Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act:

Section 1004 Medicaid Drug Review and Utilization

Federal Fiscal Year 2020 Report to Congress

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Executive Summary

BACKGROUND

This Report to Congress (RTC) fulfills the requirement of section 1902(00)(2) of the Social Security Act, as added by section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115-271, enacted October 24, 2018), for fiscal year 2020. The SUPPORT Act includes measures to combat the opioid crisis in part by reducing opioid fraud, abuse and misuse and advancing treatment and recovery initiatives, improving prevention, protecting communities and bolstering efforts to fight deadly illicit synthetic drug use. This report provides information to Congress concerning implementation of the Medicaid drug utilization review (DUR) provisions that were included in amendments made by section 1004 of the SUPPORT Act.

There are several DUR provisions in section 1004 of the SUPPORT Act with respect to Medicaid Fee-for-Service (FFS) and Managed Care Entity (MCE) pharmacy programs which cover policy goals of protecting patients from and educating providers about opioid overutilization, and addressing the clinical appropriateness of use of antipsychotic medications in children. These provisions establish drug review and utilization standards in sections 1902(a)(85) and (oo) of the Social Security Act (hereinafter referred to as "the Act") to supplement existing requirements under section 1927(g) of the Act, in an effort to reduce opioid-related fraud, misuse and abuse. This report specifically addresses the required implementation and States' status of these provisions, including requirements regarding opioid prescription claim reviews at the point of sale (POS) and retrospective reviews.

State implementation of these opioid-related strategies was required to be in place by October 1, 2019. States must include information about their programs in their annual reports to the Centers for Medicare & Medicaid Services (CMS) under section 1927(g)(3)(D) of the Act. In turn, the Secretary of the Department of Health and Human Services (HHS) is required to report to Congress on the information submitted by the States, starting with information from federal fiscal year (FFY) 2020 reports.

Specifically, the provisions added by section 1004 of the SUPPORT Act require state Medicaid programs to have in place:

- A claims review process and safety edits (as specified by the State) for subsequent opioid fills (i.e., refills) and maximum daily morphine equivalent that exceed state-defined limitations;
- An automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics;
- A program to monitor antipsychotic prescribing for children; and
- A process that identifies potential fraud or abuse of controlled substances by enrolled

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¹ https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf

individuals, prescribing health care providers, and pharmacies dispensing drugs to such individuals.

The statute also requires that States' contracts with MCEs include these provisions effective October 1, 2019.

MEDICAID DRUG UTILIZATION OVERVIEW

Medicaid DUR programs promote patient safety through state-administered drug utilization management tools and systems that interface with the claims processing systems. DUR includes both prospective and retrospective reviews. Prospective DUR reviews generally occur before the prescription is dispensed by the pharmacy, and includes a review of the new prescriptions compared to other prescriptions that the beneficiary is also taking. This helps to avoid drug interactions, therapeutic duplications, allergic reactions and underdosing or overdosing. Retrospective DUR reviews generally attempt to identify patterns of prescribing or dispensing that may require the state to engage in educational interventions with prescribers, pharmacists or beneficiaries.

There are several Medicaid-related DUR provisions for FFS and MCE pharmacy programs in the amendments made by section 1004 of the SUPPORT Act. These provisions have the goal of improving the quality of care received by Medicaid beneficiaries by reducing their exposure to hazards resulting from inappropriate prescribing, gross overuse, or inappropriate or medically unnecessary care. These basic minimum standards implemented through Medicaid DUR programs nationwide help ensure that prescriptions are appropriate and medically necessary and align with current standards of care.

SUMMARY OF DATA COMPILATION

Demographic Information

Fifty States (including the District of Columbia, which is included in counts of States hereafter) have submitted a Medicaid DUR Annual Survey encompassing Federal Fiscal Year (FFY) 2020 reported responses. The Annual DUR survey was not submitted by Arizona because of the state's existing waiver of these DUR requirements included in the state's approved 1115 demonstration; however, Arizona submitted a separate survey in reference to section 1004 of the SUPPORT Act for incorporation into this report to Congress.

States' FFY 2020 survey responses include information on 21,524,437 beneficiaries enrolled in FFS Medicaid programs and 55,550,793 beneficiaries enrolled in Medicaid managed care programs. Thirty-five States have submitted 234 Medicaid MCE DUR Annual FFY 2020 survey responses. Again, as the Annual DUR survey was not submitted by Arizona because of the state's existing waiver of these DUR requirements, Arizona submitted separate responses for incorporation into this report to Congress for their eight MCEs. MCE data include information from 49,678,994 beneficiaries enrolled in state MCEs' Medicaid programs, which include pharmacy benefits as part of the package of benefits provided by the MCE. Four States - Missouri,

Tennessee, West Virginia and Wisconsin – carved out² their drug benefit from the traditional managed care benefit at the time of the survey, and submitted an abbreviated Managed Care survey for each of their managed care programs. These reports can be accessed on <u>Medicaid.gov</u>.

Claim Reviews

- 1. Prospective Safety Edit Limitations for Opioid Prescriptions FFY 2020 survey responses confirm all Medicaid FFS programs in States set early prescription refill thresholds as a way of preventing prescriptions from being overutilized. That is, enough time must have elapsed for the beneficiary to have been able to use a designated percentage of the prescription dispensed, based on the directions for taking the drug, before another prescription or refill can be obtained.
 - <u>Controlled Substances (CII)³ Early Refills</u>: FFS-reported early refill thresholds range from 75% to 93% of a prescription being used, with a national average of 86% of the prescription being used, before a subsequent prescription could be dispensed. MCE-reported thresholds range from time for 75% to 90% of the prescription being used, with a national average of 85%. While CII prescriptions are not refillable, partial refills can be authorized. Additionally, early refill edits can determine when a subsequent new prescription is filled too early.
 - <u>Controlled Substances (CIII to CV)</u> 4.5.6 Early Refills: FFS-reported early refill thresholds range from 75% to 93% of a prescription being used, with a national average of 85%. MCE-reported thresholds range from 73% to 90% of the prescription being used, with a national average of 85%.
 - <u>Initial Opioid Rx</u>: For FFS, the median days' supply for an initial opioid prescription for an opioid naïve patient⁷ based on FFY 2020 reported responses is 7 days, which includes a national range of 5 to 100 days' supply. The median days' supply for an initial opioid prescription for an opioid naïve patient for MCE responses is 7 days, which includes a national range of 5 to 31 days.
 - <u>Duplicate Opioid Therapy</u>: Opioid duplicate safety edits for initial and subsequent prescription fills help to avoid inappropriate or unnecessary therapeutic duplication

² The term carve -out refers to States that have categories of medications and services not included in their managed care plans, but covered through the state FFS pharmacy benefits.

³ Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.

⁴ Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence.

⁵ Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.

⁶ Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.

⁷ Opioid naive patients are beneficiaries who have not received opioids within a specified timeframe. These patients who have not received opioids within a specified timeframe would be subjected to the days' supply limit on the opioid prescription. This limit would not apply to patients currently receiving opioids and is meant for beneficiaries who have not received opioids within this specified time period (as defined and implemented by the state). This limitation is required by regulation implementing the Medicaid DUR program under section 1927(g) of the Act, see 42 C.F.R. § 456.703(h)(1)(i)(A)

when simultaneous use of multiple opioids is detected. For FFS, 48 States (94%) have prospective edits in place to monitor duplicate therapy of opioid prescriptions. For MCEs, 231 MCEs (95%) have prospective edits in place to monitor duplicate therapy of opioid prescriptions.

2. Morphine Milligram Equivalent (MME) Daily Dose - MME is the amount of morphine, in milligrams, equivalent to the strength of the opioid dose prescribed. MME is used to assess the total daily dose of opioids dispensed to a patient and takes into account the comparative potency of different opioids and frequency of use. The calculation to determine MMEs includes drug strength, quantity, days' supply and a defined conversion factor unique to each drug to assess patient risk. Using an MME approach allows comparison between the strength of different types of opioids. The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain recommend that clinicians should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 MME/day and should avoid or carefully justify a decision to increase dosage to 90 MME/day.

A total of 50 States (98%) limit maximum MME daily doses to reduce potential patient harm, abuse and/or diversion. The median MME daily dose for FFY 2020 reported responses is 90 mg/day which includes a national range of 30 to 500 mg/day. Additionally, 46 States (90%) have an edit in their POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded, and 31 States (61%) have an automated retrospective claims review process to monitor the total daily dose of MMEs for opioid prescriptions dispensed.

A total of 240 MCEs (99%) limit maximum MME daily doses to reduce potential patient harm, abuse and/or diversion. The median MCE MME daily dose for FFY 2020 survey responses is 90 mg/day which includes a national range of 30 to 500 mg/day. Additionally, 238 MCEs (98%) have an edit in their POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded. There are 206 MCEs (85%) that have an automated retrospective claims review process to monitor the total daily dose of MMEs for opioid prescriptions dispensed.

3. Opioids and Concurrently-Prescribed Medications - There were 50 States (98%) with FFS programs that have prospective edits or a retrospective claims review process to monitor opioids and benzodiazepines being used concurrently, while 219 (90%) MCEs have prospective edits or a retrospective claims review process to monitor opioids and benzodiazepines being used concurrently.

For FFS programs, 47 States (92%) have prospective edits or a retrospective claims review process to monitor opioids and antipsychotics being used concurrently, while 198 MCEs (81%) have prospective edits or a retrospective claims review process to monitor opioids and antipsychotics being used concurrently. These edits allow for the evaluation of the risk of respiratory depression and overdose.

4. **Retrospective Automated Claims Review -** For FFS programs, 33 States (65%) have an automated retrospective claims DUR review process to monitor opioid prescriptions exceeding state limitations, while 162 MCEs (67%) have an automated DUR respective claims review process to monitor opioid prescriptions exceeding state limitations. These claim reviews identify potential issues such as adverse events, therapeutic appropriateness, inappropriate or medically unnecessary care, gross overuse, abuse and fraud after the prescription has been dispensed and allow for applicable actions including opportunities for provider and patient education. A lower affirmative response rate on this provision is noted because many programs surveyed stated their review process was not automated or they handle these reviews through other utilization management processes.

Antipsychotics in Children

According to FFY 2020 survey responses, all FFS programs have a program in place for monitoring or managing the appropriate use of antipsychotic drugs in children for risk assessment of such issues as adverse effects and polytherapy. Additionally, all States monitor or manage antipsychotic medication for all children in foster care. Based on FFY 2020 reported responses, 187 MCEs (77%) have a program in place for monitoring or managing the appropriate use of antipsychotic drugs in children. Additionally, 158 of these 187 MCEs (84%) monitor or manage antipsychotic medication for all children, including children in foster care, who have been identified as being at higher risk of being on these drugs. However, MCE compliance is much higher than this number appears to indicate. Of the 23% of MCEs that indicated they do not have a program in place, 49 indicated it was because these medications were carved out and managed by the state's FFS program, or they did not have any enrolled child beneficiaries. Only 5 MCEs (2%) had no program in place.

Fraud, Waste and Abuse (FWA)

With respect to certain program integrity requirements in Medicaid, CMS defines fraud as any intentional deception or misrepresentation made by a person with the knowledge that the deception could result in an unauthorized benefit to themselves or some other person. States have flexibility to define specific parameters for reviews for fraud, waste and abuse, which can involve practices such as doctor shopping, filling multiple prescriptions from providers and multiple ED visits. States also have protocols for recommendation, referral, or escalation of reviews to the relevant Program Integrity/Surveillance Utilization Review (SURS) unit, law enforcement, or state professional board, based on patterns discovered through the state's DUR process. FFY 2020 survey responses show 51 States (100%) have process to identify possible fraudulent practices or abuse of controlled drugs of beneficiaries.

For FFS programs, 48 States (94%) have processes in place to identify FWA by prescribers and 47 States (92%) have processes in place to identify potential fraudulent practices by pharmacies. FFY 2020 survey responses also show 239 MCEs (99%) have process to identify possible fraudulent practices or abuse of controlled drugs of beneficiaries. For MCEs, 237

⁸ Definitions, 42 C.F.R. § 455.2. Retrieved May 25, 2016, from https://www.eC.F.R.gov/current/title-42/chapter-IV/subchapter-C/part-455/section-455.2

programs (98%) have processes in place to identify FWA by prescribers and 237 (98%) have processes in place to identify potential fraudulent practices by pharmacies.

COMPLIANCE

CMS's review of FFS and MCE surveys for compliance with requirements added by section 1004 of the SUPPORT Act encompassed 293 total surveys (51 FFS and 242 MCEs). In a similar fashion to how the DUR survey and reports are structured, we are reporting the information as the state reported it to us, without alteration or interpretation. CMS plans to implement additional compliance reviews and follow-up with noncompliant States (including to address any noncompliance in a State's MCE program) to address potential program deficits and negative trends. We will do this after further reviewing updated information from the recently collected FFY 2021 DUR survey responses to determine the best approach for oversight for compliance action. CMS will be reaching out to States to request additional supplemental data to enable CMS to better identify and work with States to address deficiencies, and, if necessary, to address them through corrective action plans. States not taking remediation action(s) where necessary to come into compliance with amendments made by section 1004 of the SUPPORT Act and implementing regulations would be at risk of withholding of Federal Financial Participation (FFP) pursuant to regulations in 42 C.F.R. § 430.35).

In addressing noncompliance, it is important to note that some States have categories of medications and services that are carved out of managed care and instead included in FFS pharmacy benefits. These "carve-outs" occur when a state excludes certain medications and services from an MCE plan, essentially "carving" them out from that payer's coverage. In these instances, the MCEs are not responsible for the implementation of applicable DUR edits, reviews and programs as they are handled by the state through the FFS program. As a result, some seeming noncompliance of MCE plans with particular requirements are difficult to evaluate and may have valid underlying rationales, including but not limited to the relevant coverage being carved out of the MCE's contractual obligations and therefore the responsibility of the state and not the MCE. Ultimately, States are responsible for ensuring compliance with all applicable statutory and regulatory requirements.

RECOMMENDATIONS

FFY 2020 survey responses indicate the implementation of the opioid standards related to the required topics were similar in States' FFS and MCE programs. Survey responses also indicated that the majority of programs have implemented opioid edits and other standards required by the amendments made by section 1004 of the SUPPORT Act or have a plan in place to implement those standards in the near future. Variation in the methods used by States to meet the required standards were noted and further details can be found in State specific reports on Medicaid.gov. The following are recommendations to help States and MCE programs come into compliance with the amendments made by section 1004 of the SUPPORT Act.

- States should employ a system-accumulation safety edit which tracks the utilization of
 medication across multiple opioid dispensing events over prolonged periods of time to help
 prevent stockpiling;
- States should continue to utilize current maximum dosing and schedules to establish updated quantity limits of opioids consistent with current accepted medical guidelines;
- States should upgrade existing systems from manual to automated retrospective claim reviews to increase compliance and detect high doses of opioids in a timely and efficient manner; and,
- States should further develop prospective and automated retrospective claim reviews consistent with medical practice patterns and clinical considerations to limit opioids to only when necessary.

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1. Introduction

This report to Congress on State Medicaid Drug Review and Utilization Programs fulfills requirements added by section 1004 of the SUPPORT Act. In particular, section 1902(oo)(2) of the Social Security Act, as added by section 1004 of the SUPPORT Act, requires the Secretary to report annually to Congress on the most recent information submitted by States on their implementation of the DUR requirements added by section 1004 of the SUPPORT Act. This report is based on state activity concerning opioid-related DUR throughout the 2020 FFY.

Within state Medicaid programs, DUR involves the structured, ongoing review of prescribing by healthcare providers, dispensing by pharmacists and patient use of medication. DUR encompasses a comprehensive review of patients' medication use to help ensure appropriate medication decision-making and promote positive patient outcomes. Potentially inappropriate prescriptions, unexpected and potentially troublesome prescribing or dispensing patterns and other issues can be identified and addressed through prospective and retrospective DUR activities.

Prospective DUR occurs at the point of dispensing when a pharmacist submits a prescription transaction. The pharmacist will review the specific criteria of the prescription for appropriateness and will also consider all other patient medication use and medical history. This process may be guided by systematic and automated messages sent to the pharmacist, determined by algorithms operating within the electronic claims processing logic. These algorithms are determined by the claim payer organization, including state Medicaid programs. In some cases, the algorithms will require modifications to the original prescription prior to adjudicating the claim. In other cases, the algorithms will require patient counseling on important interactions or can be designed to prevent the pharmacist from dispensing the prescription entirely. Prospective DUR is an important tool for state Medicaid programs to ensure medication use is appropriate prior to the patient acquiring a medication subject to review.

Alternatively, retrospective DUR occurs after claims have been processed and prescriptions have been dispensed to the patient. Individual prescriptions, or a patient's entire medication history over a period, including aggregate dosing or concurrent use of multiple medications, may be analyzed for appropriateness. Any potential inappropriate use may be flagged and associated with patients, prescribers, or pharmacies. Once the issue is identified via retrospective DUR, state Medicaid programs have multiple intervention options to follow up, including, but not limited to, directly contacting patients or the prescribers of their medication to request or recommend a specific clinical action be taken; providing clinical education to the provider(s); notifying prescribers of patient medications of other prescribers to avoid duplicate or conflicting medications; alerting the State's Program Integrity Unit (PIU); or restricting patients to a single prescriber or pharmacy.

Often, prospective and retrospective review activities are synergistic; information gleaned through retrospective DUR claim reviews can be used to shape effective safety edits that are implemented through prospective DUR, better enabling prescribers and pharmacists to investigate prescription concerns prior to dispensing the medication to the patient. From prospective alerts (which can incorporate information from the beneficiary's claims data), potential issues can be identified to help promote the appropriate prescribing and dispensing of outpatient drugs to beneficiaries. DUR

programs play a key role in helping health care systems understand, interpret and improve the prescribing, administration and use of medications.

Consistent with section 1927(g)(3)(D) of the Act, CMS requires each state Medicaid program to submit to CMS an annual survey on the operation of its Medicaid DUR program with respect to the FFS delivery system, including information on prescribing patterns, cost savings generated by the state's DUR program, and the state's DUR program's overall operations, including any new or innovative practices. States are required to report on the nature and scope of the prospective and retrospective DUR programs, including a summary of the interventions used in retrospective DUR, an assessment of the education programs deployed, a description of DUR Board activities, as well as an overall assessment of the DUR program's impact on quality of care and cost savings generated from their DUR programs. Additionally, 42 C.F.R. §438.3(s)(4) and (5) require state contracts for any managed care plans (MCP) that cover covered outpatient drugs, to require the managed care entity to operate a DUR program that complies with section 1927(g) of the Act and 42 C.F.R. part 456, subpart K, and to submit detailed information about its DUR program activities annually.

Section 1004 of the SUPPORT Act included measures to combat the opioid crisis, in part, by reducing opioid related abuse and misuse through important opioid specific DUR standards within States' Medicaid FFS and MCE programs. Consistent with section 1927(g) of the Act, section 1004 of the SUPPORT Act had the goal of improving the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, gross overuse, or inappropriate or medically unnecessary care. These requirements added by section 1004 supplement preexisting DUR standards under section 1927(g) of the Act. State implementation of section 1004 standards was required by October 1, 2019. Additionally, States must submit, annually as part of the DUR report under section 1927(g)(3)(D) of the Act, information on activities carried out on their implementations of requirements added by section 1004 of the SUPPORT Act, starting with information collected by CMS from States in 2021, regarding their FFY 2020 activities. In turn, the Secretary of HHS is required to report to Congress on the information submitted by the States, starting with information from States' FFY 2020 DUR reports.

CMS organized this report around these strategic provisions in section 1004 of the SUPPORT Act with each section identified below detailing specific aspects of States' compliance with requirements:

- Prospective safety edits and retrospective reviews monitoring the use of opioids
- Monitoring the use of antipsychotic medication use in children
- Identification of fraud, waste and abuse (FWA) of controlled substances

This document reports on both FFS and MCE responses from the DUR survey regarding section 1004 of the SUPPORT Act implementations. A summary of relevant responses to individual FFY 2020 DUR survey questions is also included in this report. Detailed responses from each state are available in reports on Medicaid.gov. Additionally, as 36 States have multiple MCEs, responses throughout the report are identified as the representative state and total MCEs responding as follows: State (Count of MCEs), i.e., California (13) represents 13 MCEs in the state of California responding to a particular question. Individual state MCE reports, attachments and responses throughout the report can be found on Medicaid.gov.

In reviewing the report, for context on Medicaid populations in FFY 2020 for Medicaid prescription benefits, approximately 28% of all Medicaid beneficiaries were enrolled in FFS state Medicaid programs and the other 72% were enrolled in Medicaid MCE programs. There is a total of 51 FFS programs (inclusive of the 50 States and the District of Columbia) and 242 MCE programs (inclusive of 36 States) included in this report. Additionally, Missouri, Tennessee, West Virginia and Wisconsin have pharmacy benefits carved out of their MCP and covered entirely through their FFS program. These MCPs do not administer pharmacy benefits in these four States and are not included in this report.

2. Claim Reviews

Amendments made by section 1004 of the SUPPORT Act require States to have in place prospective safety edits for opioid prescriptions and an automated claims review process that identifies when an individual enrolled under the Medicaid state plan (or under a waiver of the state plan) is prescribed an opioid in excess of any limitation that may be established by the state.

In implementing the amendments made by section 1004 of the SUPPORT Act, we interpreted "safety edits" to refer to the prospective DUR review specified in section 1927(g)(2)(A) of the Act and 42 C.F.R. § 456.703. Prospective safety edits provide for identifying potential problems at POS to engage patients, prescribers and pharmacists about identifying and mitigating possible opioid misuse, abuse and overdose risk at the time of dispensing. The POS safety edits provide real-time information to the pharmacist prior to the prescription being dispensed to a patient, but do not necessarily prevent the prescription from being dispensed. When a safety edit is generated, the pharmacist receives an alert. Action is required, as dictated by good clinical practice and predetermined standards determined by the state, to take further action to resolve the alert before the prescription can be dispensed.

A claims review automated process, which we interpreted to refer to a retrospective DUR review as defined in section 1927(g)(2)(B) of the Act and 42 C.F.R. § 456.703, provides for additional examination of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. Retrospective reviews involve reviews of patient drug and disease history, clinician prescribing history and pharmacy dispensing history information that is generated from claims data after prescriptions have been dispensed to the beneficiary. For many retrospective reviews, to promote appropriate prescribing and utilization of medications, claims data are evaluated against state determined criteria on a regular basis to identify potential population-wide issues with medication prescriptions based on patterns and do not focus on particular, individual prescriptions. After these reviews, prescribers who are contacted as a result of retrospective DUR review findings often have the opportunity to review prescriptions and diagnosis history and make changes to their prescribing practices and/or individual patient therapies based on the retrospective review intervention. Retrospective claims reviews provide access to more comprehensive information relevant to the prescriptions and services that are being furnished to beneficiaries and better enable and encourage prescribers and pharmacists to minimize opioid risk in their patients, while assuring appropriate pain care.

The purpose of the safety edits and claims reviews is to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the patient's opioid use is appropriate and medically necessary and is intended to help protect beneficiaries from serious potential consequences of overutilization, including misuse, abuse, overdose and increased side effects. In addition to the risk of abuse, misuse and diversion, opioids can have side effects including respiratory depression, confusion, tolerance and physical dependence. Each state is permitted to specify its safety edits and automated claims review process with the detailed design and implementation specifications left to the state's discretion to meet state-specific needs. CMS

published final regulations in December 2020⁹ that implemented the opioid-related requirements established by amendments made by section 1004 of the SUPPORT Act and further implemented pre-existing DUR provisions under section 1927(g) of the Act, in an effort to reduce prescription-related fraud, misuse and abuse.

Consistent with the Act and federal regulations, see 42 C.F.R. § 456.703(h), claims review limitations implemented by States were defined to include:

- Prospective safety edits (as designed and implemented by the state) on early fills on subsequent opioids prescriptions, quantity limits for initial and subsequent fills, the days' supply for initial prescriptions filled for patients not currently receiving opioid therapy and therapeutically duplicative initial and subsequent fills;
- Prospective safety edits (as designed and implemented by the state) on the maximum daily morphine equivalent for treatment of pain, for initial and subsequent fills;
- Retrospective claims review automated process (as designed and implemented by the state) that indicates prescription fills of opioids in excess of the foregoing limits to provide for ongoing review of opioid claims data to identify patters of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits; monitors when an individual enrolled under the state plan (or under a waiver of the state plan) is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics; and
- A retrospective claims review automated process (and, at the option of the state, prospective safety edits) that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics.

These safety edits and claims review limitations implemented by States are intended to protect Medicaid patients from serious consequences of opioid overutilization including overdose, dangerous interactions, increased side effects and additive toxicity (i.e., additive side effects). States are required to ensure that opioid reviews consistent with current clinical practice are included within their DUR programs pursuant to 1927(g)(2)(C) and $42 \text{ C.F.R.} \S 456.703(f)$. States are encouraged to develop prospective and retrospective drug review parameters consistent with current clinical practice and to address medical practice patterns in the state, to help meet the health care needs of their Medicaid patient population. Furthermore, none of the required safety reviews prohibits the exercise of clinical judgment by a provider regarding the most appropriate care and treatment for any patient.

Additionally, the above described DUR requirements added to section 1902(00) of the Act by section 1004 of the SUPPORT Act do not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care facility, a facility described in section 1905(d) of the Act (that is, an intermediate care facility for the intellectually disabled), or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted

⁹ CMS 2482-F, Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements

from such requirements. States have considerable flexibility with DUR reviews to address complex patient populations, and the exclusion at 42 C.F.R. § 456.703(h)(2) specifies that States are not required to implement the otherwise-applicable opioid DUR requirements with respect to these populations. Additionally, States are expected to consult national guidelines and are encouraged to work with their pharmacy and therapeutics (P&T) and DUR committees to identify other clinically appropriate patient populations, such as sickle cell crisis patients, for possible exclusion from the safety reviews specified in 42 C.F.R. § 456.703(h)(1)(i) through (vii) to avoid impeding critical access to needed medication when managing specific complex disease states.

The following sections provide the survey results for state Medicaid programs related to these safety edits and claim reviews on opioid prescriptions.

2.1. Prospective Safety Edit Limitations for Opioid Prescriptions

Amendments made by section 1004 of the SUPPORT Act require States to have in place prospective safety edits (as specified by the state) for subsequent fills for opioids that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state. Consistent with amendments made by section 1004 of the SUPPORT Act and pre-existing DUR requirements under section 1927(g)(2)(A) of the Act, state-identified limitations must include safety edits on opioids prescriptions, as specified below, to identify patterns of fraud, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate inappropriate or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits (see 42 C.F.R. § 456.703(h)(1)(i)):

- Early fills on subsequent opioids prescriptions;
- Quantity limits for initial and subsequent fills;
- Days' supply for initial prescriptions filled for patients not currently receiving opioid therapy; and
- Therapeutically duplicative fills, for initial and subsequent fills.

These safety edits reinforce efforts to combat the nation's opioid crisis and help ensure DUR opioid reviews are consistent with current clinical practice. They are intended to protect Medicaid patients from serious consequences of overutilization, including overdose, drug interactions, increased side effects and additive toxicity (additive side effects). In addition, overutilization of opioids may serve as an indication for potential Opioid Use Disorder (OUD) and the need of increased monitoring and coordination of care.

2.1.1. Early Refills for Subsequent Prescription Fills

Amendments made by section 1004 of the SUPPORT Act, require that States establish safety edits to alert the dispenser before a prescription is filled prior to the previous supply being completed for an opioid product, based on the days' supply provided at the most recent fill. These early fill safety edits on opioids are intended to protect beneficiaries from adverse events associated with using an opioid medication beyond the prescribed dose schedule. Monitoring for possible early

refills for an individual also minimizes the extent to which extra opioids might be dispensed, and thus subject to possible diversion to other individuals.

Depending on state specific designs, a prior authorization may be required to be submitted by the prescriber or pharmacist to override an early refill alert and adjudicate the claim. A prior authorization is an additional administrative step where the prescriber is required to provide supplementary information to justify the necessity for an early refill. Alternatively, in some States, the early refill percent threshold may be overridden via the claims adjudication process by the pharmacist using standardized codes. These are entered onto the claim to indicate, based on the pharmacist's review, that the prescription can be filled. In these instances, if the pharmacist overrides the early refill alert, the claim will adjudicate and the prescription can be dispensed to the beneficiary.

In consideration of clinical recommendations to limit opioid use to only when necessary and as prescribed, safety edits for early refills help ensure that opioid prescriptions are appropriate, medically necessary and not likely to result in adverse medical results and accomplish purposes of the DUR program under section 1927(g) of the Act and of the amendments made by section 1004 of the SUPPORT Act.

Under the Controlled Substances Act (CSA), the Drug Enforcement Administration (DEA) classifies drugs into schedules, based on their medical value and potential for abuse. Currently, there are five schedules, schedules I through V. Schedule I drugs have no medical value and high potential for abuse, while schedule II through V substances all have some medical value but differ in ranking depending on their potential for abuse (from high to low, respectively).

Early refill is defined as when the patient requests a refill prior to the date when they are eligible based on the directions of the prescription and quantity prescribed and are designed to minimize the excessive use, waste and stockpiling of prescription medications. Based on FFY 2020 survey responses, as seen in Table 1, for FFS programs, the most frequent early refill percent for schedule II drugs ranged between thresholds of 85% and 90%. The most common response for MCE programs was a slightly lower threshold of 84% allowing prescriptions to be filled somewhat sooner than on average for FFS programs. For schedules III through V controlled drugs, the range for the most common early refill percent for FFS programs was between 85% and 90%. The most common response for MCE programs was 85%.

Table 1 – FFS and MCE Early Refill Percent Safety Edit for Controlled Drugs

Table 1 – FFS and MCE Early Refill Percent Safety Edit for Controlled Drugs					
		FFS	MCE		
C			(Average by State) ¹⁰		
State	Schedule II	Schedule III - V	Schedule II	Schedule III - V	
	Controlled Drugs ¹¹	Controlled Drugs	Controlled Drugs ¹²	Controlled Drugs	
Alabama	75%	75%	N/A	N/A	
Alaska	93%	93%	N/A N/A	N/A N/A	
Arizona	85%	85%	86%	86%	
Arkansas	75%	75%	78%	78%	
California	75%	75%	84%	83%	
Colorado	85%	85%	78%	73%	
Connecticut	93%	93%	N/A	N/A	
Delaware	90%	90%	83%	83%	
District of Columbia	80%	80%	84%	84%	
Florida	90%	90%	86%	87%	
Georgia	85%	85%	86%	85%	
Hawaii	90%	90%	83%	82%	
Idaho	75%	75%	N/A	N/A	
Illinois	90%	90%	84%	84%	
Indiana	85%	85%	86%	85%	
Iowa	90%	90%	90%	90%	
Kansas	90%	80%	90%	90%	
Kentucky	90%	90%	84%	86%	
Louisiana	90%	90%	90%	90%	
Maine	85%	85%	N/A	N/A	
Maryland	85%	85%	84%	84%	
Massachusetts	85%	85%	82%	82%	
Michigan	90%	90%	90%	90%	
Minnesota	85%	85%	85%	85%	
Mississippi	85%	85%	85%	85%	
Missouri	85%	85%	N/A	N/A	
Montana	90%	90%	N/A	N/A	
Nebraska	90%	90%	85%	85%	
Nevada	90%	90%	90%	90%	
New Hampshire	80%	80%	88%	88%	
New Jersey	85%	85%	87%	87%	
New Mexico	90%	75%	90%	90%	
New York	75%	75%	83%	83%	
North Carolina	85%	85%	N/A	N/A	
North Dakota	87%	87%	75%	75%	
Ohio	90%	90%	87%	86%	
Oklahoma	90%	90%	N/A	N/A	

 $^{^{10}}$ Thirty-six States have submitted 242 Medicaid MCE DUR Annual FFY 2020 survey responses. States that do not have MCEs or have pharmacy benefits carved-out are noted by N/A on the chart above.

¹¹ While CII prescriptions are not refillable, partial refills can be authorized. Additionally, early refill edits can determine when a subsequent prescription is filled too early.
¹² Ibid.

	FFS		MCE (Average by State) ¹⁰	
State	Schedule II Controlled Drugs ¹¹	Schedule III - V Controlled Drugs	Schedule II Controlled Drugs ¹²	Schedule III - V Controlled Drugs
Oregon	80%	80%	84%	84%
Pennsylvania	85%	85%	85%	85%
Rhode Island	85%	85%	87%	87%
South Carolina	100%	85%	83%	83%
South Dakota	85%	85%	N/A	N/A
Tennessee	95%	95%	N/A	N/A
Texas	90%	90%	86%	86%
Utah	85%	85%	86%	86%
Vermont	85%	85%	N/A	N/A
Virginia	90%	75%	87%	87%
Washington	75%	75%	84%	84%
West Virginia	85%	85%	N/A	N/A
Wisconsin	80%	80%	N/A	N/A
Wyoming	90%	90%	N/A	N/A
National Average	86%	85%	85%	85%

As shown in Tables 2 and 3 below, based on FFY 2020 survey responses, all FFS (100%) and almost all MCE programs (99%) have safety edits to monitor early refills of opioid prescriptions dispensed. Several FFS programs (29%) indicated having both safety edits and automated retrospective claim on opioid early refill claims and 32% of MCEs also implemented both types of reviews.

Table 2 - FFS Safety Edits to Monitor Early Refills of Opioid Prescriptions Dispensed

Table 2 - FFS Safety Edits to Monitor Early Reinis of Opioid Trescriptions Dispensed				
Response	States	Total	Percent of Total	
Yes, Both Safety Edits And Automated Retrospective Claims Review Process	Arkansas, Colorado, Connecticut, District of Columbia, Florida, Hawaii, Iowa, Louisiana, Maryland, New Jersey, New York, Ohio, South Carolina, Vermont, Washington	15	29%	
Yes, Safety Edits	Alabama, Alaska, Arizona, California, Delaware, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, Wisconsin, Wyoming	36	71%	
National Totals		51	100%	

Table 3 – MCE Safety Edits to Monitor Early Refills of Opioid Prescriptions Dispensed

Response	States (Count of MCEs)	Total	Percent of Total
Yes, Both Safety Edits And	California (4), District of Columbia (2), Florida (6), Georgia (1), Hawaii (4), Illinois (1), Indiana (1), Iowa	78	32%

Response	States (Count of MCEs)	Total	Percent of Total
Automated	(2), Kansas (3), Kentucky (1), Louisiana (5), Maryland		
Retrospective Claims	(6), Michigan (3), Minnesota (1), Mississippi (1),		
Review Process	Nebraska (3), Nevada (2), New Hampshire (1), New		
	Jersey (3), New York (5), North Dakota (1), Ohio (4),		
	Oregon (7), Pennsylvania (2), Rhode Island (2), Texas		
	(2), Utah (1), Virginia (3), Washington (1)		
	Arizona (8), Arkansas (3), California (21), Colorado		
	(2), Delaware (2), District of Columbia (2), Florida		
	(10), Georgia (3), Hawaii (2), Illinois (5), Indiana (3),		
	Kentucky (4), Maryland (3), Massachusetts (5),		
Yes, Safety Edits	Michigan (7), Minnesota (7), Mississippi (2), Nevada	159	66%
	(1), New Hampshire (2), New Jersey (2), New Mexico		
	(3), New York (13), Ohio (1), Oregon (13),		
	Pennsylvania (6), Rhode Island (1), South Carolina (5),		
	Texas (15), Utah (2), Virginia (3), Washington (3)		
Yes, Automated			
Retrospective Claims	Michigan (1), Washington (1)	2	1%
Review Process			
No*	California (1), Illinois (1), Utah (1)	3	1%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

2.1.2. Quantity of Prescription Dispensed for Initial and Subsequent Prescription Fills

Dose optimization is a method to consolidate the quantity of medication dispensed to the smallest amount required to achieve the desired daily dose and regimen. With these edits, States use maximum dosing and schedules to establish quantity limits for the quantity of opioids that are allowed per day without triggering the safety edit. Minimizing the medication burden (e.g., number of tablets or capsules that must be taken) improves patient compliance with taking medication as directed. Dosage optimization seeks to prospectively identify patients who have been prescribed multiple units of a dosage formulation (e.g., tablets, capsules, etc.) per day of a lower strength medication meant to be taken together to achieve higher dose, when a higher strength of medication already is available (e.g., the patient is prescribed two, 5 mg tablets, when a 10 mg strength is available in one tablet). Performing this intervention with medications that are available in multiple strengths also can yield significant drug cost savings.

When implementing section 1927(g)(1) of the Act and the amendments made by section 1004 of the SUPPORT Act, States were required to establish safety edits to implement quantity limits on initial and subsequent fills, as designed and identified by the State. See 42 C.F.R. § 456.703(h)(1)(i)(B). States are encouraged to take clinical indications and dosing schedules into account when establishing quantity limits to restrict the quantity of opioids per day to help ensure dose optimization and minimize potential for waste and diversion.

Consistent with the requirements added by section 1004 of the SUPPORT Act, FFY 2020 responses show, in Tables 4 and 5, that the vast majority of the programs (FFS: 96%, MCE: 96%) have a safety edit in place to limit the quantity dispensed of an initial opioid prescription.

Table 4 – FFS Safety Edit to Limit the Quantity Dispensed of an Initial Opioid Prescription

Response	States	Total	Percent of Total
Yes, For All Opioids	Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, Wyoming	36	71%
Yes, For Some Opioids	California, Kansas, Louisiana, Michigan, Montana, Nebraska, New Mexico, North Carolina, North Dakota, Rhode Island, Vermont, West Virginia, Wisconsin	13	25%
No, For All Opioids*	Alaska, Iowa	2	4%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

Table 5 – MCE Safety Edit to Limit the Quantity Dispensed of an Initial Opioid Prescription

Response	States (Count of MCEs)	Total	Percent of Total
Yes, For All Opioids	Arizona (6), Arkansas (3), California (19), Colorado (2), Delaware (1), District of Columbia (4), Florida (13), Georgia (4), Hawaii (4), Illinois (4), Indiana (3), Kentucky (5), Louisiana (3), Maryland (6), Massachusetts (3), Michigan (6), Minnesota (5), Mississippi (3), Nebraska (3), Nevada (2), New Hampshire (2), New Jersey (3), New Mexico (3), New York (10), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (6), Rhode Island (1), South Carolina (5), Texas (11), Utah (4), Virginia (3), Washington (4)	177	73%
Yes, For Some Opioids	Arizona (2), California (5), Delaware (1), Florida (3), Hawaii (2), Illinois (3), Indiana (1), Kansas (3), Louisiana (2), Maryland (2), Massachusetts (1), Michigan (3), Minnesota (3), Nevada (1), New Jersey (2), New York (8), Pennsylvania (2), Rhode Island (2), Texas (6), Virginia (2), Washington (1)	55	23%

Response	States (Count of MCEs)	Total	Percent of Total
No, For All Opioids*	California (2), Iowa (2), Maryland (1), Massachusetts (1), Michigan (2), New Hampshire (1), Virginia (1)	10	4%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

With respect to programs with a safety edit in place to limit the quantity dispensed of an initial opioid prescription, the majority of programs (FFS: 73%, MCE: 75%), as shown in Tables 6 and 7, have more than one quantity limit for various opioids. Programs that did not implement this particular edit cited having other edits in place instead, such as MME edits, to account for opioid safety. Further details can be found in State specific reports on Medicaid.gov.

Table 6 – FFS Safety Edit for More Than One Quantity Limit for Various Opioids

Response	States	Total	Percent of Total
Yes	Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming	37	73%
No	Arizona, Delaware, District of Columbia, Kentucky, Maine, Massachusetts, Mississippi, Nevada, New Mexico, North Carolina, Texas, Virginia	12	24%
N/A*	Alaska, Iowa	2	3%
National Totals		51	100%

^{*}Please reference Table 4.

Table 7 – MCE Safety Edits for More Than One Quantity Limit for Various Opioids

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (4), Arkansas (2), California (21), Colorado (2), Delaware (1), District of Columbia (1), Florida (12), Georgia (2), Hawaii (3), Illinois (7), Indiana (3), Kansas (3), Kentucky (4), Louisiana (5), Maryland (6), Massachusetts (4), Michigan (9), Minnesota (6), Mississippi (3), Nebraska (3), Nevada (2), New Hampshire (2), New Jersey (2), New Mexico (3), New York (12), North Dakota (1), Ohio (5), Oregon (11), Pennsylvania (8), Rhode Island (3), South Carolina (4), Texas (16), Utah (4), Virginia (3), Washington (5)	182	75%

Response	States (Count of MCEs)	Total	Percent of Total
No	Arizona (4), Arkansas (1), California (3), Delaware (1), District of Columbia (3), Florida (4), Georgia (2), Hawaii (3), Indiana (1), Kentucky (1), Maryland (2), Minnesota (2), Nevada (1), New Jersey (3), New York (6), Oregon (9), South Carolina (1), Texas (1), Virginia (2)	50	21%
N/A*	California (2), Iowa (2), Maryland (1), Massachusetts (1), Michigan (2), New Hampshire (1), Virginia (1)	10	4%
National Totals		242	100%

^{*}Please reference Table 5.

Most FFS and MCE programs have safety edits in place to limit the quantity dispensed of short-acting opioids. Pursuant to DEA Regulations found at 21 C.F.R. § 1306.24 (c)(1), not more than a 34-day supply or 100 dosage units, whichever is less, of a controlled substance listed in Schedule III, IV, or V should be dispensed on a labeled prescription at one time. FFY 2020 survey responses show that 98% of FFS and 96% of MCE programs have safety edits in place for subsequent prescriptions (new and refills) dispensing to limit the quantity dispensed of short-acting opioids as shown in Tables 8 and 9. The program that did not have these safety edits in place, responded that a quantity limit for the refills or subsequent prescriptions was not implemented because a maximum daily morphine milligram equivalent (MME) is in place. This would not satisfy compliance and we plan on following up with this program.

Table 8 – FFS Safety Edits in Place to Limit the Quantity Dispensed of Short-Acting Opioids

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	50	98%
No	Texas	1	2%
National Totals		51	100%

Table 9 – MCE Safety Edits in Place to Limit the Quantity Dispensed of Short-Acting Opioids

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (8), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (16), Georgia (4), Hawaii (6), Illinois (7), Indiana (4),	232	96%

Response	States (Count of MCEs)	Total	Percent of Total
	Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (7), Utah (4), Virginia (6), Washington (5)		
No	Texas (10)	10	4%
National Totals		242	100%

Long-acting opioids often have higher doses or potency and patient safety may require extra scrutiny via safety edits compared to short-acting opioids; long-acting opioids are generally recommended only in specific circumstances.¹³ State responses in Tables 10 and 11 show that almost all programs (FFS: 98%, MCE: 99%) have safety edits in place to limit the quantity dispensed of long-acting opioids.

Table 10 – FFS Safety Edits to Limit the Quantity Dispensed of Long-Acting Opioids

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	50	98%
No	Texas ¹⁴	1	2%
National Totals		51	100%

Table 11 – MCE Safety Edits to Limit the Quantity Dispensed of Long-Acting Opioids

Response	States (Count of MCEs)		Percent of Total
Yes	Arizona (8), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (16), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8),	241	99%

¹³ Guideline for Prescribing Opioids for Chronic Pain (cdc.gov)

¹⁴ The Texas FFS response indicated that the edit does not apply to the long-acting opioids because they are not generally approved for initial opioid therapy for an opioid naïve client. A long-acting prescription for an opioid naïve patient will require a prior authorization.

Response	States (Count of MCEs)	Total	Percent of Total
	Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (19), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)		
No	Oregon (1) ¹⁵	1	1%
National Totals		242	100%

2.1.3. Days' Supply

Consistent with section 1927(g)(1) of the Act and the amendments made by section 1004 of the SUPPORT Act as implemented in CMS 2482-F, States are required to establish safety edit limitations on the days' supply for an initial opioid prescription fill for beneficiaries who have not filled an opioid prescription within a defined period of time as specified by the state. Patients who have not received an opioid prescription within a specified timeframe are referred to as opioid naïve and would be subjected to the days' supply limit on an opioid prescription. In most cases, "Days' Supply" is calculated by dividing the dispensed quantity of medication by the amount of the medication to be taken by the patient in one day per the prescriber's instructions. Otherwise States, "Days' Supply" means how many days the supply of dispensed medication is intended to last. While the amendments made by section 1004 of the SUPPORT Act mention limits on subsequent fills of opioids, consistent with section 1927(g) of the Act, this safety edit was also implemented on initial fills of opioids through rulemaking, to help avoid excessive utilization by opioid naïve beneficiaries, with its attendant risk of adverse effects.

The Centers for Disease Control and Prevention (CDC) Guideline recommends that opioids prescribed for acute pain in outpatient primary care settings to adults generally should be limited to 3 days or fewer, and more than a 7 day supply is rarely necessary. ¹⁶ Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred [for chronic pain] and should be considered by practitioners and patients prior to treatment with opioids. ¹⁷ Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use. An expected physiologic response in patients exposed to opioids for more than a few days is physical dependence and the chances of long-term opioid use begin to increase after just 3 days of use and rise rapidly thereafter. ¹⁸

¹⁵ MCE indicated that quantity limits are handled through prior authorization approvals.

^{16 &}quot;CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf

¹⁷ Ibid.

¹⁸ Shah A., Hayes C.J., Martin B.C. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. Morbidity and Mortality Weekly Report 2017; 66:265–269 [Accessed February 11, 2019 at http://dx.doi.org/10.15585/mmwr.mm6610a1].

Limiting days for which opioids are prescribed for opioid naïve patients could minimize the need to taper opioids, the risk of which is associated with the amount of opioid initially prescribed. 19

In FFY 2020 survey responses, Table 12 show each program having varying maximum number of days allowed for an initial opioid prescription for an opioid naïve patient. FFS programs range from 5-100 days allowed with a national average of 13 days. The California FFS program shows a maximum day supply as 100 for an initial prescription for an opioid naïve patient. The rational provided by the state indicates it has established maximum quantity and dispensing limitations within any 75-day period. The MCE programs ranges from 5-31 days allowed for an initial opioid prescription with a national average of 10 days. The mean average for both FFS and MCE programs is 7 days.

Table 121 – FFS/MCE Maximum Number of Days Allowed for an Initial Opioid Prescription for an Opioid Naïve Patient

Trescription for an Optota Naive Lauent					
State	FFS Maximum Days ²⁰	MCE Maximum Days ²¹			
		(State Average)			
Alabama	7	N/A			
Alaska	N/A	N/A			
Arizona	5	5			
Arkansas	7	7			
California	100	16			
Colorado	7	7			
Connecticut	7	N/A			
Delaware	7	6			
District of Columbia	7	7			
Florida	14	9			
Georgia	30	7			
Hawaii	30	15			
Idaho	34	N/A			
Illinois	7	10			
Indiana	7	7			
Iowa	N/A	31			
Kansas	7	7			
Kentucky	7	7			
Louisiana	7	7			
Maine	7	N/A			
Maryland	30	10			
Massachusetts	7	12			
Michigan	7	13			
Minnesota	7	7			

¹⁹ Shah A, Hayes CJ, Martin BC. Characteristics of initial prescription episodes and likelihood of long-term opioid use—United States, 2006-2015. <u>MMWR Morb Mortal Wkly Rep. 2017;66(10):265-269.</u> doi:10.15585/mmwr.mm6610a1.

²⁰ Please see Table 14 regarding Alaska and Iowa

²¹ States that do not have MCEs are noted by N/A on the chart above. Thirty-six States have submitted 242 Medicaid MCE DUR Annual FFY 2020 survey responses. Missouri, Tennessee, Wisconsin, and West Virginia have their covered outpatient drugs carved-out and managed by their FFS program.

State	FFS Maximum Days ²⁰	MCE Maximum Days ²¹ (State Average)
Mississippi	7	7
Missouri	7	N/A
Montana	7	N/A
Nebraska	7	7
Nevada	7	7
New Hampshire	34	25
New Jersey	5	5
New Mexico	7	7
New York	7	7
North Carolina	7	N/A
North Dakota	7	7
Ohio	7	7
Oklahoma	7	N/A
Oregon	7	9
Pennsylvania	5	5
Rhode Island	30	30
South Carolina	5	6
South Dakota	7	N/A
Tennessee	5	N/A
Texas	10	10
Utah	7	7
Vermont	7	N/A
Virginia	7	13
Washington	7	26
West Virginia	34	N/A
Wisconsin	34	N/A
Wyoming	7	N/A
National Average	13	10

Additionally, FFY 2020 survey responses show in Tables 13 and 14 that programs vary in whether the initial day supply limit applies to all or just some opioid prescriptions if other special considerations are made. Further details can be found in State specific reports on <u>Medicaid.gov</u>.

Table 13 – FFS Initial Days' Supply Limit Applies to All Opioid Prescriptions

Response	States	Total	Percent of Total
Yes, For All Opioid Medications	Alabama, Connecticut, District of Columbia, Georgia, Idaho, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Rhode Island, South	29	57%

	Dakota, Tennessee, Texas, West Virginia, Wisconsin, Wyoming		
Yes, For Some Opioid Medications	Arizona, Arkansas, California, Colorado, Delaware, Florida, Kansas, Michigan, New Mexico, North Dakota, Ohio, Oregon, Pennsylvania, Vermont, Virginia, Washington	16	31%
No, For All Opioids*	Hawaii, Louisiana, South Carolina, Utah	4	8%
N/A**	Alaska, Iowa	2	4%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed

Table 14 – MCE Initial Days' Supply Limit Applies to All Opioid Prescriptions

Response	States (Count of MCEs)	Total	Percent of Total
Yes, For All Opioid Medications	Arizona (1), Arkansas (1), California (17), Colorado (2), Delaware (1), District of Columbia (2), Florida (7), Georgia (2), Hawaii (5), Illinois (3), Iowa (2), Kentucky (2), Maryland (3), Massachusetts (2), Michigan (5), Minnesota (4), Nebraska (2), Nevada (1), New Hampshire (3), New Jersey (2), New Mexico (1), New York (7), North Dakota (1), Oregon (14), Pennsylvania (1), Rhode Island (2), South Carolina (1), Texas (13), Virginia (2), Washington (1)	110	45%
Yes, For Some Opioid Medications	Arizona (6), Arkansas (1), California (7), Delaware (1), District of Columbia (1), Florida (4), Georgia (1), Hawaii (1), Illinois (2), Indiana (3), Kansas (3), Louisiana (3), Maryland (4), Massachusetts (1), Michigan (4), Minnesota (4), Mississippi (3), Nebraska (1), Nevada (1), New Jersey (2), New Mexico (2), New York (5), Ohio (3), Oregon (5), Pennsylvania (5), Rhode Island (1), Texas (3), Utah (4), Virginia (3), Washington (3)	87	36%
No, For All Opioids*	Arizona (1), Arkansas (1), California (2), District of Columbia (1), Florida (5), Georgia (1), Illinois (2), Indiana (1), Kentucky (3), Louisiana (2), Maryland (2), Massachusetts (2), Michigan (2), Nevada (1), New Jersey (1), New York (6), Ohio (2), Oregon (1), Pennsylvania (2), South Carolina (4), Texas (1), Virginia (1), Washington (1)	45	19%

^{**}Please reference Table 4. Based on the DUR survey, if programs did not have an edit to limit the quantity dispensed of an initial opioid prescription, a response was not required. However, CMS plans to follow up regarding compliance.

Response	States (Count of MCEs)	Total	Percent of Total
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

Of the States that implemented a day's supply safety edit on short-acting opioid prescriptions (for non-opioid naïve patients), Tables 15 and 16 show the most common maximum days' supply limit was 30 days (FFS: 32%, MCE: 53%). A variety of other maximum days' supply criteria were used by other programs. Further details can be found in State specific reports on Medicaid.gov.

Table 15 – FFS Short-Acting Opioid Maximum Days' Supply per Prescription Limitation

Response	States	Total	Percent of Total
30-Day Supply	Arizona, Connecticut, Georgia, Idaho, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Nebraska, Oklahoma, Rhode Island, South Carolina, South Dakota, Utah, Vermont	16	32%
34-Day Supply	Alabama, Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, West Virginia, Wisconsin, Wyoming	14	27%
Other	Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Missouri, Nevada, New Jersey, New York, Oregon, Pennsylvania, Tennessee, Virginia, Washington	20	39%
N/A*	Texas	1	2%
National Totals		51	100%

^{*}Please reference Table 8. Based on the DUR survey, if programs did not have an edit to limit the quantity dispensed of short-acting opioids, a response was not required. However, CMS plans to follow up regarding compliance.

Table 16 – MCE Short-Acting Opioid Maximum Days' Supply per Prescription Limitation

Response	States (Count of MCEs)	Total	Percent of Total
30-Day Supply	Arizona (5), California (21), Colorado (1), Delaware (1), District of Columbia (1), Florida (8), Georgia (1), Hawaii (6), Illinois (5), Indiana (1), Kentucky (2), Louisiana (5), Maryland (6), Massachusetts (4), Michigan (10), Minnesota (2), Nebraska (2), Nevada (1), New Hampshire (1), New Jersey (4), New York (11), North Dakota (1), Ohio (2), Oregon (13), Pennsylvania (2), Rhode Island (3), South Carolina (2), Utah (4), Washington (3)	128	53%

Response	States (Count of MCEs)	Total	Percent of Total
34-Day Supply	Michigan (1), Minnesota (4), New Hampshire (2), New Mexico (1), Pennsylvania (4), Texas (3), Virginia (2), Washington (1)	18	7%
90-Day Supply	California (1), Colorado (1), Maryland (1), New York (2), Texas (2)	7	3%
Other	Arizona (3), Arkansas (3), California (4), Delaware (1), District of Columbia (3), Florida (8), Georgia (3), Illinois (2), Indiana (3), Iowa (2), Kansas (3), Kentucky (3), Maryland (2), Massachusetts (1), Minnesota (2), Mississippi (3), Nebraska (1), Nevada (2), New Jersey (1), New Mexico (2), New York (5), Ohio (3), Oregon (7), Pennsylvania (2), South Carolina (3), Texas (2), Virginia (4), Washington (1)	79	33%
N/A*	Texas (10)	10	4%
National Totals		242	100%

^{*} Please reference Table 9. Based on the DUR survey, if programs did not have an edit to limit the quantity dispensed of short-acting opioids, a response was not required. However, CMS plans to follow up regarding compliance.

Tables 17 and 18 show the most common maximum days' supply per long-acting opioid prescription limit was also 30 days (FFS: 39%, MCE: 67%). A variety of other maximum days' supply criteria were used by other programs. State specific reports can be found on <u>Medicaid.gov</u>.

Table 17 – FFS Long-Acting Opioid Maximum Days' Supply per Prescription Limitation

Table 17 – FFS Long-Acting Optoid Maximum Days' Supply per Prescription Limitation			
Response	States	Total	Percent of Total
30-Day Supply	Colorado, Connecticut, Florida, Georgia, Idaho, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Nebraska, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont	20	39%
34-Day Supply	Alabama, Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New Mexico, North Carolina, Ohio, West Virginia, Wisconsin, Wyoming	13	26%
Other	Arizona, Arkansas, California, Delaware, District of Columbia, Hawaii, Illinois, Indiana, Iowa, Kansas, Missouri, Nevada, New Jersey, New York, Pennsylvania, Virginia, Washington	17	33%
N/A*	Texas	1	2%
National Totals		51	100%

^{*}Please reference Table 10. Based on the DUR survey, if programs did not have an edit to limit the quantity dispensed of long-acting opioids, a response was not required. However, CMS plans to follow up regarding compliance.

Table 18 – MCE Long-Acting Opioid Maximum Days' Supply per Prescription Limitation

Response	States (Count of MCEs)	Total	Percent of Total
30-Day Supply	Arizona (7), California (22), Colorado (1), Delaware (1), District of Columbia (2), Florida (15), Georgia (4), Hawaii (6), Illinois (5), Indiana (3), Kansas (1), Kentucky (5), Louisiana (5), Maryland (6), Massachusetts (4), Michigan (10), Minnesota (4), Nebraska (3), Nevada (2), New Hampshire (1), New Jersey (5), New York (13), North Dakota (1), Ohio (3), Oregon (14), Pennsylvania (3), Rhode Island (3), South Carolina (3), Texas (1), Utah (4), Virginia (1), Washington (4)	162	67%
34-Day Supply	Maryland (1), Michigan (1), Minnesota (3), New Hampshire (2), New Mexico (1), Pennsylvania (4), Texas (5), Virginia (2), Washington (1)	20	8%
90-Day Supply	California (1), Colorado (1), Maryland (1), New York (2), Texas (2)	7	3%
Other	Arizona (1), Arkansas (3), California (3), Delaware (1), District of Columbia (2), Florida (1), Illinois (2), Indiana (1), Iowa (2), Kansas (2), Maryland (1), Massachusetts (1), Minnesota (1), Mississippi (3), Nevada (1), New Mexico (2), New York (3), Ohio (2), Oregon (5), Pennsylvania (1), South Carolina (2), Texas (9), Virginia (3)	52	21%
N/A*	Oregon (1)	1	1%
National Totals		242	100%

^{*}Please reference Table 11. Based on the DUR survey, if programs did not have an edit to limit the quantity dispensed of long-acting opioids, a response was not required. However, CMS plans to follow up regarding compliance.

In addition to safety edits on days' supply and quantity limits, States may establish other reasonable and appropriate drug utilization management reviews that assist in safe administration of prescribed medications including, but not limited to, concurrent use of opioids with other medications (note: retrospective claims review is required for concurrent prescribing of opioids and benzodiazepines or antipsychotics, see 42 C.F.R. § 456.703(h)(1)(iv)), interactions between patients' medical conditions and opioid use, and the number of unique prescribers and pharmacies used by a patient to obtain opioids. State survey responses in Tables 19 and 20 show that all programs (FFS: 100%, MCE: 100%) have measures other than restricted quantities and days' supply in place to either monitor or manage the prescribing of opioids. Further details can be found in state specific reports on Medicaid.gov.

Table 19 – FFS Measures Other Than Restricted Quantities and Days' Supply in Place to Either Monitor or Manage the Prescribing of Opioids

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine,	51	100%

Response	States	Total	Percent of Total
	Maryland, Massachusetts, Michigan, Minnesota,		
	Mississippi, Missouri, Montana, Nebraska, Nevada,		
	New Hampshire, New Jersey, New Mexico, New York,		
	North Carolina, North Dakota, Ohio, Oklahoma,		
	Oregon, Pennsylvania, Rhode Island, South Carolina,		
	South Dakota, Tennessee, Texas, Utah, Vermont,		
	Virginia, Washington, West Virginia, Wisconsin,		
	Wyoming		
National Totals		51	100%

Table 20 – MCE Measures Other Than Restricted Quantities and Days' Supply in Place to Either Monitor or Manage the Prescribing of Opioids

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (8), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (16), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	242	100%
National Totals		242	100%

2.1.4. Therapeutic Duplication

When implementing section 1927(g)(1) of the Act and section 1004 of the SUPPORT Act, in accordance with the requirements finalized in CMS 2482-F, States are required to establish safety edits to alert the dispenser to potential therapeutic duplication before a prescription is filled for an opioid product that is in the same therapeutic class as an opioid product currently being prescribed for the beneficiary. Prescriptions for multiple opioids and multiple strengths of opioids increase the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.²²

Some patients, especially those living with multiple chronic conditions, may consult multiple physicians, which can put them at risk of receiving multiple medications in the same therapeutic class for the same diagnosis.²³ In some instances, the side-effects produced by overmedication, due to the duplication of prescriptions within the same therapeutic class, are more serious than the

²² Manchikanti, Laxmaiah, et al. "Opioid Epidemic in the United States." Pain Physician, U.S. National Library of Medicine, July 2012, www.ncbi.nlm.nih.gov/pubmed/22786464. ²³ Ibid.

original condition.²⁴ Opioid duplicate safety edits for initial and subsequent prescription fills help to avoid inappropriate or unnecessary therapeutic duplication when simultaneous use of multiple opioids is detected. These type of safety alerts can also help to identify when prescription drugs are being misused or if patients are moving from provider to provider to obtain multiple prescriptions for their drug(s) of choice. A common clinical therapy regimen includes a patient using both an extended-release opioid and an immediate-release opioid for breakthrough pain and should be excluded from these type of safety reviews.

FFY 2020 survey responses show in Tables 21 and 22 that almost all programs (FFS: 94%, MCE: 95%) have safety edits to monitor duplicate therapy of opioid prescriptions dispensed (this excludes regimens that include a single extended-release product and a breakthrough short-acting agent). For FFS programs, Colorado and Oregon indicated opioid prescriptions are handled through prior authorizations where duplicate opioid prescriptions are managed by limiting prior authorization approval, while the New Mexico's FFS program has retrospective reports for state staff review of opioid overutilization. MCE programs also cited having other opioid edits in place such as MME or a prior authorization review process. Further details can be found in state specific reports on Medicaid.gov.

Table 21 – FFS Safety Edits to Monitor Duplicate Therapy of Opioid Prescriptions

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	48	94%
No	Colorado, New Mexico, Oregon	3	6%
National Totals		51	100%

Table 22 – MCE Safety Edits in Place to Monitor Duplicate Therapy of Opioid Prescriptions

1 44 5 1 4 1 1	2 1/102 Surety Earls in 1 mee to 1/10meet Duplicate Therapy of Spiola 1 resembled				
Response	States (Count of MCEs)	Total	Percent of Total		
Yes	Arizona (8), Arkansas (3), California (20), Colorado (2), Delaware (2), District of Columbia (4), Florida (14), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (10), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), Ohio (5), Oregon (20),	231	95%		

²⁴ "Therapeutic Duplication." Journal of the American Medical Association, vol. 160, no. 9, 1956, p. 780., doi:10.1001/jama.1956.02960440052016.

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Response	States (Count of MCEs)	Total	Percent of Total
	Pennsylvania (7), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)		
No*	California (6), Florida (2), Michigan (1), North Dakota (1), Pennsylvania (1)	11	5%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed

2.2. Morphine Milligram Equivalent (MME) Daily Dose

Amendments made by section 1004 of the SUPPORT Act require state DUR programs to include safety edit limits (as specified by the state) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the state plan (or under a waiver of the state plan) for treatment of chronic pain (as designed and implemented by the state) that indicate when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any threshold identified by the state. Section 1004 of the SUPPORT Act specifically addresses MME limitations in the context of chronic pain. According to the CDC, acute pain (as distinct from chronic pain) usually occurs suddenly and usually has a known cause, like an injury, surgery, or infection. For example, acute pain can be caused from a broken bone after an automobile accident, a surgery, or a wisdom tooth extraction. Acute pain normally resolves as your body heals. Chronic pain, on the other hand, can last weeks, months or years. Regarding chronic pain, CDC states clinicians should use caution when prescribing opioids at any dosage, and should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 MME/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

MME safety edits include an MME threshold amount to meet statutory requirements, to assist in identifying patients at potentially high clinical risk who may benefit from closer monitoring and care coordination. Calculating the total daily dosage of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of a medication for the treatment of opioid overdoses such as naloxone, or other measures to reduce risk of overdose.

MME values are used to assess the total daily dose of opioids, taking into account the comparative potency of different opioids and frequency of use. The calculation to determine MMEs includes drug strength, quantity, days' supply and a defined conversion factor unique to each drug.²⁸

²⁵ Section 1902(oo)(1)(A)(i)(II) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

²⁶ "Opioids for Acute Pain." Centers for Disease Control and Prevention, available at https://www.cdc.gov/drugoverdose/pdf/patients/Opioids-for-Acute-Pain-a.pdf.

²⁷ "CDC Guidelines for Prescribing Opioids for Chronic pain. "Available at https://www.cdc.gov/drugoverdose/pdf/guidelines at-a-glance-a.pdf.

²⁸ Calculating Total Daily Dose of Opioids For Safer Dosage. Centers for Disease Control and Prevention, available at https://www.cdc.gov/drugoverdose/pdf/calculating total daily dose-a.pdf.

Generally, patients prescribed higher opioid dosages are at higher risk of overdose death.²⁹ Calculating the total MME daily dose of opioids can help identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.³⁰ HHS's *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*,³¹ is also a valuable resource for considering how best to taper and/or discontinue usage in a thoughtful manner consistent with best clinical practices.

MME is an opioid dosage's equivalency to morphine. The MME/day metric is often used as a gauge for the overdose potential of the amount of opioid that is being given at a particular time. In 42 C.F.R. § 456.703(h)(1)(ii) States are required to implement prospective safety edit limitations for opioid prescriptions, as specified by the state, on the maximum daily MME for treatment of pain, for initial and subsequent prescription refills. When States implement the maximum daily MME limits, this does not mean to suggest rapid discontinuation of opioids already prescribed at higher dosages, rather the MME/day metric is often used as a gauge of the overdose potential of the amount of opioid that is being given at a particular time.³² When implementing this safety edit, we noted in the final rule that HHS does not recommend opioids be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal. The Food and Drug Administration (FDA) issued a safety announcement on tapering in April 2019 noting concerns about safely decreasing or discontinuing doses of opioids in patients who are physically dependent after hearing reports about serious harm.³³ Additionally, States were reminded that clinical resources, including, for example, the CDC Guideline, ³⁴ recommend caution when prescribing opioids for chronic pain in certain circumstances, and recommend that primary care practitioners reassess evidence of individual benefits and risks when increasing doses and subsequently, justifying decisions by thoroughly documenting the clinical basis for prescribing in the patient's medical record.³⁵

FFY 2020 survey responses show in Tables 23 and 24 that almost all programs are in compliance with this requirement and set recommended maximum MME daily dose measures (FFS: 98%, MCE: 99%). Rhode Island indicated their FFS does not set recommended maximum MME daily dose limits. However, Rhode Island stated they are in the process of implementing additional opioid safety edits. Two MCE programs (California (1), New York (1)) specified they did not have this edit in place. However, both indicate they utilize other opioid safety edits.

31 https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf).

²⁹ Guideline for Prescribing Opioids for Chronic Pain. www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.

³⁰ Ibid.

³² Ibid.

³³ "FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering." Food and Drug Administration. Available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.

pain-medicines-and-requires-label-changes.

34 Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016.

MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501el.

https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.

³⁵ Dowell, Deborah, et al. "CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016." JAMA, U.S. National Library of Medicine, 19 Apr. 2016, https://www.ncbi.nlm.nih.gov/pubmed/26977696.

Table 23 – FFS Recommended Maximum MME Daily Dose Measures

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming	50	98%
No*	Rhode Island	1	2%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

Table 24 - MCE Recommended Maximum MME Daily Dose Measures

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (8), Arkansas (3), California (25), Colorado (2), Delaware (2), District of Columbia (4), Florida (16), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (17), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	240	99%
No*	California (1), New York (1)	2	1%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

Of the States that set recommended maximum MME daily dose safety edits, Tables 25 and 26 show the median MME daily dose for FFY 2020 reported responses was 90 mg/day for both FFS and MCE programs. For both FFS and MCE programs, responses ranged from less than 50 mg/day to greater than 200 MME.

Table 25 – FFS Maximum Morphine Equivalent Daily Dose Limit in Milligrams

Response	States	Total	Percent of Total
Less Than 50 MME	Maine, Ohio	2	4%
50 MME	Indiana, Nevada, Pennsylvania, Vermont, West Virginia	5	10%
80 MME	Georgia	1	2%
90 MME	Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Montana, Nebraska, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, South Carolina, South Dakota, Texas, Utah, Virginia, Wisconsin	28	54%
100 MME	New Hampshire	1	2%
120 MME	Hawaii, Massachusetts, Michigan, New Jersey, Washington, Wyoming	6	12%
200 MME	Alabama, Alaska, Colorado, Kentucky, Missouri, Tennessee	6	12%
Greater Than 200 MME	California	1	2%
N/A*	Rhode Island	1	2%
National Totals		51	100%

^{*}Please reference Table 23

Table 26 - MCE Maximum Morphine Equivalent Daily Dose Limit in Milligrams

Response	States (Count of MCEs)	Total	Percent of Total
Less Than 50 MME	Massachusetts (1), Ohio (1), Pennsylvania (1)	3	1%
50 MME	California (1), Georgia (1), Indiana (3), Kentucky (1), Pennsylvania (7)	13	5%
80 MME	Kentucky (1), Ohio (3)	4	2%
90 MME	Arizona (8), Arkansas (3), California (11), Delaware (2), District of Columbia (4), Florida (15), Georgia (3), Hawaii (3), Illinois (5), Indiana (1), Iowa (2), Kansas (3), Kentucky (2), Louisiana (5), Maryland (8), Massachusetts (3), Michigan (2), Minnesota (8), Mississippi (3), Nebraska (1), Nevada (3), New Jersey (2), New Mexico (3), New York (11), Ohio (1), Oregon (19), Rhode Island (3),	165	68%

Response	States (Count of MCEs)	Total	Percent of Total
	South Carolina (5), Texas (17), Utah (3), Virginia (6)		
100 MME	Massachusetts (1), New Hampshire (3)	4	2%
120 MME	California (3), Hawaii (3), Michigan (7), Nebraska (2), New Jersey (3), Utah (1), Washington (5)	24	10%
200 MME	California (8), Colorado (1), Illinois (2), Kentucky (1), Maryland (1), Michigan (2), New York (6), North Dakota (1), Oregon (1)	23	9%
Greater Than 200 MME	California (2), Colorado (1), Florida (1)	4	2%
No*	California (1), New York (1)	2	1%
National Totals		242	100%

^{*}Please reference Table 24

Automated retrospective claims reviews may detect high doses of opioids and allow for the program to follow up on prescription trends or issues found on prescriptions that have already been dispensed. As depicted in Tables 27 and 28, FFY 2020 survey responses show that a majority of programs have automated retrospective claim reviews to monitor total daily MME dose of opioid prescriptions dispensed (FFS: 61%, MCE: 85%). These reviews also assist in determining overall trending of prescriptions in the state by MME.

Table 27 – FFS Automated Retrospective Claim Reviews to Monitor Total Daily MME Dose of Opioid Prescriptions Dispensed

WINTE Dose of Optoid Trescriptions Dispensed			
Response	State	Total	Percent of Total
Yes	Alaska, Arizona, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Mississippi, Missouri, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin	31	61%
No*	Alabama, Arkansas, California, Georgia, Idaho, Illinois, Kentucky, Massachusetts, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, Pennsylvania, Rhode Island, South Carolina, Vermont, West Virginia, Wyoming	20	39%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed.

Table 28 – MCE Automated Retrospective Claim Reviews to Monitor Total Daily MME Dose of Opioid Prescriptions Dispensed

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (6), Arkansas (2), California (21), Colorado (1), Delaware (1), District of Columbia (3), Florida (11), Georgia (4), Hawaii (6), Illinois (6), Indiana (4), Iowa (2), Kansas (3), Kentucky (3), Louisiana (5), Maryland (9), Massachusetts (4), Michigan (10), Minnesota (5), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (15), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (6), Rhode Island (3), South Carolina (5), Texas (14), Utah (3), Virginia (4), Washington (4)	206	85%
No*	Arizona (2), Arkansas (1), California (5), Colorado (1), Delaware (1), District of Columbia (1), Florida (5), Illinois (1), Kentucky (2), Massachusetts (1), Michigan (1), Minnesota (3), New York (3), Pennsylvania (2), Texas (3), Utah (1), Virginia (2), Washington (1)	36	15%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

2.3. Opioids and Concurrently Prescribed Medications

Section 1902 of the Act, as amended by section 1004 of the SUPPORT Act, requires States to have an automated process for claims review (as designed and implemented by the state) that monitors when an individual enrolled under the state plan (or under a waiver of the state plan) is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics. This requirement is consistent with the requirement in section 1927(g)(1)(A) of the Act that state DUR programs must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The concurrent use of opioids with benzodiazepines and/or antipsychotics significantly increases the risk of adverse effects including undesirable changes in mental status or overdose. Using automated retrospective claim reviews, concurrent use of opioids and benzodiazepines and/or opioids and antipsychotics can be reduced, as well as potential complications resulting from the medications. The requirement for a retrospective automated claims review added by section 1004 of the SUPPORT Act does not preclude the state from also establishing a prospective safety edit system to provide additional information to patients and providers at the POS about concurrent utilization alerts.

Opioid and Benzodiazepines Concurrent Fill Reviews: In 2016, the FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently. The

³⁶ Section 1902(oo)(1)(A)(i)(III) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

CDC Guideline recommends that clinicians avoid prescribing benzodiazepines concurrently with opioids whenever possible. Benzodiazepines may be abused for recreational purposes by some individuals, with some opioid overdoses also involving opioids and benzodiazepines or other substances, such as alcohol.³⁷ Studies show that people concurrently using both drugs are at higher risk of visiting the emergency department (ED) or being admitted to a hospital for a drug-related emergency.³⁸ Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, such as an additive sedative effect and increased risk for respiratory depression, physicians should avoid the initial combination of opioids and benzodiazepines by offering alternative approaches.³⁹ This review alerts providers when these drugs have been prescribed concurrently to assist in avoiding and mitigating these associated risks.

Opioid and Antipsychotic Concurrent Fill Reviews: This review is supported by the FDA's warning of increased risk of respiratory and Central Nervous System (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur. Despite the risks, patients with increased coordination of care may benefit from concurrent opioid and antipsychotic therapy. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of opioid use disorder (OUD), and the treatment of pain.

As the Pain Management Task Force (PMTF) report noted, "the occurrence of pain and mental health comorbidities, including depression, [post-traumatic stress disorder] (PTSD), and [substance use disorder] (SUD), is well documented," and it is established that "[p]sychosocial distress can contribute to pain intensity, pain-related disability, and poor response to treatment."⁴⁰ Evidence indicates that optimizing mental health and pain treatment can improve outcomes in both areas for patients seen in primary and specialty care settings. Untreated psychiatric conditions may increase the risk of both unintentional and intentional medication mismanagement, OUD, and overdose. Given the intersection between psychiatric/psychological symptoms and chronic pain, it is important that the behavioral health needs of patients with pain are appropriately and carefully evaluated and treated with the concurrent physical pain problem. As such, beneficiaries who are concurrently prescribed both opioids and antipsychotics should be considered from a health system or policy perspective when addressing their treatment. A patient's unique presentation and circumstances should be considered when prescribing opioids and antipsychotics. This review

³⁷ Jones, Jermaine D, et al. "Polydrug Abuse: a Review of Opioid and Benzodiazepine Combination Use." Drug and Alcohol Dependence, U.S. National Library of Medicine, 1 Sept.

^{2012,} www.ncbi.nlm.nih.gov/pmc/articles/PMC3454351/.

³⁸ Forum, Addiction Policy. "Sedative Use Disorder." Addiction Policy Forum, https://www.addictionpolicy.org/sedative-use-disorder.

³⁹ "Reduce Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing Benzodiazepines." MLN Matters Number: SE19011. Available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19011.pdf.

⁴⁰ Pain Management Best Practices Inter-Agency Task Force. "Pain Management Best Practices." Available at https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.

⁴¹ Ibid.

⁴² Ibid.

⁴³ Davis, Matthew A., et al. "Prescription Opioid Use among Adults with Mental Health Disorders in the United States." The Journal of the American Board of Family Medicine, vol. 30, no. 4, 2017, pp. 407–417., doi:10.3122/jabfm.2017.04.170112.

encourages coordination of care for patients taking antipsychotic and opioid medication concurrently.

2.3.1. Concurrent Opioids and Benzodiazepines

DUR safety edits can detect if a patient has active prescriptions of both opioids and benzodiazepines and require review by the pharmacist. Based upon the review, the pharmacist may counsel the patient on the interaction, alert prescribers of the concurrent medications, suggest a therapy change, or take no action. Automated retrospective claims reviews may detect the same scenario and allow for the program to follow up.

FFY 2020 survey responses show that most programs have prospective safety edits or a retrospective claims review process to monitor opioids and benzodiazepines being used concurrently (FFS: 98%, MCE: 91%) as shown in Tables 29 and 30. The New Mexico FFS program indicated they were in the process of implementing at the time survey responses were collected. Twenty-three MCE programs, almost 10%, indicated they do not have these reviews in place; (California (1), Hawaii (1), Illinois (1), Kentucky (1), Maryland (8), Michigan (6), Pennsylvania (1), Utah (4)). However, of these MCEs, 7.6% of the programs (Maryland (8), Michigan (6), and Utah (4)), have either opioids or benzodiazepines carved out and the process is handled by the state's program. The MCE programs in Pennsylvania and Kentucky indicated the review of concurrent use of opioids and benzodiazepine is part of their prior authorization criteria.

Table 29 – FFS Safety Edits or Retrospective Claims Review to Monitor Opioids and Benzodiazepines Used Concurrently

Response	States	Total	Percent of Total
Yes, Automated Retrospective Claim Reviews	Alabama, Hawaii, Michigan, Washington, Wisconsin	5	10%
Yes, Both Safety Edits And Automated Retrospective Claim Reviews	Alaska, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Minnesota, Missouri, Montana, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, West Virginia	32	63%
Yes, Safety Edits	Arizona, Illinois, Kentucky, Maine, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, North Dakota, Oklahoma, Tennessee, Wyoming	13	25%
No	New Mexico	1	2%
National Totals		51	100%

Table 30 – MCE Safety Edits or Retrospective Claims Review to Monitor Opioids and Benzodiazepines Used Concurrently

Response	States (Count of MCEs)	Total	Percent of Total
Yes, Automated Retrospective Claims Review Process	California (6), Delaware (1), Florida (2), Georgia (1), Illinois (1), Massachusetts (1), Michigan (3), Minnesota (2), Mississippi (1), North Dakota (1), Ohio (1), Oregon (10), Texas (1), Washington (1)	32	13%
Yes, Both Safety Edits And Automated Retrospective Claims Review Process	Arizona (5), Arkansas (2), California (13), Colorado (1), District of Columbia (2), Florida (8), Georgia (3), Hawaii (4), Illinois (3), Indiana (2), Iowa (2), Kansas (3), Kentucky (1), Louisiana (5), Massachusetts (3), Michigan (1), Minnesota (4), Mississippi (2), Nebraska (3), Nevada (3), New Hampshire (2), New Jersey (5), New Mexico (3), New York (16), Ohio (4), Oregon (9), Pennsylvania (4), Rhode Island (3), South Carolina (3), Texas (5), Virginia (3), Washington (3)	130	54%
Yes, Safety Edits	Arizona (3), Arkansas (1), California (6), Colorado (1), Delaware (1), District of Columbia (2), Florida (6), Hawaii (1), Illinois (2), Indiana (2), Kentucky (3), Maryland (1), Massachusetts (1), Michigan (1), Minnesota (2), New Hampshire (1), New York (2), Oregon (1), Pennsylvania (3), South Carolina (2), Texas (11), Virginia (3), Washington (1)	57	24%
Carve-Out Program Managed By The State	Maryland (8), Michigan (6), and Utah (4)	18	7%
No*	California (1), Hawaii (1), Illinois (1), Kentucky (1), Pennsylvania (1)	5	2%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance for additional information and rationales as DUR survey responses need clarification.

2.3.2. Concurrent Opioids and Antipsychotics

Safety edits can detect if a patient has active prescriptions of both opioids and antipsychotics and require review by the pharmacist. The pharmacist will review the patient's medical history and determine if there is a safety concern with concurrent use. If so, the pharmacist may alert the

prescribers, suggest a therapy change, or counsel the patient on risks such as respiratory depression, extreme sleepiness, slowed or difficult breathing, unresponsiveness or increased risk of death. Automated retrospective claims reviews may detect the same scenario and allow for the program to follow up.

Tables 31 and 32 show that FFY 2020 survey responses indicate a large majority of programs have safety edits in place or automated retrospective claims review to monitor opioids and antipsychotics being used concurrently (FFS: 92%, MCE: 82%). A large portion of States and MCE programs had both safety edits and automated retrospective claim reviews in place (FFS: 41%, MCE: 33). Note that 13% of MCEs (California, Maryland, Michigan, Oregon, and Utah), have medications carved out of their MCE program with reviews being performed by the state's FFS program.

Table 31 – FFS Safety Edits or Retrospective Claims Review to Monitor Opioids and Antipsychotics Being Used Concurrently

Response	States	Total	Percent of Total
Yes, Automated Retrospective Claim Reviews	Alabama, Arkansas, Hawaii, Idaho, Louisiana, Michigan, Montana, Oregon, Pennsylvania, Texas, Utah, Vermont, Washington, Wisconsin, Wyoming	15	29%
Yes, Both Safety Edits And Automated Retrospective Claim Reviews	Alaska, California, Connecticut, Delaware, Florida, Indiana, Iowa, Maryland, Minnesota, Mississippi, Missouri, New Hampshire, New York, North Carolina, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Virginia, West Virginia	21	41%
Yes, Safety Edits	Arizona, Colorado, District of Columbia, Georgia, Illinois, Kansas, Massachusetts, Nebraska, Nevada, New Jersey, North Dakota	11	22%
No*	Kentucky, Maine, New Mexico, Tennessee	4	8%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

Table 32 – MCE Safety Edits or Retrospective Claims Review to Monitor Opioids and Antipsychotics Being Used Concurrently

Response	States (Count of MCEs)	Total	Percent of Total
Yes, Automated Retrospective Claims Review Process	Arizona (4), California (6), Florida (2), Georgia (1), Hawaii (1), Illinois (1), Indiana (1), Kansas (3), Kentucky (1), Louisiana (4), Michigan (4), Minnesota (4), Mississippi (2), Nebraska (1), Nevada (1), New Jersey (2), New York (3), North Dakota (1), Oregon (16), Pennsylvania (3), Rhode	69	29%

	Island (1), South Carolina (1), Texas (2), Virginia (2), Washington (2)		
Yes, Both Safety Edits And Automated Retrospective Claims Review Process	Arizona (1), Arkansas (2), California (7), Delaware (1), District of Columbia (2), Florida (6), Georgia (3), Hawaii (4), Illinois (3), Indiana (1), Iowa (2), Kentucky (2), Louisiana (1), Massachusetts (4), Minnesota (3), Nebraska (2), Nevada (2), New Hampshire (1), New Jersey (3), New Mexico (2), New York (10), Ohio (5), Oregon (2), Pennsylvania (2), Rhode Island (2), South Carolina (2), Texas (2), Virginia (2), Washington (1)	80	33%
Yes, Safety Edits	Arizona (3), Arkansas (1), Colorado (2), Delaware (1), District of Columbia (2), Florida (5), Illinois (1), Indiana (2), Kentucky (1), Massachusetts (1), Michigan (1), Minnesota (1), Mississippi (1), New Hampshire (2), New Mexico (1), New York (5), Oregon (1), Pennsylvania (1), South Carolina (2), Texas (12), Virginia (2), Washington (1)	49	20%
Carve-Out Program Managed By The State	California (13), Maryland (9), Michigan (6), Oregon (1), and Utah (4)	33	14%
No*	Florida (3), Hawaii (1), Illinois (2), Kentucky (1), Pennsylvania (2), Texas (1), Washington (1)	11	5%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance for additional information and rationales as DUR survey responses need clarification.

2.4. Automated Claim Reviews

In accordance with the amendments made by section 1004 of the SUPPORT Act and the requirements in the CMS 2482-F final rule, States must have in place a claims automated review process (as designed and implemented by the state) that indicates when an individual enrolled under the State plan (or under a waiver of the state plan) is prescribed opioids in excess of limitations identified by the state. In these ongoing, comprehensive reviews of opioid claims data, States should continuously monitor opioid prescriptions, including overrides of safety edits by the prescriber or pharmacist on initial fill days' supply for opioid naïve patients, quantity limits, therapeutically duplicative fills, early refills and maximum daily MME limitations on opioids prescriptions.

These are important reviews regarding prescription data in the state which aim to detect patterns in prescribing, dispensing or administering drugs. Based on current trends of medication use, prospective standards and provider or beneficiary educational interventions can be developed to prevent recurrence of inappropriate medication use or abuse. Outcomes of these reviews may aid prescribers in improving the care of their patients, either individually or within a certain target population via provider education. For example, a retrospective DUR review may be the

identification of a group of patients whose therapy does not meet approved guidelines or an identification of beneficiaries who could benefit from co-prescribing naloxone. Additionally, these opioid claim reviews are necessary to allow States to monitor opioid prescriptions beneficiaries are receiving and determine and refine future potential prospective DUR safety edits, based on the findings of the claims reviews. These DUR reviews play a key role in helping programs understand, interpret and improve the prescribing, administration and use of opioids.

Based on 42 C.F.R. § 456.703(h)(1)(iii), states are required to conduct retrospective claims review automated processes that indicate prescription fills in excess of the prospective safety edit limitations specified by the State under 42 C.F.R. § 456.703(h)(1)(i) or (h)(1)(ii) to provide for the ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits.

In addition to opioid claims data, States should consider incorporating other available records to provide for the ongoing periodic reviews of opioids claim data and other records in their retrospective claims review automated processes (including but not limited to prescription histories, diagnoses, medical records, and prescription drug monitoring program (PDMP) files, when available). While prospective DUR safety edits are employed for screening prescription drug claims to identify prescription problems prior to the dispensing of the prescription to the patient, automated retrospective reviews of claims data, guided by algorithmic logic determined by each state Medicaid program, identifies patterns of unsafe or inappropriate use, fraud, waste, abuse, or medically unnecessary care based on ongoing and periodic examination and reviews of claims data for prescriptions that were already dispensed.

In these ongoing, comprehensive reviews of opioid claim data, States should continuously monitor opioid prescriptions, including overrides of safety edits by the prescriber or pharmacist on initial fill days' supply for opioid naïve patients, quantity limits, therapeutically duplicative fills, early refills and maximum daily MME limitations on opioids prescriptions. Through ongoing monitoring and observation of trends over time, these reviews will allow for regular updates to safety edits in an evolving pain treatment landscape.

When asked if state programs have a comprehensive automated retrospective claims review process to monitor opioid prescriptions exceeding restricted quantity, days' supply, and/or duplicate therapy limitations, FFY 2020 survey responses show that continued work needs to be done by both FFS and MCE programs. Tables 33 and 34 show approximately 65% of FFS and 67% of MCE programs have automated retrospective claim reviews to monitor opioid prescriptions exceeding state defined limitations. Many of the remaining programs surveyed said either their review process was not automated, the programs have prospective safety edits in place or use prior authorization reviews to handle this requirement.

Table 33 – FFS Comprehensive Claims Review Automated Retrospective Process to Monitor Opioid Prescriptions Exceeding State Limitations

Response	States	Total	Percent of Total
Yes	Alaska, Arizona, Arkansas, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii,	33	65%

Response	States	Total	Percent of Total
	Indiana, Iowa, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin		
No*	Alabama, California, Delaware, Idaho, Illinois, Kansas, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, Oklahoma, South Dakota, Vermont, West Virginia, Wyoming	18	35%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed

Table 34 – MCE Comprehensive Claims Review Automated Retrospective Process to Monitor Opioid Prescriptions in Excess of State Limitations

States (Count of MCEs) Response Total **Percent of Total** Arizona (5), Arkansas (2), California (18), Colorado (1), Delaware (1), District of Columbia (3), Florida (11), Georgia (4), Hawaii (6), Illinois (4), Indiana (1), Iowa (2), Kansas (2), Kentucky (2), Louisiana (5), Maryland (6), Massachusetts (5), Michigan (4), Yes 162 67% Minnesota (3), Mississippi (2), Nebraska (2), Nevada (2), New Hampshire (3), New Jersey (3), New Mexico (3), New York (13), Ohio (5), Oregon (20), Pennsylvania (5), Rhode Island (2), South Carolina (5), Texas (4), Utah (3), Virginia (2), Washington (3) Arizona (3), Arkansas (1), California (8), Colorado (1), Delaware (1), District of Columbia (1), Florida (5), Illinois (3), Indiana (3), Kansas (1), Kentucky (3), Maryland (3), Michigan (7), Minnesota (5), Mississippi No* 80 33% (1), Nebraska (1), Nevada (1), New Jersey (2), New York (5), North Dakota (1), Pennsylvania (3), Rhode Island (1), Texas (13), Utah (1), Virginia (4), Washington (2) **National Totals** 242 100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, need clarification or additional information is needed

3. Antipsychotics in Children

Under the amendments made by section 1004 of the SUPPORT Act, States must have a program (as designed and implemented by the state) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the state plan (or under a waiver of the state plan), including any Medicaid expansion group for Children's Health Insurance Program (CHIP).⁴⁴ Antipsychotic medications are increasingly used for a wide range of clinical indications in diverse populations, including privately and publicly insured youth.⁴⁵

Antipsychotics' adverse metabolic effects have heightened concern over growth in prescribing to youth, including off-label prescribing and polytherapy of multiple antipsychotics. ⁴⁶ Studies have raised concerns regarding the long-term safety and effectiveness of antipsychotics in this broadened population. Studies in adults have found that antipsychotics can cause serious side effects and long-term safety and efficacy for off-label utilization is a particular concern in children. ⁴⁷ Some of the most concerning effects include uncontrollable movements and tremors, an increased risk of diabetes, substantial weight gain, elevated cholesterol, triglycerides and prolactin, changes in sexual function, and abnormal lactation. ⁴⁸ Children appear to be at higher risk than adults for a number of adverse effects, such as extrapyramidal symptoms and metabolic and endocrine abnormalities. Additionally, some studies suggest that antipsychotic treatment may be associated with increased mortality among children and youths and the distal benefit/risk ratio for long-term off-label treatment remains to be determined. ^{49,50}

Based on clinical recommendations to monitor and manage the appropriate use of antipsychotic medications by children and to assess the clinical benefits and harms of treatment on an ongoing basis, these monitoring programs assure children are receiving appropriate treatment that is not likely to result in adverse medical results. As implemented by 42 C.F.R. § 456.703(h)(1)(v) States are required to implement programs to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the state plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP). These monitoring provisions were not meant to prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient, and States are expected to consult national guidelines and are encouraged to work with their pharmacy and therapeutics (P&T) and DUR committees to identify clinically appropriate safety edits and reviews. Additionally, state DUR programs could consider to include reviews on children for additional concerns such as for polytherapy (therapy that uses more than one medication), inappropriate utilization or off label utilization of other medications as well.

⁴⁴ Section 1902(oo)(1)(B) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

⁴⁵ Crystal, Stephen et al. "Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges." *Health affairs (Project Hope)* vol. 28,5 (2009): w770-81. doi:10.1377/hlthaff.28.5.w770.

⁴⁶ Ibid.

⁴⁷ Ibid.

⁴⁸ Marder SR, et al. Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004;161(8):1334.

⁴⁹ https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2717966.

⁵⁰ https://www.healthline.com/health/consumer-reports-antipsychotics-children#1.

The following sections provide the survey results for state Medicaid programs related to antipsychotic medication use in children.

3.1. Programs to Monitor and Manage Antipsychotics in Children

Pursuant to section 1927(g) of the Act and to the amendments made by section 1004 of the SUPPORT Act, as implemented by 42 C.F.R. § 456.703(h)(1)(v), States are required to implement programs to monitor and manage the appropriate use of antipsychotic medications by children.

Tables 35 and 36 show that all FFS programs (100%) have a program in place for managing or monitoring appropriate use of antipsychotic drugs in children, while a majority of MCEs have such a program in place (77%). However, MCE compliance is much higher than this number appears to indicate. Of the 23% of MCEs that indicated they do not have a program in place, 17% (California (17), Michigan (5), Maryland (8), Oregon (11), and Utah (4)), indicated it was because these medications were carved out, restricted to FFS programs or the monitoring and managing was handled through the FFS program. Additionally, 4 MCEs (Florida (1), Minnesota (1), North Dakota (1), Texas (1)), indicated they have no children beneficiaries in their program. There were three programs that indicated implementation of the program occurred after the FFY of this reporting period or was still in the process of being implemented (Colorado (1), Illinois (1) and District of Columbia (1)). The remaining MCEs (2%) did not provide an explanation.

Table 35 – FFS Program in Place for Either Managing or Monitoring Appropriate
Use of Antipsychotic Drugs in Children

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	51	100%
National Totals		51	100%

Table 36 – MCE Program in Place for Either Managing or Monitoring Appropriate
Use of Antipsychotic Drugs in Children

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (8), Arkansas (3), California (9), Colorado (1), Delaware (2), District of Columbia (3), Florida (15), Georgia (4), Hawaii (6), Illinois (5), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (1), Massachusetts (5), Michigan (6), Minnesota (7),	188	78%

Response	States (Count of MCEs)	Total	Percent of Total
	Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), Ohio (5), Oregon (9), Pennsylvania (7), Rhode Island (3), South Carolina (5), Texas (16), Virginia (6), Washington (5)		
Carved-Out Program Managed By The State	California (17), Maryland (8), Michigan (5), Oregon (11), and Utah (4)	45	19%
Children Not Enrolled In MCE	Florida (1), Minnesota (1), North Dakota (1), Texas (1)	4	1%
No*	Colorado (1), District of Columbia (1), Illinois (2), Pennsylvania (1)	5	2%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

As shown in Tables 37 and 38, the majority of programs that either manage or monitor antipsychotic medication use in children include the monitoring of all children, not only children in foster care (FFS: 90%, MCE: 86%). For the 5 FFS States (Arizona, Illinois, New Mexico, Oregon, Wisconsin) selecting "other", all indicated some degree of monitoring and managing antipsychotic medication in all children. The Maine FFS program specified they only monitored children in foster care. Of the 27 MCE programs that selected "other", 9 programs specified they manage all children, but only under the age of 10 (Florida (2), Georgia (1), Hawaii (2), Kentucky (1), New Jersey (1), New York (1), South Carolina (1)); 12 programs specified that their monitoring strategy of antipsychotics not only applies to all children, but all adult members as well (Arizona (1), Nebraska (1), Florida (1), Louisiana (1), Mississippi (1), Nevada (1), New Jersey (1), New York (1), Ohio (1), Rhode Island (1), Texas (1), Virginia (1)); and 3 MCE programs in Oregon indicated the state covers all monitoring and supplementation occurs by the MCP. An additional program in Arizona specified that prior authorization is required for antipsychotic drug use in children less than 6 or children less than 18 depending on the drug and the other 3 MCEs provided an explanation of safety edit(s) that occur in these populations, such as monitoring of all antipsychotics and opioids in children.

Table 37 – FFS Categories of Children Either Managed or Monitored for Appropriate Use of Antipsychotic Drugs

Appropriate Ose of Antipsychotic Drugs				
Response	States	Total	Percent of Total	
All Children	Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma,	45	88%	

Response	States	Total	Percent of Total
	Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming		
Only Children In Foster Care*	Maine	1	2%
Other*	Arizona, Illinois, New Mexico, Oregon, Wisconsin	5	10%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

Table 38 – MCE Categories of Children Either Managed or Monitored for Appropriate Use of Antipsychotic Drugs

States (Count of MCEs) Total **Percent of Total** Response Arizona (4), Arkansas (3), California (7), Colorado (1), Delaware (2), District of Columbia (3), Florida (12), Georgia (3), Hawaii (4), Illinois (5), Indiana (4), Iowa (2), Kansas (3), Kentucky (4), Louisiana (4), Maryland (1), Massachusetts (5), Michigan (5), Minnesota (7), All Children 158 84% Mississippi (2), Nebraska (2), Nevada (2), New Hampshire (3), New Jersey (3), New Mexico (3), New York (16), Ohio (4), Oregon (6), Pennsylvania (7), Rhode Island (2), South Carolina (4), Texas (15), Virginia (5), Washington (5) **Only Children** In Foster Arizona (1), Michigan (1) 2 1% Care* Arizona (3), California (2), Florida (3), Georgia (1), Other* Hawaii (2), Kentucky (1), Louisiana (1), Mississippi (1), Nebraska (1), Nevada (1), New Jersey (2), New York 28 15% (2), Ohio (1), Oregon (3), Rhode Island (1), South

Carolina (1), Texas (1), Virginia (1)

National Totals

3.2. Types of Safety Edits in Place to Monitor Antipsychotic Utilization in Children

Antipsychotic drug monitoring by state programs helps to prevent adverse outcomes in the pediatric population. States have a variety of safety edits in place to monitor antipsychotic drug use in children, including edits to monitor child's age, dosage, indication, and polypharmacy. FFY 2020 survey responses show in Tables 39 and 40 that various antipsychotic safety edits are in place

100%

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^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

to monitor for appropriate use in children including child's age (FFS: 94%, MCE: 92%), dosage (FFS: 76%, MCE: 83%), indication (FFS: 63%, MCE: 52%), and polypharmacy (FFS: 76%, MCE: 76%).

Table 39 – FFS Antipsychotic Safety Edits in Place to Monitor for Appropriate Use in Children*

Response	FS Antipsychotic Safety Edits in Place to Monitor for Ap States	ppropriate Osc Total	Total Percent
Child's Age	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	48	94%
Dosage	Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming	39	76%
Indication	Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Mississippi, Missouri, Montana, Nevada, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington	32	63%
Polypharmacy	Alaska, Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, West Virginia, Wyoming	39	76%
Other	Illinois, Kansas, Kentucky, Louisiana, Maine, Massachusetts, New Mexico, North Carolina, Ohio, Oregon, Tennessee, Vermont, Washington	13	25%

Table 40 – MCE Antipsychotic Safety Edits in Place to Monitor for Appropriate Use in Children *

	CE Antipsychotic Safety Edits in Place to Monitor for A		
Response	States (Count of MCEs)	Total	Total Percent
Child's Age	Arizona (7), Arkansas (3), California (6), Colorado (1), Delaware (2), District of Columbia (2), Florida (15), Georgia (4), Hawaii (4), Illinois (5), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Massachusetts (5), Michigan (5), Minnesota (6), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (17), Ohio (5), Oregon (6), Pennsylvania (7), Rhode Island (1), South Carolina (5), Texas (16), Virginia (6), Washington (5)	172	92%
Dosage	Arizona (7), Arkansas (3), California (5), Delaware (2), District of Columbia (2), Florida (13), Georgia (4), Hawaii (6), Illinois (5), Indiana (4), Kansas (3), Kentucky (5), Louisiana (5), Massachusetts (5), Michigan (3), Minnesota (2), Mississippi (2), Nebraska (3), Nevada (3), New Hampshire (2), New Jersey (5), New Mexico (3), New York (12), Ohio (5), Oregon (6), Pennsylvania (7), Rhode Island (2), South Carolina (5), Texas (16), Virginia (6), Washington (5)	156	83%
Indication	Arizona (6), Arkansas (2), California (6), Delaware (2), District of Columbia (1), Florida (5), Georgia (2), Hawaii (4), Illinois (3), Indiana (2), Kansas (3), Kentucky (2), Louisiana (5), Massachusetts (2), Minnesota (2), Mississippi (3), Nebraska (3), Nevada (1), New Hampshire (1), New Jersey (3), New Mexico (1), New York (8), Ohio (2), Pennsylvania (5), Rhode Island (1), South Carolina (3), Texas (13), Virginia (4), Washington (3)	98	52%
Polypharmacy	Arizona (5), Arkansas (2), California (6), Delaware (2), District of Columbia (2), Florida (9), Georgia (4), Hawaii (6), Illinois (3), Indiana (4), Iowa (2), Kansas (2), Kentucky (3), Louisiana (4), Maryland (1), Massachusetts (5), Michigan (3), Minnesota (4), Mississippi (1), Nebraska (3), Nevada (2), New Hampshire (3), New Jersey (3), New Mexico (2), New York (15), Ohio (5), Oregon (6), Pennsylvania (6), Rhode Island (1), South Carolina (5), Texas (14), Virginia (4), Washington (5)	142	76%
Other	Arizona (1), Arkansas (1), California (2), Colorado (1), District of Columbia (1), Florida (6), Georgia (1), Hawaii (1), Illinois (2), Indiana (1), Kansas (3), Kentucky (1), Louisiana (1), Maryland (1), Michigan	38	20%

^{*}A program may select multiple answers to this question.

Response	States (Count of MCEs)	Total	Total Percent
	(1), Minnesota (1), New Jersey (1), New York (1),		
	Oregon (3), Pennsylvania (1), Rhode Island (1), Texas		
	(2), Virginia (2), Washington (2)		

^{*}A program may select multiple answers to this question.

3.3. Future Implementation of Antipsychotic Monitoring Programs in Children

The amendments made by section 1004 of the SUPPORT Act require implementation of a program to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan) for children, including individuals not more than the age of 18 years old generally, and children in foster care specifically, in the both FFS and MCE programs. For the state programs that specified they did not manage or monitor antipsychotic use in all children, they were asked if they plan on implementing such a program in the future. FFY 2020 survey responses indicate in Table 41 that 72% of MCE programs do not plan to implement a program to monitor or manage antipsychotic medication use in children. These programs indicated either they do not have beneficiaries under the age of 18 in their Medicaid population or this category of medication was carved-out and handled by the FFS program. The remaining 27% of MCEs were all planning to implement such a program in the future. Included in this 27% were programs where the FFS already monitors antipsychotic medications, but the MCE programs are implementing additional supplemental monitoring programs focusing on behavioral health (California (6), Michigan (2), Oregon (1), Utah (2)).

Table 41 – MCE Future Monitoring Program for Appropriate Use of Antipsychotic Drugs in Children

Response	States (Count of MCEs)	Total	Percent of Total
Yes	California (6), Colorado (1), District of Columbia (1), Illinois (1), Michigan (2), Minnesota (1), Oregon (1), Utah (2)	15	28%
No	California (11), Florida (1), Illinois (1), Maryland (8), Michigan (3), North Dakota (1), Oregon (10), Pennsylvania (1), Texas (1), Utah (2)	39	72%
National Totals		54	100%

4. Fraud, Waste and Abuse (FWA) Detection

Consistent with section 1927(g) of the Act, the amendments made by section 1004 of the SUPPORT Act has the goal of improving the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, gross overuse, or inappropriate or medically unnecessary care. In this context, strategies to assure the appropriate use of opioids are now being implemented in clinical settings, health care systems and public health agencies. Efforts to prevent harms associated with overuse and misuse of opioids must be integrated to ensure patients are receiving appropriate pain care.

Pursuant to the amendments made by section 1004 of the SUPPORT Act, States must have in place a process (as designed and implemented by the state) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the state plan (or under a waiver of the state plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled. In implementing this requirement, States could operate this process in a coordinated fashion with other state program integrity (PI) efforts and have flexibility to define specific parameters for DUR reviews for fraud and abuse of controlled drugs as well as protocols for recommendation, referral, or escalation of reviews to the relevant PI or Surveillance Utilization Review (SUR) unit, law enforcement, or state professional board, based on patterns discovered through the proposed DUR process. Existing state initiatives can also work synergistically to help reduce fraud, misuse and abuse related to opioids. For example, patient review and restriction (PRR) programs (lock-in programs)⁵¹ and Prescription Drug Monitoring Programs (PMDP)⁵² also play an important role in detecting and preventing opioid-related fraud, misuse and abuse.

Lock-in programs, also called PRR or drug management programs, are meant to cut down on "doctor shopping"—the practice of going to several doctors or pharmacies to fill multiple prescriptions for opioids or other controlled substances for illicit sale or misuse or to support an addiction. Such programs are used primarily to restrict overutilization of medications. Additionally, programs may require beneficiaries to receive all prescriptions through one pharmacy, have all prescriptions written by one prescriber, receive health care services from one clinical professional, or all three depending on how the program is designed. ⁵³

PDMPs are database tools utilized by state, federal and law enforcement entities for reducing prescription drug fraud, abuse and diversion. PDMPs collect electronically transmitted prescribing and some dispensing data submitted by pharmacies and dispensing practitioners. Data is monitored and analyzed to support States' efforts in education, research, enforcement and abuse

⁵¹ "Pharmacy Lock-In Programs Slated For Expanded Use." OPEN MINDS, <u>www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/</u>.

⁵² Office of National Drug Control Policy. Prescription Drug Monitoring Program. Prescription Drug Monitoring Program, April 2011. https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf.

⁵³ "Pharmacy Lock-In Programs Slated For Expanded Use." OPEN MINDS, <u>www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/</u>.

prevention.⁵⁴ Additionally, PDMPs are used to monitor controlled substance use by healthcare providers including prescribers and pharmacists in the prevention of fraud, waste and abuse. The following sections provide the survey results for state Medicaid programs' related to potential FWA of controlled substances.

4.1. FWA of Beneficiaries

Based on FFY 2020 survey responses, Table 42 and 43 show all FFS (100%) and most MCE programs (99%) have a documented process in place that identifies potential fraud or abuse of controlled drugs by a beneficiary.

Table 42 – FFS Process in Place to Identify Potential Fraud or Abuse of Controlled Drugs by Beneficiaries

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	51	100%
National Totals		51	100%

Table 43 – MCE Process in Place to Identify Potential Fraud or Abuse of Controlled Drugs by Beneficiaries

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (8), Arkansas (3), California (24), Colorado (2), Delaware (2), District of Columbia (4), Florida (16), Georgia (4), Hawaii (6), Illinois (6), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	239	99%

⁵⁴ "Prescription Drug Monitoring Frequently Asked Questions (FAQ): The PDMP Training and Technical Assistance Center." *Prescription Drug Monitoring Frequently Asked Questions (FAQ)* | *The PDMP Training and Technical Assistance Center*, www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

Response	States (Count of MCEs)	Total	Percent of Total
No*	California (2), Illinois (1)	3	1%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

4.2. Patient Review and Restriction (PRR) Programs

A PRR program plays an important role in preventing opioid-related FWA. This program, upon state review, may elect to restrict patients whose utilization of medical services is documented as being potentially unsafe, excessive, or could benefit from increased coordination of care. In some instances, PRR programs may be used to restrict a patient to a single prescriber and/or a single pharmacy to monitor services being utilized and reduce unnecessary or inappropriate utilization. FFY 2020 survey responses show in Tables 44 and 45 that most programs (FFS: 92%, MCE: 90%) have a PRR program for beneficiaries with potential misuse or abuse of controlled substances.

Table 44 – FFS Patient Review and Restriction Program

Table 44 – FFS Latient Review and Restriction Linguis			
Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	47	92%
No	California, Florida, Iowa, South Dakota	4	8%
National Totals		51	100%

Table 45 – MCE Patient Review and Restriction Program

Table 43 – Weel Lattent Review and Restriction Flogram				
Response	States (Count of MCEs)	Total	Percent of Total	
Yes	Arizona (8), Arkansas (3), California (13), Colorado (2), Delaware (2), District of Columbia (4), Florida (15), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (1), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (12), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	219	90%	

Response	States (Count of MCEs)	Total	Percent of Total
No	California (13), Florida (1), Iowa (1), Oregon (8)	23	10%
National Totals		242	100%

Potential FWA of controlled substances by patients may be detected through either manual or algorithmic review of claims data. There are many patient indicators and use patterns that may be concerning or could possibly be indicative of misuse or abuse. These include, but are not limited to, seeing multiple prescribers for opioids, using multiple pharmacies, frequently using small amounts of short-acting opioids, frequently visiting ED's seeking opioids, and/or using multiple types of opioids in a short time period. Beneficiary criteria for PRR programs in FFY 2020 survey responses, shown in Tables 46 and 47, are identified through multiple resources. Top criteria include beneficiaries using multiple prescribers of controlled substances (FFS: 98%, MCE: 89%) and multiple pharmacies to obtain controlled substances (FFS: 96%, MCE: 88%).

Table 46 – FFS Patient Review and Restriction Program Beneficiary Identification Criteria*

Response	States	Total	Total Percent
Different Prescribers Of Controlled Substances	Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	46	98%
Exclusivity Of Short- Acting Opioids	Delaware, Georgia, Maryland, New York, North Dakota	5	11%
Multiple ER Visits	Alabama, Alaska, Arizona, Colorado, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New York, North Dakota, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia	31	66%
Multiple Pharmacies	Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New	45	96%

Response	States	Total	Total Percent
	Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming		
Number Days' Supply Of Controlled Substances	Alabama, Arkansas, Connecticut, Delaware, Georgia, Kansas, Louisiana, Maryland, Michigan, Missouri, New York, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin	21	45%
Number Of Controlled Substances	Alabama, Alaska, Arizona, Arkansas, Colorado, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	41	87%
PDMP Data	Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Michigan, Mississippi, Montana, Nevada, North Dakota, Oklahoma, Tennessee, Utah, Virginia, West Virginia	16	34%
Other	Arizona, Arkansas, Connecticut, District of Columbia, Idaho, Illinois, Indiana, Maine, Mississippi, Montana, Nebraska, Nevada, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin	22	47%

^{*}A program may select multiple answers to this question.

Table 47 - MCE Patient Review and Restriction Program Beneficiary Identification Criteria*

Response	States (Count of MCEs)	Total	Total Percent
Different Prescribers Of Controlled Substances	Arizona (8), Arkansas (3), California (12), Colorado (2), Delaware (2), District of Columbia (4), Florida (15), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (1), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (12),	216	89%

Response	States (Count of MCEs)	Total	Total Percent
	Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (16), Utah (4), Virginia (6), Washington (4)		
Exclusivity Of Short- Acting Opioids	California (1), Colorado (1), Delaware (1), Georgia (1), Indiana (1), Kansas (1), Maryland (1), Massachusetts (1), Michigan (1), Minnesota (2), Nebraska (1), New Jersey (1), New York (3), Ohio (1), Pennsylvania (3), Texas (1), Utah (1), Virginia (1), Washington (1)	24	10%
Multiple ER Visits	Arizona (2), California (4), Colorado (2), Delaware (1), District of Columbia (1), Florida (2), Georgia (3), Hawaii (4), Illinois (4), Indiana (4), Kansas (2), Kentucky (5), Louisiana (1), Maryland (1), Massachusetts (3), Michigan (9), Minnesota (8), Mississippi (1), Nebraska (2), Nevada (1), New Hampshire (2), New Jersey (3), New Mexico (3), New York (15), North Dakota (1), Ohio (2), Pennsylvania (7), Rhode Island (1), South Carolina (3), Texas (13), Utah (4), Virginia (3), Washington (3)	120	50%
Multiple Pharmacies	Arizona (8), Arkansas (3), California (11), Colorado (2), Delaware (2), District of Columbia (4), Florida (15), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (1), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (17), North Dakota (1), Ohio (5), Oregon (12), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (16), Utah (4), Virginia (6), Washington (4)	214	88%
Number Days' Supply Of Controlled Substances	Arizona (2), Arkansas (1), California (3), Delaware (1), District of Columbia (1), Florida (1), Georgia (2), Hawaii (2), Illinois (3), Indiana (1), Kansas (2), Louisiana (4), Maryland (2), Massachusetts (2), Michigan (1), Minnesota (2), Nevada (1), New Hampshire (2), New Jersey (1), New Mexico (1), New York (6), North Dakota (1), Ohio (2), Oregon (6), Pennsylvania (4), South Carolina (3), Texas (13), Utah (1), Virginia (3), Washington (2)	76	31%
Number Of Controlled Substances	Arizona (8), Arkansas (3), California (10), Colorado (2), Delaware (2), District of Columbia (4), Florida (15), Georgia (4), Hawaii (6), Illinois (7), Indiana (4), Iowa (1), Kansas (3), Kentucky	208	86%

Response	States (Count of MCEs)	Total	Total Percent
	(5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi		
	(3), Nebraska (3), Nevada (3), New Hampshire		
	(3), New Jersey (5), New Mexico (3), New York		
	(17), North Dakota (1), Ohio (5), Oregon (9),		
	Pennsylvania (7), Rhode Island (3), South		
	Carolina (5), Texas (16), Utah (4), Virginia (5),		
	Washington (4)		
	Arizona (5), California (4), Hawaii (1), Illinois		
	(5), Indiana (1), Kansas (1), Kentucky (1),		
PDMP Data	Maryland (1), Michigan (3), Minnesota (7),	47	19%
	Mississippi (1), New Mexico (3), New York (1),		
	Texas (2), Utah (3), Virginia (5), Washington (3)		
	Arizona (5), District of Columbia (2), Florida		
	(8), Georgia (1), Hawaii (1), Illinois (1), Indiana		
Same FFS State	(2), Kansas (2), Louisiana (3), Maryland (5),		
Criteria Is Applied	Massachusetts (2), Michigan (4), Minnesota (4),	67	28%
orium is rippium	New Hampshire (1), New York (6), Ohio (1),		
	Pennsylvania (3), South Carolina (1), Texas (4),		
	Utah (4), Virginia (5), Washington (2)		
	Arizona (1), Arkansas (1), California (4),		
	Delaware (2), Florida (3), Georgia (1), Hawaii (3), Illinois (3), Indiana (1), Kansas (2),		
	(5), filmois (5), fildiana (1), Kansas (2), Kentucky (1), Louisiana (2), Maryland (1),		
Other	Massachusetts (3), Michigan (3), Mississippi (2),	83	34%
Other	Nebraska (1), Nevada (1), New Jersey (2), New	63	34/0
	York (5), North Dakota (1), Ohio (4), Oregon		
	(11), Pennsylvania (6), Rhode Island (3), South		
	Carolina (3), Texas (11), Washington (2)		

^{*}A program may select multiple answers to this question.

State Medicaid programs have a variety of mechanisms for recourse once a patient has been detected for potential FWA. Interventions may include denying claims, PRR programs, and/or requiring prior authorization for all controlled substance claims. FFY 2020 survey responses depicted in Tables 48 and 49 show potential recourses to initiate multiple actions such as PRR programs (FFS: 88%, MCE: 86%), alerting the PIU (FFS: 75%, MCE: 64%), denying claims (FFS: 59%, MCE: 43%), and/or requiring prior authorization (FFS: 51%, MCE: 45%).

Table 48 – FFS Actions when Potential Fraud or Abuse of Controlled Drugs by Beneficiaries is Detected*

Response	States	Total	Total Percent
Deny Claims	Alaska, Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Maine, Massachusetts, Michigan, Missouri,	30	59%

Response	States	Total	Total Percent
	Montana, Nebraska, New Jersey, New York, North Carolina, North Dakota, Oregon, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia		
Refer To PRR Program	Alabama, Alaska, Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	45	88%
Refer To Office Of Inspector General (OIG)	Arizona, Arkansas, Indiana, Kentucky, Maryland, Michigan, Minnesota, New York, North Carolina, North Dakota, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Wisconsin	16	31%
Refer To PIU And/Or SUR Unit For Audit/Investigation	Alabama, Arizona, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississisppi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, West Virginia, Wyoming	38	75%
Require Prior Authorization	Alaska, Arizona, Arkansas, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, New York, North Dakota, Oregon, South Carolina, Tennessee, Utah, Vermont, Virginia, West Virginia	26	51%
Other	Alabama, Alaska, California, Connecticut, Florida, Indiana, Mississippi, Montana, New Hampshire, New Jersey, North Carolina, Texas, Vermont, Virginia	14	27%

^{*}A program may select multiple answers to this question.

Table 49 – MCE Actions when Potential Fraud or Abuse of Controlled Drugs by Beneficiaries is Detected*

Response	States (Count of MCEs)	Total	Total Percent
Deny Claims	Arizona (5), Arkansas (2), California (12), Colorado (2), District of Columbia (1), Florida (7), Georgia (1), Hawaii (2), Illinois (5), Indiana (3), Kansas (1), Kentucky (3), Maryland (5), Massachusetts (2), Michigan (5), Minnesota (4), Mississippi (1), New Hampshire (1), New Jersey (2), New Mexico (3), New York (3), North Dakota (1), Ohio (2), Oregon (3), Pennsylvania (3), South Carolina (2), Texas (15), Utah (4), Virginia (4), Washington (1)	105	43%
Refer To PRR Program	Arizona (8), Arkansas (3), California (13), Colorado (1), Delaware (2), District of Columbia (4), Florida (14), Georgia (4), Hawaii (6), Illinois (6), Indiana (4), Iowa (1), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (2), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (17), North Dakota (1), Ohio (5), Oregon (7), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (16), Utah (4), Virginia (6), Washington (5)	208	86%
Refer To Office Of Inspector General (OIG)	Arizona (1), Arkansas (2), California (5), Florida (6), Georgia (1), Hawaii (2), Illinois (4), Indiana (2), Kansas (2), Kentucky (2), Louisiana (1), Maryland (6), Michigan (6), Minnesota (1), Mississippi (1), Nebraska (1), Nevada (1), New Jersey (2), New York (6), North Dakota (1), Ohio (2), Oregon (1), Pennsylvania (3), Rhode Island (1), Texas (6), Utah (2), Virginia (3), Washington (1)	72	30%
Refer To PIU And/Or SUR Unit For Audit/Investigation	Arizona (3), Arkansas (3), California (15), Delaware (2), District of Columbia (2), Florida (13), Georgia (3), Hawaii (6), Illinois (4), Indiana (3), Iowa (1), Kansas (3), Kentucky (4), Louisiana (3), Maryland (6), Massachusetts (3), Michigan (11), Minnesota (4), Mississippi (1), Nebraska (2), Nevada (1), New Hampshire (3), New Jersey (5), New Mexico (2), New York (12), North Dakota (1), Ohio (3), Oregon (9), Pennsylvania (6), Rhode Island (2), South Carolina (3), Texas (6), Utah (3), Virginia (5), Washington (2)	155	64%

Response	States (Count of MCEs)	Total	Total Percent
Require Prior Authorization	Arizona (4), Arkansas (1), California (12), Colorado (2), District of Columbia (2), Florida (7), Georgia (1), Hawaii (1), Illinois (5), Indiana (2), Kansas (2), Kentucky (3), Maryland (6), Massachusetts (1), Michigan (6), Minnesota (3), Mississippi (2), Nebraska (1), New Hampshire (1), New Jersey (2), New Mexico (3), New York (3), North Dakota (1), Ohio (2), Oregon (5), Pennsylvania (2), South Carolina (2), Texas (15), Utah (4), Virginia (5), Washington (2)	108	45%
Other	Arkansas (2), California (9), Colorado (1), Delaware (2), District of Columbia (2), Florida (10), Georgia (1), Hawaii (5), Illinois (2), Indiana (1), Iowa (1), Kansas (3), Kentucky (2), Louisiana (3), Maryland (5), Massachusetts (2), Michigan (3), Minnesota (2), Mississippi (1), Nebraska (2), Nevada (1), New Hampshire (1), New Jersey (3), New Mexico (1), New York (4), North Dakota (1), Ohio (2), Oregon (8), Pennsylvania (3), Rhode Island (2), South Carolina (2), Texas (8), Virginia (3), Washington (1)	99	41%

^{*}A program may select multiple answers to this question.

4.3. FWA of Prescribers

Potential FWA of controlled substances by prescribers may be detected through either manual or algorithmic review of claims data. FFY 2020 survey responses show in Tables 50 and 51 that most programs (FFS: 94%, MCE: 98%) have a documented process in place that identifies possible FWA of controlled drugs by prescribers. Those programs without a documented program to detect FWA of controlled substances review claims data through their prior authorization process and other state review initiatives to identify outlying prescribers. Once identified, these programs will provide case management and/or forward these outlying prescribers to their state PIU, SUR Unit, medical board and/or to the DEA for action.

Table 50 – FFS Documented Process to Identify Possible FWA of Controlled Drugs by Prescribers

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island,	48	94%

Response	States	Total	Percent of Total
	South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming		
No*	Idaho, Montana, Nevada	3	6%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

Table 51 – MCE Documented Process to Identify Possible FWA of Controlled Drugs by Prescribers

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (7), Arkansas (3), California (25), Colorado (2), Delaware (1), District of Columbia (4), Florida (16), Georgia (4), Hawaii (6), Illinois (6), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (7), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	237	98%
No*	Arizona (1), California (1), Delaware (1), Illinois (1), Minnesota (1)	5	2%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

State Medicaid programs have a variety of mechanisms for recourse once a prescriber has been detected for potential FWA. FFY 2020 survey responses show potential recourse may initiate multiple actions as seen in Tables 52 and 53. The top action for both the FFS and MCE programs are to alert their PI unit and/or SUR Unit for audit/investigation (FFS: 88%, MCE: 79%). Another action initiated by these programs is to alert the appropriate Medical Board (FFS: 56%, MCE: 45%).

Table 52 – FFS Actions Process Initiates when Possible FWA of Controlled Drugs by Prescribers is Detected*

Response	States	Total	Total Percent
Deny Claims Written By This Prescriber	California, Florida, Georgia, Indiana, Maine, Massachusetts, Michigan, New Hampshire, New York, North Dakota, Oregon, Vermont, West Virginia	13	27%
Refer To PIU And/Or SUR Unit For Audit/Investigation	Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa,	42	88%

Response	States	Total	Total Percent
	Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming		
Refer To The Appropriate Medical Board	Alabama, Arizona, Connecticut, Delaware, District of Columbia, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Tennessee, Vermont, West Virginia, Wyoming	27	56%
Other	Alaska, Arkansas, California, Connecticut, Georgia, Illinois, Kansas, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, Wisconsin	25	52%

^{*}A program may select multiple answers to this question.

Table 53 – MCE Actions Process Initiates when Possible FWA of Controlled Drugs by Prescribers is Detected*

Response	States (Count of MCEs)	Total	Total Percent
Deny Claims Written By This Prescriber	Arizona (5), Arkansas (1), California (7), Colorado (1), District of Columbia (2), Florida (3), Georgia (4), Hawaii (4), Illinois (2), Indiana (4), Kansas (1), Kentucky (2), Louisiana (1), Maryland (5), Massachusetts (1), Michigan (9), Minnesota (4), Nebraska (1), New Hampshire (1), New Jersey (3), New Mexico (2), New York (4), North Dakota (1), Ohio (3), Oregon (5), Pennsylvania (2), South Carolina (2), Texas (3), Utah (3), Virginia (3), Washington (2)	91	38%
Refer To PIU And/Or SUR Unit For Audit/ Investigation	Arizona (6), Arkansas (3), California (20), Delaware (1), District of Columbia (4), Florida (11), Georgia (4), Hawaii (6), Illinois (6), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (8), Massachusetts (2), Michigan (10), Minnesota (7), Mississippi (2), Nebraska (3), Nevada (3), New Hampshire (2), New Jersey (5), New Mexico (3), New York (15), North	187	79%

Response	States (Count of MCEs)	Total	Total Percent
	Dakota (1), Ohio (4), Oregon (10), Pennsylvania (6), Rhode Island (3), South Carolina (4), Texas (6), Utah (3), Virginia (6), Washington (4)		
Refer To The Appropriate Medical Board	Arizona (3), Arkansas (2), California (9), Colorado (1), Delaware (1), District of Columbia (1), Florida (3), Georgia (1), Hawaii (3), Illinois (1), Indiana (4), Iowa (1), Kansas (2), Kentucky (3), Louisiana (4), Maryland (6), Massachusetts (2), Michigan (5), Minnesota (5), Mississippi (1), Nebraska (2), Nevada (2), New Jersey (4), New Mexico (1), New York (10), North Dakota (1), Ohio (3), Oregon (1), Pennsylvania (4), Rhode Island (2), South Carolina (3), Texas (4), Utah (2), Virginia (6), Washington (3)	106	45%
Other	Arizona (1), Arkansas (3), California (15), Colorado (1), Delaware (1), District of Columbia (3), Florida (14), Georgia (3), Hawaii (4), Illinois (3), Indiana (3), Iowa (1), Kansas (2), Kentucky (3), Louisiana (2), Maryland (7), Massachusetts (4), Michigan (5), Minnesota (2), Mississippi (2), Nebraska (1), Nevada (1), New Hampshire (2), New Jersey (3), New Mexico (2), New York (11), Ohio (2), Oregon (10), Pennsylvania (3), Rhode Island (2), South Carolina (5), Texas (14), Utah (2), Virginia (3), Washington (3)	143	60%

^{*}A program may select multiple answers to this question.

4.4. FWA of Pharmacy Providers

Potential FWA of controlled substances by pharmacies may be detected through either manual or algorithmic review of claims data. FFY 2020 survey responses show that most programs (FFS: 92%, MCE: 98%) have a documented process in place that identifies possible FWA of controlled drugs by pharmacies as shown in Tables 54 and 55. Those programs without a documented program to detect FWA of controlled substances review claims data and heavily rely on safety edits and prior authorization processes to help detect pharmacies committing potentially fraudulent activities. These States also limit pharmacist overrides which prevent these providers from most forms of fraud or abuse of controlled drugs.

Table 54 – FFS Documented Process to Identify Possible Fraud or Abuse of Controlled Drugs by Pharmacy Providers

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts,	47	92%

Response	States	Total	Percent of Total
	Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming		
No*	Idaho, Kansas, Montana, Nevada	4	8%
National Totals		51	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

Table 55 – MCE Documented Process to Identify Possible Fraud or Abuse of Controlled Drugs by Pharmacy Providers

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (7), Arkansas (3), California (25), Colorado (2), Delaware (2), District of Columbia (4), Florida (16), Georgia (4), Hawaii (5), Illinois (6), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (11), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (18), North Dakota (1), Ohio (5), Oregon (20), Pennsylvania (7), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	237	98%
No*	Arizona (1), California (1), Hawaii (1), Illinois (1), Pennsylvania (1)	5	2%
National Totals		242	100%

^{*} CMS will follow up with these programs regarding compliance as DUR survey responses were not provided, require clarification or need additional information.

State Medicaid programs have a variety of mechanisms for recourse once a pharmacy has been detected for potential fraud, waste or abuse of controlled substances. FFY 2020 survey responses show potential recourse may initiate multiple actions as seen in Tables 56 and 57. The top action for both the FFS and MCE programs are to alert their PI unit and/or SUR Unit for audit/investigation (FFS: 87%, MCE: 75%). Another action initiated by these programs is to alert the State Board of Pharmacy (FFS: 53%, MCE: 41%).

Table 56 – FFS Actions Process Initiates when Possible FWA of Controlled Drugs by Pharmacy Providers is Detected*

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Response	States	Total	Total Percent
Deny Claim	California, Florida, Georgia, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Dakota, Oregon, Vermont, West Virginia	16	34%

Response	States	Total	Total Percent
Refer To Board Of Pharmacy	Alabama, Arizona, Connecticut, Delaware, District of Columbia, Georgia, Illinois, Indiana, Iowa, Kentucky, Maine, Massachusetts, Michigan, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Tennessee, Vermont, West Virginia, Wyoming	of Columbia, Georgia, Illinois, Indiana, entucky, Maine, Massachusetts, n, New Hampshire, New Mexico, New 25 orth Carolina, North Dakota, Ohio, na, Pennsylvania, Tennessee, Vermont,	
Refer To PIU And/Or SUR Unit For Audit/Investigation	Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming	41	87%
Alaska, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, North Carolina, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Washington, Wisconsin		22	47%

^{*}A program may select multiple answers to this question.

Table 57 – MCE Actions Process Initiates when Possible FWA of Controlled Drugs by Pharmacy Providers is Detected*

Response	States (Count of MCEs)	Total	Total Percent
Deny Claims	Arizona (4), Arkansas (2), California (12), Colorado (1), District of Columbia (4), Florida (7), Georgia (3), Hawaii (3), Illinois (4), Indiana (4), Iowa (1), Kentucky (3), Louisiana (1), Maryland (3), Massachusetts (3), Michigan (7), Minnesota (5), Nebraska (1), Nevada (1), New Hampshire (2), New Jersey (3), New Mexico (3), New York (7), North Dakota (1), Ohio (2), Oregon (8), Pennsylvania (1), Rhode Island (1), South Carolina (3), Texas (12), Utah (1), Virginia (3), Washington (3)	119	50%
Refer To PIU And/Or SUR Unit For Audit/ Investigation	Arizona (5), Arkansas (2), California (20), Delaware (2), District of Columbia (4), Florida (9), Georgia (4), Hawaii (4), Illinois (6), Indiana (4), Iowa (2), Kansas (3), Kentucky (3), Louisiana (5), Maryland (6), Massachusetts (2), Michigan (9), Minnesota (6), Mississippi (2), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (4), New Mexico (3), New York (13), North Dakota (1), Ohio (3), Oregon (17),	177	75%

Response	States (Count of MCEs)	Total	Total Percent
	Pennsylvania (6), Rhode Island (3), South Carolina (4), Texas (5), Utah (3), Virginia (5), Washington (3)		
Refer To The Board Of Pharmacy	Arizona (2), California (11), Colorado (1), Delaware (1), District of Columbia (1), Florida (4), Georgia (2), Hawaii (3), Illinois (1), Indiana (2), Kansas (1), Kentucky (1), Louisiana (1), Maryland (3), Massachusetts (2), Michigan (3), Minnesota (5), Mississippi (1), Nebraska (3), Nevada (1), New Hampshire (1), New Jersey (3), New Mexico (3), New York (5), North Dakota (1), Ohio (3), Oregon (11), Pennsylvania (5), Rhode Island (2), South Carolina (3), Texas (3), Utah (1), Virginia (4), Washington (2)	96	41%
Other	Arizona (3), Arkansas (2), California (11), Colorado (1), Delaware (2), District of Columbia (2), Florida (12), Georgia (2), Hawaii (5), Illinois (3), Indiana (2), Kansas (2), Kentucky (4), Louisiana (4), Maryland (7), Massachusetts (4), Michigan (8), Minnesota (6), Mississippi (2), Nebraska (1), Nevada (1), New Hampshire (2), New Jersey (4), New Mexico (2), New York (15), North Dakota (1), Ohio (4), Oregon (4), Pennsylvania (5), Rhode Island (3), South Carolina (3), Texas (14), Utah (2), Virginia (4), Washington (3)	150	63%

^{*}A program may select multiple answers to this question.

5. Managed Care Organizations (MCE) Compliance

Consistent with section 1902(oo)(1)(A)(ii) of the Act, as added by section 1004 of the SUPPORT Act, States must ensure that their contracts with their MCEs under section 1903(m) of the Act, require that the contracted entity has in place opioid safety edits, automated claims review processes, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements. State implementation of these DUR provisions in contracts was required by October 1, 2019.

This section provides the survey results for state Medicaid programs related to MCE compliance with the relevant provisions added by section 1004 of the SUPPORT Act.

FFY 2020 survey responses show in Table 58 that 97% of state Medicaid programs have updated their MCE contracts to comply with section 1004 of the SUPPORT Act.

Table 58 – MCE Contract Compliance for Section 1004 of the SUPPORT*

Response	States	Total	Percent of Total
Yes, Contracts	Arizona, Arkansas, California, Colorado, Delaware,		
Are Updated To	District of Columbia, Florida, Georgia, Hawaii,	35	97%
Address Each	Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana,	33	9/70
Provision	Maryland, Massachusetts, Michigan, Minnesota,		

Response	States	Total	Percent of Total
	Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Utah, Virginia, Washington		
No, Contracts Are Not Updated To Address Each Provision**	New York	1	3%
National Totals		36***	100%

^{*} Missouri, Tennessee, Wisconsin, and West Virginia have their covered outpatient drugs carved-out and managed by their FFS program; therefore, an MCE contract amendment is not required.

All FFS programs (100%) reported they are monitoring MCE compliance with provisions added by section 1004 of the SUPPORT Act, as shown in Table 59.

Table 59 – State Reported Compliance with Federal Law In Monitoring MCE Compliance with Section 1004 of the SUPPORT Act

Response	States	Total	Percent of Total
Yes, State Is Complying With Federal Law And Monitoring MCE Compliance With Section 1004 Of The SUPPORT Act Provisions	Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin	40	100%
National Totals		40*	100%

*Note: Not all States have MCE programs

^{**} State responded they were unable to update their MCE contracts during the SPA review process due to work on amendments required to address the COVID crisis. In the fall of 2019, all Medicaid MCE's were surveyed by the Department to confirm compliance with the SUPPORT ACT. The State will add requirements of section 1004 as described in section 1927(g) of the Act and 42 C.F.R. part 456, subpart K to the next contract update. This is currently in progress.

^{***} Not all States have MCE programs.

6. Discussion and Recommendations

The SUPPORT Act includes measures to address the opioid crisis in part by reducing opioid fraud, abuse and misuse by advancing treatment and recovery initiatives, improving treatment, protecting communities, and bolstering prevention efforts to fight illicit drugs. Section 1004 of the SUPPORT Act addresses FFS and MCE policy goals of protecting patients from and educating providers about opioid overutilization, addressing the clinical appropriateness of use of antipsychotic medications in children and bolstering State Program Integrity Programs. State implementation of these standards was required by October 1, 2019, and States included information about their implementation in their FFY 2020 annual DUR reports.

The survey question responses for the following topics have been included in this report:

- Prospective claim safety edits, including on initial prescription fill days' supply for patients not currently receiving opioid therapy; quantity limits for initial and subsequent fills, therapeutically duplicative fills, and early fills on opioids prescriptions at point of dispensing to determine appropriate opioid use;
- Safety edit limits (as specified by the state) on the maximum daily morphine equivalent that can be prescribed to an individual;
- Retrospective reviews and, at the option of the state, prospective safety edits monitoring the use of opioids concurrently with benzodiazepines and/or antipsychotics;
- Claims review automated process that indicates prescription fills of opioids in excess of these limitations to provide for the ongoing periodic reviews of opioids claim data;
- Monitoring the use of antipsychotic medication use in children; and,
- Identification of FWA of controlled substances.

Variation in the methods used by States to meet the required standards were noted and further details can be found in state specific reports on <u>Medicaid.gov</u>.

Broadly, the implementation of standards related to these provisions were similar in States' FFS and MCE programs. As seen below in Table 60, the majority of programs have already implemented standards required by amendments made by section 1004 of the SUPPORT Act or have a plan in place to implement those standards in the near future. State survey question responses included in the FFY 2019 and the FFY 2020 annual DUR reports for both FFS and MCE programs have been combined to allow for comparison of progress by States.

Table 60 – National Improvements in Implementing Selected DUR Safety Reviews

Provision	FFS FFY 2020 Responses	FFS +/- % FFY 2019	MCE FFY 2020 Responses	MCE +/- % FFY 2019
Short-Acting Opioid Quantity Edits	98%	+2%	96%	+4%
Long-Acting Opioid Quantity Edits	98%	+2%	99%	+4%
Opioid Benzodiazepine Edits	98%	+12%	90%	+2%
Duplicate Opioid Therapy Edits	94%	+2%	95%	+2%
MME Limits	96%	+10%	99%	+5%
Program In Place To Manage/Monitor Antipsychotic Use In Children	100%	+4%	77%	+6%
Contract Updates Between State And Their MCEs Addressing Provisions In Section 1004 Of The SUPPORT Act	97%			

The following are recommendations to help States and MCE programs more effectively implement the prospective safety edits and retrospective claims reviews required under or contemplated by the amendments made by section 1004 of the SUPPORT Act.

States Should Employ System-Accumulation Safety Edits

FFY 2020 survey responses indicate only approximately 50% of state and MCE programs have accumulation safety edits to prevent patients from continuously filling prescriptions early. Patients who continually refill a prescription early may be able to stockpile or overutilize their mediation by repeatedly refilling prescriptions early. Stockpiling of medication may be an indication of misuse and may increase a patient's potential for overdose or medication diversion. System accumulation safety edits track the utilization of medication across multiple dispensing events to prevent stockpiling and overutilization

<u>States Should use Clinical Indications and Dosing Schedules to Establish Quantity Limits of Opioids</u>

FFY 2020 survey responses indicate high compliance with the requirement to establish quantity limits of opioids in both FFS and MCE programs. However, there are still some programs that need to implement these safety edits based on clinical indications and dosing schedules. Dose optimization involves States taking maximum dosing and schedules to establish quantity limits to restrict the quantity of opioids that are allowed per day. By prospectively identifying patients who have been prescribed multiple dosage formulations per

day of lower strength medication meant to be taken together to achieve a higher dose when a higher strength of medication already is available, improves compliance and can yield significant drug cost savings while decreasing diversion.

<u>States Should Upgrade Existing Systems from Manual to Automated Retrospective Claim Reviews to Increase Compliance and Detect High Doses of Opioids in a Timely and Efficient Manner</u>

FFY 2020 survey responses show that approximately 39% of FFS and 15% of MCE programs need additional system enhancements to be considered compliant. Amendments made by section 1004 of the SUPPORT Act require automated retrospective claim reviews to detect high doses of opioids and program follow up on prescription trends or issues found on prescriptions that have already been dispensed. While many programs indicated they do perform retrospective claim reviews on a regular basis, continued progress is needed in automating the process.

States Should Further Develop Prospective and Automated Retrospective Claim Reviews Consistent with Medical Practice Patterns and Clinical Considerations to Limit Opioids to Only When Necessary

States are encouraged to continue to develop and fine tune prospective and retrospective drug reviews consistent with medical practice patterns to help meet the health care needs of their Medicaid patient population. Safety edits and claim review limitations are intended to protect Medicaid patients from serious consequences of opioids including overdose, dangerous interactions, increased side effects, and additive toxicity (i.e., additive side effects). State FFS and MCE programs should ensure their opioid reviews are consistent with current clinical guidelines.

While there has been continued improvement in many of these initiatives, there is room for additional enhancements to reach a point where all state and MCE programs have fully implemented DUR standards required by the amendments made by section 1004 of the SUPPORT Act and by section 1927(g) of the Act and implementing regulations. As a result of data-related nuances, some aspects of compliance are difficult to determine. CMS plans to implement an outreach program with potentially noncompliant state programs to address program deficits.

Appendix A – Acronyms

AK Alaska
AL Alabama
AR Arkansas
AZ Arizona
CA California
CD Compact D

CD Compact Disc

CDC Centers for Disease Control and Prevention

C.F.R. Code of Federal Regulations

CHIP Children's Health Insurance Program

CMS Centers for Medicare and Medicaid Services

CNS Central Nervous System

CO Colorado

CSA Controlled Substances Act

CT Connecticut

DC District of Columbia

DE Delaware

DEA Drug Enforcement Administration

DUR Drug Utilization ReviewED Emergency Department

FDA Food and Drug Administration

FFS Fee-for-Service

FFY Federal Fiscal Year

FL Florida

FWA Fraud, Waste and Abuse

GA Georgia

HHS Department of Health and Human Services

HI Hawaii
IA Iowa
ID Idaho
IL Illinois
IN Indiana
KS Kansas

KY Kentucky LA Louisiana

MA Massachusetts

MAT Medication-assisted Treatment

MCE Managed Care EntityMCP Managed Care Program

MD MarylandME MaineMI Michigan

MME Morphine Milligram Equivalent

MN Minnesota
MO Missouri
MS Mississippi
MT Montana

NC North Carolina
ND North Dakota

NE Nebraska

NH New Hampshire

NJ New JerseyNM New Mexico

NV Nevada NY New York

OEOCR Office of Equal Employment Opportunity & Civil Rights

OH Ohio

Office of Inspector General

OKOklahomaOROregon

OUD Opioid Use Disorder

PA Pennsylvania

PDMP Prescription Drug Monitoring Program

PI Program Integrity

PIU Program Integrity Unit

PMTF Pain Management Task Force

POS Point of Sale

PRR Patient Review and Restriction Program

RI Rhode Island
SC South Carolina
SD South Dakota

SUD Substance Use Disorder

SUR Surveillance Utilization Review Unit

TN Tennessee

TPL Third Party Liability

TX TexasUT UtahVA Virginia

VBP Value-Based Purchasing

VT Vermont
WA Washington
WI Wisconsin
WV West Virginia

WY Wyoming