

# Medicaid Drug Utilization Review Requirements

In response to the nationwide opioid epidemic, state Medicaid programs are increasing efforts to address prescription opioid misuse. Drug utilization review (DUR) is one of the tools they can use for this purpose. 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 2019a). DUR programs must be conducted in accordance with Section 1927(g) of the Social Security Act (the Act).

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act, P.L. 115-271) required all states to implement several drug utilization management policies by October 1, 2019.<sup>1</sup> Generally, these requirements relate to controlled substances, including opioids; however, the SUPPORT Act also requires states to implement a program to monitor antipsychotic medications used by children. Certain populations, such as individuals in hospice care or those receiving cancer treatment, are exempt from these requirements.

In August 2019, the Centers for Medicare & Medicaid Services (CMS) issued guidance requiring states to submit state plan amendments (SPAs) by December 31, 2019 to describe how they will comply with these provisions and actions they will take based on the monitoring of opioid prescribing patterns required through the SUPPORT Act (CMS 2019b).<sup>2</sup> On June 17, 2020, CMS issued a proposed rule implementing requirements under Section 1004 of the SUPPORT Act for state Medicaid DUR standards in fee-for-service (FFS) and managed care programs. The proposed rule would also require states to establish DUR policies to monitor subsequent opioid prescriptions for beneficiaries receiving medications for opioid use disorder (MOUD), and to identify beneficiaries who should be considered for co-prescribing or co-dispensing of naloxone to reduce the risk of opioid overdose.

Many states already had opioid-specific policies included in their Medicaid DUR programs prior to the enactment of the SUPPORT Act. For example, 32 states had quantity limits in place for certain opioid prescriptions above a certain threshold. Some states had also established an automated claims review process to monitor concurrent prescribing of opioids and benzodiazepines.

This fact sheet describes federal statute and regulations related to drug utilization control, summarizes the SUPPORT Act's DUR requirements for state Medicaid programs, and examines compliance with these requirements as of fiscal year (FY) 2018 (the most recent year for which data are available).<sup>3</sup> A [companion compendium](#) of state DUR policies can be found on MACPAC's website.<sup>4</sup>

## State DUR Policies

State Medicaid programs have been using DUR for decades to monitor and address patterns of prescription drug misuse. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90, P.L. 101-508)



mandated the use of DUR as part of the Medicaid outpatient prescription drug benefit. Specifically, federal law requires state DUR programs to include the following policies:

- prospective drug review;
- retrospective drug use review; and
- an educational program.

States also have the option to create a point-of-sale electronic claims management system for covered outpatient drugs (42 CFR 456.722).<sup>5</sup> These requirements are meant to ensure prescriptions are medically necessary, not likely to result in adverse events, and to identify patterns of fraud, waste, and abuse (§ 1927(g) of the Act).<sup>6</sup>

States are required to report annually on their state's FFS DUR program, including cost savings, physician prescribing habits, and adoption of new innovative DUR practices. This information is gathered through an annual survey conducted by CMS. Federal regulations also require that each Medicaid managed care organization (MCO) annually submit a summary of its DUR activities (42 CFR 438.3(s)(5)).<sup>7</sup> CMS compiled this information for FY 2018 and summarized the findings in the DUR FY 2019 FFS and MCO annual reports.

Most states have DUR policies that are specific to controlled substances, including opioids. These policies include lock-in programs that require beneficiaries to use a specific provider or pharmacy; opioid prescribing controls or safety edits; additional policies to identify fraud, waste, and abuse at the prescriber, pharmacy, and beneficiary level; and manage use of antipsychotics in children.

## Prospective DUR

Prospective DUR is composed of three components: point of sale review, drug counseling, and profiling.

**Point of sale review.** At the point of sale, a review must occur to identify certain potential drug therapy problems: therapeutic duplication, drug-disease contradiction, adverse drug-drug interaction, incorrect dosage, incorrect duration of drug treatment, drug allergy interactions, and clinical misuse.

**Drug counseling.** The state Medicaid agency must establish standards for pharmacists to provide counseling to beneficiaries or their caregivers. Such standards must address special situations in which the patient or patient's representative is not readily available to receive the offer to counsel or the act of counseling (e.g., when prescriptions are delivered through the mail). Counseling standards must also comply with certain minimum requirements set in federal regulations.<sup>8</sup>

**Profiling.** The state Medicaid agency must require a pharmacist to make a reasonable attempt to obtain, record, and maintain a patient profile. At a minimum, information kept in the patient profile must include the beneficiary's name, address, telephone number, date of birth (or age), and gender. It must also include a history of known allergies and drug interactions, a comprehensive list of medications the beneficiary is taking, and the pharmacist's comments relative to the beneficiary's drug therapy (42 CFR 456.705).



## Retrospective DUR

State Medicaid agencies must describe their retrospective DUR policies in their state plan. Retrospective DUR includes, but is not limited to, using predetermined standards to monitor the following:

- therapeutic appropriateness of a drug;
- overutilization and underutilization;
- appropriate use of generic products;
- therapeutic duplication;
- drug-disease contradiction;
- drug-drug interaction;
- incorrect drug dosage;
- incorrect duration of drug treatment; and
- clinical abuse or misuse.

Through established retrospective DUR processes, claims data and other records must be examined at least quarterly to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care associated with specific drugs or groups of drugs. Generally, retrospective DUR must occur through the state's Medicaid Management Information System (MMIS) or an electronic drug claims processing system that is integrated with the state's MMIS (42 CFR 456.709).

## Educational programs

The state must provide ongoing educational outreach programs that educate practitioners on common drug therapy problems. The educational program must include certain interventions such as written and oral electronic reminders containing patient-specific or drug-specific information and suggested changes in prescribing or dispensing practices, as well as face-to-face discussions with health care prescribers and pharmacists who have been targeted for educational intervention (42 CFR 456.711).

## DUR Requirements in the SUPPORT Act

In addition to the DUR requirements listed above, Section 1004 of the SUPPORT Act requires states to implement several other DUR policies, many of which are specific to opioid prescribing. The law also requires Medicaid MCOs to operate a DUR program that complies with these new requirements.<sup>9</sup> Specifically, the following Medicaid DUR policies took effect on October 1, 2019:

- safety edits and automated claims review processes for opioid refills and refill thresholds;
- automated claims review processes for monitoring concurrent prescribing of opioids and benzodiazepines;
- safety edits and automated claims review processes for monitoring maximum daily morphine equivalency prescribing;
- processes to identify potential fraud or abuse of controlled substances by prescribers;
- processes to identify potential fraud or abuse of controlled substances by pharmacies;
- processes to identify potential fraud or abuse of controlled substances by beneficiaries; and
- programs to monitor antipsychotic prescribing to children.



Certain beneficiaries are exempt from these requirements, including individuals who are receiving hospice or palliative care or treatment for cancer; residents of a long-term care facility or another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or any other individual the state decides to exempt from these requirements.<sup>10</sup>

## State compliance with FFS DUR requirements in the SUPPORT Act

Using the CMS DUR FY 2019 FFS annual report, MACPAC examined the extent to which state FFS programs met the SUPPORT Act's DUR requirements prior to their effective date (Table 1). Nearly all states complied with requirements to monitor opioid refills and refill thresholds, and potential fraud or abuse of controlled substances by beneficiaries, but more than half complied with the requirements to implement claims review processes for concurrent prescribing of opioids and benzodiazepines, and safety controls related to prescriptions in excess of maximum daily morphine equivalency. A description of each DUR policy and overview of state compliance is provided below.

**TABLE 1.** State Implementation of Drug Utilization Review Policies under Fee for Service Required by the SUPPORT Act, FY 2018

Policy	Number of state FFS programs with policy as of FY 2018
Safety edits and automated claims review processes for opioid refills and refill thresholds	49 states and the District of Columbia
Automated claims review processes for monitoring concurrent prescribing of opioids and benzodiazepines	28 states and the District of Columbia
Safety edits and automated claims review processes for monitoring maximum daily morphine equivalency prescribing	29 states
Processes to identify potential fraud or abuse of controlled substances by prescribers	35 states and the District of Columbia
Processes to identify potential fraud or abuse of controlled substances by pharmacies	36 states and the District of Columbia
Processes to identify potential fraud or abuse of controlled substances by beneficiaries	47 states and the District of Columbia
Programs to monitor antipsychotic prescribing to children	48 states

**Notes:** SUPPORT Act is Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. FY is fiscal year. Totals exclude U.S. territories and Arizona. Arizona did not submit responses to the DUR survey because of its existing waiver of these requirements under its Section 1115 demonstration waiver valid until September 2021. States report their DUR activities through an annual survey. CMS compiles the results from the survey and produces a summary report.

**Source:** CMS 2019c.



**Safety edits and automated claims review processes for opioid refills and refill thresholds.** States are required to use safety edits and an automated claims review process that indicates when an enrollee is prescribed an opioid refill that exceeds any limitation applied by the state, with restrictions on duplicate fills, early refills, and drug quantity limitations (CMS 2019b). Forty-nine states and the District of Columbia set early refill thresholds for controlled substances, including opioids, to prevent prescriptions from being refilled too soon.<sup>11</sup> States reported thresholds separately for Schedule II controlled drugs, and Schedule III through V controlled drugs.<sup>12,13</sup> These thresholds ranged from 75 percent to 100 percent before prescriptions for controlled substances could be refilled.

**Automated claims review processes for monitoring concurrent prescribing of opioids and benzodiazepines.** Opioids taken with benzodiazepines, a type of prescription sedative commonly prescribed for anxiety or insomnia, are high-risk drug combinations that can result in adverse health outcomes. According to the National Institute on Drug Abuse (NIDA), more than 30 percent of overdoses involving opioids also involve benzodiazepines (NIDA 2018). Recent data show an increase in the percentage of patients receiving concurrent opioid and benzodiazepine prescriptions (Sun et al. 2017). In 2016, the Centers for Disease Control and Prevention (CDC) recommended that clinicians avoid prescribing benzodiazepines concurrently with opioids.

States are required to have a retrospective automated claims review process that monitors when an enrollee is concurrently prescribed opioids and benzodiazepines. States may also implement a prospective safety edit system to provide educational information to patients and providers at the point of sale (CMS 2019b). As of FY 2018, 28 states and the District of Columbia had edits in place to monitor opioids and benzodiazepines being prescribed concurrently (CMS 2019c). States reported using prior authorization for concurrent prescribing, as well as prospective and retrospective DUR. Some states had additional monitoring processes in place. For example, prescribers in Arkansas, Colorado, and Mississippi who were flagged through retrospective DUR received educational intervention letters notifying them of the risks of this combination therapy (CMS 2019c).<sup>14</sup>

**Safety edits and automated claims review processes for monitoring maximum daily morphine equivalency prescribing.** Morphine milligram equivalents (MME) represent the value assigned to opioids to indicate their potency. An equivalency factor is used to calculate a dose of morphine that is equivalent to the opioid being prescribed or dispensed. The SUPPORT Act requires states to use safety edits for the maximum daily morphine equivalent for treatment of chronic pain, and an automated claims review process that indicates when an enrollee is prescribed the morphine equivalent that exceeds any limitation applied by the state. The safety edits must include an MME threshold amount (CMS 2019b).

As of FY 2018, 29 states had safety edits in place to alert pharmacy providers that the morphine equivalent daily dose prescribed had been exceeded. Of these states, 28 had an MME threshold amount. Sixteen of these states followed the CDC 2016 prescribing guidelines that recommended limiting opioid dosages to no more than 90 MME per day (Dowell et al. 2016). The remaining states had limits above the CDC recommended level; five states had a threshold of up to 120 MME per day and seven states had a threshold above this amount (CMS 2019c).



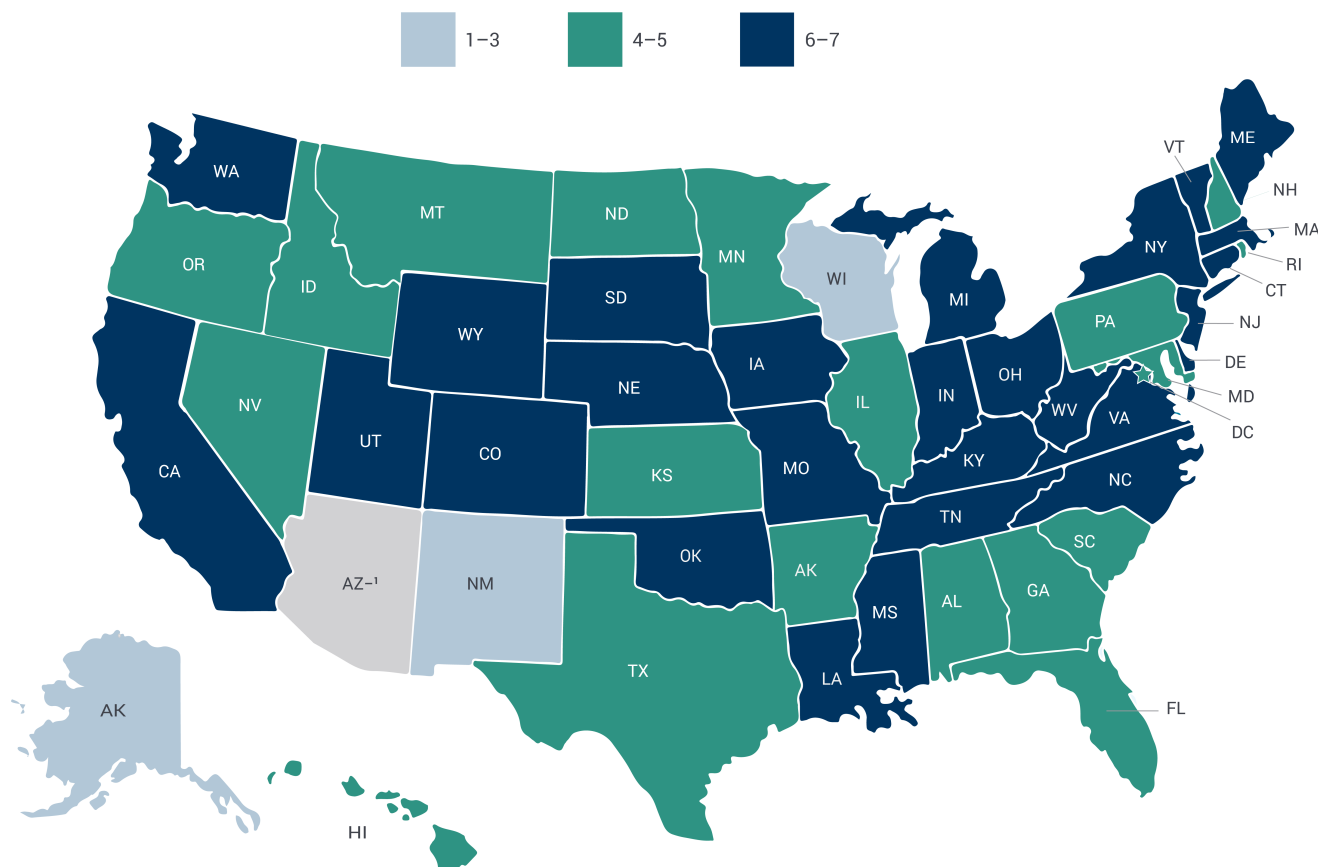
**Processes to identify potential fraud or abuse of controlled substances.** States are required to have a process in place to identify potential fraud or abuse of controlled substances by prescribers, pharmacies, and beneficiaries. States reported using various approaches to manage potential fraud and abuse, such as denying claims, referring cases to state program integrity units, referring providers to the appropriate medical board, or referring prescribers to the board of pharmacy. As of FY 2018, 35 states and the District of Columbia had processes to identify potential fraud by prescribers, and 36 states and the District of Columbia had processes to identify potential fraud by pharmacies. In addition, 47 states and the District of Columbia had processes to identify potential fraud by beneficiaries.

**Programs to monitor antipsychotic prescribing to children.** The SUPPORT Act requires states to monitor appropriate prescribing of antipsychotic medication to children, and states are required to report on monitoring activities for children in foster care or children less than 18 years of age. Forty-eight states either managed or monitored the appropriate use of antipsychotic medications in children as of FY 2018. Of these states, three states (Delaware, Oregon, and Utah) only monitored children in foster care, while 42 states had programs for all children (CMS 2019c). In addition, 41 states monitored the child's age, 36 states monitored antipsychotic dosage, and 32 states monitored concurrent use of multiple medications, known as polypharmacy. The most common types of monitoring programs involved prior authorization, age controls, prospective and retrospective DUR, diagnosis requirements, and dosing limits.

As of FY 2018, nearly all state FFS programs were complying with at least four of the seven DUR policies required through the SUPPORT Act (Figure 1). Eleven states had implemented all DUR policies required by the SUPPORT Act, while three states (Alaska, New Mexico, and Wisconsin) had only three of these policies in place.<sup>15</sup>



**FIGURE 1.** State Compliance with SUPPORT Act Requirements under Fee for Service by Number of Drug Utilization Review Policies in Place, FY 2018



**Notes:** SUPPORT Act is Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. FY is fiscal year.

<sup>1</sup> Arizona did not submit responses to the DUR survey because of its existing waiver of these requirements under its Section 1115 demonstration waiver, which is valid until September 2021. States report their DUR activities through an annual survey. CMS compiles the results from the survey and produces a summary report.

**Source:** CMS 2019c.

## Managed care compliance with DUR requirements in the SUPPORT Act

MCO DUR reporting is a new component of CMS reporting on DUR. The most recent report captures the number of MCOs in each state with specific DUR policies in place as of FY 2018 and includes data for 34 states and the District of Columbia.

MCO compliance with the DUR requirements varied by state and by policy type. For example, most (80 percent) MCOs in nearly all reporting states had programs to monitor maximum daily morphine



equivalency prescribing as of FY 2018. Similarly, nearly all MCOs in all reporting states had processes in place to identify fraud or abuse of controlled substances by prescribers, pharmacies, or beneficiaries. In contrast, just over half of MCOs in nearly all reporting states had implemented programs to monitor antipsychotic prescribing to children, and processes to monitor concurrent prescribing of opioids and benzodiazepines (CMS 2019d). Details are as follows.

**Safety edits and automated claims review processes for opioid refills and refill thresholds.** For most states, refill thresholds varied by MCO. The average MCO early refill threshold by state for Schedule II through Schedule V controlled drugs ranged from 73 percent in Colorado to 90 percent in Iowa, Kansas, Michigan, Nevada, and Mexico.

**Automated claims review processes for monitoring concurrent prescribing of opioids and benzodiazepines.** Slightly more than half (57 percent) of MCOs in 30 states and the District of Columbia monitored concurrent prescribing of opioids and benzodiazepines. States varied widely in terms of compliance, ranging from 20 percent of MCOs with this policy in place in South Carolina to 100 percent in Kansas, Massachusetts, New Hampshire, North Dakota, and Virginia.

**Safety edits and automated claims review processes for monitoring maximum daily morphine equivalency prescribing.** MCOs in 32 states and the District of Columbia monitored maximum daily morphine equivalency prescribing. In these states, nearly 80 percent of MCOs had this policy in place. In addition, 33 states and the District reported having an MME threshold amount; ten of these states had a threshold at or below the CDC-recommended level of 90 MME per day.

**Processes to identify potential fraud or abuse of controlled substances.** On average, nearly all MCOs in 34 states and the District of Columbia had policies in place to identify potential fraud or abuse of controlled substances by prescribers, pharmacies, or beneficiaries. In 17 states and the District of Columbia, all MCOs reported having policies in place to identify fraud or abuse for all three groups.

**Programs to monitor antipsychotic prescribing to children.** Approximately 60 percent of Medicaid MCOs in 30 states and the District of Columbia had these programs in place. MCOs were consistent in the populations and prescribing practices they monitored. For example, nearly 75 percent of MCOs monitored antipsychotic prescribing to all children. In addition, approximately one-third of MCOs monitored the child's age, antipsychotic dosage, and polypharmacy.

## Endnotes

<sup>1</sup> These requirements are consistent with prior guidance from the Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services, (CMS), and other entities regarding state monitoring of prescription opioid use (CMS 2016, Pew 2016, Pew 2015, CDC 2012).





<sup>2</sup> All 50 states and the District of Columbia submitted a SPA prior to the December 31, 2019 deadline. As of June 2020, 50 SPAs have been approved (Coster 2020).

<sup>3</sup> The information in this brief is drawn from the CMS *National Medicaid Drug Utilization Review (DUR) Federal Fiscal Year (FFY) 2019 Fee-For-Service (FFS) Annual Report* and the *National Medicaid Drug Utilization Review (DUR) Federal Fiscal Year (FFY) 2019 Managed Care Organization (MCO) Annual Report*, both of which capture state DUR policies as of FY 2018.

<sup>4</sup> The MACPAC compendium on *State Medicaid Fee-for-Service and Managed Care Organization Drug Utilization Review Program Policies* also captures features of pharmacy and provider lock-in programs, and state policies on quantity limits for opioids. Additional information on the use of such programs is discussed in a MACPAC issue brief on [Pharmacy and Provider Lock-in Programs in Medicaid Fee for Service](#).

<sup>5</sup> To evaluate the appropriateness and quality of Medicaid services, state Medicaid agencies must establish and use written criteria (42 CFR 456). States with managed care must monitor plan performance in utilization management (42 CFR 438.66). Additional requirements for state managed care contracts are listed below.

- The contract must permit the plan to place appropriate limits using utilization control, so long as the services can still reasonably achieve their intended purpose. For individuals with ongoing or chronic conditions, the provided services reflect the enrollee's continued need for them (42 CFR 438.210b). Compensation to those conducting utilization management may not incentivize limiting of medically necessary services (42 CFR 438.210e).
- The contract must require the plan to adopt practice guidelines that reflect clinical evidence and expert consensus. Utilization management decisions must be consistent with these guidelines (42 CFR 438.236).
- The contract must require the plan and its subcontractors to follow written policies and procedures for prior and re-authorization of services. The plan must ensure consistent application of the review criteria. Any service denial or authorization must be made by an individual with appropriate expertise (42 CFR 438.210b). Standard authorization decisions must be made within 14 calendar days. If the standard timeframe could seriously jeopardize the enrollee's life or health, the plan must make a decision as quickly as possible within 72 hours (42 CFR 438.210d).
- The contract must require the plan to comply with parity in mental health (MH) and substance use disorder (SUD) benefits. In the case of utilization management practices applied to MH and SUD benefits (and the underlying processes, evidentiary standards, and other factors driving them), these must be comparable to, and not more stringently applied than, those used in medical and surgical care (42 CFR 438.900-438.930, 42 CFR 440.345(c), 42 CFR 440.395).

While CMS reviews and approves managed care contracts, oversight of managed care organization (MCO) compliance with contract provisions lies with the states. States are required to contract with an outside organization to conduct external quality reviews, which include a review of compliance with the above managed care contracting requirements (42 CFR 438.358).

<sup>6</sup> States with managed care must also require MCOs to operate a DUR program and prior authorization program in line with the requirements under the state plan's drug coverage (42 CFR 438.3(s)). States were required to include these DUR provisions in managed care contracts with MCOs by October 1, 2019.

<sup>7</sup> Medicaid MCOs report details of their DUR activities through a separate survey. State Medicaid agencies then collect and submit both the FFS and MCO surveys to CMS.

<sup>8</sup> At a minimum, the state agency must account for the following in their counseling standards: (1) whether the offer to counsel is required for new prescriptions only, or for both new and refill prescriptions; (2) whether a pharmacist must make the offer to counsel or auxiliary personnel are authorized to make the offer; (3) whether only a patient's refusal to counsel must be documented, or whether documentation of all offers is required; (4) whether documentation of counseling is



required; and (5) whether counseling is required in situations where the patient’s representative is not readily available to receive a counseling offer or the counseling itself.

<sup>9</sup> CMS encouraged states to impose the new DUR requirements consistently on all MCOs in subsequent guidance issued in August 2019 (CMS 2019b). For example, CMS clarified that states may include these requirements in Prepaid Inpatient Health Plan and Prepaid Ambulatory Health Plan contracts. CMS may consider future rulemaking to codify the SUPPORT Act requirements for state Medicaid FFS programs and managed care organizations (Coster 2020).

<sup>10</sup> The Secretary of Health and Human Services must waive DUR requirements in the case of a natural disaster.

<sup>11</sup> This excludes Arizona, which did not submit responses to the DUR survey because of its existing waiver of these requirements under its Section 1115 demonstration waiver, which is valid until September 2021.

<sup>12</sup> States also reported early refill thresholds for non-controlled drugs.

<sup>13</sup> Drugs and other substances that are considered controlled substances under the Controlled Substances Act are divided into five schedules based on whether they have a currently accepted medical use in treatment, their relative misuse potential, and likelihood of causing dependence when misused (DOJ 2020). For example, Schedule I controlled substances have no currently accepted medical use in the U.S., and have the highest potential for misuse. Examples of Schedule I controlled substances include heroin and lysergic acid diethylamide (LSD).

<sup>14</sup> In Washington, as part of a one-time intervention in August 2018, the state generated prescribing reports for concurrent prescribers of opioids and sedatives such as benzodiazepines. These compared their prescribing patterns to other providers and a list of clients to whom they had prescribed.

<sup>15</sup> The states that have implemented all DUR policies required through the SUPPORT Act are Colorado, Delaware, Indiana, Kentucky, Maine, North Carolina, Ohio, Tennessee, Vermont, Virginia, and Wyoming.

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