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A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019

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PROVIDER TYPES AFFECTED

This MLN Matters Special Edition Article is intended for physicians and other prescribers who prescribe opioid medications to patients with a Medicare Part D prescription drug benefit.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) understands the magnitude of our nation's opioid epidemic and its impact on communities. Opioid medications are effective at treating certain types of pain, but have serious risks such as increasing tolerance, addiction, overdose, and death. Given the scope of the crisis, CMS published a roadmap in June 2018 outlining our efforts to address this issue. The roadmap details our three-pronged approach to combating the opioid epidemic going forward: 1) **prevention** of new cases of opioid use disorder (OUD); 2) **treatment** of patients who have already become dependent on or addicted to opioids; and 3) utilization of **data** from across the country to better target prevention and treatment activities. Through our 2019 Medicare Part D opioid overutilization initiatives, CMS seeks to strengthen and broaden our partnership with providers to address the opioid crisis.

WHAT PROVIDERS NEED TO KNOW

CMS finalized new policies for Medicare drug plans to follow starting on January 1, 2019. These policies involve further partnership with providers and prescription drug plans. Providers are in the best position to identify and manage potential opioid overutilization in the Medicare Part D population. Medicare prescription drug plans can assist providers by alerting them about unusual utilization patterns in prescription claims.

The new policies include improved safety alerts when opioid prescriptions are dispensed at the pharmacy, and drug management programs to better coordinate care when chronic high-risk opioid use is present.

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Real-Time Safety Alerts at the Time of Dispensing

Part D plans commonly implement safety alerts (pharmacy claim edits) for pharmacists to review at the time of dispensing the medication to prevent the unsafe utilization of drugs. These alerts are typically for drug-drug interactions, therapeutic duplication, or a potentially incorrect drug dosage (for example, doses above the maximum dosing in the Food and Drug Administration (FDA)-approved labeling).

Specific to prescription opioids, beginning in January 2019, Medicare Part D plans will employ the following new safety alerts at the pharmacy:

- **7 day supply limit for opioid naïve patients**: Part D plans are expected to implement a hard safety edit to limit initial dispensing to a supply of 7 days or less. A hard safety edit stops the pharmacy from processing a prescription until an override is entered or authorized by the plan. This policy will affect Medicare patients who have not filled an opioid prescription recently (for example, within the past 60 days) when they present a prescription at the pharmacy for an opioid pain medication for greater than a 7 day supply.

  CMS' goal with this policy is to reduce the potential for chronic opioid misuse through closer management of opioid naïve patients. Clinical evidence cited by the Centers for Disease Control and Prevention (CDC) 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.[1] Recommendation 6 of the CDC Guideline states that opioids prescribed for acute pain should be limited to 3 days or fewer, and that more than a 7 day supply is rarely necessary. Limiting the amount dispensed with the first opioid prescription may reduce the risk of patients developing a future dependency or overuse of these drugs.

  A pharmacist can dispense partial quantities of an opioid prescription consistent with state and federal regulations. However, if a prescriber believes that an opioid naïve patient will need more than a 7 day supply initially, the provider can proactively request a coverage determination on behalf of the patient attesting to the medical need for a supply greater than 7 days. Additionally, if a provider assesses upon re-evaluation that a patient will need additional opioid therapy, subsequent prescriptions will not be subject to the 7 day supply limit, as the patient will no longer be considered opioid naive.

- **Opioid care coordination alert**: This policy will affect Medicare patients when they present an opioid prescription at the pharmacy and their cumulative morphine milligram equivalent (MME) per day across all of their opioid prescription(s) reaches or exceeds 90 MME. Regardless of whether individual prescription(s) are written below the threshold, the alert will be triggered by the fill of the prescription that reaches the cumulative threshold of 90 MME or greater. It is the prescriber who writes the prescription that triggers the alert who will be contacted by the pharmacy even if that prescription itself is below the 90 MME threshold.

[1] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

This safety alert includes a 90 MME threshold for identifying potentially high risk patients who may benefit from closer monitoring and care coordination. 90 MME is cited in the CDC Guideline as the level above which prescribers should generally avoid. This is not a prescribing limit. In reviewing the alert, the pharmacist may need to consult with the prescriber to confirm medical need for the higher MME. The pharmacist can then indicate that the prescriber was consulted so the prescription claim can pay.

The care coordination safety alert is a proactive step to give prescribers more information, and if warranted, to encourage prescribers to emphasize opioid overdose risk and prevention with their patients, especially if the patient is receiving prescription opioids from multiple prescribers or pharmacies.

Drug Management Programs

The Comprehensive Addiction and Recovery Act of 2016 included provisions that give Part D plans important new tools to use in 2019 to address opioid overutilization. To implement this law, CMS adopted a regulation so that Part D plans may implement a drug management program that limits access to certain controlled substances that have been determined to be "frequently abused drugs" for patients who are considered to be at-risk for prescription drug abuse. Limiting access means that the patient might only be able to obtain these medications from a specified prescriber or pharmacy. For 2019, CMS has identified opioids and benzodiazepines as frequently abused drugs.

The goal of drug management programs is better care coordination for safer use. Potential at-risk patients are identified by their opioid use which involve multiple doctors and pharmacies. Therefore, these are patients who could potentially abuse or misuse prescription drugs. One of the key components of a drug management program is prescriber involvement in case management.

If a provider prescribes opioids or benzodiazepines for a patient who is identified as a potential at-risk patient, the Part D plan will contact the provider to review the patient's total utilization pattern of frequently abused drugs. The plan will ask the prescriber:

- Are the prescription opioid medications appropriate, medically necessary, and safe for the patient's medical condition and treatment;
- Is the patient at-risk for misusing or abusing opioids and benzodiazepines; and
- Would one of the drug management program tools help the prescriber better manage their patient's prescription drug use?

The potential tools include:

1. **Patient-specific point of sale (POS) claim edit**: This is an individualized POS edit for the specific patient. It limits the amount of frequently abused drugs that may be dispensed to the patient. This limitation could be a restriction on all frequently abused drugs or limitations to specific drugs and/or specific amounts, which the plan will

determine on a case by case basis as a result of their review. The plan will make every effort to obtain a prescriber's agreement for this limitation, but is authorized to implement it if no prescriber responds to the plan's attempts at contacting the prescriber through case management.

2. **Pharmacy limitation (also known as "pharmacy lock-in")**: This limitation will require the patient to obtain prescriptions for frequently abused drugs at a certain pharmacy(ies). Before implementing this limitation, the plan must verify with a prescriber that the patient is at-risk, but is not required to obtain a prescriber's agreement to the limitation. Patients can choose which pharmacy(ies) they prefer to use and may update those preferences as needed.
3. **Prescriber limitation (also known as "prescriber lock-in")**: A limitation that will require the patient to obtain their prescriptions for frequently abused drugs from a certain prescriber(s). The plan must obtain the prescriber's agreement to be a prescriber and confirm the prescriber's selection for this limitation. Patients can choose which prescribers(s) they prefer to use and may update those preferences as needed.

After the Medicare drug plan conducts case management with prescribers, and before the plan implements a tool, the plan will notify the patient in writing that coverage of opioid and/or benzodiazepine medication(s) will be limited, or if the patient must obtain these prescriptions from certain prescriber(s) or pharmacy(ies). Plans are required to make reasonable efforts to send the prescriber a copy of the notice sent to the patient. The prescriber and patient will have the opportunity to provide a response to this written notice and the requested information to the Part D plan within 30 days.

After this 30 day time period, if the Part D plan determines based on its review that the patient is at-risk and implements a limitation, it must send the patient a second written notice confirming the specific limitation and its duration. The initial limitation period could be for a maximum of 12 months and extend to an additional 12 months. Alternatively, if the plan determines that the patient is not at-risk, it must send a written notice confirming that a coverage limitation will not be implemented after all.

Provider Action

Why are there new Medicare Part D opioid overutilization policies for 2019?

The opioid epidemic is a top priority at CMS. We are working with multiple stakeholders to find ways to reduce the negative impacts of the opioid epidemic on the general public. These new Medicare Part D opioid overutilization policies encourage interdisciplinary collaboration as well as care coordination among Part D plans, pharmacies, prescribers, and patients in improving opioid utilization management, preventing opioid misuse, reducing serious adverse risks, and promoting safer prescribing practices.

Are any patients exempt from the new opioid safety alert and drug management program policies?

CMS recognizes that a "one size fits all" approach does not take into account different

circumstances related to opioid use. All of the approaches are tailored to address the distinct populations of Medicare Part D prescription opioid users. Residents of long-term care facilities, those in hospice care, patients receiving palliative or end-of-life care, and patients being treated for active cancer-related pain are exempt from these interventions.

CMS would like to remind providers that access to medication-assisted treatment (MAT) such as buprenorphine will not be impacted by these initiatives. CMS recognizes the importance for patients who are on MAT drugs to continue therapy without disruption.

Will the pharmacy call the provider every time a patient has an opioid prescription that reaches or exceeds 90 MME for the care coordination safety alert?

No. The provider will be initially contacted by the pharmacist if a patient presents to the pharmacy with a prescription that reaches a cumulative threshold of 90 MME or greater across all of the patient's opioid prescriptions and triggers the alert at the pharmacy. Once a pharmacist consults with a prescriber on a patient's prescription for a plan year, the pharmacist does not have to consult with the prescriber on every opioid prescription written for the same patient after that unless the plan implements further restrictions. For example, Part D plans also have the option to set an additional alert that stops a prescription from being filled at the pharmacy if the opioid threshold reaches 200 MME or greater and may additionally include prescriber and pharmacy counts.

Why is the provider contacted by the pharmacy for only certain patients?

Prescribers may be contacted by the pharmacy for only some Medicare patients but not for all, depending on which Part D plan the patient is enrolled in because the plan sponsor has the flexibility to modify the care coordination safety alert parameters. A plan sponsor may customize this alert so that it would be triggered based on the patient's total number of opioid prescribers and/or opioid dispensing pharmacies specified in the care coordination safety alert.

What is the provider's role for a patient in the Medicare Part D drug management program?

If a patient is identified as being potentially at-risk for prescription drug abuse by his or her Part D plan, the plan will initiate case management. As part of the case management process, the Part D plan will contact the patient's providers who prescribed opioids and benzodiazepines for clinical information needed to make a decision on whether a patient is at-risk and should have his or her access to frequently abused drugs limited through one of the available tools. The provider's role is to respond to the Part D plan if and when they contact the provider for further information about a patient's prescription use history.

How can the provider help his or her patient if their prescription triggers an opioid safety alert, such as the 7 day supply alert for opioid naïve patients or the care coordination alert?

If one of these opioid safety alerts is triggered and the prescription cannot be filled as written or cannot be resolved at the pharmacy, the pharmacist should provide a written copy of the standardized CMS pharmacy notice, "Medicare Prescription Drug Coverage and Your Rights" to

the patient.

The patient, the patient's representative, or the physician or other prescriber, on the patient's behalf, has the right to request a coverage determination for a drug(s) subject to the alert, including the right to request an expedited or standard coverage determination in advance of prescribing an opioid (for example, after a surgical procedure).

The timeframe for an expedited coverage determination request applies when the prescriber indicates, or the plan decides, that applying the standard timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. CMS generally expects coverage determinations related to any opioid safety alerts to meet the criteria for expedited review. If the request meets the criteria for an expedited review by the plan, the plan must make its decision and notify the patient as expeditiously as their health condition requires, but no later than 24 hours after receipt of the request.

Would the patient or the provider be able to request an appeal if the Part D plan determines a patient to be an at-risk patient under the drug management program?

A patient, a patient's representative, or the physician or other prescriber may request an appeal within 60 calendar days from the date of the second written notice, notifying the patient that he or she has been identified as an at-risk patient. At-risk determinations are subject to the existing Part D benefit appeals process. If the patient or the physician or other prescriber disagrees with the at-risk determination, the patient, the patient's representative, or the physician or other prescriber may request a redetermination and a change to the limitations can be made as a result of an appeal. The party may request an expedited or standard redetermination under 42 CFR § 423.580. The standard timeframe for notification of a redetermination made by the plan is as expeditiously as the patient's health condition requires, but no later than 7 days from receipt of the request. The plan must notify the patient of its decision on an expedited redetermination as expeditiously as the patient's health condition requires, but no later than 72 hours from receipt of the request. In addition to the right to appeal an at-risk determination, the patient has the right to request a coverage determination, as explained in the previous response.

How else can a provider prepare for the new 2019 Medicare Part D overutilization policies?

Many patients have difficulty understanding the risk of using opioids and may underestimate their chances of overdosing. Providers may want to discuss the risks of an accidental overdose or having an adverse reaction to opioids since these risks are not necessarily associated with misuse.

As the new opioid safety alerts are implemented in 2019, on-going communication among the pharmacist, the Part D plan, and the prescriber will be critical. Physicians and other prescribers can protect their patients' access to medically necessary drugs by responding to pharmacists' or plan sponsors' telephone calls or case management notices. Providers will also want to initiate coverage determinations or exceptions, when clinically appropriate. To avoid a prescription being rejected at the pharmacy, prescribers may proactively request a coverage determination in advance of prescribing an opioid prescription if the prescriber has assessed that the patient

will need the full quantity written (for example a plan may not be aware a patient is exempt based on a new exclusion such as cancer). Additionally, to resolve opioid safety alerts expeditiously and avoid withdrawal or disruption of therapy, CMS encourages prescribers to respond to pharmacists' outreach in a timely manner and give the appropriate training to on-call prescribers when necessary.

ADDITIONAL INFORMATION

- For additional information regarding the final 2019 Medicare Parts C&D Call Letter, please visit https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.
- For additional information regarding the 2019 Part C and D Regulation (CMS-4182-F), please visit https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.
- For information on Medicare Prescription Drug Appeals and Grievances, visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminationsandExceptions.html.
- For additional information regarding the CDC Guideline for Prescribing Opioids for Chronic Pain, please visit https://www.cdc.gov/drugoverdose/prescribing/guideline.html.
- To review the CMS Roadmap to Address the Opioid Epidemic, please visit https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.
- To review the Medicare Prescription Drug Coverage and Your Rights, please visit https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/yourrightsfactsheet.pdf.

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