U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

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 2021
Report to Congress

The Centers for Medicare & Medicaid Services (CMS) is committed to making its programs, benefits, services, facilities, information, and technology accessible in accordance with sections 504 and 508 of the Rehabilitation Act of 1973 and section 1557 of the Patient Protection and Affordable Care Act of 2010, and their respective implementing regulations. CMS provides various auxiliary aids and services, including written information in alternate formats (large print, audio, accessible electronic formats, other formats), and qualified interpreters for individuals with disabilities at no cost to communicate effectively with people with disabilities. In addition, CMS provides free language services to people whose primary language is not English, such as qualified interpreters for individuals with limited English proficiency and information written in other languages.

To request an auxiliary aid or service:

1. For Medicare publications, call 1-800-MEDICARE. TTY users should call 1-877-486-2048.
2. For all other CMS publications, you can:
    - Call 1-844-ALT-FORM (1-844-258-3676). TTY users should call 1-844- 716-3676.
    - Send a fax to 1-844-530-3676.
    - Send an email to AltFormatRequest@cms.hhs.gov.
    - Send a letter to:
      Centers for Medicare & Medicaid Services
      Office of Equal Employment Opportunity & Civil Rights (OEOCR)
      7500 Security Boulevard, Room N2-22-16
      Baltimore, MD 21244-1850
      Attn: CMS Alternate Format Team

Note: Your request for CMS publications should include:

- Your name, phone number, and the mailing address where we should send the publications.
- The publication title and CMS Publication No., if available.
- The format you need, like Braille, large print, compact disc (CD), audio CD, or a qualified reader.

CMS does not exclude, deny benefits to, or otherwise discriminate against any person on the basis of race, color, national origin, disability, sex, sexual orientation, gender identity, or age in admission to, participation in, or receipt of the services and benefits under any of its programs and activities, whether carried out by CMS directly or through a contractor or any other entity with which CMS arranges to carry out its programs and activities.

If you believe you have been subjected to discrimination in a CMS program or activity, there are three ways to file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights:

- Online at http://www.hhs.gov/civil-rights
- By phone: Call 1-800-368-1019. TDD users should call 1-800-537-7697.
- In writing: Send information about your complaint to:

Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, DC 20201

For additional information, email AltFormatRequest@cms.hhs.gov

Executive Summary

BACKGROUND

This Report to Congress (RTC) fulfills the requirement of section 1902(oo)(2) of the Social Security Act (hereinafter referred to as "the 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), for federal fiscal year (FFY) 2021. The SUPPORT Act includes measures to combat the opioid crisis in part by reducing opioid fraud, 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 Act to supplement existing requirements under section 1927(g) of the Act, in an effort to reduce opioid-related fraud and misuse. This report specifically addresses the required implementation and states' status of these provisions, including requirements regarding opioid prescription claims review 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 and section 1004 SUPPORT Act provisions 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 FFY 2020 reports.[1] The first annual report to Congress covered the FFY 2020 reporting period from October 1, 2019, to September 30, 2020, and was published on November 7, 2022. This report addresses compliance with provisions for FFY 2021 for the October 1, 2020 to September 30, 2021 reporting period.[2]

Specifically, the provisions added by section 1004 of the SUPPORT Act required 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

[1] https://www.medicaid.gov/medicaid/downloads/sud-prev-medicaid-drug-rev-util.pdf.
[2] 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 required 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 under dosing 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 FFY 2021 reported responses. The Annual DUR survey was not submitted by the State of Arizona because of the 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 RTC. For purposes of this report, when referencing FFY 2021 survey data, Arizona's separate survey information is included with the other 50 states.

States' FFY 2021 survey responses include information on 22,561,578 beneficiaries enrolled in FFS Medicaid programs, a 5% increase from FFY 2020, and 62,887,720 beneficiaries enrolled in Medicaid managed care programs, a 12% increase from FFY 2020. Thirty-four states have submitted a total of 229 Medicaid MCE DUR Annual FFY 2021 survey responses. Again, as the Annual DUR survey was not submitted by the State of Arizona because of the existing waiver of these DUR requirements, Arizona submitted separate responses for incorporation into this report to Congress for their FFS and 7 MCE programs. Arizona's data includes information on 293,450 beneficiaries enrolled in FFS programs, a 5% increase from FFY 2020, and 1,997,993 beneficiaries enrolled in the state's Medicaid managed care programs, a 12% increase from FFY 2020. At the

time of the survey, five states, Missouri, North Dakota, Tennessee, West Virginia and Wisconsin carve out[3] their drug benefit from the traditional managed care benefit and submitted an abbreviated Managed Care survey for each of their managed care programs. These reports can be accessed on Medicaid.gov.[4]

Claim Review

1. **Prospective Safety Edit Limitations for Opioid Prescriptions -** FFY 2021 survey responses confirm all Medicaid FFS and MCE 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.
    - *Controlled Substances (CII)*[5] *Early Refills:* FFS-reported early refill thresholds range from 75% to 100% of a prescription being used, with a national average of 86% of the prescription being used before a subsequent prescription could be dispensed, which is consistent with FFY 2020. MCE-reported thresholds range from 79% to 90% of the prescription being used, with a national average of 86% (a 1% increase from FFY 2020). 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.
    - *Controlled Substances (CIII to CV)*[6,7,8] *Early Refills:* FFS-reported early refill thresholds range from 75% to 95% of a prescription being used, with a national average of 85%, which is consistent with FFY 2020. MCE-reported thresholds range from 77% to 90% of the prescription being used, with a national average of 85% (consistent with FFY 2020).
    - *Initial Opioid Rx:* For FFS, the median days' supply for an initial opioid prescription for an opioid naïve patient[9] based on FFY 2021 reported responses is 7 days, which includes a national range of 5 to 34 days' supply. Additionally, the median days' supply for an initial opioid prescription for an opioid naïve patient for MCE responses is also 7 days, which includes a national range of 5 to 30 days. Both FFS and MCE

[3] 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.
[4] Please reference the following URL throughout this report to access Medicaid.gov state specific DUR reports: https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html.
[5] 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. Additional drugs may be also considered Schedule II as defined by state specific law.
[6] Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Additional drugs may be also considered Schedule III as defined by state specific law.
[7] Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Additional drugs may be also considered Schedule IV as defined by state specific law.
[8] 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 Additional drugs may be also considered Schedule V as defined by state specific law.
[9] 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) at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-456/subpart-K/section-456.703.

median figures are consistent with FFY 2020.

- *Duplicate Opioid Therapy:* 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. FFY 2021 survey responses show all FFS and MCE programs have safety edits to monitor duplicate therapy of opioid prescriptions dispensed, a 6% increase for FFS programs and 3% increase for MCEs from FFY 2020.

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 2022 Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain recommend that before increasing total opioid dosage to ≥50 MME/day, clinicians should pause and carefully reassess evidence of individual benefits and risks.[10] If a decision is made to increase dosage, clinicians should use caution and increase dosage by the smallest practical amount.[11]

   All FFS and MCEs limit maximum MME daily doses to reduce potential patient harm, misuse and/or diversion. The median MME daily dose for FFY 2021 FFS and MCEs reported responses is 90 mg/day which includes a national range from less than 50 mg/day to greater than 200 mg/day. Additionally, 50 states (98%) have an edit in their POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded, a 6% increase from FFY 2020, and 31 states (61%) have an automated retrospective claims review process to monitor the total daily dose of MMEs for opioid prescriptions dispensed, which is consistent with FFY 2020. In contrast, all MCEs have an edit in their POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded, and there are 207 MCEs (88%) that have an automated retrospective claims review process to monitor the total daily dose of MMEs for opioid prescriptions dispensed, which is consistent with FFY 2020.

3. **Opioids and Concurrently Prescribed Medications -** There are 50 states (98%) with FFS programs that have prospective edits or a retrospective claims review process to monitor opioids and benzodiazepines being used concurrently, which is consistent with FFY 2020. There were 220 (99%) MCEs that have prospective edits or a retrospective claims review process to monitor opioids and benzodiazepines being used concurrently, a 9% increase from FFY 2020.

   Additionally, there are 49 states with FFS programs (96%) that have prospective edits or a retrospective claims review process to monitor opioids and antipsychotics being used

[10] When referencing the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain throughout this report, the recommendations related to opioid dosages are not intended to be used as an inflexible, rigid standard of care; rather, they are intended to be guideposts to help inform clinician-patient decision-making.
[11] CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm.

concurrently, a 4% increase from FFY 2020. All MCEs have prospective edits or a retrospective claims review process to monitor opioids and antipsychotics being used concurrently (note that MCEs in several states have antipsychotics carved out to their states FFS program). These edits allow for the evaluation of the risk of respiratory depression and overdose.

4. **Retrospective Automated Claims Review -** For FFS programs, 46 states (90%) have an automated retrospective claims DUR review process to monitor opioid prescriptions exceeding state limitations, a 25% increase from FFY 2020, and 208 MCEs (87%) have an automated DUR respective claims review process to monitor opioid prescriptions exceeding state limitations, a 17% increase from FFY 2020. These claims review identify potential issues such as adverse events, therapeutic appropriateness, inappropriate or medically unnecessary care, gross overuse, misuse and fraud after the prescription has been dispensed. This also allows 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 that their review process was not automated, or that they manage these reviews through other utilization management processes.

Antipsychotics in Children

According to FFY 2021 survey responses, all FFS and MCE 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, consistent with FFY 2020. Additionally, all FFS and MCE programs monitor or manage antipsychotic medication for all children in foster care. It is important to note that several MCE programs have antipsychotics carved out to their states' FFS program or have no pediatric population enrolled.

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.[12] States have flexibility to define specific parameters for reviews for FWA, which can involve practices such as doctor shopping, filling multiple prescriptions from providers, and multiple Emergency Department (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 2021 FFS survey responses show all states have a process to identify possible fraudulent practices or abuse of controlled drugs by beneficiaries, consistent with FFY 2020. Additionally, 48 states (94%) have processes in place to identify FWA by prescribers, which is consistent with FFY 2020, and 48 states (94%) have processes in place to identify potential fraudulent practices by pharmacies, a 2% increase from FFY 2020.

FFY 2021 survey responses also show all MCEs have a process to identify possible fraudulent

[12] Definitions, 42 C.F.R. § 455.2. https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol4/pdf/CFR-2011-title42-vol4-sec455-2.pdf.

practices or abuse of controlled drugs of beneficiaries, which is consistent with FFY 2020. Additionally, all MCEs have processes in place to identify FWA by prescribers, a 1% increase from FFY 2020, and all MCEs have processes in place to identify potential fraudulent practices by pharmacies, a 2% increase from FFY 2020.

DISCUSSION, COMPLIANCE AND RECOMMENDATIONS

CMS reviewed all of the surveys for compliance with section 1004, which encompassed 51 FFS programs, and 236 MCEs, a total of 287 surveys. 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. The information was reported to CMS either from DUR reports or through follow-up correspondence with states regarding compliance reviews based on state and MCE specific DUR responses.

The adoption of standards pertaining to Section 1004 Support Act requirements have similarly trended upwards from FFY 2020 to FFY 2021 for both FFS and MCE programs. According to responses received, the majority of FFS and MCE programs have integrated the mandated standards. The remaining programs where additional compliance is needed for one or more provisions, have indicated their plans for future implementation.

To address potential program deficits, CMS implemented additional compliance reviews for all specific noncompliance findings in state and MCE programs. After reviewing FFY 2021 survey responses for each FFS and MCE program, CMS reached out to 45 states to request additional supplemental data and to work with these states to address deficiencies, misunderstandings, and errors, and if necessary, to implement corrective action plans for their applicable programs. States were asked to provide explanations for responses indicating noncompliance, actions taken to address the issue, and any dates involved in implementation, and to provide supportive materials. States were expected to correct actual errors and discrepancies and take steps to ensure compliance with all federal regulations. All states responded to CMS's correspondence regarding compliance with applicable requirements. States either corrected the action immediately or implemented a corrective action plan (CAP) to remediate any identified noncompliance.

CMS will continue to ensure oversight and corrective actions by states, as necessary. 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 the 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 managed by the state through the FFS program. As a result, some 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.

FFY 2021 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 DUR reports on Medicaid.gov. The following are recommendations to help states and MCE programs maintain or improve compliance with the amendments made by section 1004 of the SUPPORT Act.

- States should upgrade existing systems from manual to automated retrospective claims review to increase compliance and detect high doses of opioids in a timely and efficient manner.
- States should further develop prospective and automated retrospective claims review, consistent with medical practice patterns and clinical considerations, to limit opioid overutilization/misuse.
- States should continue to meet the care needs and the clinical circumstances on a patient specific basis. CMS recommends that persons with pain receive appropriate pain treatment, with careful consideration of the benefits and risks of all treatment options in the context of the patient's circumstances.
- States should take the necessary steps to ensure compliance with all federally required opioid minimum standards including approaches to identify when:
    1. A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more medications for opioid use disorder (MOUD) or has been diagnosed with an OUD within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as new cancer diagnosis or entry into hospice care); and
    2. A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of any FDA-approved opioid antagonist/reversal agent.
- States should continue to strategize to increase access to substance use disorder (SUD) treatment, such as MOUD, and accompanying behavioral therapies.

Table of Contents

List of Tables

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 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 FFY 2021.

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.

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 of time, 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 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 claims review 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 MCE 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 conducted on their implementation 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. This report represents information submitted by the states with information from FFY 2021.

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:

- Claims review involving prospective safety edits and retrospective reviews monitoring the use of opioids,
- Monitoring the use of antipsychotic medication use in children, and
- Identification of 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. Detailed responses from each state are available in reports on Medicaid.gov. Additionally, as 35 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 2021 for Medicaid prescription benefits, approximately 26% of all Medicaid beneficiaries were enrolled in FFS state Medicaid programs, a 2% decrease from FFY 2020, and the other 74% were enrolled in Medicaid MCE programs, a 2% increase from FFY 2020. There are a total of 51 FFS programs (inclusive of the 50

states and the District of Columbia) and 236 MCE programs (inclusive of 35 states) included in this report. Additionally, Missouri, North Dakota, Tennessee, West Virginia and Wisconsin have pharmacy benefits carved out of their MCE programs and covered entirely through their FFS program. The MCEs do not administer pharmacy benefits in these five states and only the FFS report from these five states are included in this report.

2. Claims Review

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, CMS 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 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 CMS 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, opioid use disorder (OUD), overdose and increased side effects. In addition to the risk of OUD, 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 2020[13] 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 within 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 opioid 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 processes (as designed and implemented by the state) that:
    - Indicate prescription fills of opioids in excess of the foregoing limits to provide for ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization,
    - Identify 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; and
    - Monitor 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 C.F.R. § 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. N one of the required safety reviews prohibit 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(oo) 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 those with intellectual disabilities), or of another facility for which frequently abused drugs are dispensed for residents through a contact with

[13] 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.

a single pharmacy; or other individuals the state elects to treat as exempted 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.

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 claims review 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 OUD and the need for 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 override of a prospective edit such as 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 the 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 misuse. Currently, there are five schedules for controlled drugs, schedules I through V. Schedule I drugs have no medical value and high potential for misuse, while schedule II through V substances all have some medical value but differ in ranking depending on their potential for misuse (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 2021 survey responses, as seen in Table 1, for FFS programs, the early refill percent for schedule II drugs ranged between 75% and 100% and schedules III through V early refill percent ranged between 75% to 95%. For MCE programs, the early refill percent for schedule II drugs ranged between 79% and 90% and schedules III through V early refill percent ranged between 77% to 90%.

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

State	FFS		MCE (Average by State)*	
	Schedule II Controlled Drugs**	Schedule III - V Controlled Drugs	Schedule II Controlled Drugs***	Schedule III - V Controlled Drugs
Alabama	75%	75%	N/A	N/A
Alaska	93%	93%	N/A	N/A
Arizona	85%	85%	86%	86%
Arkansas	90%	90%	90%	90%
California	75%	75%	84%	84%
Colorado	85%	85%	88%	83%
Connecticut	93%	93%	N/A	N/A
Delaware	90%	90%	83%	83%
District of Columbia	80%	80%	81%	81%
Florida	90%	90%	85%	86%
Georgia	85%	85%	86%	85%

State	FFS		MCE (Average by State)*	
	Schedule II Controlled Drugs**	Schedule III - V Controlled Drugs	Schedule II Controlled Drugs***	Schedule III - V Controlled Drugs
Hawaii	90%	90%	83%	83%
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%	80%	88%	79%
Louisiana	90%	90%	90%	90%
Maine	85%	85%	N/A	N/A
Maryland	85%	85%	84%	84%
Massachusetts	85%	85%	79%	77%
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%	90%	90%
Nevada	90%	90%	90%	90%
New Hampshire	80%	80%	83%	83%
New Jersey	85%	85%	87%	87%
New Mexico	90%	75%	90%	90%
New York	75%	75%	84%	84%
North Carolina	85%	85%	N/A	N/A
North Dakota	87%	87%	N/A	N/A
Ohio	90%	90%	87%	86%
Oklahoma	90%	90%	N/A	N/A
Oregon	80%	80%	84%	84%
Pennsylvania	85 %	85%	85%	85%
Rhode Island	85%	85%	87%	83%
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%**	**86%**	**85%**

* Thirty-five states have submitted 236 Medicaid MCE DUR Annual FFY 2021 survey responses. States that do not have MCEs or have pharmacy benefits carved-out are noted by N/A on the chart above.

** 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.

*** Ibid.

As shown in Tables 2 and 3 below, based on FFY 2021 survey responses, 100% of FFS and MCE programs have safety edits to monitor early refills of opioid prescriptions dispensed. Additionally, several programs (65% of FFS, and 70% of MCE) indicated having both safety edits and automated retrospective reviews on opioid early refill claims.

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

Response	States	Total	Percent of Total
Yes, Both Safety Edits and Automated Retrospective Claims Review Process	Alaska, Arizona, Arkansas, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New Jersey, New Mexico, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington	33	65%
Yes, Safety Edits	Alabama, California, Delaware, Idaho, Illinois, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, North Dakota, Oklahoma, Vermont, West Virginia, Wisconsin, Wyoming	18	35%
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 Automated Retrospective Claims Review Process	Arizona (5), Arkansas (2), California (17), Colorado (1), Delaware (1), District of Columbia (3), Florida (10), Georgia (4), Hawaii (5), Illinois (3), Indiana (3), Iowa (2), Kansas (2), Kentucky (5), Louisiana (5), Maryland (6), Massachusetts (5), Michigan (5), Minnesota (3), Mississippi (2), Nebraska (2), Nevada (2), New Hampshire (3), New Jersey (4), New Mexico (3), New York (12), Ohio (5), Oregon (21), Pennsylvania (5), Rhode Island (2), South Carolina (5), Texas (4), Utah (3), Virginia (2), Washington (3)	165	70%
Yes, Safety Edits	Arizona (2), Arkansas (1), California (9), Colorado (1), Delaware (1), District of Columbia (1), Florida (3), Hawaii (1), Illinois (3), Indiana (2), Kansas (1), Kentucky (1), Maryland (3), Michigan (5), Minnesota (5), Mississippi (1), Nebraska (1), Nevada (1), New Jersey (1), New York (4)*, Pennsylvania (3), Rhode Island (1), Texas (13), Utah (1), Virginia (4), Washington (2)	71	30%
National Totals		**236**	**100%**

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 is already 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 can also 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 per 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 2021 responses indicate that almost all programs have safety edit(s) in place to limit the quantity dispensed of an initial opioid prescription whether it is a quantity edit to limit short-acting opioids, long-acting opioids, or both. 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 2021 survey responses show that 98% of FFS and 91% of MCE programs have safety edits in place to limit the quantity dispensed of short-acting opioids to specific quantities. These edits were established taking clinical indications and dosing schedules into account to restrict the number of opioids to the lowest quantity per day to ensure dose optimization and to minimize potential for waste and diversion. FFS and MCE programs that have safety edits in place to limit the quantity of short-acting opioids are shown in Tables 4 and 5.

Table 4 FFS Safety Edits in Place to Limit the Quantity Dispensed of Short-Acting Opioids

Response	States	Total	Percent of Total
Yes	Arkansas, California, Georgia, Idaho, Louisiana, Mississippi, Nebraska, Oklahoma, Rhode Island, South Carolina, West Virginia	11	22%
No	Minnesota	1	2%

Response	States	Total	Percent of Total
Other*	Alabama, Alaska, Arizona, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, Wisconsin, Wyoming	39	76%
National Totals		**51**	**100%**

* As there are no specific federal requirements for short and long-acting drugs, there is discretion how this edit is applied. Program details can be found on Medicaid.gov.

Table 5 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 (7), California (6), Colorado (1), Delaware (1), Florida (1), Kentucky (1), Louisiana (2), Mississippi (1), Nebraska (3), New York (4), Oregon (2), Pennsylvania (1), Utah (1)	31	13%
No	Florida (1), Hawaii (1), Minnesota (1), Nevada (1), New Hampshire (1), New Jersey (1), New York (1), Pennsylvania (1), South Carolina (2), Texas (10)	20	9%
Other*	Arkansas (3), California (20), Colorado (1), Delaware (1), District of Columbia (4), Florida (11), Georgia (4), Hawaii (5), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (5), Louisiana (3), Maryland (9), Massachusetts (5), Michigan (10), Minnesota (7), Mississippi (2), Nevada (2), New Hampshire (2), New Jersey (4), New Mexico (3), New York (11), Ohio (5), Oregon (19), Pennsylvania (6), Rhode Island (3), South Carolina (3), Texas (7), Utah (3), Virginia (6), Washington (5)	185	78%
National Totals		**236**	**100%**

*As there are no specific federal requirements for short and long-acting drugs, there is discretion how this edit is applied. Program details can be found on Medicaid.gov.

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.[14] State responses in Tables 6 and 7 show that almost all programs (90% of FFS, and 95% of MCE) have safety edits in place to limit the quantity dispensed of long-acting opioids.

[14] Fact Sheet for Prescribing Opioids for Pain

Table 6 FFS Safety Edits to Limit the Quantity Dispensed of Long-Acting Opioids

Response	States	Total	Percent of Total
Yes	California, Georgia, Idaho, Louisiana, Mississippi, South Carolina, West Virginia	7	14%
No	Arizona, Minnesota, New York, Rhode Island, Tennessee	5	10%
Other*	Alabama, Alaska, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Utah, Vermont, Virginia, Washington, Wisconsin, Wyoming	39	76%
National Totals		**51**	**100%**

*As there are no specific federal requirements for short and long-acting drugs, there is discretion how this edit is applied. Program details can be found on Medicaid.gov.

Table 7 MCE Safety Edits to Limit the Quantity Dispensed of Long-Acting Opioids

Response	States (Count of MCEs)	Total	Percent of Total
Yes	California (5), Colorado (1), Florida (1), Kentucky (1), Mississippi (1), New Jersey (1), New York (4), Oregon (1), Pennsylvania (1), Texas (1), Utah (1)	18	8%
No	Arizona (1), California (1), Hawaii (1), Minnesota (2), Nevada (1), New Hampshire (1), New Jersey (1), New York (1), Oregon (2), Pennsylvania (1), South Carolina (1)	13	5%
Other*	Arizona (6), Arkansas (3), California (20), Colorado (1), Delaware (2), District of Columbia (4), Florida (12), Georgia (4), Hawaii (5), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (10), Minnesota (6), Mississippi (2), Nebraska (3), Nevada (2), New Hampshire (2), New Jersey (3), New Mexico (3), New York (11), Ohio (5), Oregon (18), Pennsylvania (6), Rhode Island (3), South Carolina (4), Texas (16), Utah (3), Virginia (6), Washington (5)	205	87%
National Totals		**236**	**100%**

*As there are no specific federal requirements for short and long-acting drugs, there is discretion how this edit is applied. Program details can be found on Medicaid.gov.

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. In other circumstances, "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 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain recommends that clinicians maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute, subacute, and chronic pain if benefits are anticipated to outweigh risks to the patient.[15] Clinical evidence cited by the CDC 2022 Clinical Practice Guideline for Prescribing Opioids for Pain 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.[16] 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.[17]

FFY 2021 survey responses displayed in Table 8 show that each program has varied maximum number of days allowed for an initial opioid prescription for an opioid naïve patient. FFS programs range from 5-34 days allowed with a national average of 11 days. The MCE programs ranges from 5-30 days allowed for an initial opioid prescription with a national average of 8 days.

Table 8 FFS/MCE Maximum Number of Days Allowed for an Initial Opioid Prescription for an Opioid Naïve Patient

State	FFS Maximum Days*	MCE Maximum Days ** (State Average)
Alabama	7	N/A
Alaska	N/A	N/A
Arizona	5	5
Arkansas	7	7

[15] Guideline: Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1

[16] 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].

[17] Ibid

State	FFS Maximum Days*	MCE Maximum Days ** (State Average)
California	7	13
Colorado	7	7
Connecticut	7	N/A
Delaware	15	6
District of Columbia	7	7
Florida	14	7
Georgia	30	7
Hawaii	30	11
Idaho	34	N/A
Illinois	7	7
Indiana	7	7
Iowa	7	7
Kansas	7	7
Kentucky	7	7
Louisiana	7	7
Maine	7	N/A
Maryland	7	7
Massachusetts	7	7
Michigan	7	9
Minnesota	7	7
Mississippi	7	7
Missouri	7	N/A
Montana	7	N/A
Nebraska	7	7
Nevada	7	7
New Hampshire	34	21
New Jersey	5	5
New Mexico	7	7
New York	7	7
North Carolina	7	N/A
North Dakota	7	N/A
Ohio	7	7
Oklahoma	7	N/A
Oregon	7	7
Pennsylvania	5	5
Rhode Island	30	30
South Carolina	5	7
South Dakota	7	N/A
Tennessee	5	N/A
Texas	10	10
Utah	7	7
Vermont	7	N/A
Virginia	7	8
Washington	7	7
West Virginia	34	N/A
Wisconsin	34	N/A

State	FFS Maximum Days*	MCE Maximum Days ** (State Average)
Wyoming	7	N/A
National Average	**11**	**8**

* Please see Table 14 regarding Alaska and Iowa

** States that do not have MCEs are noted by N/A on the chart above. Thirty-five states have submitted 236 Medicaid MCE DUR Annual FFY 2021 survey responses. Missouri, North Dakota, Tennessee, Wisconsin, and West Virginia have their covered outpatient drugs carved-out and managed by their FFS program.

State responses in Tables 9 and 10 show that almost all programs (98% in FFS and 99% in MCE) have safety edits in place to limit the days' supply dispensed of an initial opioid prescription for opioid naïve patients. FFY 2021 survey responses show that programs vary in whether the initial day supply limit applies to all or just select opioid prescriptions if other special considerations are made. Further details can be found in state specific reports on Medicaid.gov.

Table 9 FFS Days' Supply Limitation of an Initial Opioid Prescription for Opioid Naïve Patients

Response	States	Total	Percent of Total
Yes, For All Opioids	Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, North Carolina, Ohio, Oklahoma, Oregon, , South Carolina, South Dakota, Tennessee, Texas, Virginia, Washington, Wisconsin, Wyoming	37	73%
Yes, For Some Opioids	Hawaii, Kansas, Louisiana, Michigan, Montana, New Mexico, New York, North Dakota, Pennsylvania, Rhode Island, Utah, Vermont, West Virginia	13	25%
No	Alaska*	1	2%
National Totals		**51**	**100%**

* Based on data collected in FFY 2021, Alaska Medicaid is working with their DUR Committee to put prospective edits in place to limit initial opioid prescriptions to 7 days.

Table 10 MCE Days' Supply Limitation of an Initial Opioid Prescription for Opioid Naïve Patients

Response	States (Count of MCEs)	Total	Percent of Total
Yes, For All Opioids	Arizona (3), Arkansas (3), California (18), Colorado (1), Delaware (1), District of Columbia (4), Florida (12), Georgia (4), Hawaii (5), Illinois (3), Indiana (3), Iowa (2), Kentucky (6), Louisiana (3), Maryland (6), Massachusetts (3), Michigan (6), Minnesota (6), Mississippi (3), Nebraska (2), Nevada (2), New Hampshire (2), New Jersey (4), New Mexico (3), New York (9), Ohio (4), Oregon (20), Pennsylvania (6), Rhode Island (1), South Carolina (5), Texas (15), Utah (3), Virginia (3), Washington (5)	176	75%
Yes, For Some Opioids	Arizona (4), California (8), Colorado (1), Delaware (1), Florida (1), Hawaii (1), Illinois (3), Indiana (2), Kansas (3), Louisiana (2), Maryland (3), Massachusetts (1), Michigan (4), Minnesota (2), Nebraska (1), Nevada (1), New Hampshire (1), New Jersey (1), New York (7), Ohio (1), Oregon (1), Pennsylvania (2), Rhode Island (1), Texas (2), Utah (1), Virginia (3)	58	24%
No	Massachusetts (1)*, Rhode Island (1)**	2	1%
National Totals		**236**	**100%**

* Based on FFY 2021 response, Massachusetts indicated they do not have this edit; however, they are directing the MCE to implement this edit addressing days supply for initial prescription fills for opioid naïve patients.
** MCE has quantity limits on initial fills of select short-acting opioids for members with no opioids claims in the last 60 days.

States were required to establish safety edit limitations on the days' supply for an initial prescription opioid fill for beneficiaries who have not filled an opioid prescription within a defined time period to be specified by the state. The majority of programs also established an additional days' supply edit to limit the days' supply of subsequent opioid prescriptions. Tables 11 and 12 show the most common maximum days' supply limit was 34 days for FFS, and 30 days for MCEs.

Table 11 FFS POS Edits in Place to Limit Days' Supply of Subsequent Opioid Prescriptions

Response	States	Total	Percent of Total
30-Day Supply	Arizona, Connecticut, District of Columbia, Georgia, Hawaii, Louisiana, Maryland, Massachusetts, Mississippi, Nebraska, New York, Oklahoma, Rhode Island, South Carolina, Utah, Vermont	16	31%
34-Day Supply	Alabama, Alaska, Idaho, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, West Virginia, Wisconsin, Wyoming	18	36%

Response	States	Total	Percent of Total
Other Day Supply Limits	Arkansas, California, Colorado, Delaware, Florida, Illinois, Indiana, Iowa, Kansas, Maine, Missouri, Nevada, Oregon, Tennessee, Virginia, Washington	16	31%
No	Texas*	1	2%
National Totals		**51**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

Table 12 MCE POS Edits in Place to Limit Days' Supply of Subsequent Opioid Prescriptions

Response	States (Count of MCEs)	Total	Percent of Total
30-Day Supply	Arizona (5), California (19), Colorado (1), District of Columbia (1), Florida (9), Georgia (2), Hawaii (3), Illinois (3), Indiana (1), Kentucky (1), Louisiana (5), Maryland (5), Massachusetts (5), Michigan (7), Minnesota (2), Nebraska (1), Nevada (1), New Hampshire (1), New Jersey (3), New York (9), Ohio (1), Oregon (10), Pennsylvania (3), Rhode Island (3), South Carolina (2), Texas (1), Utah (4), Virginia (1)	109	46%
34-Day Supply	Delaware (2), Illinois (1), Michigan (3), Minnesota (4), New Hampshire (2), New Mexico (1), Oregon (3), Pennsylvania (2), Texas (4), Virginia (3)	25	11%
90-Day Supply	Arizona (1), Maryland (1), Oregon (2), Texas (1)	5	2%
Other Day Supply Limits	Arizona (1), Arkansas (3), California (6), District of Columbia (2), Florida (3), Georgia (2), Hawaii (3), Illinois (2), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Maryland (3), Minnesota (2), Mississippi (3), Nebraska (2), Nevada (2), New Jersey (2), New Mexico (2), New York (4), Ohio (4), Oregon (6), Pennsylvania (3), South Carolina (3), Texas (1), Virginia (2), Washington (5)	80	34%
No*	California (1), Colorado (1), District of Columbia (1), Florida (1), New York (3), Texas (10)	17	7%
National Totals		**236**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for 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, interactions between patients' medical conditions and opioid use, and the number of unique prescribers and pharmacies used by a patient to obtain opioids. Retrospective claims review is required for concurrent prescribing of opioids and benzodiazepines or antipsychotics in 42 C.F.R. § 456.703(h)(1)(iv).

State survey responses in Tables 13 and 14 show that all programs (100% of FFS and MCE) 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 13 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, 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 14 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 (7), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (13), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	236	100%
National Totals		**236**	**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 misuse, as well as the opportunity for self- medication and dose escalation.[18]

[18] 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.

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.[19] 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 original condition.[20] 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. States must also determine what constitutes therapeutic duplication as opposed to appropriate care. For example, a common clinical therapy regimen for patients with chronic pain may include a patient using both an extended-release opioid and an immediate-release opioid for breakthrough pain. States may choose to not define this as therapeutic duplication.

FFY 2021 survey responses show in Tables 15 and 16 that all programs (100% of FFS and MCE) have safety edits to monitor duplicate therapy of opioid prescriptions dispensed. FFY 2021 FFS responses indicating compliance with this requirement remain consistent with FFY 2020, and MCE responses increased by 5%. This excludes regimens that include a single extended-release product and a breakthrough short-acting agent.

Table 15 FFS Safety Edits to Monitor Duplicate Therapy of Opioid Prescriptions

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Colorado, 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%**

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

Table 16 MCE Safety Edits in Place to Monitor Duplicate Therapy of Opioid Prescriptions

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (7), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (13), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (9), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (16), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	236	100%
National Totals		**236**	**100%**

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 (MME) 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.[21] Section 1004 of the SUPPORT Act specifically addresses MME limitations in the context of chronic pain. According to the CDC, acute pain is usually sudden in onset and time limited (defined in the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain as having a duration of <1 month) and often is caused by injury, trauma, or medical treatments such as surgery. For example, acute pain can be caused from a broken bone after an automobile accident, a surgery, or a wisdom tooth extraction. Unresolved acute pain or subacute pain (defined in the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain as pain that has been present for 1–3 months) can evolve into chronic pain. Chronic pain, typically lasts >3 months and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause.[22] Regarding chronic pain, CDC indicates clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks.[23]

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, tapering of opioids, prescribing of a medication for the reversal of opioid overdoses such as naloxone, or other measures to reduce risk of respiratory failure. Many patients do not experience benefit in pain or function from increasing opioid dosages to ≥50 MME/day but are exposed to progressive increases in risk as dosage increases. Therefore, before increasing total

[21] Section 1902(oo)(1)(A)(i)(II) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[22] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1
[23] Ibid.

opioid dosage to ≥50 MME/day, clinicians should pause and carefully reassess evidence of individual benefits and risks. If a decision is made to increase dosage, clinicians should use caution and increase dosage by the smallest practical amount.[24] HHS's Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,[25] is also a valuable resource for considering how best to taper and/or discontinue usage in a thoughtful manner consistent with best clinical practices.

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.[26] 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.[27] Additionally, states were reminded that clinical resources, including, for example, the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain, 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.[28,29]

FFY 2021 survey responses show in Tables 17 and 18 that all programs have safety edits in place to alert the pharmacy provider if the MME daily dose prescribed has been exceeded.

[24] Ibid.
[25] https://www.hhs.gov/system/files/Dosage_Reduction_Discontinuation.pdf .
[26] Ibid.
[27] "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.
[28] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.
[29] Ibid.

Table 17 FFS Safety Edits to Alert the Pharmacy Provider that the MME Daily Dose Prescribed Has Been Exceeded

Response	States	Total	Percent of Total
Yes	Alabama, Alaska, Arkansas, 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	50	98%
No	California*	1	2%
National Totals		**51**	**100%**

* During FFY 2021, California was in the process of changing a POS system with the planned implementation date of 1/1/2021. The implementation was postponed, and the legacy system did not have the capability to perform MME edit and inform the pharmacy when a prescription exceeds the limit. This was implemented 1/1/2022.

Table 18 MCE Safety Edits to Alert the Pharmacy Provider that the MME Daily Dose Prescribed Has Been Exceeded

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (13), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	236	100%
National Totals		**236**	**100%**

Tables 19 and 20 show the median MME daily dose for FFY 2021 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. Overall, all FFS and MCE programs have established MME limits in FFY 2021, a 2% increase from FFY 2020 in FFS programs and 1% increase in MCE programs.

Table 19 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	Pennsylvania, Vermont, West Virginia	3	6%
80 MME	Georgia	1	2%
90 MME	Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Idaho, Illinois, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Wisconsin	29	56%
100 MME	Mississippi, New Hampshire	2	4%
120 MME	Hawaii, Kansas, Massachusetts, Wyoming	4	8%
200 MME	Alabama, Colorado, Kentucky, Missouri, Tennessee, Washington	6	12%
Greater Than 200 MME	California	1	2%
Other	Alaska, Indiana, Nevada	3	6%
National Totals		**51**	**100%**

Table 20 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 (2), Pennsylvania (6)	10	5%
80 MME	Ohio (3)	3	1%
90 MME	Arizona (7), Arkansas (3), California (11), Colorado (1), Delaware (2), District of Columbia (4), Florida (12), Georgia (3), Hawaii (3), Illinois (4), Indiana (1), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (8), Massachusetts (4), Michigan (10), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Jersey (5), New Mexico (3), New York (9), Ohio (1), Oregon (20), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6)	181	76%
100 MME	New Hampshire (3)	3	1%
120 MME	California (3), Hawaii (3), Washington (5)	11	5%
200 MME	California (8), Colorado (1), Illinois (2), Maryland (1), New York (6), Oregon (1)	19	8%
Greater Than 200 MME	California (3), Florida (1), Kentucky (1)	5	2%
Other	Indiana (1)	1	1%
National Totals		**236**	**100%**

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 21 and 22, FFY 2021 survey responses show that a majority of programs have automated retrospective claims review to monitor total daily MME dose of opioid prescriptions dispensed (61% in FFS, and 88% in MCE). These reviews also assist in determining overall trending of prescriptions in the state by MME.

Table 21 FFS Automated Retrospective Claims Review to Monitor Total Daily MME Dose of Opioid Prescriptions Dispensed

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

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

Table 22 MCE Automated Retrospective Claims Review to Monitor Total Daily MME Dose of Opioid Prescriptions Dispensed

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (7), Arkansas (2), California (22), Colorado (2), Delaware (1), District of Columbia (1), Florida (11), Georgia (4), Hawaii (6), Illinois (5), Indiana (5), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (9), Massachusetts (4), Michigan (9), Minnesota (5), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (14), Ohio (5), Oregon (21), Pennsylvania (6), Rhode Island (3), South Carolina (5), Texas (14), Utah (3), Virginia (4), Washington (4)	207	88%
No*	Arkansas (1), California (4), Delaware (1), District of Columbia (3), Florida (2), Illinois (1), Kentucky (1), Massachusetts (1), Michigan (1), Minnesota (3), New York (2), Pennsylvania (2), Texas (3), Utah (1), Virginia (2), Washington (1)	29	12%
National Totals		**236**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

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.[30] 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 claims review, concurrent use of opioids and benzodiazepines and/or opioids and antipsychotics can be reduced, as can 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 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain recommends that clinicians avoid prescribing benzodiazepines concurrently with opioids whenever possible.

Benzodiazepines may be misused by some individuals, with some opioid overdoses also involving opioids and benzodiazepines or other substances, such as alcohol.[31] Studies show that people concurrently using both opioids and benzodiazepines are at higher risk of visiting the emergency department (ED) or being admitted to a hospital for a drug-related emergency.[32] 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.[33] 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 may benefit from concurrent opioid and antipsychotic therapy with the appropriate coordination of care and drug monitoring. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of OUD, and determining the best approach for pain management.

[30] Section 1902(oo)(1)(A)(i)(III) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[31] 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/.
[32] Benzodiazepines and Opioids, https://nida.nih.gov/research-topics/opioids/benzodiazepines-opioids.
[33] "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.

As the Pain Management Task Force (PMTF)[34] 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."[35] 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 adverse events, OUD, and overdose.[36] 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 co-occurring chronic pain condition.[37] A patient's unique presentation and circumstances should be considered when prescribing opioids and antipsychotics. This review 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 generate an alert for 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.

In consideration of clinical recommendations to limit opioids interactions with certain other drugs and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, states were required to establish retrospective reviews on individuals concurrently prescribed opioids and benzodiazepines to assure at-risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results. The requirement for a retrospective automated claims review added by section 1004 of the SUPPORT Act did not preclude states from also establishing a prospective safety edit to provide additional information to patients and providers at the POS about concurrent utilization alerts.

FFY 2021 survey responses show that most programs have retrospective claims review process to monitor opioids and benzodiazepines being used concurrently (75% of FFS, and 76% of MCE) as shown in Tables 23 and 24. There were 12 FFS (23%) programs that only had prospective safety edits in place and 1 FFS program (2%) without either reviews or edits. The New Mexico FFS program indicated they were developing these processes for FFY 2022 or FFY 2023. There were 50 MCE (23%) programs that only had prospective safety edits in place and 2 MCE programs (1%) without either reviews or edits on benzodiazepine and opioid interactions. The 2 MCE programs that indicated they do not have these reviews in place, Florida (1) and Hawaii (1), specified they were either in the process of implementing a program or had other edits in place. Maryland (7), Michigan

[34] The Pain Management Best Practices Inter-Agency Task Force was convened by the U.S. Department of Health and Human Services in conjunction with the U.S. Department of Defense and the U.S. Department of Veterans Affairs with the Office of National Drug Control Policy to address acute and chronic pain in light of the ongoing opioid crisis. The Task Force mandate is to identify gaps, inconsistencies, and updates and to make recommendations for best practices for managing acute and chronic pain. The 29-member Task Force included federal agency representatives as well as nonfederal experts and representatives from a broad group of stakeholders.
[35] 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.
[36] Ibid.
[37] Ibid.

(4), and Utah (3) MCE programs have either opioids or benzodiazepines carved out to FFS.

Overall, from FFY 2020 to FFY 2021, FFS programs remained consistent as MCE programs showed an increase (90% to 99%) with their opioid and benzodiazepine concurrent utilization reviews.

Table 23 FFS Safety Edits or Retrospective Claims Review to Monitor Opioids and Benzodiazepines Used Concurrently

Response	States	Total	Percent of Total
Yes, Automated Retrospective Claims Review	Alabama, Hawaii, Massachusetts, Michigan, Rhode Island, Washington, Wisconsin	7	14%
Yes, Both Safety Edits and Automated Retrospective Claims Review	Alaska, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Louisiana, Maryland, Minnesota, Missouri, Montana, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, West Virginia	31	61%
Yes, Safety Edits*	Arizona, Illinois, Kentucky, Maine, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, Oklahoma, Tennessee, Wyoming	12	23%
No*	New Mexico	1	2%
National Totals		**51**	**100%**

* CMS is continuing to work with programs and follow up regarding compliance as DUR survey responses were not provided, need clarification or additional information and state action is needed.

Table 24 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 (5), Delaware (1), Georgia (1), Massachusetts (1), Michigan (3), Minnesota (1), Ohio (1), Oregon (11), Texas (1), Virginia (1), Washington (1)	27	12%
Yes, Both Safety Edits and Automated Retrospective Claims Review Process	Arizona (6), Arkansas (2), California (14), Colorado (2), Delaware (1), District of Columbia (2), Florida (9), Georgia (3), Hawaii (5), Illinois (4), Indiana (3), Iowa (2), Kansas (3), Kentucky (2), Louisiana (5), Maryland (2), Massachusetts (3), Michigan (2), Minnesota (5), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (2), New Jersey (4), New Mexico (3), New York (14), Ohio (4), Oregon (10), Pennsylvania (4), Rhode Island (3), South Carolina (3), Texas (5), Utah (1), Virginia (3), Washington (3)	143	64%

Response	States (Count of MCEs)	Total	Percent of Total
Yes, Safety Edits*	Arizona (1), Arkansas (1), California (7), District of Columbia (2), Florida (3), Illinois (2), Indiana (2), Kentucky (4), Massachusetts (1), Michigan (1), Minnesota (2), New Hampshire (1), New Jersey (1), New York (2), Pennsylvania (4), South Carolina (2), Texas (11), Virginia (2), Washington (1)	50	23%
No*	Florida (1), Hawaii (1)	2	1%
National Totals		**222****	**100%**

* CMS is continuing to work with programs and follow up regarding compliance as DUR survey responses were not provided, need clarification or additional information and state action is needed.
** Maryland (7), Michigan (4), and Utah (3) have either opioids or benzodiazepines carved out to FFS.

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 such scenarios and allow for the program to follow up.

The requirement for retrospective automated claims review on concurrently prescribed opioids and antipsychotics, as added by section 1004 of the SUPPORT Act, did not preclude states from also establishing a prospective safety edit to provide additional information to patients and providers at the POS. As such, many states implemented both prospective safety edits and retrospective claims review (43% of both, FFS and MCE).

Tables 25 and 26 show that FFY 2021 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 (96% of FFS, and 100% MCE). A large number of states and MCE programs had both safety edits and automated retrospective claims review in place (43%, of both FFS and MCE). There were 10 FFS states (20%) and 44 MCE programs (21%) that indicated only safety edits were implemented. FFS Programs in New Mexico, and Tennessee report manual retrospective reviews only. Note that MCEs (California, Maryland, Michigan, Oregon, and Utah) have antipsychotics carved out of their managed care program and are not required to perform these reviews. Overall, from FFY 2020 to FFY 2021, both FFS and MCE programs increased compliance rates with opioid and antipsychotic concurrent utilization reviews.

Table 25 FFS Safety Edits or Retrospective Claims Review to Monitor Opioids and Antipsychotics Being Used Concurrently

Response	States	Total	Percent of Total
Yes, Automated Retrospective Claims Review	Alabama, Arkansas, Hawaii, Idaho, Louisiana, Michigan, Montana, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, Texas, Utah, Washington, Wisconsin, Wyoming	17	33%
Yes, Both Safety Edits and Automated Retrospective Claims Review	Alaska, California, Connecticut, Delaware, Florida, Indiana, Iowa, Kansas, Kentucky, Maryland, Minnesota, Mississippi, Missouri, New Hampshire, New York, North Carolina, Oklahoma, South Carolina, South Dakota, Vermont, Virginia, West Virginia	22	43%
Yes, Safety Edits*	Arizona, Colorado, District of Columbia, Georgia, Illinois, Maine, Massachusetts, Nebraska, Nevada, New Jersey	10	20%
No*	New Mexico,** Tennessee***	2	4%
National Totals		**51**	**100%**

* CMS continues to monitor state specific trends and will follow up with these programs for compliance.
** Development in process for FFY22.
*** TennCare performed ongoing retrospective reviews and in October 2022, TennCare implemented a message-only prospective safety edit to notify pharmacists when patients are concomitantly prescribed opioids and antipsychotic medications.

Table 26 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 (7), Georgia (1), Hawaii (2), Illinois (1), Indiana (2), Kansas (3), Kentucky (1), Louisiana (4), Maryland (2), Michigan (5), Minnesota (3), Mississippi (1), Nebraska (2), Nevada (1), New Jersey (2), New York (3), Ohio (1), Oregon (16), Pennsylvania (5), Texas (2), Virginia (3), Washington (2)	73	35%
Yes, Both Safety Edits and Automated Retrospective Claims Review Process	Arizona (1), Arkansas (2), California (6), Colorado (1), Delaware (1), District of Columbia (2), Florida (9), Georgia (3), Hawaii (3), Illinois (3), Indiana (1), Iowa (2), Kentucky (1), Louisiana (1), Massachusetts (4), Minnesota (4), Mississippi (2), Nebraska (1), Nevada (2), New Hampshire (1), New Jersey (3), New Mexico (2), New York (10), Ohio (4), Oregon (4), Pennsylvania (2), Rhode Island (3), South Carolina (3), Texas (3), Utah (1), Virginia (2), Washington (2)	89	43%

Response	States (Count of MCEs)	Total	Percent of Total
Yes, Safety Edits*	Arkansas (1), Colorado (1), Delaware (1), District of Columbia (2), Florida (4), Hawaii (1), Illinois (2), Indiana (2), Kentucky (4), Massachusetts (1), Michigan (1), Minnesota (1), New Hampshire (2), New Mexico (1), New York (3), Pennsylvania (1), South Carolina (2), Texas (12), Virginia (1), Washington (1)	44	21%
National Totals		**208****	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.
** 28 MCEs (California (13), Maryland (7), Michigan (4), Oregon (1), and Utah (3)) have antipsychotics carved out to FFS.

2.4. Automated Claims Review

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 misuse. 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 claims review are necessary to allow states to monitor the opioid prescriptions beneficiaries are receiving, and then 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 misuse 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 2021 survey responses show many states made progress from last year for both FFS and MCE programs. Tables 27 and 28 indicated approximately 90% of FFS and 87% of MCE programs indicated compliance with having automated retrospective claims review to monitor opioid prescriptions exceeding state defined limitations for the FFY 2021 calendar year. Many of the remaining programs surveyed said either their review process was not automated, the programs have prospective safety edits in place, or they were using prior authorization reviews to manage this requirement.

Table 27 FFS Comprehensive Claims Review Automated Retrospective Process to Monitor Opioid Prescriptions Exceeding State Limitations

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, Michigan, 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, Virginia, Vermont, Washington, Wisconsin, Wyoming	46	90%
No*	Massachusetts, Minnesota, Montana, Nevada, West Virginia	5	10%
National Totals		**51**	**100%**

*Programs provided information on alternate processes in lieu of this requirement. CMS will monitor these programs for compliance.

Table 28 MCE Comprehensive Claims Review Automated Retrospective Process to Monitor Opioid Prescriptions in Excess of State Limitations

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (5), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4),Florida (12),Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (2), Kentucky (6), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (10), Minnesota (6), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (12), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (4), Utah (3), Virginia (2), Washington (5)	208	87%
No*	Arizona (2), Florida (1), Kansas (1), Minnesota (2), New York (4), Texas (13), Utah (1), Virginia (4)	28	13%
National Totals		**236**	**100%**

*Programs provided information on alternate processes in lieu of this requirement. CMS will monitor these programs for compliance.

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).[38] Antipsychotic medications are increasingly used for a wide range of clinical indications in diverse populations, including privately and publicly insured youth.[39]

Antipsychotics' adverse metabolic effects have heightened concern over increases in prescribing to youth, including off-label prescribing and polytherapy of multiple antipsychotics.[40] 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.[41] 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.[42] 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.[43, 44]

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 are 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 P&T and DUR committees to identify clinically appropriate safety edits and reviews. Additionally, state DUR programs could consider including 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. The following sections provide the survey results for state Medicaid programs related to antipsychotic medication use in children.

[38] Section 1902(oo)(1)(B) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[39] 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.
[40] Ibid.
[41] Ibid.
[42] Marder SR, et al. Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004;161(8):1334.
[43] https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2717966
[44] https://www.healthline.com/health/consumer-reports-antipsychotics-children#1

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 29 and 30 show that all FFS (consistent with FFY 2020) and MCE programs have a program in place for managing and monitoring appropriate use of antipsychotic drugs in children. Forty-four MCEs indicated they do not have a program in place; however, they maintain compliance as they have no children beneficiaries, or they have these medications carved out and managed by the FFS program.

Table 29 FFS Program in Place for Managing and 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 30 MCE Program in Place for Managing and Monitoring Appropriate Use of Antipsychotic Drugs in Children

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (7), Arkansas (3), California (10), Colorado (2), Delaware (2), District of Columbia (4), Florida (12), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), Louisiana (5), Maryland (3), Massachusetts (5), Michigan (8), Minnesota (7), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (16), Ohio (5), Oregon (7), Pennsylvania (7), Rhode Island (3), South Carolina (5), Texas (16), Utah (2), Virginia (6), Washington (5)	192	100%
National Totals		**192***	**100%**

* MCEs in California (16), Michigan (2), Maryland (6), Minnesota (1), Oregon (14), and Utah (2) have these medications carved out and managed by the FFS program. The MCEs in Florida (1), Pennsylvania (1), Texas (1) have no children enrolled. Of these MCEs, 13 MCEs (California (9), Maryland (1), Michigan (2), Oregon (1)) indicated they are implementing additional monitoring programs focusing on behavioral health to supplement the reviews provided by FFS, which would be considered best practice recommended by CMS.

As shown in Tables 31 and 32, all FFS and MCE programs manage and monitor antipsychotic medication use in foster care children. For 5 FFS programs (Alabama, Illinois, New Mexico, Oregon, Wisconsin) that selected "other," all indicated some degree of monitoring and managing antipsychotic medication in children. Of the 28 MCE programs that selected "other", these MCEs had antipsychotics carved out, did not have all types of children enrolled in their program or had monitoring restricted to certain ages.

Table 31 FFS Categories of Children Managed and Monitored for Appropriate Use of Antipsychotic Drugs

Response	States	Total	Percent of Total
All Children	Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, 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, Wyoming	46	90%
Other*	Alabama, Illinois, New Mexico, Oregon, Wisconsin	5	10%
National Totals		**51**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

Table 32 MCE Categories of Children Managed and Monitored for Appropriate Use of Antipsychotic Drugs

Response	States (Count of MCEs)	Total	Percent of Total
All Children	Arizona (5), Arkansas (3), California (8), Colorado (1), Delaware (2), District of Columbia (3), Florida (11), Georgia (4), Hawaii (3), Illinois (5), Indiana (4), Iowa (2), Kansas (2), Kentucky (5), Louisiana (5), Maryland (2), Massachusetts (5), Michigan (7), Minnesota (6), Mississippi (2), Nebraska (2), Nevada (2), New Hampshire (3), New Jersey (3), New Mexico (3), New York (15), Ohio (4), Oregon (4), Pennsylvania (7), Rhode Island (2), South Carolina (5), Texas (15), Utah (2), Virginia (5), Washington (5)	163	85%
Only Children in Foster Care*	Illinois (1)	1	1%
Other	Arizona (2), California (2), Colorado (1), District of Columbia (1), Florida (1), Hawaii (3), Indiana (1), Kansas (1), Kentucky (1), Maryland (1), Michigan (1), Mississippi (1), Nebraska (1), Nevada (1), New Jersey (2), New York (1), Ohio (1), Oregon (3), Rhode Island (1), Texas (1), Virginia (1)	28	14%
National Totals		**192**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

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 2021 survey responses show in Tables 33 and 34 that various antipsychotic safety edits are in place to monitor for appropriate use in children including child's age (82% of FFS, and 71% of MCE:), dosage (76% of FFS, and 77% of MCE), indication (61% of FFS, and 55% of MCE), and polypharmacy (73% of FFS, and 69% of MCE).

*Table 33 FFS Antipsychotic Safety Edits in Place to Monitor for Appropriate Use in Children**

Response	States	Total	Total Percent
Child's Age	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Missouri, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	42	82%
Dosage	Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming	39	76%
Indication	Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Mississippi, Missouri, Montana, Nevada, New York, North Carolina, North Dakota, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington	31	61%
Polypharmacy	Alabama, Alaska, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Washington, West Virginia, Wyoming	37	73%
Other**	Alabama, Arkansas, Delaware, Illinois, Indiana, Kansas, Louisiana, Maine, Massachusetts, Michigan, Mississippi, New Mexico, North Carolina, Ohio, Oregon, Rhode Island, Tennessee, Texas, Vermont, Washington	20	39%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

*Table 34 MCE Antipsychotic Safety Edits in Place to Monitor for Appropriate Use in Children**

Response	States (Count of MCEs)	Total	Total Percent
Child's Age	Arizona (7), Arkansas (3), California (7), Delaware (2), District of Columbia (3), Florida (7), Georgia (2), Hawaii (3), Illinois (4), Indiana (4), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (1), Massachusetts (5), Michigan (3), Minnesota (6), Nebraska (2), Nevada (2), New Hampshire (3), New Jersey (4), New Mexico (2), New York (12), Ohio (3), Oregon (1), Pennsylvania (7), South Carolina (3), Texas (14), Virginia (6), Washington (5)	136	71%
Dosage	Arizona (6), Arkansas (3), California (5), Colorado (1), Delaware (2), District of Columbia (2), Florida (11), Georgia (4), Hawaii (5), Illinois (5), Indiana (5), Kansas (3), Kentucky (6), Louisiana (5), Massachusetts (5), Michigan (3), Minnesota (2), Mississippi (1), Nebraska (3), Nevada (3), New Hampshire (2), New Jersey (5), New Mexico (3), New York (11), Ohio (4), Oregon (2), Pennsylvania (7), Rhode Island (2), South Carolina (4), Texas (16), Virginia (6), Washington (5)	147	77%
Indication	Arizona (5), Arkansas (2), California (5), Colorado (1), Delaware (2), District of Columbia (1), Florida (7), Georgia (1), Hawaii (3), Illinois (2), Indiana (3), Kansas (3), Kentucky (6), Louisiana (5), Massachusetts (2), Michigan (2), Minnesota (2), Mississippi (3), Nebraska (3), Nevada (1), New Hampshire (1), New Jersey (4), New Mexico (1), New York (9), Ohio (2), Oregon (2), Pennsylvania (4), South Carolina (4), Texas (13), Utah (1), Virginia (4), Washington (2)	106	55%
Polypharmacy	Arizona (6), Arkansas (3), California (4), Colorado (1), Delaware (1), District of Columbia (3), Florida (9), Georgia (4), Hawaii (5), Illinois (3), Indiana (5), Iowa (2), Kansas (2), Kentucky (3), Louisiana (3), Maryland (1), Massachusetts (5), Michigan (1), Minnesota (3), Mississippi (2), Nebraska (3), Nevada (2), New Hampshire (3), New Jersey (3), New Mexico (1), New York (13), Ohio (5), Oregon (1), Pennsylvania (5), Rhode Island (1), South Carolina (5), Texas (13), Utah (1), Virginia (4), Washington (5)	131	69%
Other**	Arizona (3), Arkansas (1), California (3), Colorado (2), District of Columbia (2), Florida (8), Georgia (3), Hawaii (1), Illinois (5), Indiana (4), Kansas (2), Kentucky (4), Louisiana (2), Maryland (3), Michigan (6), Minnesota (1), Mississippi (3), Nebraska (1), Nevada (1), New Hampshire (2), New Jersey (2), New Mexico (2), New York (6), Ohio (2), Oregon (3), Pennsylvania (3), Rhode Island (2), South Carolina (2), Texas (4), Utah (1), Virginia (2), Washington (4)	90	47%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

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 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 misuse 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 and misuse related to opioids. For example, patient review and restriction (PRR) programs (lock-in programs)[45] and PDMP's[46] also play an important role in detecting and preventing opioid-related fraud and misuse .

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.[47]

PDMPs are database tools utilized by state, federal and/or law enforcement entities depending on how the program is designed for clinical patient management, as well as, reducing prescription drug fraud, misuse and diversion. Depending on state specific designs, PDMPs collect electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. In some states, data is monitored and analyzed to support states' efforts in education, research, enforcement and/or misuse prevention.[48]

---

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

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

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

[48] "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.

Additionally, PDMPs can be used to monitor controlled substance use by healthcare providers, including prescribers and pharmacists in the prevention of FWA. 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 2021 survey responses, Table 35 and 36 show all FFS and MCE programs have a documented process in place that identifies potential fraud or abuse of controlled drugs by a beneficiary. FFY 2021 MCE survey responses show the 3 MCE outliers from FFY 2020 are now in compliance.

Table 35 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 36 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 (7), Arkansas (3), California (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (13), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	236	100%
National Totals		**236**	**100%**

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 2021 survey responses in Tables 37 and 38 show that 92% of both FFS and MCE programs have a PRR program for beneficiaries with potential misuse of controlled substances. FFY 2021 survey responses also show a 2% increase within MCE programs from FFY 2020.

Table 37 FFS Patient Review and Restriction Program

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 38 MCE Patient Review and Restriction Program

Response	States (Count of MCEs)	Total	Percent of Total
Yes	Arizona (7), Arkansas (3), California (12), Colorado (2), Delaware (2), District of Columbia (4), Florida (12), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (16), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	216	92%
No	California (14), Florida (1), Oregon (5)	20	8%
National Totals		**236**	**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. These include, but are not limited to, seeing multiple prescribers for opioids, using multiple pharmacies, frequently using small amounts of short-acting opioids, and/or frequently visiting EDs seeking opioids. Beneficiary criteria for PRR programs in FFY 2021 survey responses, shown in Tables 39 and 40, are identified through multiple resources. Top criteria include beneficiaries using multiple prescribers of controlled substances (98% in FFS, and 97% MCE) and multiple pharmacies to obtain controlled substances (96% in both FFS and MCE). FFY 2021 responses show an 8% increase within MCE programs in both of these top identification criteria from FFY 2020.

*Table 39 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	Arkansas, Delaware, Georgia, Maryland, Michigan, New York, North Dakota, Utah	8	17%
Multiple ER Visits	Alabama, Alaska, Arizona, Colorado, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, 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	32	68%
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 Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	45	96%
Number Days' Supply of Controlled Substances	Alabama, Arizona, Arkansas, Connecticut, Delaware, Georgia, Kansas, Louisiana, Maryland, Michigan, Missouri, New York, Oklahoma, Oregon, South Carolina, Utah, Virginia, West Virginia, Wisconsin	19	40%

Response	States	Total	Total Percent
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, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	40	85%
PDMP Data*	Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Michigan, Mississippi, Montana, Nevada, North Dakota, Pennsylvania, Tennessee, Utah, Virginia, West Virginia	17	36%
Other**	Arkansas, Connecticut, District of Columbia, Idaho, Illinois, Indiana, Maine, Mississippi, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Tennessee, Texas, Utah, Washington, West Virginia, Wisconsin	19	40%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

*Table 40 MCE Patient Review and Restriction Program Beneficiary Identification Criteria**

Response	States (Count of MCEs)	Total	Total Percent
Different Prescribers of Controlled Substances	Arizona (7), Arkansas (3), California (11), Colorado (2), Delaware (2), District of Columbia (4), Florida (12), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (13), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (16), Utah (4), Virginia (6), Washington (4)	210	97%
Exclusivity of Short-Acting Opioids	California (1), Delaware (1), Kansas (1), Maryland (1), Massachusetts (1), Michigan (1), Minnesota (2), Nebraska (1), New Hampshire (1), New Jersey (1), New York (2), Pennsylvania (3), Texas (1), Utah (1), Virginia (1), Washington (1)	20	9%

Response	States (Count of MCEs)	Total	Total Percent
Multiple ER Visits	Arizona (2), Arkansas (1), California (4), Colorado (2), Delaware (1), District of Columbia (1), Florida (1), Georgia (3), Hawaii (4), Illinois (4), Indiana (3), Kansas (3), Kentucky (4), Louisiana (1), Maryland (1), Massachusetts (3), Michigan (8), Minnesota (8), Mississippi (1), Nebraska (1), Nevada (1), New Hampshire (3), New Jersey (3), New Mexico (3), New York (13), Ohio (1), Pennsylvania (7), Rhode Island (1), South Carolina (2), Texas (15), Utah (4), Virginia (3), Washington (3)	115	53%
Multiple Pharmacies	Arizona (7), Arkansas (3), California (10), Colorado (2), Delaware (2), District of Columbia (4), Florida (12), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), Louisiana (5), Maryland (9), Massachusetts (5), Michigan (9), Minnesota (8), Mississippi (3), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (15), Ohio (5), Oregon (13), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (16), Utah (4), Virginia (6), Washington (4)	207	96%
Number Days' Supply of Controlled Substances	Arizona (3), Arkansas (1), California (2), Delaware (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 (2), New York (5), Ohio (1), Oregon (6), Pennsylvania (4), South Carolina (3), Texas (10), Utah (1), Virginia (2), Washington (2)	69	32%
Number of Controlled Substances	Arizona (7), Arkansas (3), California (9), Colorado (2), Delaware (2), District of Columbia (4), Florida (12), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (9), Pennsylvania (7), Rhode Island (3), South Carolina (5), Texas (16), Utah (4), Virginia (5), Washington (4)	202	94%
PDMP Data*	Arizona (5), California (4), District of Columbia (1), Florida (2), Hawaii (1), Illinois (4), Indiana (2), Kansas (1), Kentucky (2), Michigan (3), Minnesota (7), Mississippi (1), New Mexico (3), Pennsylvania (1), Texas (1), Utah (3), Virginia (5), Washington (3)	49	23%

Response	States (Count of MCEs)	Total	Total Percent
Same FFS State Criteria Is Applied	Arizona (6), District of Columbia (3), Florida (8), Georgia (1), Hawaii (2), Indiana (2), Kansas (2), Kentucky (2), Louisiana (4), Maryland (7), Massachusetts (3), Michigan (4), Minnesota (4), New Hampshire (2), New York (4), Ohio (1), Pennsylvania (3), South Carolina (2), Texas (4), Utah (4), Virginia (5), Washington (2)	75	35%
Other**	Arizona (1), Arkansas (1), California (4), Delaware (2), District of Columbia (1), Florida (3), Georgia (1), Hawaii (3), Illinois (3), Indiana (1), Kansas (2), Kentucky (2), Louisiana (2), Maryland (1), Massachusetts (3), Michigan (4), Minnesota (1), Mississippi (2), Nebraska (1), Nevada (1), New Jersey (3), New York (6), Ohio (4), Oregon (15), Pennsylvania (6), Rhode Island (3), South Carolina (2), Texas (12), Virginia (1), Washington (2)	93	43%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

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, DUR-related education and notification to prescribers, and/or requiring prior authorization for all controlled substance claims. FFY 2021 survey responses depicted in Tables 41 and 42 show potential recourses to initiate multiple actions such as PRR programs (88% of FFS, and 94% of MCE), alerting the PIU (78% of FFS, and 70% of MCE), denying claims (57% of FFS, and 49% of MCE), and/or requiring prior authorization (53% of FFS, and 51% of MCE).

*Table 41 FFS Actions when Potential Fraud or Abuse of Controlled Drugs by Beneficiaries is Detected**

Response	States	Total	Total Percent
Deny Claims	Alaska, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Maine, Massachusetts, Michigan, Missouri, Montana, Nebraska, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, South Carolina, Texas, Utah, Vermont, Virginia, West Virginia	29	57%
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%

Response	States	Total	Total Percent
Refer to Office of Inspector General (OIG)	Arizona, Arkansas, Indiana, Kentucky, Maryland, Michigan, Minnesota, New Mexico, New York, North Carolina, North Dakota, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Wisconsin	17	33%
Refer to PIU and/or SUR Unit for Audit/Investigation	Alabama, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, Wyoming	40	78%
Require Prior Authorization	Alaska, Arkansas, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, New Jersey, New York, North Carolina, North Dakota, Oregon, South Carolina, Tennessee, Vermont, Virginia, West Virginia	27	53%
Other**	Alabama, Alaska, California, Connecticut, Florida, Indiana, Mississippi, Montana, New Hampshire, New Jersey, North Carolina, Utah, Vermont, Virginia	14	27%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

*Table 42 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 (2), Florida (5), Georgia (2), Hawaii (3), Illinois (5), Indiana (3), Kansas (1), Maryland (7), Massachusetts (2), Michigan (5), Minnesota (4), New Hampshire (1), New Jersey (3), New Mexico (3), New York (5), Ohio (2), Oregon (3), Pennsylvania (3), South Carolina (1), Texas (15), Utah (3), Virginia (5), Washington (1)	105	49%

Response	States (Count of MCEs)	Total	Total Percent
Refer to PRR Program	Arizona (7), Arkansas (3), California (13), Colorado (1), Delaware (2), District of Columbia (4), Florida (11), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (1), 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 (15), Ohio (5), Oregon (8), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	204	94%
Refer to Office of Inspector General (OIG)	Arkansas (2), California (5), District of Columbia (1), Florida (4), Georgia (1), Hawaii (2), Illinois (3), Indiana (3), Kansas (2), Kentucky (1), Louisiana (1), Maryland (6), Michigan (7), Minnesota (1), Mississippi (1), Nebraska (1), Nevada (1), New Jersey (2), New York (6), Ohio (2), Oregon (1), Pennsylvania (3), Rhode Island (1), Texas (5), Utah (2), Virginia (3), Washington (1)	68	31%
Refer to PIU and/or SUR Unit for Audit/ Investigation	Arizona (5), Arkansas (2), California (15), Delaware (2), District of Columbia (1), Florida (10), Georgia (3), Hawaii (6), Illinois (3), Indiana (4), Iowa (1), Kansas (3), Kentucky (3), Louisiana (3), Maryland (7), Massachusetts (3), Michigan (10), Minnesota (4), Mississippi (1), Nebraska (2), Nevada (1), New Hampshire (3), New Jersey (5), New Mexico (2), New York (12), Ohio (3), Oregon (10), Pennsylvania (6), Rhode Island (2), South Carolina (3), Texas (6), Utah (3), Virginia (6), Washington (2)	152	70%
Require Prior Authorization	Arizona (4), Arkansas (1), California (12), Colorado (2), District of Columbia (3), Florida (7), Georgia (1), Hawaii (2), Illinois (5), Indiana (2), Kansas (2), Kentucky (2), Maryland (6), Massachusetts (1), Michigan (6), Minnesota (3), Mississippi (2), Nebraska (1), New Hampshire (1), New Jersey (3), New Mexico (3), New York (3), Ohio (2), Oregon (6), Pennsylvania (2), South Carolina (2), Texas (15), Utah (4), Virginia (6), Washington (2)	111	51%
Other**	Arizona (1), Arkansas (2), California (10), Colorado (1), Delaware (1), District of Columbia (3), Florida (8), Georgia (1), Hawaii (4), Illinois (2), Indiana (2), Iowa (1), Kansas (3), Kentucky (3), Louisiana (3), Maryland (6), Massachusetts (2), Michigan (3), Minnesota (2), Mississippi (1), Nebraska (1), Nevada (1), New Hampshire (1), New Jersey (4), New Mexico (1), New York (3), Ohio (2), Oregon (8), Pennsylvania (3), Rhode Island (2), South Carolina (2), Texas (9), Virginia (4), Washington (1)	101	47%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

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 2021 survey responses show in Tables 43 and 44 that most programs (94% of FFS, and 100% of MCE) have a documented process in place that identifies possible FWA of controlled drugs by prescribers. Those FFS programs without a documented program to detect FWA of controlled substances review claims data through their prior authorization process and other established state review initiatives, including their program integrity unit 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 43 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, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	48	94%
No*	Idaho, Montana, Nevada	3	6%
National Totals		**51**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

Table 44 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 (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (13), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	236	100%
National Totals		**236**	**100%**

State Medicaid programs have a variety of mechanisms for recourse once a prescriber has been detected for potential FWA. FFY 2021 survey responses show potential recourse may initiate multiple actions as seen in Tables 45 and 46. The top action for both the FFS and MCE programs are to alert their PIU and/or SUR Unit for audit/investigation (87% of FFS, and 78% of MCE). Another action initiated by these programs is to alert the appropriate Medical Board (60% of FFS, and 41% of MCE).

*Table 45 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	Arizona, California, Connecticut, Florida, Georgia, Indiana, Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Dakota, Oregon, Texas, Utah, Vermont, West Virginia	18	37%
Refer to PIU and/or SUR Unit for Audit/Investigation	Alabama, Alaska, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, 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 Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming	42	87%
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, South Dakota, Tennessee, Texas, Vermont, West Virginia, Wyoming	29	60%
Other**	Alaska, Arizona, Arkansas, California, Connecticut, Georgia, Illinois, Kansas, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, Vermont, Washington, Wisconsin	25	52%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

*Table 46 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 (3), Florida (2), Georgia (4), Hawaii (5), Illinois (3), Indiana (4), Iowa (1), Kansas (1), Kentucky (1), Louisiana (1), Maryland (5), Massachusetts (1), Michigan (7), Minnesota (4), Nebraska (1), New Hampshire (1), New Jersey (3), New Mexico (2), New York (3), Ohio (2), Oregon (5), Pennsylvania (2), South Carolina (1), Texas (3), Utah (2), Virginia (3), Washington (2)	86	37%
Refer to PIU and/or SUR Unit for Audit/Investigation	Arizona (7), Arkansas (2), California (20), Delaware (2), District of Columbia (4), Florida (11), Georgia (4), Hawaii (4), Illinois (4), Indiana (5), 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 (4), New Mexico (3), New York (13), Ohio (3), Oregon (11), Pennsylvania (6), Rhode Island (3), South Carolina (4), Texas (7), Utah (3), Virginia (6), Washington (4)	182	78%
Refer to the Appropriate Medical Board	Arizona (3), Arkansas (1), California (8), Colorado (1), Delaware (1), District of Columbia (1), Florida (3), Georgia (1), Hawaii (5), Illinois (2), Indiana (4), Kansas (2), Kentucky (2), Louisiana (3), Maryland (4), Massachusetts (2), Michigan (5), Minnesota (5), Mississippi (1), Nebraska (2), Nevada (2), New Hampshire (1), New Jersey (4), New Mexico (1), New York (7), Ohio (3), Oregon (1), Pennsylvania (4), Rhode Island (2), South Carolina (2), Texas (4), Utah (2), Virginia (5), Washington (2)	96	41%
Other**	Arkansas (3), California (15), Colorado (1), Delaware (1), District of Columbia (3), Florida (10), Georgia (2), 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 (3), Oregon (10), Pennsylvania (3), Rhode Island (2), South Carolina (5), Texas (13), Utah (2), Virginia (3), Washington (3)	137	59%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

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 2021 survey responses show that most programs (94% of FFS, and 100% of MCE) have a documented process in place that identifies possible FWA of

controlled drugs by pharmacies as shown in Tables 47 and 48. Those FFS 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, in addition to working collaboratively with their PI and SUR units. The majority of these FFS programs also limit pharmacist overrides which prevent these providers from most forms of fraud or misuses of controlled drugs.

Table 47 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, 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, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming	48	94%
No*	Idaho, Montana, Nevada	3	6%
National Totals		**51**	**100%**

*CMS continues to monitor state specific trends and will follow up with these programs for compliance.

Table 48 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 (26), Colorado (2), Delaware (2), District of Columbia (4), Florida (13), Georgia (4), Hawaii (6), Illinois (6), Indiana (5), Iowa (2), Kansas (3), Kentucky (6), 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 (16), Ohio (5), Oregon (21), Pennsylvania (8), Rhode Island (3), South Carolina (5), Texas (17), Utah (4), Virginia (6), Washington (5)	236	100%
National Totals		**236**	**100%**

State Medicaid programs have a variety of mechanisms for recourse once a pharmacy has been detected for potential fraud, waste or misuse of controlled substances. FFY 2021 survey responses show potential recourse may initiate multiple actions as seen in Tables 49 and 50. The top action for

both the FFS and MCE programs are to alert their PI unit and/or SUR Unit for audit/investigation (87% of FFS, and 81% of MCE). Another action initiated by these programs is to alert the State Board of Pharmacy (55% of FFS, and 44% of MCE).

*Table 49 FFS Actions Process Initiates when Possible FWA of Controlled Drugs by Pharmacy Providers is Detected**

Response	States	Total	Total Percent
Deny Claim	California, Connecticut, Delaware, Florida, Georgia, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Dakota, Oregon, Texas, Vermont, West Virginia	19	40%
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, South Dakota, Tennessee, Texas, Vermont, West Virginia, Wyoming	26	55%
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, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming	41	87%
Other**	Alaska, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New Jersey, North Carolina, Pennsylvania, Tennessee, Texas, Utah, Washington, Wisconsin	22	47%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

*Table 50 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 (5), Arkansas (2), California (12), Colorado (1), District of Columbia (4), Florida (6), Georgia (4), Hawaii (3), Illinois (3), Indiana (4), Iowa (1), Kentucky (5), Louisiana (4), Maryland (3), Massachusetts (3), Michigan (6), Minnesota (5), Nebraska (2), Nevada (1), New Hampshire (2), New Jersey (3), New Mexico (3), New York (4), Ohio (2), Oregon (9), Pennsylvania (1), Rhode Island (1), South Carolina (3), Texas (13), Utah (1), Virginia (2), Washington (3)	121	52%
Refer to PIU and/or SUR Unit for Audit/Investigation	Arizona (7), Arkansas (2), California (22), Delaware (2), District of Columbia (4), Florida (10), Georgia (4), Hawaii (4), Illinois (5), Indiana (5), Iowa (2), Kansas (3), Kentucky (5), Louisiana (5), Maryland (6), Massachusetts (2), Michigan (10), Minnesota (6), Mississippi (2), Nebraska (3), Nevada (3), New Hampshire (3), New Jersey (5), New Mexico (3), New York (11), Ohio (3), Oregon (18), Pennsylvania (7), Rhode Island (3), South Carolina (4), Texas (7), Utah (3), Virginia (6), Washington (3)	188	81%
Refer to the Board of Pharmacy	Arizona (3), California (11), Colorado (1), Delaware (1), District of Columbia (2), Florida (4), Georgia (2), Hawaii (3), Illinois (1), Indiana (3), Kansas (1), Kentucky (5), Louisiana (1), Maryland (3), Massachusetts (2), Michigan (3), Minnesota (5), Mississippi (1), Nebraska (2), Nevada (2), New Hampshire (1), New Jersey (3), New Mexico (3), New York (3), Ohio (3), Oregon (12), Pennsylvania (5), Rhode Island (2), South Carolina (3), Texas (3), Utah (1), Virginia (4), Washington (2)	101	44%
Other**	Arizona (1), Arkansas (2), California (11), Colorado (1), Delaware (2), District of Columbia (2), Florida (9), Georgia (2), Hawaii (5), Illinois (3), Indiana (3), Kansas (2), Kentucky (1), Louisiana (4), Maryland (7), Massachusetts (4), Michigan (8), Minnesota (6), Mississippi (2), Nevada (1), New Hampshire (2), New Jersey (4), New Mexico (2), New York (15), Ohio (4), Oregon (3), Pennsylvania (5), Rhode Island (3), South Carolina (3), Texas (14), Utah (2), Virginia (4), Washington (3)	140	60%

* A program may select multiple answers to this question.
** Access state specific reports at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/drug-utilization-review-annual-report/index.html

5. Managed Care Entity (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 2021 survey responses show in Table 51 that all state Medicaid programs managing MCEs have updated their MCE contracts to comply with section 1004 of the SUPPORT Act. To note: New York, Missouri, North Dakota, Tennessee, West Virginia, and Wisconsin have their covered outpatient drugs carved-out and managed by their FFS program; therefore, an MCE contract amendment is not required.

*Table 51 MCE Contract Compliance for Section 1004 of the SUPPORT**

Response	States	Total	Percent of Total
Yes, Contracts are Updated to Address Each Provision	Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Utah, Virginia, Washington	35	85%
No, Contracts Not Required**	New York***, Missouri, North Dakota, Tennessee, West Virginia, Wisconsin	6	15%
National Totals		**41**	**100%**

* Not all states have MCE programs.
** New York, Missouri, North Dakota, Tennessee, West Virginia and Wisconsin have their covered outpatient drugs carved-out and managed by their FFS program; therefore, an MCE contract amendment is not required.
*** New York, in FFY 2023, this past fiscal year carved-out their covered outpatient drugs from their MCE program and they now are managed by the state's FFS program.

All FFS programs (100%) reported they are monitoring MCE compliance with provisions added by section 1004 of the SUPPORT Act, as shown in Table 52.

*Table 52 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 Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin	41	100%
National Totals		**41**	**100%**

*Note: 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 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 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 and 2021 annual DUR reports, or in the case of Arizona, through a separate Section 1004 report.

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 without recent history of opioid therapy, quantity limits for initial and subsequent fills, therapeutically duplicative fills, and early fills on opioid prescriptions at point of dispensing to determine appropriate opioid use;
- Safety edit limits (as specified by the state) on the maximum daily MME 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 claims 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 Medicaid.gov.

Broadly, the implementation of standards related to these provisions were similar in states' FFS and MCE programs. As seen below in Tables 53 and 54, the majority of programs have already implemented the 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, 2020 and 2021 annual DUR reports for both FFS and MCE programs have been combined to allow for comparison of progress by states.

Table 53 National FFS Improvements in Implementing Selected DUR Safety Reviews

Provision	FFS FFY 2019	FFS FFY 2020	FFS FFY 2021
Process to Identify FWA in Beneficiaries	100%	100%	100%
Opioid/Benzodiazepine Safety and/or Retrospective Edits	86%	98%	98%
Opioid/Antipsychotic Safety and/or Retrospective Edits	82%	92%	96%
Duplicate Opioid Therapy Edits	100%	100%	100%
MME Limits	92%	98%	100%
Program in Place to Manage/Monitor Antipsychotic Use in Children	96%	100%	100%
Contract Updates Between State and their MCEs Addressing Provisions in Section 1004 of the SUPPORT Act	-------	97%	100%

Table 54 National MCE Improvements in Implementing Selected DUR Safety Reviews

Provision	MCE FFY 2019	MCE FFY 2020	MCE FFY 2021
Process to Identify FWA in Beneficiaries	99%	99%	100%
Opioid/Benzodiazepine Safety and/or Retrospective Edits	90%	90%	99%
Opioid/Antipsychotic Safety and/or Retrospective Edits	68%	82%*	100%
Duplicate Opioid Therapy Edits	93%	95%	100%
MME Limits	94%	99%	100%
Program in Place to Manage/Monitor Antipsychotic Use in Children	71%*	77%*	100%

* Following CMS oversight in reaching out to MCE's, it was determined that MCE compliance is much higher than this number appears. MCEs indicated it was because these medications were carved out, restricted to FFS programs or the monitoring and managing was handled through the FFS programs.

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

States Should Upgrade Existing Systems from Manual to Automated Retrospective Claims Review to Increase Compliance and Detect High Doses of Opioids in a Timely and Efficient Manner.

FFY 2021 survey responses show a significant increase, as compared to FFY 2020, within FFS and MCE programs implementing automated retrospective claims review. For FFS programs, 46 states (90%) have an automated retrospective claims DUR review process to monitor opioid prescriptions exceeding state limitations, a 25% increase from FFY 2020, and 208 MCEs (87%) have an automated DUR respective claims review process to monitor opioid prescriptions exceeding state limitations, a 17% increase from FFY 2020. Amendments made by section 1004 of the SUPPORT Act require automated retrospective claims review to detect high doses of opioids and program follow up on prescription trends or issues found on prescriptions that have already been dispensed. While there has been significant improvement, several programs need to continue their progress with implementing automated retrospective claims review.

States Should Further Develop Prospective and Automated Retrospective Claims Review 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.

States Should Also Consider Patient Specific Clinical Circumstances When Performing Reviews.

To enhance state clinical reviews, pursuant to the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain, a multimodal and multidisciplinary approach to pain management attending to the health and well-being of each person is critical. Flexibility to meet the care needs and the clinical circumstance of a specific patient is paramount. Use of electronic health records and web-based technologies has resulted in widespread use on feedback interventions to monitor and operationalize patient specific clinical circumstances.[49] The updated 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain were developed to 1) ensure a clinical tool to improve communication between clinicians and patients and empower them to make informed, person-centered decisions related to pain care together; 2) improve the safety and effectiveness of pain treatment; mitigate pain; improve function and quality of life for patients with pain; and 3) reduce risks associated with opioid pain therapy, including OUD, overdose, and death.[50]

[49] Dowding D, Randell R, Gardner P, Fitzpatrick G, Dykes P, Favela J, et al. Dashboards for improving patient care: review of the literature. Int J Med Inform. 2015;84(2):87–100.
[50] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1

In Operating Their DUR Programs, States Must Include All Required Federal DUR Minimum Standards.

We acknowledge that other initiatives, which many states may be already undertaking, work synergistically with the SUPPORT Act requirements to further help reduce fraud and misuse related to opioids. In addition to codifying the SUPPORT Act requirements, additional minimum DUR standards were implemented at 42 C.F.R. § 456.703(h)(1)(vii) to prevent opioid related overdoses. States should take the necessary steps to ensure compliance with these additional provisions which include prospective safety edits, retrospective claims review automated processes, or a combination of these approaches as determined by the state, to identify when:

1) A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more medications for opioid use disorder (MOUD) or has been diagnosed with an OUD, within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as new cancer diagnosis or entry into hospice care); and
2) A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of any FDA-approved opioid antagonist/reversal agent.

States Should Continue to Strategize to Increase Access to Substance Use Disorder Treatment, such as Medications for Opioid Use Disorder, and Accompanying Behavioral Therapies.

Other policies can be implemented to prevent opioid misuse and overdose, such as working with PDMP's to track prescribing patterns and identify potential misuse and improving access to mental health services for individuals with or at risk for substance use disorders. Ultimately, a multifaceted approach is necessary to effectively prevent and address this public health crisis.

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. Additionally, some states have initiatives beyond what is required and have been engaged in a number of activities related to the opioid crisis for several years.

CMS has begun to reach out to states, including their MCEs to address program deficits. After reviewing FFY 2020 noncompliance for each FFS and MCE program, CMS implemented additional compliance reviews addressing all specific noncompliance findings in state and MCE programs. CMS reached out to 45 states to request additional supplemental data to enable CMS to better identify and work with these states to address deficiencies, misunderstandings and errors, and, if necessary, to address them through corrective action plans for their applicable FFS and/or MCE programs. States were asked to provide explanations for responses indicating noncompliance, actions taken to address the issue, and any dates involved in implementation, and to provide supportive materials. States were expected to correct actual errors and discrepancies and take steps to ensure compliance with all federal regulations. All states responded to CMS's noncompliance correspondence. States either corrected the action immediately or implemented a corrective action plan (CAP) to remediate their noncompliance.

Based on this current report to Congress, CMS will continue to conduct oversight and request corrective actions by states where necessary to come into compliance with federal requirements. 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 Federal Financial Participation (FFP) pursuant to regulations in 42 C.F.R. § 430.35.

Appendix A – Acronyms

AK	Alaska
AL	Alabama
AR	Arkansas
AZ	Arizona
CA	California
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 Review
ED	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
MCE	Managed Care Entity
MCP	Managed Care Program

MD	Maryland
ME	Maine
MI	Michigan
MME	Morphine Milligram Equivalent
MN	Minnesota
MO	Missouri
MOUD	Medications for Opioid Use Disorder
MS	Mississippi
MT	Montana
NC	North Carolina
ND	North Dakota
NE	Nebraska
NH	New Hampshire
NJ	New Jersey
NM	New Mexico
NV	Nevada
NY	New York
OEOCR	Office of Equal Employment Opportunity & Civil Rights
OH	Ohio
OIG	Office of Inspector General
OK	Oklahoma
OR	Oregon
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	Texas
UT	Utah
VA	Virginia
VBP	Value-Based Purchasing

VT	Vermont
WA	Washington
WI	Wisconsin
WV	West Virginia
WY	Wyoming