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TO: All Prescription Drug Plans, Medicare Advantage- Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans

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SUBJECT: Contract Year (CY) 2021 Opioid Safety Edit Reminders and Recommendations

This memorandum provides helpful reminders and recommendations as Part D sponsors prepare to implement opioid point-of-sale (POS) safety edit(s) for CY 2021 and summarizes trends in the types of edits sponsors have implemented. Educational materials are available (such as slide decks and tip sheets for prescribers, pharmacists, and patients, including a beneficiary fact sheet) on the CMS Part D Overutilization website at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html> which sponsors may use to supplement their outreach efforts.

Background

Medicare Part D sponsors must have concurrent drug utilization review (DUR) systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale (POS) or point of distribution as described in 42 CFR 423.153(c)(2). To help prevent and address prescription opioid overuse through improved concurrent DUR, sponsors can fulfill 42 CFR 423.153(c)(2) by implementing opioid safety edits at the POS,¹ including:

- Care coordination edit at 90 morphine milligram equivalents (MME) per day,
- Hard edit at 200 MME per day or more (optional),
- Hard edit for 7 day supply limit for initial opioid fills (opioid naïve),
- Soft edit for concurrent opioid and benzodiazepine use, and
- Soft edit for duplicative long-acting (LA) opioid therapy.

¹ Refer to the [2019 Final Call Letter](#) and [2020 Final Call Letter](#), as well as the October 23, 2018 HPMS memorandum: *Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits*, Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits document, and the May 22, 2020 memorandum: *Information Related to Coronavirus Disease 2019 – COVID-19* available on the CMS Part D Overutilization website: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>.

Important Reminders

- The purpose of the opioid safety edits is to prompt prescribers and pharmacists to conduct additional safety review to determine if the enrollee’s opioid use is appropriate and medically necessary. Plan sponsors are expected to implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.
- The opioid safety edits should not be implemented as prescribing limits or as a substitute for clinical judgment. Rather, the opioid safety edits aim to strike a better balance between identifying potential opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.
- Decisions by clinicians to taper opioid dosages should be carefully considered and individualized, if appropriate. Opioids should not be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. Tapering is most likely to be effective when there is patient buy-in and collaboration, tapering is gradual, and clinicians provide support.²
- Part D sponsors are expected to develop opioid safety edit specifications that exclude beneficiaries who are residents of a long-term care facility, are in hospice care or receiving palliative or end-of-life care, have sickle cell disease, or are being treated for active cancer-related pain. Sponsors are encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the opioid safety edits.
- The care coordination and hard MME edits may also include prescriber counts, pharmacy counts, or both. We recommend including a minimum threshold (“count”) of 2 or more opioid prescribers in these edit specifications.
- Coordinated, repetitive, and well-timed outreach to prescribers, pharmacies, and enrollees is strongly recommended ahead of the new contract year to reinforce the opioid safety edit policies. As noted above, educational resources are available on the CMS Part D Overutilization website. Throughout the year, Part D sponsors should repeat their education and outreach efforts to ensure that clinicians are aware of the policies, pharmacists are aware of the options to resolve rejected claims at POS if appropriate, and beneficiaries are aware of their right to request a coverage determination when a prescription cannot be filled at the pharmacy as written.

² More information on the risks of rapid tapering and guidance for gradual, individualized tapering can be found with the [HHS Joint statement on tapering](#) and the [HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics](#).

Trends in Implementation of Opioid Safety Edits and Other Recommendations

Annually, Part D sponsors provide information to CMS on the opioid safety edits they implement using a template.³ Based on this information, trends in the types of edits sponsors implemented for 2019 through 2021 are summarized in this section. We also share other recommendations based on program experience and feedback.

Cumulative MME safety edits

For 2019 through 2021, most Part D contracts have included either a prescriber count, pharmacy count, or both, in the specifications for the 90 MME care coordination edit. As seen in Table 1, contracts were more likely to use prescriber counts than pharmacy counts for the care coordination edit, though a significant portion chose to implement edits with both prescriber and pharmacy counts.

Table 1: Contract specifications of care coordination edits, 2019 -2021

Year	Total contracts	No prescriber or pharmacy count	Prescriber count only	Pharmacy count only	Both prescriber and pharmacy count
	Number	Number (% of contracts)	Number (% of contracts)	Number (% of contracts)	Number (% of contracts)
2021	898	104 (11.6%)	574 (63.9%)	1 (0.1%)	219 (24.4%)
2020	820	170 (20.7%)	515 (62.8%)	0 (0.0%)	135 (16.5%)
2019	722	125 (17.4%)	453 (62.7%)	1 (0.1%)	143 (19.8%)

From 2019 to 2021, contracts with prescriber counts were more likely to implement criteria with 2 prescribers, and in 2021, contracts are increasingly adopting criteria with a prescriber count of 3 (not shown).

In 2019 and 2020, most contracts with pharmacy counts implemented either 3 or 4 pharmacies. For 2021, however, contracts are increasingly using a pharmacy count of 2 or 3, with 3 being most used.

Table 2: Contracts with optional hard MME edits, by MME thresholds, 2019 - 2021

Year	Total Contracts with Hard Edits (% of contracts)	200 MME	>200-300 MME	360 MME	>360 MME
2021	446 (49.7%)	442	3	0	1
2020	415 (50.6%)	410	3	1	1
2019	339 (47.0%)	335	3	0	1

About half of contracts have included an optional MME hard edit from 2019 to 2021 (Table 2), the vast majority of which have been at 200 MME.

³ HPMS memorandum on July 17, 2020, *Submission Template – Contract Year (CY) 2021 Opioid Safety Edits*, available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization>

Table 3: Prescriber and pharmacy counts of MME hard edits, 2020 - 2021

Year	Total Contracts with Hard Edits (% of contracts)	No prescriber or pharmacy count (% of contracts)	Prescriber count only (% of contracts)	Pharmacy count only (% of contracts)	Both prescriber and pharmacy count (% of contracts)
2021	446 (49.7%)	183 (41.0%)	203 (45.5%)	1 (0.2%)	59 (13.2%)
2020	415 (50.6%)	250 (60.2%)	155 (37.3%)	0 (0.0%)	10 (2.4%)

Similar to care coordination edits, a large proportion of contracts with optional MME hard edits utilize prescriber counts only, and a smaller proportion utilize both prescriber and pharmacy counts. However, the optional MME hard edits have a much larger percentage of contracts with no prescriber or pharmacy counts than the care coordination edits. From 2020 to 2021, contracts shifted from MME hard edits with no prescriber or pharmacy counts to either a prescriber count only or both prescriber and pharmacy counts (Table 3).

In 2020 and 2021, the largest percentage of contracts with an MME hard edit and a prescriber count submitted criteria with 2 prescribers (not shown). In 2021, however, there was a shift from 2 prescribers to 3 or 4.

In 2020, most contacts with an MME hard edit and a pharmacy count submitted criteria using pharmacy counts of either 2 or 3. In 2021, most contracts implementing an MME hard edit and a pharmacy count submitted a pharmacy count of 3.

Opioid naïve edits

Part D sponsors specify the number of days applied for their opioid naïve edit look-back period (Table 4). From 2019 to 2021, the most common look-back window used by Part D sponsors was 108 days. The next most common look-back window was 90 days in 2019, and 120 days in 2020 and 2021.

Table 4: Contract specifications of opioid naïve edits, look-back windows (days), 2019 – 2021

Year	Total contracts	< = 30 days	60 days	90 days	108 days	120 days	> 120 days
2021	898	4 (0.4%)	114 (12.7%)	94 (10.5%)	502 (55.9%)	181 (20.1%)	3 (0.3%)
2020	820	2 (0.2%)	107 (13.0%)	133 (16.2%)	367 (44.7%)	206 (25.1%)	5 (0.6%)
2019	722	1 (0.1%)	71 (9.8 %)	166 (23.0%)	332 (46.0%)	152 (21.0%)	0 (0.0%)

Recommendations for Part D Sponsors

Based on program experience and feedback from stakeholders, CMS recommends that Part D sponsors do the following:

- Monitor the override rates for soft edits by pharmacy to identify outliers or educational opportunities.
- Review the volume of claims that are rejected at POS and override rates for the care coordination edit. If the vast majority of rejections are being overridden, consider adding a prescriber and/or pharmacy count.
- Assess coverage determination request volume and approval rates (e.g., attestation from the prescriber) for the hard MME edit. For example, sponsors who implemented edit specifications with a minimum of one prescriber may experience a higher number of rejections and/or approvals. The single prescriber will likely attest that the opioid dosage was medically necessary, potentially delaying beneficiary access.
- Conversely, identify low rejection rates based on contract enrollment which may be indicative of ineffective opioid safety controls at POS and reassess the edit specifications as needed.
- Reinforce to pharmacists and customer service representatives that the plan may not have opioid claims history for new enrollees, especially at the start of a new contract year, and they may experience a claim rejection due to the opioid naïve edit with their first opioid prescription over 7 days supply. Pharmacists often have existing knowledge or information that a beneficiary is not opioid naïve and may submit an override code to the plan to avoid an interruption in treatment.
- Instruct pharmacists on how to communicate to the plan when an enrollee should be excluded from any of the opioid safety edits.

Conclusion

In 2020, CMS monitored complaints data, appeals data, and other sources of information to identify potential issues with the enhanced opioid safety edits. In 2021, CMS will continue to monitor the impact of these strategies on Medicare Part D prescription opioid overuse to evaluate the need for potential modifications or development of alternative or additional approaches in the future.

For questions related to Medicare Part D opioid safety edits, please email PartD_OM@cms.hhs.gov.