally, care must be taken to ensure that locked-in individuals retain free choice of provider to treat other health conditions such as high blood pressure or an infection.

Judicial opinions addressing beneficiary lock-in

A handful of court decisions discuss the requirements for Medicaid lock-in restrictions. The most frequently cited case, *Tripp v. Coler*, involved a multi-pronged challenge to the Illinois lock-in program.[27] Plaintiffs, first, challenged a policy that determined beneficiaries to be overusers based solely on absolute numbers and without regard to their medical conditions. The court enjoined the policy, holding that "[t]he Department's practice of targeting overusers solely by a statistical review of level of medical usage without any information on his or her medical condition or needs contravenes the [federal Medicaid] statute."[28]

The plaintiffs also challenged the Illinois program because it restricted all the members of an "assistance unit" to the same physician when only one member had

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[26] CMS, *Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid* 4-5 (Jan. 2012), https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaidintegrityprogram/downloads/drugdiversion.pdf (last visited June 1, 2016); *see generally* Dep't of Health & Human Servs. Office of Inspector Gen'l, *Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs* 21 (Aug. 2014) (recommending that CMS restrict certain beneficiaries to a limited number of pharmacies or prescribers), http://oig.hhs.gov/oei/reports/oei-02-11-00170.pdf (last visited June 1, 2016).

[27] *Tripp v. Coler*, 640 F. Supp. 848 (N.D. Ill. 1986).

[28] *Id.* at 855. *Cf. Gross v. North Dakota Dep't of Health Servs.,* 652 N.W.2d 354 (N.D. 2002) (affirming administrative hearing decision allowing lock-in where beneficiary had a history of consulting many physicians simultaneously for the same condition, two of his primary care physicians recommended lock-in, and as a result of uncoordinated care, he had experienced adverse health problems); *Gerber v. Comm'r., Dep't of Pub. Welf.*, 577 A.2d 948 (Pa. Commw. Ct. 1990) (affirming lock-in where history profile showed petitioner used six different physicians for purpose of receiving same or similar services and same or similar prescriptions for analgesics and tranquilizers).

been determined to be an over-user. Applying straightforward statutory construction, the court enjoined this policy because the statute, 42 U.S.C. § 1396n(a)(2), consistently refers to restricting the "individual," not a "family unit."[29]

On the other hand, the court concluded that the State could lock the beneficiary into a primary care provider so long as the provider was qualified by training and by the strictures of medical ethics to provide the overall treatment and supervision the state plan calls upon the primary care physician to provide. Nevertheless, the court did require the state to institute a mechanism for reviewing the choice of primary care physician based on the overuser's medical needs so as to assure that the designated physician could provide the needed treatment supervision.[30]

Additionally, the court held the state could not withhold Medicaid eligibility and care as a sanction for overuse if, after receiving notice, the alleged overuser did not make a timely identification of a primary care provider.[31] Nor could the state lock the overuser in indefinitely; it could either automatically lift the sanction at the end of a fixed period of time or adopt a review procedure that would be triggered at a certain point.[32]

Finally, the plaintiffs criticized the notices the Medicaid agency used to inform families that they were locked-in. The court enjoined the notices because they failed to provide an adequate explanation of the reasons for the decision. Instead, the notices gave ultimate reasons, did not identify the legal standard by which a beneficiary's usage was judged, did not identify the precise medical items or services at issue, and failed to identify which person in the family was determined to have overused medical care.[33]

Even after *Tripp*, additional courts have had to clarify the meaning of the Medicaid laws. For instance, in *Matthews ex rel. Matthews v. Ibarra*, the court enjoined Colorado's beneficiary lock-in program because it was restricting the plaintiffs' children, not just the plaintiff. To add insult, the court noted that Ms. Matthews had been placed in lock-in even though her physical disabilities required various prescription drugs and her frequent use of Medicaid services was medically necessary.[34]

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[29] *Tripp*, 640 F. Supp. at 853 (citing a federal HHS finding that family unit lock-in violates the statute).
[30] *Id*. at 854.
[31] *Id*. at 855.
[32] *Id.* at 857.
[33] *Id.* at 858-59. *Accord Parham v. Perales,* 132 A.D.2d 557 (N.Y. 1987) (directing removal of lock-in restriction following notice and fair hearing, when state representative at the hearing was not the person who made the lock-in determination or even had any personal knowledge of the determination).
[34] *Matthews ex rel. Matthews v. Ibarra*, 703 F. Supp. 68, 69 (D. Colo. 1989).

Conclusion

Whether your state has a long-standing lock-in program or is considering implementing such a program, the program must be designed and operated in compliance with federal standards. And while states have a modicum of discretion regarding the nature and extent of their lock-in provisions, all states must comply with the following federal requirements:

1. Lock-in must be limited to a **reasonable period** of time.
2. Lock-in must be based on a finding by the state that the individual is using services that are **not medically necessary**.
3. Lock-in can restrict **only the over-user**, not other family members.
4. Locked-in enrollees must have access to a quality provider who can actually provide the needed services and treatments and supervision for these services and treatments, taking into account **geographic location and travel time.**
5. Lock-in cannot apply to **emergencies**.
6. Lock-in must be preceded by an **individualized written notice and the opportunity for a hearing**.

Finally, these programs need to be integrated and monitored. A recent assessment of Medicaid lock-in programs concluded that "most Medicaid agencies appear to have little ongoing interaction with … enrollees after locking them in, such as recommendations or referrals to pain management specialists or substance use treatment, if warranted."[35] As a result, lock-in enrollment is an underused opportunity to provide case management and education. Montana Medicaid has reportedly established its lock-in program to address this problem—among other things, enrolling beneficiaries as "clients" in Team Care, which provides multidisciplinary care and education over a 24-month enrollment period.[36]

Lock-in programs also need to be the subject of ongoing evaluation. Unfortunately, to date, there is a "remarkable dearth of peer-reviewed literature evaluating the design and effectiveness of Medicaid lock-in programs."[37] Most of the attention has focused on cost (with studies suggesting the potential to generate savings

[35] *See* A.W. Roberts & A.C. Skinner, *Assessing the present state*, *supra* n.6, at 439.
[36] *Id.*
[37] *Id.*

for Medicaid programs).[38] Importantly, future evaluations need to monitor the extent to which lock-in programs are coupled with case management and care coordination activities that result in Medicaid enrollees reducing their use of multiple doctors, unneeded pharmaceuticals, and/or emergency rooms. Clearly, care coordination lock-in programs will feature criteria that differ from programs being implemented as a straightforward cost saving mechanism.

[38] CDC National Center for Injury Prevention & Control, *Patient Review & Restriction Programs* 2-3 (2012), https://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf (last visited June 26, 2016).