



New Medicare Part D Prescription Opioid Policies for 2019



*Information for
Prescribers*

Background

- CMS understands the magnitude of the 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, development of opioid use disorder, and overdose.
- CMS published a roadmap with a three-pronged approach to address this issue:
 - **Prevention** of new cases of opioid use disorder (OUD).
 - **Treatment** of patients who have already become dependent on or addicted to opioids.
 - Utilization of **data** from across the country to better target prevention and treatment activities.

Background

- 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.

Opioid Policy Summary

- The new policies include (1) improved **safety edits** when opioid prescriptions are dispensed at the pharmacy and (2) **drug management programs** for patients determined to be at-risk for misuse or abuse of opioids or other frequently abused drugs.
- CMS tailored its approach to help distinct populations of Medicare Part D opioid users:
 - New opioid users (opioid naïve),
 - Chronic opioid users,
 - Users with potentially problematic concurrent medication use, and
 - High risk opioid users.

Opioid Policy Exclusions

- The policies are not “one size fits all”.
- 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.
- These policies also should not impact patients’ access to medication-assisted treatment (MAT), such as buprenorphine.

Myth #1

MYTH:

“Medicare is requiring that all patients fill opioid prescriptions for a 7 days supply at a time.”

FACT:

- A fill for a prescription opioid will be limited to a 7 days supply only for Medicare Part D patients who have not filled an opioid prescription recently (such as within the past 60 days).
- This does not apply to patients already taking opioids.

Myth #2

MYTH

“Medicare is forcing all patients to taper their prescription opioids below a certain amount.”

FACT:

- Decisions to taper or stop prescription opioids must be carefully considered and are individualized between the patient and prescriber.
- Tapering opioids can be especially challenging in established patients who have been on high dosages of opioids for many years.
- Policies seek to address opioid overuse without negative impact on patient-doctor relationship.

Myth #3

MYTH:

“There is nothing I can do to help my patients who need more opioids.”

FACT:

- If patient is subject to an opioid safety edit at the pharmacy, and the pharmacy can't fill the prescription as written, the prescriber can contact the plan to ask for a coverage determination on their behalf.
- Prescriber can also request an expedited or standard coverage determination in advance of prescribing an opioid.
- Prescriber only needs to attest to the plan that the cumulative level or days supply is the intended and medically necessary amount.

1. Opioid Safety Alerts

- CMS expects Medicare Part D drug plans to implement the following safety alerts (pharmacy claim edits) for pharmacists to review when an opioid prescription is filled at the pharmacy:
 - Seven-day supply limit for initial opioid fills for opioid naïve patients (hard edit),
 - Care coordination edit at 90 morphine milligram equivalents (MME) (soft edit with pharmacist-prescriber consultation),
 - Concurrent opioid and benzodiazepine use (soft edit),
 - Duplicative long-acting (LA) opioid therapy (soft edit), and
 - Optional safety alert at 200 MME or more (hard edit).

Opioid Naïve Seven-day Supply Limit

- Medicare Part D patients who have not filled an opioid prescription recently (such as within the past 60 days) will be limited to a supply of 7 days or less.
- *This alert should not impact patients who already take opioids.*
- Pharmacists can dispense partial quantities of an opioid prescription consistent with state and federal regulations.
- Limiting the amount dispensed with the first opioid prescription may reduce the risk of patients developing a future dependency or overuse of these drugs.

Opioid Naïve Seven-day Supply Limit

Prescriber Actions

- When the alert is triggered, the opioid naïve patient may receive up to a 7 days supply.
- If a prescriber assesses upon re-evaluation that a patient will need additional opioid therapy, subsequent prescriptions will not be subject to the 7 days supply limit, as the patient will no longer be considered opioid naïve.

Opioid Naïve Seven-day Supply Limit

Prescriber Actions

- If patient needs the full days supply initially, the patient or prescriber on the patient's behalf has the right to request a coverage determination, including the right to request an expedited or standard coverage determination in advance of prescribing an opioid (for example, for a surgical procedure).
- Prescriber only needs to attest to plan that the days supply is the intended and medically necessary amount.

Care Coordination Alert

- This alert will be triggered at the pharmacy when a Medicare Part D patient presents 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.
- Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.
- The pharmacist will consult with the prescriber to resolve the alert. This may be an opportunity for pharmacists to inform the prescriber of other opioid prescribers or increasing level (MME) of opioids.

Care Coordination Alert

Prescriber Actions

- *This alert is not a prescribing limit.* Decisions to taper or discontinue prescription opioids are individualized and agreed upon between the patient and prescriber.
- 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.
- CMS encourages prescribers to respond to pharmacists' outreach in a timely manner.

Care Coordination Alert

Prescriber Actions

- Once a pharmacist consults with a prescriber on a patient's prescription for a plan year, the prescriber will not be contacted on every opioid prescription written for the same patient after that unless the plan implements further restrictions.
- If the prescription cannot be filled at the pharmacy, the patient or the prescriber on the patient's behalf has the right to request a coverage determination for a drug(s), including the right to request an expedited or standard coverage determination in advance of prescribing an opioid.

Additional Opioid Safety Alerts

- Other soft edits will trigger when the patient is taking opioids and benzodiazepines concurrently or is taking multiple duplicate long-acting opioids.
- The pharmacist will conduct additional safety reviews to determine if the patient's opioid use is safe and clinically appropriate. The prescriber may be contacted.

Optional Safety Alert at 200 MME or Higher

- Some plans may implement a hard safety alert when a patient's cumulative opioid daily dosage reaches 200 MME or more.
- Some plans use this alert only when the patient uses multiple opioid prescribers and/or opioid dispensing pharmacies.
- ***This is not a prescribing limit.*** Decisions to taper or discontinue prescription opioids are between the patient and prescriber.

Optional Safety Alert at 200 MME or Higher

Prescriber Actions

- On the patient's behalf, the physician or other prescriber has the right to request a coverage determination for the drug(s), including the right to request an expedited or standard coverage determination in advance of prescribing an opioid.
- In the absence of other submitted and approved utilization management requirements, the plan should allow the patient to access his/her medication(s) once the prescriber(s) attests that the identified cumulative MME level is the intended and medically necessary amount for the patient.

Coverage Determination Request Reminders

- In the case of one of the opioid safety alerts, if the prescription cannot be filled as written, the pharmacist should provide the patient with a written copy of the standardized CMS pharmacy notice, “Medicare Prescription Drug Coverage and Your Rights.”
- On the patient’s behalf, the physician or other prescriber 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, for 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.

2. Drug Management Programs

- Medicare 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” (FADs) for patients who are considered to be at-risk for prescription drug abuse.
- For 2019, CMS has identified opioids and benzodiazepines as FADs.
- Potential at-risk patients are identified by their opioid use which involve multiple doctors and pharmacies.
- The goal of drug management programs is better care coordination for safer use.

Case Management Process

- The plan will make clinical contact with the potential at-risk patient's prescriber and conduct case management.
- 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?
- At this point, prescribers may also help plans determine whether a patient falls into one of the exemptions, since the plan may not always have this information.

Drug Management Program Tools

- Limiting access (through “coverage limitation” tools) means:
 - The patient might only be able to obtain these medications from a specified prescriber or pharmacy, or
 - An individualized pharmacy point of sale claim alert may be put in place which limits the amount of frequently abused drugs that may be dispensed to the patient.
- The coverage limitation tools may be put in place for 12 months and extended for an additional 12 months (total of 24 months).

Drug Management Program Tools

- **Patient-specific point of sale (POS) claim edits** are individualized for the specific patient and limit the amount of FADs that the plan will cover for the patient.
 - Could be a restriction on all FADs or limitations to specific drugs and/or specific amounts (case-by-case basis).
 - 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.

Drug Management Program Tools

- **Pharmacy limitation** requires 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.

Drug Management Program Tools

- **Prescriber limitation** requires the patient to obtain their prescriptions for frequently abused drugs from 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.

Initial Notification

- 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 letter 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.

Second Notification

- After the 30-day time period has passed, the Medicare drug plan will determine, based on its review of the information it has, including new information from the patient or prescriber, whether to proceed with the drug management program for the patient.
- If it does, the plan must send the patient a second letter confirming that the patient has been determined to be **at-risk** and the specific tools that will be used and the duration of the drug management program.
- Alternatively, if the plan determines that the patient is **not at-risk**, it must send a written notice confirming that a drug management program will not be established for the patient after all.

Appealing an At-risk Determination

- 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 using the plan's usual 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 an appeal and a change to the limitations can be made as a result of an appeal.
- The plan must respond to the appeal request within seven days for standard requests and within 72 hours for expedited requests.
- In addition to the right to appeal an at-risk determination, the patient has the right to request a coverage determination as explained previously.

Preparing for New 2019 Opioid Policies

- Providers may want to discuss the risks of an accidental overdose or having an adverse reaction to opioids with patients 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 Medicare drug plan, and the prescriber will be critical.
- Actions that prescribers may want to consider taking include:
 - Responding to pharmacists' or plan sponsors' telephone calls or case management notices in a timely manner.
 - Initiating coverage determinations when clinically appropriate and, where possible, proactively in advance of prescribing an opioid if the prescriber has assessed that the patient will need the full quantity written (e.g. a plan may not be aware a patient is exempt based on a new exclusion such as cancer).
 - Give appropriate training to on-call prescribers when necessary.

Additional Resources

- Medicare Prescription Drug Coverage and Your Rights Fact Sheet at: <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/yourrightsfactsheet.pdf>
- Information regarding the CDC Guideline for Prescribing Opioids for Chronic Pain, please visit <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.
- A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019 at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE18016.pdf>
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits or Medicare Part D Drug Management Programs at: <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>
- To review the notice of appeal rights that patients receive from pharmacies about their appeal rights when a prescription is not filled as written, please visit <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/yourrightsfactsheet.pdf>

Academic Resources

- For additional information on the risks of diversion and misuse when the amount of opioid prescribed is in excess of the amount needed to treat an acute event, see Centers for Disease Control and Prevention (CDC). Adult use of prescription opioid pain medications—Utah, 2008. *MMWR Morb Mortal Wkly Rep.* 2010;59(6):153-157.
- For additional information regarding the benefit of limiting the initial amount of prescription opioids dispensed in order to reduce the risk that patients develop an affinity for these drugs and transition to chronic use or misuse, see Bateman, BT, Choudhry, NK. Limiting the Duration of Opioid Prescriptions: Balancing Excessive Prescribing and the Effective Treatment of Pain. *JAMA Intern Med.* 2016;176(5):583-584. doi:10.1001/jamainternmed.2016.0544
- For additional information on the association of use of long-acting opioids and the number of opioid prescriptions with a higher risk of mortality, see 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. See also Baumlatt 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.
- For additional information on the risks (in terms of both diversion and the opportunity for self-medication and dose escalation) associated with prescriptions for multiple opioids and/or multiple strengths, see Manchikanti, L, Helm II, S, Fellows, B, Janata, J.W, Pampati,V., Grider, J.S, Boswell, M.V. Opioid Epidemic in the United States. *Pain Physician* 2012; 15:ES9-ES38.