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Center for Medicaid and CHIP Services

CMCS Informational Bulletin

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SUBJECT: **State Guidance for Implementation of Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (P.L. 115-271)**

This guidance provides information to the states concerning implementation of the new Medicaid Drug Utilization Review (DUR) provisions that were included in Section 1004 of the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act*, also referred to as the *SUPPORT for Patients and Communities Act* or the SUPPORT Act,[1] that are designed to reduce opioid related fraud, misuse and abuse. This document addresses the required implementation of these provisions, including requirements regarding opioid prescription claim reviews at the point of sale (POS) and retrospective reviews; the monitoring and management of antipsychotic medication in children; identification of processes to detect fraud and abuse; and mandatory DUR report updates, as well as requirements for Medicaid Managed Care Organizations (MCOs).[2] This guidance also describes the components of the State Plan Amendment (SPA) that each state must submit by December 31, 2019, in order to comply with these new requirements.

BACKGROUND

Section 1927(g) of the Social Security Act (the Act) requires each state to develop a DUR program targeted, in part, at reducing clinical abuse and misuse of prescription drugs covered under the

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

[2] Although the text of the provisions added by the SUPPORT for Patients and Communities Act (and therefore, this guidance) addresses only MCOs in the managed care context, CMS encourages states to act consistently in imposing the new requirements on all managed care plans with regards to the new responsibilities added by the SUPPORT Act. States may include Prepaid Ambulatory Health Plans (PAHP) and Prepaid Inpatient Health Plans (PIHP) when implementing SUPPORT for Patients and Communities Act updates. CMS intends to consider future rulemaking to implement the requirements of the SUPPORT for Patients and Communities Act discussed in this Bulletin uniformly for all Medicaid managed care plans.

State's Medicaid Program. In implementing these requirements, CMS regulations at 42 CFR 456.703(e)[3,4] require that the state assess drug use information against predetermined standards. Pursuant to 42 CFR 456.703(e), these predetermined standards may be developed directly by the state or its contractor, obtained by the state through commercial vendors of DUR services, obtained by the state from independent organizations, or any combination of these means. Thus, in administering their DUR programs, states have had the flexibility to use standards that may best fit their Medicaid programs and patient populations.

Consistent with section 1927(g)(3)(D) of the Act, CMS requires each State Medicaid Program to submit to CMS an annual report on the operation of its Medicaid DUR fee-for-service (FFS) program, 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. Additionally, § 438.3(s)(4) and (5) require any MCO, PIHP or PAHP that covers covered outpatient drugs to operate a DUR program that complies with section 1927(g) and 42 CFR 456, subpart K and to submit detailed information about its DUR program activities to the state. CMS has compiled state Medicaid DUR annual reports since 1995 and has published them on Medicaid.gov since 2010. As part of its 2019 DUR report for Federal Fiscal Year (FFY) 2018 data, CMS is collecting from states using managed care plans the same DUR data that states report on FFS plans. See 42 C.F.R. § 438.3(s).

The recently-enacted SUPPORT for Patients and Communities Act includes measures to combat the opioid crisis in part by reducing opioid abuse and misuse by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs. There are several Medicaid-related DUR provisions contained within Section 1004 of the SUPPORT for Patients and Communities Act with respect to FFS and MCO pharmacy programs. These provisions establish drug review and utilization standards to supplement existing requirements under Section 1927(g) of the Act, in an effort to reduce opioid-related fraud, abuse and misuse. State implementation of these strategies is required by October 1, 2019, and the Secretary is required to report to Congress starting with information from states' fiscal year 2020 DUR reports.

DISCUSSION

Section 1004 of the SUPPORT for Patients and Communities Act requires states to implement minimum opioid standards within their FFS and managed care programs. Through amendments to Section 1902 of the Act, Section 1004 of the SUPPORT for Patients and Communities Act requires States to implement "safety edits" and "claims review automated process[es]." CMS interprets "safety edits" to refer to a prospective drug review, of the sort defined in section 1927(g)(2)(A) of the Act. These safety edits provide for a prospective DUR review for each prescription identifying potential problems at point of sale (POS) to engage both patients and prescribers about possible opioid abuse and overdose risk at the time of dispensing. The POS

[3] With respect to a managed care organization, prepaid inpatient health plan, or prepaid ambulatory health plan that provides covered outpatient drugs, see 42 CFR 438.3(s)(4) and (5).
[4] 42 CFR 456.703(e). GovInfo, October, 2018. www.govinfo.gov/content/pkg/CFR-2018-title42-vol4/pdf/CFR-2018-title42-vol4-sec456-703.pdf

prospective safety edits provide real-time information prior to the prescription being dispensed to the patients. When a safety edit is triggered, the pharmacist receives an alert and may be required to take further action to resolve the alert before the prescription can be dispensed.[5] A "claims review automated process", which we interpret to refer to a retrospective drug use review of the sort defined in section 1927(g)(2)(B) of the Act, provides for additional examination of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. These retrospective claims reviews give healthcare providers access to information relevant to the items and services they furnish to beneficiaries, and better enable and encourage prescribers and dispensers to minimize opioid risk in their patients, such as avoiding duplicate prescriptions.

CMS encourages states to develop prospective and retrospective DUR reviews that are consistent with medical practice patterns in the state to help meet the health care needs of the Medicaid patient population. In doing so, CMS encourages states to utilize, for example, the 2016 Centers for Disease Control and Prevention (CDC) Guideline for primary care practitioners on prescribing opioids in outpatient settings for chronic pain. Translation and support materials related to the CDC Guideline are also available.

The SUPPORT for Patients and Communities Act requires State Medicaid Programs to have in place the following:

I. Claims Review Requirements

1. **Safety Edits Including Early, Duplicate, and Quantity Limits**: The SUPPORT for Patients and Communities Act requires states to have in place prospective safety edits (as specified by the state) for subsequent fills for opioids and a claims review automated 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 a subsequent fill of opioids in excess of any limitation that may be identified by the state.[6] State-identified limitations should include restrictions on duplicate fills, early fills, and drug quantity limitations.

   The use of multiple opioids is associated with a higher risk of mortality, with mortality risk increasing in direct relation to the number of opioids prescribed concurrently. [7,8] Beneficiaries who receive multiple opioids may lack coordinated care and be at higher risk for opioid overdose.[9]

[5] Prada, Sergio. (2019). Comparing the Medicaid Prospective Drug Utilization Review Program Cost-Savings Methods Used by State Agencies in 2015 and 2016. American Health and Drug Benefits. 12. 7-12.
[6] Section 1902(oo)(1)(A)(i)(I) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[7] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14; 315(22):2415-23.
[8] Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796-801.
[9] Bonnie, Richard J., et al. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. The National Academies Press, 2017.

2. **Maximum Daily Morphine Milligram Equivalents (MME) Safety Edits:** The SUPPORT for Patients and Communities Act requires prospective safety edits (as specified by the state) on maximum MMEs 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 and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of the maximum MME dose limitation identified by the state.[10]

   This safety edit must include a MME threshold amount to meet the statutory requirement, which may assist in identifying patients at potentially high clinical risk who may benefit from closer monitoring and care coordination.[11]

3. **Concurrent Utilization Alerts**: The SUPPORT for Patients and Communities 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.[12]

   Clinically, through the use of retrospective automated claim reviews, concurrent use of opioids and benzodiazepines and/or opioids and antipsychotics, as well as potential complications resulting from other medications concurrently being prescribed with opioids, can be reduced. States are reminded that the requirement for a retrospective automated claims review added by section 1004 of the SUPPORT for Patients and Communities 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.[13]

   - Opioid and Benzodiazepines Concurrent Fill Reviews: In 2016, the Food and Drug Administration (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.[14] This review will alert providers when these drugs have been prescribed concurrently to assist in avoiding and mitigating these associated risks.

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

[11] Staff, News. "CDC Clarifies Opioid Guideline Dosage Thresholds." AAFP Home, 12 Jan. 2018, www.aafp.org/news/health-of-the-public/20180112cdcopioidclarify.html

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

[13] *See* Section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[14] Office of the Commissioner. "Press Announcements - FDA Requires Strong Warnings for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepine Labeling Related to Serious Risks and Death from Combined Use." *U S Food and Drug Administration Home Page*, Office of the Commissioner, www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

- Opioid and Antipsychotic Concurrent Fill Reviews: This alert 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.[15] Patients concurrently prescribed opioid and antipsychotic drugs benefit from increased coordination of care. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of opioid use disorders, and the treatment of pain. This review will encourage coordination of care for patients taking antipsychotic and opioid medication concurrently.

Permitted Exclusions: The above described safety edits and claims review requirements added by section 1004 of the SUPPORT for Patients And Communities Act to subsection 1902(oo) of the Act do not apply with respect to individuals who are receiving hospice or palliative care; receiving treatment for cancer; residents of a long-term care facility, a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.[16] States are expected to develop specifications that will exclude these beneficiaries from all of the opioid review activities outlined above.

When implementing these requirements, CMS encourages states to offer education and training and to provide consistent messaging across all healthcare providers. Education and training of all providers on new opioid provisions will help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner. In order to avoid abrupt opioid withdrawal, prior authorization may be necessary for patients who will need clinical intervention to taper off high doses of opioids to minimize potential symptoms of withdrawal and manage their treatment regimen, while encouraging pain treatment using non-pharmacologic therapies and non-opioid medications, where appropriate. CMS recognizes that patients who are on opioid-based MAT drugs should continue their therapy without disruption. In this regard, states may at their discretion include these drugs in their DUR programs when clinically appropriate.

II. Program to Monitor Antipsychotic Medications by Children

The state must have in place 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).[17] Additionally the state must submit, annually as part of the DUR report under section 1927(g)(3)(D) of the Act, information on activities carried out under this program for individuals not more than the age of 18 years old generally, and children in foster care specifically.

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[15] Center for Drug Evaluation and Research. "Drug Safety and Availability - FDA Drug Safety Communication: FDA Warns about Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires Its Strongest Warning." *U S Food and Drug Administration Home Page*, Center for Drug Evaluation and Research, https://www.fda.gov/downloads/Drugs/DrugSafety/UCM518672.pdf

[16] Section 1902(oo)(3) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

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

III. Fraud and Abuse Identification Requirements

The state 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.[18] Lock in programs[19] and prescription drug monitoring programs[20] play an important role in detecting and preventing opioid-related fraud and abuse. Data analytics can help to determine the extent to which beneficiaries are prescribed high amounts of opioids, identify beneficiaries who may be at serious risk of opioid misuse or overdose, and identify prescribers with questionable opioid prescribing patterns with respect to these beneficiaries.[21]

IV. Managed Care Organization Requirements

Each Medicaid MCO within a state must operate a DUR program that complies with the above specified requirements.[22] Furthermore, states must include these DUR provisions in managed care contracts with MCOs by October 1, 2019**.** CMS encourages states to consider including similar requirements in PIHP and PAHP contracts.

Consistent with section 1902(oo)(1)(A)(ii) of the Act, as added by the SUPPORT for Patients and Communities Act, states also must ensure that their contract with an MCO requires that the contracted entity has in place, for individuals eligible for medical assistance under the State plan (or waiver of the State plan) who are enrolled with the entity, subject to the exemptions for individuals described above, safety edits, claims review automated processes, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements, as described above.

STATE PLAN AMENDMENT (SPA) REQUIREMENTS

Section. 1004 of the SUPPORT for Patients and Communities Act amends section 1902(a) of the Social Security Act to include a new paragraph (85), requiring the State plan to provide that the state is in compliance with the new drug review and utilization requirements set forth in section 1902(oo) of the Act. States are required to submit an amendment to their State plan for CMS review and approval for implementation of these DUR requirements.

Section 1004 of the SUPPORT for Patients and Communities Act also requires all states to implement these requirements by October 1, 2019, and to submit an amendment to their State plan no later than December 31, 2019 in order to describe how the state addresses these provisions in

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[18] Section 1902(oo)(1)(C) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[19] "Pharmacy Lock-In Programs Slated For Expanded Use." OPEN MINDS, www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/
[20] Office of National Drug Control Policy. Prescription Drug Monitoring Program. Prescription Drug Monitoring Program, April, 2011. https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf
[21] Beaton, Thomas. "Preventing Provider Fraud through Health IT, Data Analytics." *HealthPayerIntelligence*, 5 Oct. 2018, https://healthpayerintelligence.com/news/preventing-provider-fraud-through-health-it-data-analytics
[22] H.R. 6. 24 Oct. 2018, www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf . Page 17.

the State plan. States are also expected to give appropriate tribal notification, as required, if applicable.

CMS understands it may take time for states to implement these new strategies. The October 1, 2019 date should give states sufficient time to update systems if not already implemented and to document processes, policies and procedures in order to address these new requirements.

Required Provisions to include in State Plans:

In its State plan submission, each state should provide a description of how it currently supports or is implementing and providing oversight for the new requirements added by Section 1004 of the SUPPORT for Patients and Communities Act in the pharmacy coverage pages (3.1 A (Categorically Needy) and, if applicable, 3.1 B (Medically Needy)). States do not have to list specific numbers or quantities in the SPA for the safety edits (e.g. "100 MME quantity limitation", "do not refill until 75% used", etc.), as these could change from time to time based on considerations including updated clinical guidelines. However, CMS will review each state's safety edits annually upon submission of the state's report required under section 1927(g)(3)(D) of the Act to assess the consistency of the state's safety edits with current medical best practices, for example, as informed by the current CDC opioid guideline. Therefore, CMS requests that each state address the provisions below in the state's SPA submission, in the following order:

1. **Claims Review Limitations:** Describe the opioid related prospective POS safety edits and retrospective reviews the state has in place to address: duplicate fill and early fill alerts, quantity limits, dosage limits, and MME limitations. Additionally, describe concurrent utilization reviews for opioids and benzodiazepines or opioids and antipsychotics. Describe all actions for these reviews that will occur.

2. **Program to Monitor Antipsychotic Medications by Children:** Describe the program the state uses to monitor and manage utilization of antipsychotic medications in children and foster children. Describe the actions that the state will take based on the monitoring undertaken in the program.

3. **Fraud and Abuse Identification:** Describe the state program in place to identify and address fraud and abuse. Describe the actions that the state will take based on the program's findings.

4. **Medicaid Managed Care Organizations Requirements:** Specifications regarding MCOs do not have to appear on the State plan's pharmacy pages, as these pages apply to FFS populations only. However, states should confirm that they have updated their contracts with MCOs to comply with the requirements applicable to MCOs as added by section 1004 of the SUPPORT for Patients and Communities Act. (*Beginning in October 2019, the SUPPORT for Patients and Communities Act requires each MCO also be compliant with utilizing safety edits relating to subsequent fills of opioids, MME limitations, and concurrent prescribing of opioids and benzodiazepines and opioids and antipsychotics. Additionally, as a reminder, the state is required to modify the MCO's contracts regarding these new DUR requirements in order to be in compliance by October 1, 2019.)*

Availability of Enhanced Federal Matching Funds

Under 42 CFR §433.112(a), CMS provides 90 percent enhanced federal financial participation (FFP) for Medicaid technology investments for design, development, installation, or enhancement of mechanized claims processing and information retrieval systems, provided they meet specified requirements. Such expenditures to meet the new requirements of section 1004 of the SUPPORT for Patients and Communities Act may qualify for this enhanced matching rate. States should also review SMD # 18-006, "Leveraging Medicaid Technology to Address the Opioid Crisis," to consider if there are complementary efforts around technology that could assist with states' efforts. Also, states should review section 5042 of the SUPPORT for Patients and Communities Act and consider if there are opportunities to acquire technologies which complement these efforts or further promote interoperability and data sharing. These can all be funded through an approved Advanced Planning Document (APD) provided the requirements of 42 CFR part 433, subpart C and all other applicable requirements are met.[23]

CMS looks forward to continuing to work together with the states to implement DUR provisions within Section 1004 of the SUPPORT for Patients and Communities Act. Questions can be submitted through the CMS DUR resource mailbox at CMSDUR@cms.hhs.gov.

[23] Medicaid.gov. https://www.medicaid.gov/federal-policy-guidance/downloads/smd18005.pdf