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CMS Continues to Focus Medicare Plans on Preventing Opioid Abuse

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As we highlighted earlier this month, CMS released both the Contract Year 2019 Final Rules for Medicare Advantage and Part D (Final Rules) and the 2019 Call Letter. These documents are not typically released at the same time, so there is a lot of information for Medicare Advantage organizations and Part D plan sponsors to absorb. One major topic area that CMS focuses on in these documents is the prevention of opioid misuse and abuse.

As you know, we have been following this topic closely in the last few months: first, we discussed how the proposed rules set out a framework for plan sponsors to monitor and reduce the potential misuse of frequently abused prescription drugs. We then discussed the Advance Notice and Call Letter outlining utilization review controls for Part D plans to use to address opioid misuse and abuse.

The Final Rules and 2019 Call Letter work together to establish a number of new policies aimed at helping Medicare plan sponsors prevent and combat prescription opioid overuse. There is significant discussion, including CMS's response to commenters, in the final documents linked above. Here, we provide a high-level overview of the new policies.

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Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)

CARA requires CMS to establish a framework for Part D sponsors to implement a drug management program whereby the sponsor can limit at-risk beneficiaries' access to coverage for frequently abused drugs. (NOTE: "Frequently abused drugs" include opioids and benzodiazepines.) As proposed, the Final Rules integrate the new drug management program with CMS's existing Overutilization Monitoring System (OMS). Under the expanded OMS, sponsors may limit (i.e., "lock-in") an at-risk beneficiary's access to frequently abused drugs to specific prescribers and pharmacies and apply beneficiary-specific point-of-sale (POS) claim edits (noting though, that POS edits are already permitted under the current OMS). However, sponsors must engage in case management with the prescribers of these drugs prior to implementing any such limitations. Beneficiaries may also submit prescriber and pharmacy preferences.

Both the Final Rules and the Call Letter exempt from drug management programs beneficiaries who are being treated for active cancer-related pain, are receiving palliative or end-of-life care, or are in hospice or long-term care. At-risk determinations, which include prescriber and pharmacy lock-in, will also be subject to the existing beneficiary appeals process.

Populations of Prescription Opioid Users

In the Call Letter, CMS explains that its expectations of sponsors to reduce opioid misuse are tailored to distinct beneficiary populations:

1. **New Opioid Users:** Sponsors are expected to implement a hard safety edit to limit initial opioid

prescriptions fills for treatment of acute pain to no more than 7 days' supply.

2. **High-Risk Users/Users with Uncoordinated Care:** Sponsors are expected to implement the expanded requirements of the OMS described above. The OMS will retrospectively identify potentially at-risk beneficiaries so that sponsors can engage in case management with prescribers.
3. **Chronic Users:** Sponsors are expected to implement safety alerts at the POS to proactively engage patients and prescribers in a discussion about risk and prevention. Sponsors must also implement formulary-level safety edits based on specific clinical guidelines. The clinical guidelines are based on the CDC Guidelines for Prescribing Opioids for Chronic Pain. CMS expects sponsors to engage with prescribers regarding the CDC's recommendations: MA-PD sponsors must include the expectation that prescribing will be based on the CDC guidelines in the provider contract; PDP sponsors should reinforce the message through interactions with prescribers.
4. **Concurrent Use of Opioids and Benzodiazepines:** Sponsors are expected to implement POS safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines. CMS will also revise the Pharmacy Quality Alliance (PQA) opioid overuse measures and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines.

2019 Part C Risk Adjustment Model

CMS also finalized an updated HCC model that incorporates most of the proposed changes, including the addition of substance use disorder.

We encourage readers to review the Final Rules and Call Letter to gain insight into CMS's discussion and ensure compliance with 2019 requirements.

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