

Pharmacy and Provider Lock-in Programs in Medicaid Fee for Service

Lock-in programs, sometimes referred to as patient review and restriction programs, require patients considered at risk for misuse of certain drugs to obtain and fill prescriptions from predesignated pharmacies and prescribers. Such at-risk patients are identified through criteria that may include the number of prescriptions and pharmacies they have visited to obtain controlled substance prescriptions within a certain time frame (CMS 2016). These patterns are generally identified through claims data; however, some states also allow medical professionals to refer patients to the lock-in program.

Historically, lock-in programs have been used in Medicaid under both fee for service (FFS) and managed care to address fraud, waste, and abuse—including provider or pharmacy shopping, which contributes to controlled substance misuse, diversion, and overdose (Roberts et al. 2016). Given that Medicaid beneficiaries experience opioid use disorder at higher rates than individuals who are privately insured, federal and state policymakers are focusing on Medicaid lock-in programs as part of a strategy to reduce opioid misuse and ultimately drug overdose (MACPAC 2017, Roberts and Skinner 2014).¹

States that operate lock-in programs must do so within certain federal regulations, but also have flexibility in program design. In this brief, we provide a summary of lock-in policies used in Medicaid FFS. State specific lock-in policies for both FFS and managed care, and other policies specific to controlled substances, can be found in [MACPAC's drug utilization review \(DUR\) compendium](#).²

This issue brief begins with background on the federal regulation of lock-in programs. It then describes the variation across states on several dimensions, including how states account for federal regulatory requirements; whether beneficiaries are restricted to a designated pharmacy, prescriber, or both; the criteria states use to lock-in beneficiaries; the timeframe beneficiaries are locked in; and the number of beneficiaries affected by these programs. The brief concludes with a discussion of how beneficiaries may circumvent lock-in programs through out-of-pocket payments for controlled substances.

Medicaid Lock-in Programs in Brief

Generally, a lock-in program is one tool used by states as part of a broader DUR strategy.³ Most states have DUR policies in place that are specific to controlled substances. These policies include opioid prescribing controls or safety edits; additional policies to identify fraud, waste, and abuse at the prescriber, pharmacy, and beneficiary level; and managing use of antipsychotics in children. Most states use lock-in programs to limit a beneficiary's overuse or misuse of certain medications, particularly controlled substances, including opioids. However, these programs may sometimes lock-in beneficiaries who are not misusing opioids (e.g., individuals receiving cancer treatment) and may create additional risk for those already seeking treatment for opioid use disorder. For example, buprenorphine is an opioid used for



medication-assisted treatment of opioid use disorder in office-based settings. In the early stages of treatment, it is not uncommon to make several buprenorphine dosage adjustments, thus increasing the likelihood that beneficiaries may be locked in because they are receiving multiple prescriptions within a certain timeframe (Gerther 2018).

Federal regulations authorize the establishment of lock-in programs within Medicaid; however, states have broad discretion to determine whether and how they are implemented. Programs may only restrict beneficiaries to designated providers if the following conditions are met:

- The state gives the beneficiary notice and opportunity for a hearing before imposing restrictions.
- The state ensures that the beneficiary has reasonable access to Medicaid services of adequate quality.
- The restrictions do not apply to emergency services (42 CFR 431.54(e)).

The Centers for Medicare & Medicaid Services (CMS) has not issued specific guidance for state Medicaid programs beyond these regulations (GAO 2015).

Use of lock-in programs is widespread, with 45 states and the District of Columbia operating FFS lock-in programs during fiscal year (FY) 2018.⁴ Although lock-in programs are intended to prevent fraud, waste, and abuse, states do not have a consistent method of measuring lock-in program performance, and there is no federal guidance on the appropriate pre- and post-lock-in time period when accounting for savings. Even so, 24 states did not report any savings in the most recent annual report, while others reported savings of as much as \$52.8 million (North Carolina). For states reporting savings, the majority (19 states) report savings of less than \$70,000 annually (CMS 2019a). Such savings may capture cost avoidance associated with decreases in unnecessary prescriptions, ancillary tests, and hospital, physician and emergency department claims.

There is little peer-reviewed research on the design and effectiveness of lock-in programs (ASAM 2016, Roberts and Skinner 2014). State-specific evaluations have shown that lock-in programs can help reduce use of controlled substances. But evidence linking lock-in programs to lower diversion rates, lower rates of substance use disorders (SUDs), increased engagement in SUD treatment, or reduced overdose deaths among Medicaid beneficiaries has not been established (ASAM 2016). The Centers for Disease Control and Prevention (CDC) has also called for additional evaluations of lock-in programs to examine their impact on health-related outcomes, including hospitalizations and overdose deaths.

State Variation in Lock-in Programs

States must follow federal regulations regarding notification and right to appeal, reasonable access to services, and exemptions for emergency services, but the implementation of these requirements can vary across states. In addition, states vary in whether they restrict beneficiary access to a designated pharmacy, prescriber, or both. Program criteria that states use to identify which Medicaid beneficiaries are eligible for enrollment in a lock-in program also differ.⁵ Other areas of variation include the number of beneficiaries enrolled in a lock-in program, the timeframe for which beneficiaries are restricted to designated pharmacies or providers, and whether beneficiaries are referred to additional medical services (e.g. pain management). Below we describe state variation across these dimensions.



Medicaid and CHIP Payment
and Access Commission

www.macpac.gov

Notification and right to appeal

Generally, beneficiaries receive a written notice that they have been identified for inclusion in a lock-in program before they are enrolled in the program. Typically, this notice also provides beneficiaries with instructions to assist them in selecting a designated provider (e.g., pharmacy, prescriber, or both) that is part of the lock-in program. Written notification is usually provided approximately 30 days before a beneficiary is locked in; however, some states have shorter or longer notification periods (Pew 2016).

The written notice also explains the beneficiary's right to appeal enrollment in the lock-in program. Most states give beneficiaries at least 30 days to file an appeal. However, states such as Colorado give beneficiaries a 10-day window, while Vermont and Washington allow up to 90 days (Pew 2016a).

Reasonable access to services

Medicaid programs must ensure beneficiaries still have reasonable access to services, and they must exempt emergency services from lock-in restrictions. As a result, some states exclude beneficiaries with complex medical needs from lock-in programs; for example, beneficiaries with certain types of cancer and those in long-term care. Some states also exclude beneficiaries in hospice care or skilled nursing facilities. States may also exclude beneficiaries on a case-by-case basis if a clinical review determines that their medication use is appropriate for their health condition (Pew 2016a).

Exemption for emergency services

Little information is available on how states apply the exemption for emergency services. North Carolina allows for an emergency short-term supply (e.g., three days) of a controlled substance to be provided to a locked-in beneficiary by a pharmacy or prescriber to which they are not locked in (Werth et al. 2014). Maryland exempts prescriptions from the lock-in program if they were written as a part of an emergency department visit, were pursuant to hospital inpatient treatment, or were for specialty drugs.⁶ Texas specifically defines the emergency medical conditions that are exempt from lock-in restrictions.⁷

Designated providers

Restricting access to prescribers and pharmacies is intended to enhance care coordination for these patients and curb provider and pharmacy shopping, thereby reducing controlled substance abuse, overdose, and diversion (Roberts et. al 2016). Thirty-four states can restrict beneficiaries to both a prescriber and a pharmacy; 36 states and the District of Columbia have the ability to restrict a beneficiary to just a pharmacy; and 25 states can restrict beneficiaries to a specific prescriber (CMS 2019a).

In lock-in programs restricting the beneficiary to one pharmacy, a patient may still obtain prescriptions from multiple prescribers and fill them at a designated pharmacy. This approach has been criticized, however, as prescribers may be unaware that patients are receiving controlled substances from multiple providers, putting beneficiaries at risk for dangerous drug interactions (Pew 2016b).

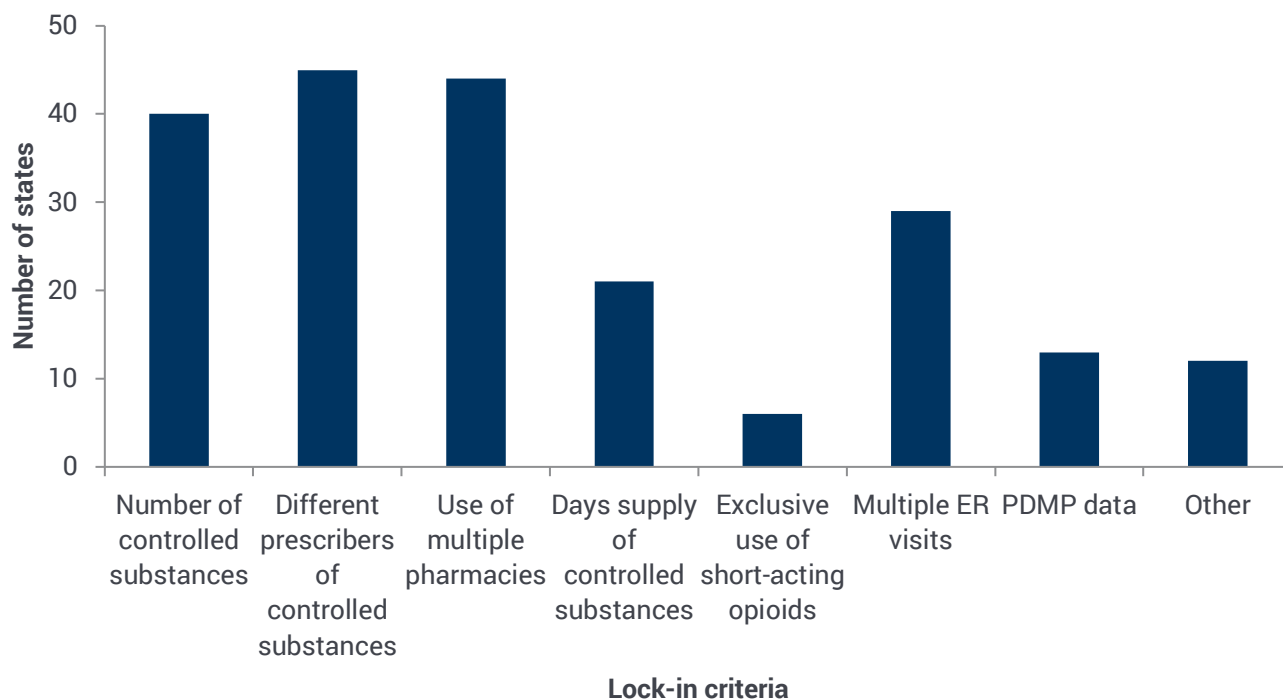


While not captured in CMS’s annual report, some states may also lock in a beneficiary to one hospital. A 2014 study of lock-in programs noted at least seven states lock in beneficiaries to one prescriber, one pharmacy, and one hospital (Pew 2016a).

Enrollment criteria

Medicaid beneficiaries typically become eligible for enrollment in a lock-in program because they meet a state-defined threshold of controlled substance prescription fills, use different prescribers of controlled substances, or use multiple pharmacies in a specified time period (Figure 1). These thresholds vary and are defined by each state. For example, Maryland enrolls beneficiaries with six or more prescriptions for controlled substances and three or more pharmacies or prescribers (COMAR 2019). In comparison, Wyoming sets a threshold at two or more controlled substance prescriptions from different prescribers and use of two or more pharmacies within a designated time period (Pew 2016a). Because there is wide variation in criteria being used, there is no consensus on best practice for these programs (CDC 2012, Pew 2016b, Roberts and Skinner 2014).⁸

FIGURE 1. Number of States with Selected Lock-in Program Criteria in Medicaid FFS, FY 2018



Notes: FFS is fee for service. ER is emergency room. FY is fiscal year. PDMP is prescription drug monitoring program. This table includes the criteria used in Medicaid FFS programs for states that had a lock-in program in fiscal year (FY) 2018. California, Florida, Iowa, and South Dakota did not have such a program in place in FY 2018. In addition, this figure does not include information on the state of Arizona because of the state’s existing waiver of drug utilization review requirements included in their approved Section 1115 waiver, valid until September 2021.

Source: CMS 2019a.



Medicaid and CHIP Payment
and Access Commission

www.macpac.gov

Lock-in programs use a variety of criteria to identify at-risk beneficiaries. In some cases, beneficiaries only need to meet a subset of state-adopted criteria to be locked in. For example, in New Hampshire, beneficiaries who meet three of the following criteria must be enrolled in the lock-in program:

- used three or more pharmacies within a 90-day period;
- used three or more physicians prescribing within a 90-day period;
- visited the emergency room twice or more within 90 days, or exceeded emergency room and physician visit service limits;
- received 100 units per prescription per seven-day supply;
- received three or more medications prescribed of the same drug class within 90 days; or
- received the same or a similar drug within 2 days from different pharmacies (Pew 2016).

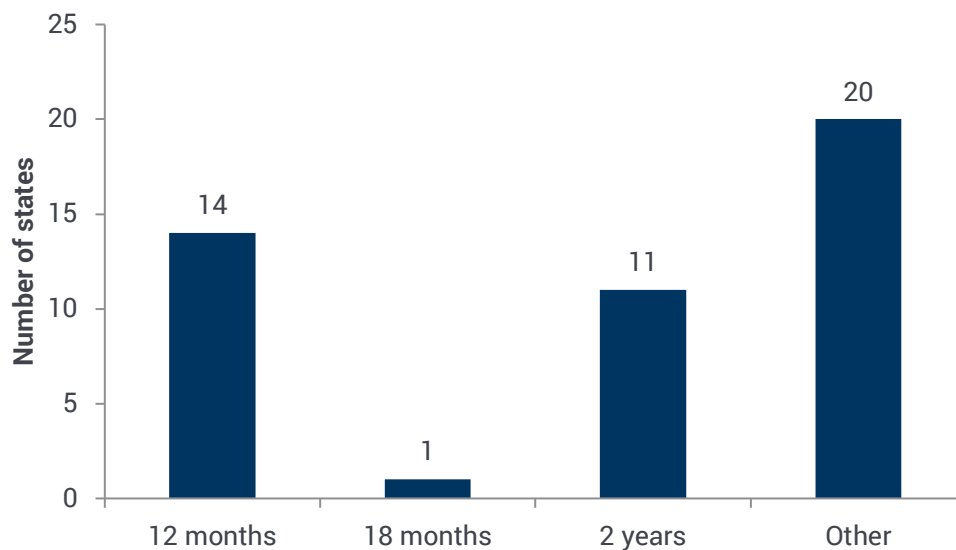
Thirty-one states allow medical professionals to refer a Medicaid beneficiary to a lock-in program. As of 2016, three states reported that they were not using state-established criteria to identify new beneficiaries for the lock-in program, or these states were only identifying patients via a referral process due to limited program resources (Pew 2016a).

Ensuring a wider range of drugs is included in lock-in programs. Lock-in programs have primarily been used for controlled substances. In 2015, the U.S. Government Accountability Office noted that expanding them to include other medications (e.g., drugs used to treat HIV or certain antiepileptic medications) would address broader patterns of drug misuse (GAO 2015). At that time, CMS did not collect information on non-controlled substances in its annual DUR survey, but such information is now included. In FY 2018, 26 states had a process in place to identify potential fraud or abuse of non-controlled drugs by beneficiaries. However, only four states specifically noted that beneficiaries may be enrolled in a lock-in program for use of non-controlled substances (CMS 2019a).

Timeframe

Generally, Medicaid FFS lock-in programs enroll beneficiaries for one to two years before assessing them for re-enrollment (Figure 2). In some states, the timeframes are shorter. For example, in Arkansas, beneficiaries are not locked-in for a specific time period. Rather, they are reassessed for re-enrollment annually. In comparison, beneficiaries in Pennsylvania may be locked in for five years. In some instances, the lock-in time period is determined on a case-by-case basis (New Jersey and New Mexico).



FIGURE 2. States Adopting an Initial Timeframe for Lock-in Program Enrollment in Medicaid FFS, FY 2018

Notes: FFS is fee for service. FY is fiscal year. This table includes the criteria used in Medicaid fee-for-service programs for states reporting to have a lock-in program for FY 2017. California, Florida, Iowa, and South Dakota did not have such a program in place in FY 2018. In addition, this figure does not include information on Arizona because of the state's existing waiver of drug utilization review requirements included in their approved Section 1115 waiver, valid until September 2021.

Source: CMS 2019a.

Enrollment

Very few beneficiaries are enrolled in a lock-in program at any given time. In FY 2018, 18 states reported that, on average, less than 0.1 percent of FFS beneficiaries were enrolled in the state's lock-in program. In eight states, approximately 1 percent of FFS Medicaid beneficiaries were locked in annually.

The number of beneficiaries affected by these programs is small in comparison to total Medicaid enrollment. For example, in 2014, Texas had over 3.8 million Medicaid beneficiaries, but only 1,145 were enrolled in the state's lock-in program. Factors such as the rate of prescription drug abuse, budget constraints, and the criteria used to identify at-risk beneficiaries contribute to variation in lock-in program enrollment across states (Pew 2016a).

Referrals for additional services

Lock-in programs could potentially be used to help promote more appropriate care for beneficiaries, for example by providing referrals to pain specialists or SUD treatment providers when a health care provider deems it clinically appropriate (ASAM 2016 and Pew 2016b).⁹ However, most Medicaid FFS lock-in programs do not connect beneficiaries to such care (Gerther 2018, Roberts and Skinner 2014). A 2016 survey by the Pew Charitable Trusts found only two states offered referrals to SUD treatment and only one state made referrals to pain specialists (Pew 2016b).



Circumventing Lock-in Programs

In some states, enrolled patients can avoid enforcement of lock-in restrictions by paying the full out-of-pocket price for controlled substance prescription fills at a pharmacy to which they are not locked in. Typically, the state Medicaid program may be unaware that this has occurred, since such transactions do not generate a Medicaid claim.

A review of North Carolina's lock-in program that matched Medicaid pharmacy claims with data from the state's prescription drug monitoring program (PDMP) documented this phenomenon. (PDMPs are statewide electronic databases that collect dispensing data on controlled substances.) While the number of prescription fills decreased after lock-in enrollment, beneficiaries were more likely to purchase a controlled substance out of pocket (Box 1).¹⁰

Beneficiaries in states that do not require managed care organizations (MCOs) to operate a lock-in program may circumvent lock-in by enrolling in managed care. For example, Illinois operates a lock-in program for FFS beneficiaries but does not currently require managed care plans to operate such a program. Beneficiaries are removed from lock in if they enroll with an MCO. In other states, MCOs may use different criteria to identify at-risk beneficiaries for lock-in program enrollment. Beneficiaries may switch plans to avoid plans with more restrictive criteria.

BOX 1. North Carolina Lock-in Program, Out-of-Pocket Spending for Medicaid Beneficiaries

In October 2010, North Carolina established a lock-in program targeting beneficiaries with at least seven opioid claims, seven benzodiazepine claims, or claims from at least four unique prescribers of these medications in two calendar months. Beneficiaries who were dually eligible for Medicare and Medicaid or had cancer were excluded from the lock-in program. Once beneficiaries were locked in, they were restricted to one prescriber and one pharmacy of their choosing for a 12-month period. After 12 months, beneficiaries were evaluated for reenrollment.

Among beneficiaries who had long-term Medicaid coverage, the average number of per-person per-month fills of opioid and benzodiazepine prescriptions decreased by 17 percent after beneficiaries were enrolled in the lock-in program. This includes prescriptions paid for by Medicaid as well as prescriptions that were paid out-of-pocket. In addition, per-person per-month prescription claims for opioids and benzodiazepines covered by Medicaid decreased 43 percent after lock-in enrollment.

However, approximately half of the observed reduction in Medicaid claims for controlled substance prescriptions after lock-in enrollment was offset by new out-of-pocket controlled substance prescription fills. Circumvented controlled substance prescription fills increased 195 percent after lock-in program enrollment, and locked-in beneficiaries were also 3.6 times more likely to purchase a controlled substance prescription out-of-pocket after lock-in program enrollment than before it (Andrews et al. 2016).



State Medicaid agencies may be able to use PDMPs to identify beneficiaries who circumvent lock-in programs as these include information on controlled substance prescriptions that are paid out-of-pocket. However, the extent to which they do so is unclear. Traditionally, lock-in programs rely on pharmacy claims data, which limits their ability to monitor and restrict services that are paid out-of-pocket. While policies vary by state, physicians and pharmacists may have access to these databases to identify prescribers and patients that engage in potential fraud or misuse of controlled substances (CMS 2019a).

As of FY 2018, 49 states and the District of Columbia operated a PDMP; in 32 of these states, Medicaid programs could query the PDMP database to review prescribing data. In some states, including Colorado and Nebraska, state law does not grant Medicaid programs access to the state's PDMP. When Medicaid agencies do have access to the PDMP, they often encounter barriers when accessing this data. For example, they may only be able to access PDMP data for one patient at a time, PDMP data may not be available in real time, or they may only be able to access PDMP data if they have a formal investigation underway.

In states where Medicaid lock-in programs do not have access to the state's PDMP, state Medicaid programs and other payers can still require prescribers and dispensers to check the state's PDMP before a controlled substance is prescribed or dispensed to beneficiaries (ASAM 2016). Sixteen states require prescribers to access patient history in the PDMP prior to prescribing controlled substances, as specified in provider agreements with the state Medicaid agency (CMS 2019a).

Endnotes

¹ The Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198) established a controlled substance lock-in program in every Medicare Part D prescription drug plan, beginning in January 2019. Private payers have also recently established lock-in programs in response to the opioid epidemic (Roberts et al. 2016).

² Drug utilization review (DUR) is a two-phase process consisting of prospective and retrospective screening and monitoring of prescription drug claims to identify potential fraud, misuse, or medically unnecessary care, and to implement corrective action as needed (CMS 2019b). Every state operates a DUR program in accordance with federal statute.

³ The SUPPORT for Patients and Communities Act (SUPPORT Act, P.L. 115-271) required all states to implement several drug utilization review (DUR) policies by October 1, 2019. Generally, these requirements relate to controlled substances, including opioids; however, the SUPPORT Act also required states to implement a program to monitor antipsychotic medications used by children. Additional information on SUPPORT Act requirements related to DUR policies are discussed in a MACPAC fact sheet on *Medicaid Drug Utilization Review Requirements*.

⁴ California, Florida, Iowa and South Dakota reported that they did not have a FFS lock-in program for FY 2018. In addition, information on the state of Arizona is excluded from this analysis because of the state's existing waiver of drug utilization review requirements included in their approved Section 1115 waiver, valid until September 2021.

⁵ While FFS lock-in criteria vary by state, they also vary in managed care. The majority (95 percent) of managed care organizations use lock-in criteria that differ from the state's FFS criteria.

⁶ Md. Code Ann., Corrective Managed Care Plan § 10.09.75.02 (2019). <http://mdrules.elaws.us/comar/10.09.75.02>.



⁷ An emergency medical condition is defined as “... a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain), such that the absence of immediate medical attention could reasonably be expected to result in: placing the client’s health (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; serious impairment to bodily functions; and serious dysfunction of any bodily organ or part” (HHSC 2019).

⁸ CDC recommends that in developing patient selection criteria, states should consider including behaviors that have been shown to be a health risk to beneficiaries in terms of risk of abuse or overdose. For example, high daily opioid dosage (e.g., more than 100 or 120 morphine milligram equivalents per day), the number of prescriptions obtained by a patient during a given period, the number of prescribers for a patient in a given period, or the number of pharmacies dispensing to a patient during a given period (CDC 2012).

⁹ Some stakeholders have recommended that beneficiaries enrolled in lock-in programs, should be referred to a pain specialist or an SUD treatment provider when it is deemed clinically appropriate (ASAM 2016 and Pew 2016b).

¹⁰ Findings from North Carolina may not be generalizable to other lock-in programs due to state variation in beneficiary characteristics, program design, and program size (Andrews et al. 2016).

References

The American Society of Addiction Medicine (ASAM). 2016. *Public policy statement on patient review and restriction programs*. Washington, DC: ASAM. https://www.asam.org/docs/default-source/public-policy-statements/11-2-public-policy-statement-on-prr-programs--updated.pdf?sfvrsn=5b5d74c2_0.

Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services. 2012. *Patient review & restriction programs: lessons learned from state Medicaid programs*. Atlanta, GA: CDC. https://www.cdc.gov/drugoverdose/pdf/PDO_patient_review_meeting-a.pdf.

Gerther, Alex K. 2018. *Lock-in programs may be doing more harm than good—and Congress is considering expanding them*. Health Affairs. <https://www.healthaffairs.org/doi/10.1377/hblog20180629.14455/full/>.

Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services. 2019a. *National Medicaid Drug Utilization Review (DUR) Federal Fiscal Year (FFY) 2019 Fee-For-Service (FFS) Annual Report (for the period October 2017–September 2018)*. Baltimore, MD: CMS. November 2019. <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/drug-utilization-review/2018-dur-ffs-summary-report.pdf>

Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services. 2019b. Drug Utilization Review. Baltimore, MD: CMS. <https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/index.html>.

Health and Human Services Commission, State of Texas (HHSC). 2019. Section 4: Client eligibility. In *Texas Medicaid provider procedures manual: Volume 1*. Austin, TX: HHSC. http://www.tmhp.com/manuals_pdf/tmppm/tmppm_living_manual_current/1_04_Client_Eligibility.pdf.

The Pew Charitable Trusts (Pew). 2016a. *Curbing prescription drug abuse with patient review and restriction programs: Learning from Medicaid agencies*. Washington, DC: Pew. <https://www.pewtrusts.org/-/media/assets/2017/01/prr-chartbook-122016.pdf>.

The Pew Charitable Trusts (Pew). 2016b. *Patient review and restriction programs in Medicaid: Expert panel recommendations to help curb misuse of prescription drugs*. Washington, DC: Pew. https://www.pewtrusts.org/-/media/assets/2015/12/prrmedicaidbrief_v2.pdf.

Medicaid and CHIP Payment
and Access Commission

www.macpac.gov

Roberts, A.W., and A.C. Skinner. 2014. Assessing the present state and potential of Medicaid controlled substance lock-in programs. *Journal of Managed Care Pharmacy*, 20(5): 439–46.
<https://www.jmcp.org/doi/pdf/10.18553/jmcp.2014.20.5.439>.

Roberts, A.W., J.F. Farley, G.M Holmes et. al. 2016. Controlled substance lock-in programs: examining an unintended consequence of a prescription drug abuse policy. *Health Affairs* 31, No 10: 1884–1892.
<https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2016.0355>.

U.S. Government Accountability Office (GAO). 2015. *Additional reporting may help CMS oversee prescription-drug fraud controls*. Washington, DC: GAO. <https://www.gao.gov/assets/680/671241.pdf>.

Werth, S.R., N. Sachdeva, A.W. Roberts, et al. 2014. North Carolina Medicaid recipient management lock-in program: The pharmacist's perspective. *Journal of Managed Care & Specialty Pharmacy* 11, No. 20: 1122–1128.
<https://pdfs.semanticscholar.org/d699/e8dd7eb648a88062b9be630c7c620567914c.pdf>.

