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# A Prescriber's Guide to Medicare Prescription Drug (Part D) Opioid Policies


## What's Changed?

Added information on the expansion of the exempted patient definition as of January 1, 2025 (page 5).

Substantive content changes are in dark red.



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Medicare Part D opioid policies encourage collaboration among Part D plans, prescribers, and pharmacies to:

- Manage opioid use
- Prevent misuse
- Reduce serious adverse risks
- Promote safe prescribing practices

Prescribers like you play a vital role in identifying and managing potential opioid overuse in the Part D population. Medicare drug plans can help by alerting you about unusual patterns in prescription claims.

Our Medicare Part D opioid policies include:

- Real-time safety alerts when pharmacies dispense opioid prescriptions
- Drug management programs (DMPs) to identify and manage high-risk opioid use

## Real-Time Safety Alerts at the Pharmacy

Part D plans use safety alerts, or pharmacy claim edits, to help prevent unsafe drug use. Pharmacists review the safety alerts when they dispense the medication. Safety alerts are typically for:

- Drug interactions
- Therapeutic duplication
- Potentially incorrect drug dosage

There are 4 different opioid-specific safety alerts and actions you can take to help your patients:

**1. Seven-day supply limit for opioid naïve patients**

- This alert limits initial opioid fills for Part D patients who haven't filled an opioid prescription recently, such as within the past 60 days, to a supply of 7 days or less.
- This alert shouldn't affect patients who already take opioids. It may occur for those who enroll in a new plan that doesn't know their current prescription information.
- Pharmacists can dispense partial quantities of an opioid prescription consistent with state and federal regulations.
- Once the patient fills an initial opioid prescription, including a partial fill up to a 7-day supply, additional prescriptions filled within the plan's look back window aren't subject to the 7-day limit.
- Consider requesting a coverage determination before prescribing an opioid if the patient will need more than a 7-day supply and hasn't filled an opioid prescription recently.

**2. Opioid care coordination alert at 90 morphine milligram equivalent (MME)**

- This alert triggers when a patient's cumulative MME per day for **all** their opioid prescriptions reach or exceed 90 MME.
- The pharmacist may call to confirm the dose and medical need for the prescription that prompts the alert, even if it's below 90 MME.
- This consultation usually occurs once per plan year. Your staff or a covering physician may confirm medical necessity on your behalf. Once confirmed, the pharmacist can then document the consultation so the claim can pay.
- Some plans use this alert only when the patient also uses multiple opioid prescribers or pharmacies. The pharmacist may tell you if a patient's MME is increasing or if there are other opioid prescribers.

**3. Concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy**

- This alert triggers when a patient fills multiple long-acting opioids or opioids and benzodiazepines
- The pharmacist may conduct additional safety reviews and may contact you
- The pharmacist can enter an override code that allows the claim to pay

**4. Optional safety alert at 200 MME or more**

- Plans may use this alert when a patient's cumulative opioid daily dosage reaches or exceeds 200 MME with or without multiple opioid prescribers or pharmacies
- This alert stops the pharmacy from processing the prescription under Part D unless it's overridden due to an exemption, or the plan authorizes coverage through a coverage determination or appeal

Safety alerts are NOT prescribing limits. You and your patient make decisions to either taper or discontinue prescription opioids. If a prescription triggers an opioid safety alert that shouldn't apply, the pharmacist can enter or request an override that allows the claim to pay per the exemptions below.

## Coverage Determinations

If an opioid safety alert can't be resolved at the point-of-sale (POS), the pharmacist will provide the patient with a written copy of the standardized CMS pharmacy notice, Medicare Prescription Drug Coverage and Your Rights.

The patient, their representative, or their prescriber has the right to request a standard or expedited coverage determination from the plan at any time, including before the pharmacy gets the prescription.

Coverage determination requests meet the criteria for expedited review if you show, or the plan decides, that applying the standard timeframe may seriously jeopardize the patient's life, health, or ability to regain maximum function.

Timeframes are as follows:

- Standard: no later than 72 hours after the plan gets the request
- Expedited: no later than 24 hours after the plan gets the request

## Drug Management Programs (DMPs)

All Part D plans have a DMP that limits access to controlled substances that are frequently abused drugs, currently defined as opioids and benzodiazepines, for patients at risk for prescription drug abuse or misuse. The goal of DMPs is better care coordination for safer use of these drugs.

CMS or Part D plans identify potential at-risk patients based on opioid use involving multiple prescribers and pharmacies or a history of opioid-related overdose. Plans must review all potential at-risk patients and must ask your opinion before implementing a limitation. Your input is a key component of DMPs. By responding to the plan quickly, you can make sure your patients can receive the care they need while reducing the need for appeals.

During case management, the plan may ask you:

- Are the prescribed 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 or benzodiazepines?
- Would one of the DMP coverage limitations help you better manage your patient's prescription drug use?

There are 3 coverage limitations available under a DMP:

- **Patient-specific POS claim alert:** restricts all frequently abused drugs or sets limitations to specific drugs or specific amounts. The plan will attempt to get your agreement for this limitation but can implement it if you don't respond.
- **Pharmacy limitation:** requires the patient to get prescriptions for frequently abused drugs at certain pharmacies. The plan will attempt to get your agreement for this limitation but can implement it if you don't respond. Patients can generally choose, and update, their preferred pharmacies.
- **Prescriber limitation:** requires the patient to get their prescriptions from certain prescribers. Patients can generally choose, and update, their preferred prescribers. The plan can't implement this limitation unless the selected prescribers agree.

After conducting case management, the plan will decide whether the patient is at risk and whether to implement a coverage limitation. If the plan determines the patient is at risk, it will notify the patient in writing that it intends to implement a coverage limitation.

The patient, their representative, or you on the patient's behalf may respond to the notice. After 30 days, the plan will send the patient a second notice confirming the coverage limitation and its duration. The plan can put coverage limitations in place for 1 year and extend them for another year for a total of 2 years. If the plan

determines the patient isn't at risk, it will send a notice confirming they won't implement a coverage limitation. Plans must make reasonable efforts to send copies of all DMP notices to the involved prescribers.

### Appealing an At-risk Determination

A patient, their representative, or you on the patient's behalf may request an expedited or standard appeal ("redetermination") of an at-risk determination, as well as any coverage determination, made under a DMP. An appeal request must be made within 60 calendar days from the date of the second written notice.

Redetermination timeframes are as follows:

- Standard: no later than 7 days after the plan gets the request
- Expedited: no later than 72 hours after the plan gets the request

## Exemptions

Patients in long-term care facilities, those getting hospice, palliative, or end-of-life care, those with sickle cell disease, or those being treated for cancer-related pain are exempt from opioid safety alerts and DMPs.

These policies don't impact access to medication-assisted treatment (MAT) such as buprenorphine.

Starting on January 1, 2025, we're expanding the definition of an exempted patient being treated for cancer-related pain to include:

- Patients undergoing active cancer treatment
- Cancer survivors:
    - With chronic pain who've completed cancer treatment
    - In clinical remission
    - Under cancer surveillance only

## How You Can Help

Ongoing communication among the pharmacist, the plan, and the prescriber is critical. You can protect your patients' access to medically necessary prescription drug therapy by:

- Responding to calls and case management notices as soon as possible
- Educating on-call prescribers and office staff
- Requesting a coverage determination before prescribing

Many patients may not understand the risk of using opioids and may underestimate their chances of overdosing. You may want to consider co-prescribing naloxone, and talk with your patient about:

- The risks of an accidental overdose
- Whether opioids are the best treatment
- If there are other options to help manage their pain with less risk

You should also consider assessing your patients' behavioral health needs as part of overall pain management, including screening for opioid use disorder or the need for MAT.

## Prescriber Resources

- CDC's Opioid Prescribing Guideline
- HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics
- HHS Opioids Webpage
- Improving Drug Utilization Review Controls in Part D
- MLN Matters® Article SE19011
- Opioid Treatment Programs (OTP)
- Resources to Reduce Opioid Misuse
- SBIRT Services

## Patient Resources

- Pain Management Insurance Coverage
- Safer Use of Opioid Pain Medication

## Other Resources

- Improving Drug Utilization Review Controls in Part D
- 2019 Parts C & D Final Rule
- 2022 Parts C & D Final Rule
- 2025 Parts C & D Final Rule