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

• Manage opioid utilization
• Prevent misuse
• Reduce serious adverse risks
• Promote safer prescribing practices

Prescribers like you play a vital role in identifying and managing potential opioid overutilization 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 implement safety alerts (pharmacy claim edits) to help prevent unsafe drug utilization. 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 (like 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 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 of their opioid prescriptions reaches or exceeds 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.

• Unless the plan has further specifications, this consultation usually occurs once per plan year. Your staff or a covering physician may confirm medical necessity on your behalf. The pharmacist can then show they consulted you 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 or the plan authorizes coverage through a coverage determination or appeal.

Safety alerts aren’t prescribing limits. You and your patient make decisions to 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 (see 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 indicate, 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)

As of January 1, 2022, all Part D plans will have a DMP that limits access to controlled substances that we determined are frequently abused drugs (currently 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 beneficiaries based on opioid use involving multiple doctors and pharmacies or a history of opioid-related overdose. Plans must review all potential at-risk beneficiaries, 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 that patients get the care they need while reducing the number of 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 try to get your agreement, but they can implement this limitation without it. 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 prescriber(s) agree.

After conducting case management, the plan will decide whether the patient is at risk. 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, or you on their 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 12 months and extend them for another 12 months (total of 24 months). If the plan determines the patient isn’t at risk, it will send a notice confirming that no coverage limitation will be implemented.

Plans must make reasonable efforts to send copies of all DMP notices to involved prescribers.

**Appealing an At-risk Determination**

A patient, their representative, or you 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 active cancer-related pain are exempt from opioid safety alerts and DMPs.

The policies don’t affect access to medication-assisted treatment (MAT) such as buprenorphine.

**How You Can Help**

Ongoing communication among the pharmacist, plan, and 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 patients 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 care needs as part of overall pain management, including screening for opioid use disorder or the need for MAT.

**Prescriber Resources:**

- HHS.gov/Opioids
- Pain Management Best Practices
- CDC’s Opioid Prescribing Guideline
- HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics
- Substance Abuse and Mental Health Services Administration
- Resources to Reduce Opioid Misuse
- Improving Drug Utilization Review Controls in Part D
- Medicare Prescription Drug Appeals & Grievances
- Opioid Treatment Programs (OTP)

**Patient Resources:**

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

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