Improving Drug Utilization Review Controls in Medicare Part D

In the final 2013 Call Letter and supplemental guidance, CMS described a medication safety approach by which sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications.[1] In July 2013, CMS launched the Overutilization Monitoring System (OMS) to help oversee sponsors' compliance with this CMS overutilization guidance.

CMS continues to focus on and expect sponsors to further reduce opioid and acetaminophen (APAP) overutilization in the Medicare Part D program. In this section, we describe the results of Part D sponsors' implementation of improved drug utilization controls to prevent overutilization and improve medication use since January 2013, and our additional expectations for further reductions of overutilization based on enhancements and clarifications of the policy. We appreciate the comments and suggestions submitted by sponsors, PBMs, and other organizations about the policies described below to reduce the unsafe overutilization of medications by Part D beneficiaries and increase access to treatment.

- Timeliness of beneficiary-level opioid point of sale (POS) edit submissions to the Medicare Advantage and Prescription Drug System;
- Discontinuation of OMS APAP reporting through the OMS;
- Changes to the OMS opioid overutilization methodology;
- Formulary-level cumulative morphine equivalent dose (MED) POS edits;
- Soft opioid POS edit following initiation of buprenorphine -for the treatment of opioid use disorder;
- Access to medication-assisted treatment for opioid use disorder;
- Elimination of utilization management processes that may lead to inappropriate use of methadone in pain management.

In addition, the Enhancements to the 2017 Star Ratings and Beyond section of the 2017 Call Letter discusses implementation of three new PQA-endorsed opioid overutilization measures.

[1] An excerpt from the Final 2013 Call Letter, the supplemental guidance and additional information about the OMS are available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

New Expectation for Entering Opioid Point of Sale Claims Edit Information in the Medicare Advantage and Prescription Drug System (MARx)

CMS enhanced MARx in February 2014 to automate the process by which sponsors notify other sponsors about their beneficiary-level opioid POS claim edit decisions. In accordance with current guidance, sponsors enter information in MARx when they have made a decision to implement a beneficiary-level opioid POS claim edit. MARx then alerts a new sponsor when a beneficiary identified in this manner by the previous sponsor enrolls in the new sponsor's plan. To facilitate data sharing between Part D sponsors, CMS has expected sponsors to submit POS edit notifications into MARx in a timely manner, which we are now specifying as within seven (7) business days of the date on the beneficiary's written advance notice. CMS also expects sponsors to submit implementations, terminations, and modifications of such POS edits within seven (7) business days of the event. We encourage sponsors to use the MARx User Interface for faster submissions than the batch file process; instructions are available in the Medicare Advantage and Prescription Drug Plans Communications User Guide, which is available on the CMS webpage, https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html. As of March 10, 2016, CMS has received 2,693 contract-beneficiary-level opioid POS edit notifications through MARx for 2,520 unique beneficiaries.

Results of Overutilization Policy

Part D sponsors have had a significant impact on reducing overutilization of opioids and APAP. From 2011 through 2015, there was a 47% decrease or 13,753 fewer Medicare Part D beneficiaries identified as potential opioid overutilizers (i.e., beneficiaries with at least 90 consecutive days with greater than 120 mg MED daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims). This represents a 57% decrease in the share of beneficiaries using opioids who are identified as potential opioid overutilizers (see Table 20).

Table 20. OMS Part D Potential Opioid Overutilization Rates, 2011 – 2015*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries with at Least 90 Consecutive Days >120 mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims	Difference Year-to-Year	Share of Opioid Utilizers Flagged as Outliers	Difference in Share Year-to-Year
2011	31,483,841	10,049,914	31.9%	29,404		0.29%	
2013	37,842,632	11,794,908	31.2%	25,347	− 4,057 *47% decrease*	0.21%	−0.08% *57% decrease*
2014	39,982,962	12,308,735	30.8%	21,838	− 3,509	0.18%	−0.04%
2015	41,835,016	12,510,448	29.9%	15,651	− 6,187	0.13%	−0.05%

*Table 20 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. For these opioid utilization comparisons, CMS used OMS methodology and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.

The number of beneficiaries identified annually as potentially overutilizing APAP from 2011 to 2015, based on the CMS definition in the OMS, decreased by 94%, from 76,681 to 4,539 (see Table 21).

Table 21. OMS Part D Potential APAP Overutilization Rates, 2011-2015*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing APAP	% Part D Enrollees Utilizing APAP	Total Beneficiaries with Daily APAP Dose Exceeding 4 g for 30 or More Days Within Any Six-month Period with at Least One Day Exceeding 4 g Within the Most Recent Calendar	Difference Year-to-Year	Share of APAP Utilizers Flagged as Outliers	Difference in Share Year-to-Year
2011	31,483,841	9,449,693	30.0%	76,581		0.81%	
2013	37,842,632	10,591,651	28.0%	26,122	−50,459	0.25%	−0.56%
2014	39,982,962	10,845,499	27.1%	6,286	−19,836	0.06%	−0.19%
2015	41,835,016	10,712,430	25.6%	4,539	−1,747	0.04%	−0.02%

*For these APAP utilization comparisons, CMS used OMS methodology and PDE TAP Data. For 2011, PDE TAP Data were processed through 13AUG2012; subsequent year analyses used PDE TAP data processed with cut-off dates in the early January of the following year.

Updates to Overutilization Policy for Contract Year (CY) 2017

Discontinuation of APAP Reporting through the OMS

Since the annual number of beneficiaries overutilizing APAP has decreased dramatically since 2011, we will discontinue the reporting of APAP overutilization tickets in the OMS beginning with the April 2016 OMS reports. However, we will continue to monitor APAP overuse through a new Patient Safety measure. The High APAP Daily Dose Rate will be defined as the number of APAP days exceeding a 4 g daily dose (DD) per 1,000 APAP user days, and will be reported for CY 2016 at the contract level for information purposes only. We will also identify outliers at the contract level, and will implement new outlier response requirements beginning in 2017 similar to the process used for other Patient Safety measures. The current Patient Safety outlier methodology can be found on the Patient Safety Website under Documentation › Help Documents › Outlier Threshold Reports. CMS thanks sponsors for their APAP utilization efforts, encourages continuation of these efforts, and reinforces that implementation of APAP safety edits based on FDA labelling do not require a formulary submission to CMS.

Opioids

Compliance Activities and Changes to the OMS Opioid Overutilization Methodology

Since the OMS was launched in July 2013, CMS has used the following criteria to identify beneficiaries who may potentially be overutilizing opioids:

> Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

In the 2015 Call Letter, we described our concern that some sponsors' internal criteria or processes to identify and address potential opioid overutilization may be insufficient. For the January 2014 OMS reports, 67% of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria (OMS response code BSC). CMS also announced that beginning January 2015, sponsors' internal opioid criteria for retrospective identification of egregious patterns of opioid overutilization and subsequent case management should be no less restrictive than 120 mg daily MED over at least 90 consecutive days.[2] Other criteria, such as the number of prescribers and pharmacies, could vary from CMS specifications. Sponsors may also vary the measurement period, and our understanding is that most sponsors look back 90 to 120 days.

Continued review of sponsors' responses to the OMS in 2015 suggested potential noncompliance with CMS guidance. In light of this, we performed additional outreach to assess compliance with CMS guidance by select Part D sponsors who were identified as outliers based on their APAP and opioid responses to the OMS. CMS contacted Part D sponsors at the parent organization level to obtain information about their overutilization criteria and case management programs, and for the sponsors to explain their responses to specific tickets received through the OMS. Overall, we found that sponsors were generally compliant with CMS guidelines.

Based on our analysis of the information from this effort, we identified opportunities to potentially modify the OMS opioid overutilization criteria in the future (as early as 2018) to reduce the number of tickets for which sponsors repetitively submit response codes BSC (No further review planned: Beneficiary did not meet the sponsor's internal criteria) and BOR (Beneficiary-level POS edit determined not necessary: Beneficiary's overutilization resolved).

Ideas include to:

- Shorten the measurement period from 12 months to 6 months; and
- Use average MED rather than a count of 90 consecutive days of high MED.

The revised 'Overutilization of Opioids' criteria would be:

> Use of opioids with an average daily MED exceeding 120 mg for an episode of at least 90 days with more than 3 prescribers and more than 3 pharmacies contributing to their

[2] Note: The OMS 'Overutilization of Opioids' criteria was developed and the compliance activities occurred prior to the recent publication of the CDC Guideline for Prescribing Opioids for Chronic Pain discussed later in the Call Letter. We will consider changes to the criteria based on the CDC Guideline for presentation in the 2018 Call Letter.

opioid claims, during the most recent 6 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

The average MED is calculated by summing each PDE's MED and dividing this sum by the duration of the opioid episode in days. An opioid episode consists of at least two opioid PDE fills. The episode duration is the number of days between the first and last opioid PDE's dispensing date during the measurement period plus the last PDE's days' supply plus 1 day (end-date). If the end-date is beyond the last day of the measurement period, the quantity is multiplied by the percent of the days' supply that occurs during the measurement period, and the end-date becomes the last calendar day of the measurement period.

By allowing gaps between prescription fills and days' supply in the calculation, the average MED per 90-day episode methodology may identify more beneficiaries who are chronic users of high opioid doses than the consecutive days method. Shortening the measurement period from 12 months to the most recent 6 months may better identify current potential overutilization and reduce the number of repeat cases reported by the OMS. We are analyzing the impact of these potential revisions in identifying beneficiaries who may potentially be overutilizing opioids.

In addition, CMS is investigating how prescribers are counted in the OMS opioid overutilization criteria. We are analyzing the feasibility of grouping NPIs (National Provider Identifiers) within a clinical practice as reported in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) rather than count unique NPIs, which would reduce false positives in the group practice setting. Suggestions include grouping based upon Tax ID number (TIN), Employer ID number (EIN), or primary location address. Identifying common clinical practice groups based on prescribers whose NPIs are associated only with one primary location TIN or a single EIN could prevent mismatching of prescribers who participate in multiple clinical practices. This conservative grouping methodology resulted in a 4.8% decrease in the number of beneficiaries potentially overutilizing opioids that would have been identified by the OMS in the October 2015 cycle.

We thank those commenters who offered suggestions on how to improve the metric and the grouping of NPIs. CMS plans to continue to investigate potential modification of this measure for implementation in 2018 based on experience from compliance activities, additional analyses, and the CDC guideline (as described further below).

Other findings and takeaways from our compliance activities include:

- Sponsors should review repeat OMS response replies. For example, instead of resubmitting the BSC response code repeatedly for the same case, sponsors may confirm medical necessity with the prescribers. The DMN (Determined Medically Necessary) response code triggers the OMS exception logic for one year.

- Although several morphine equivalent conversion factors exist, CMS encourages

sponsors to use the CDC morphine milligram equivalent (MME[3]) conversion factors within their opioid overutilization programs. The MME conversion table is available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html), which contains information to help Part D sponsors create or revise their programs to address the unsafe use of opioid pain medications.

We thank the sponsors that participated in this outreach effort. We were not only able to assess potential non-compliance, but we gained information on ways to improve our guidance and overutilization methodology.

CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017

Although the overutilization of opioids has decreased in Part D as discussed above, CMS has indicated on multiple occasions that we believe Part D sponsors should implement formulary-level cumulative opioid edits at POS to prospectively prevent opioid overutilization. Industry reaction had previously been that such edits were premature due their complexity. As described in the final 2016 Call Letter, we commenced a pilot project in 2015 to assess the feasibility and impact of such POS edits.

Through the pilot project, we noted that Part D sponsors demonstrated that they can effectively implement a soft or hard formulary-level cumulative opioid MED edit at POS while blocking the edit for beneficiaries with known exceptions. The sponsors evaluated their own data when developing edit specifications and exclusion criteria to identify potential opioid overutilization while maintaining access to opioids when needed for their enrollees. Formal complaints were not received from beneficiaries or providers. Additional information about the pilot project experience was described in the draft CY 2017 Call Letter.

- For CY 2017, we proposed that sponsors' implement both the soft and hard[4] cumulative MED POS edits. Soft edit claim rejections could be overridden at the pharmacy level by the pharmacist submitting appropriate NCPDP codes, and with respect to hard edit claim rejections, the rejected prescription drug claim would not be approved in the absence of a plan decision to override the edit. In the draft Call Letter, we proposed the following parameters for the POS edits: Soft edits that can be overridden at the pharmacy level when a prescription claim will result in the

[3] Note: CDC's terminology, morphine milligram equivalents (MME), is equal to morphine equivalent dose (MED) in milligrams as used by CMS. Often calculated as a daily dose.

[4]More information about soft and hard rejects and edits is available from the Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf, and the National Council for Prescription Drug Programs: "Telecommunication Version D and Above Questions, Answers and Editorial Updates," NCPDP, February 2014, http://www.ncpdp.org/NCPDP/media/pdf/VersionD-Editorial.pdf (accessed 1/22/2015).

beneficiary's active or overlapping opioid prescriptions reaching or exceeding a certain daily cumulative MED threshold. This threshold may be set at 90 mg to 120 mg MED. The soft-edit rejection can be overridden by the pharmacist submitting appropriate NCPDP codes.

- Hard edits for daily cumulative MED threshold at or above 200 mg MED.

We also described methods to minimize false positives by accounting for known exceptions.

Commenters supported our original proposal for both types of edits, and some supported only soft or hard edits for CY 2017. Others expressed concern for potential delay of beneficiary access to needed medications, the short time between the final Call Letter and the formulary submission deadline, and the need for more time to develop, test, and implement the edits. Due to the comments received, we are revising our expectations for CY 2017 formulary-level cumulative opioid MED POS safety edits. For CY 2017, we expect sponsors to implement either a soft edit or a hard edit, or they may use both soft and hard edits as we originally proposed in the draft Call Letter, and work toward a hard edit at a minimum in 2018 using reasonable controls to limit false positives. We will review 2016 and 2017 experience with these edits to inform content in the CY 2018 Call Letter.

For CY 2017, we expect sponsors' Pharmacy and Therapeutics (P&T) committees to develop the specifications for their formulary-level cumulative MED POS edit(s) based on the opioid overutilization in their Part D plans, and reasonable numbers of targeted beneficiaries for plan oversight. We recommend that a soft opioid edit threshold should be set at levels no lower than 90 mg MED, and a hard opioid edit threshold should set no lower than 200 mg MED. We also expect sponsors to apply specifications to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeals processes. If sponsors decide to include a provider count criterion in the soft or hard edit specifications, we recommend two prescribers of the active opioid prescriptions as the threshold (at a minimum). We also do not recommend a consecutive high-MED days criterion because it would not prevent beneficiaries from reaching high opioid doses.

In order to allow more time to develop and test the full edit specifications, Part D sponsors will have until September 1, 2016 to submit the detailed operational information to CMS for review. The documentation must include information such as the type of edit(s), the MED level being utilized, exclusion criteria, and other screening information, as well as a written description of the program's mechanics, including the mechanism by which the edits will be resolved. This information must be submitted via e-mail to partdformularies@cms.hhs.gov with a subject line of "Cumulative MED – [applicable FID number]." A submission template will be provided to

Part D sponsors' formulary contacts at a later date. Finally, we wish to clarify the HPMS formulary submission requirements with respect to quantity limits. Opioids that have a quantity limit that is below any applicable FDA-approved maximum doses must be submitted as part of the HPMS formulary submission. However, if the only quantity restriction that will be applied at POS is a cumulative MED edit described in this section, a quantity limit does not need to be reflected on the HPMS formulary submission. The cumulative MED edit is considered to be a safety edit. This guidance updates that which is included in section 30.2.2.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. We are also clarifying that non-formulary opioids can be included in the cumulative MED editing even though they are not included on the formulary.

Concurrent Use of Opioids and Buprenorphine

As described in the 2016 Call Letter, we investigated the concurrent use of buprenorphine and opioids in Part D as a potential new measure for the OMS as informational only. Currently, the sublingual (SL) and buccal formulations of buprenorphine and buprenorphine-naloxone film or tablets are only approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorder and not for the treatment of pain. Because buprenorphine effectively blocks the analgesic properties of other opioids used to treat acute pain, it generally prevents the use of other opioids as an adjunctive treatment for pain syndromes.

An analysis of PDE data from April 1, 2014 through March 31, 2015 identified over 24,500 Medicare Part D beneficiaries with concurrent buprenorphine buccal and SL formulations and opioid use, including over 20% with 30 or more concurrent opioid days. CMS believes there are additional opportunities for improvements through drug utilization management. Therefore, we expect sponsors to implement a soft POS edit when an opioid prescription is presented following the initiation of buprenorphine for the treatment of opioid use disorder. CMS believes that a soft edit that only rejects the opioid prescription following the buprenorphine claim should not impede access to buprenorphine for the treatment of opioid use disorder. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims. At this time, we will not include a measure of concurrent use of opioids and buprenorphine in the OMS, but we will continue to monitor utilization trends. For additional guidance in the use of buprenorphine in the treatment of opioid use disorders refer to http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

Concurrent Use of Opioids and Benzodiazepines

CMS is also concerned with the concurrent use of opioids and benzodiazepines, and we want to raise public awareness of this important issue. The combination of opioids and benzodiazepines can exacerbate respiratory depression, the primary factor in fatal opioid overdose. The risk of opioid-related morbidity and mortality is increased in all patients, even those who do not show signs of aberrant drug behavior. In a 2015 study, investigators found that 49% of a study

population who died from a drug overdose while taking opioid analgesics were concurrently prescribed benzodiazepines.[5] Further, the CDC advises clinicians to avoid prescribing opioids and benzodiazepines concurrently whenever possible.[6]

We found through analysis of 2015 PDE data (as of March 2016) that almost 3.1 million beneficiaries were dispensed an opioid medication with at least one day overlap with a benzodiazepine medication, excluding beneficiaries enrolled in hospice or with a cancer diagnosis. This represents 24% of opioid users and 8% of Part D enrollees (non-hospice/non-cancer). Also, about one-third of beneficiaries concurrently utilizing opioids and benzodiazepines only had one event (most less than 30 days), whereas over two-thirds had more than one event of overlap usage. The top three opioid and benzodiazepine combinations by number of events in 2015 included hydrocodone-acetaminophen with alprazolam, lorazepam, or clonazepam. We encourage Part D sponsors to evaluate their claims data and use drug utilization management tools that are available to them as necessary to help address the concurrent use of these drug classes.

CMS will continue to monitor concurrent use of opioids and benzodiazepines among Medicare Part D enrollees. Also, we are aware that a measure concept, Double Threat: Concurrent Use of Opioids and Benzodiazepines, is in development by the PQA, which may be considered for future use in oversight or performance measurement.

Access to Medication-Assisted Treatment

Despite efforts such as those outlined above, opioid use disorder continues to be a significant public health concern. In October 2015, the President issued a Memorandum to Federal Departments and Agencies to identify barriers to medication-assisted treatment (MAT) for opioid use disorders and develop action plans to address these barriers. In response, CMS will use available vehicles to inform physicians, MA organizations and Part D sponsors about MAT coverage, including clarifying that MA plans have the same obligation to cover substance use disorder treatment as is available under Original Medicare and that Part D plans must ensure access to MAT that are covered under Medicare Part D.

Currently only buprenorphine, buprenorphine/naloxone, and naltrexone are covered Part D drugs when used for medication-assisted treatment (MAT) of opioid use disorder. It is critical that Medicare beneficiaries who are in need of these therapies have appropriate access to these drugs in Part D. Given the requirements imposed by the Drug Addiction Treatment Act of 2000 and Risk Evaluation and Mitigation Strategy for buprenorphine-containing products for MAT, Part D sponsors should not impose prior authorization criteria that simply duplicate these requirements. When prior authorizations are utilized, Part D sponsors must also carefully consider approval

[5] Park TW, Saitz R, Ganoczy D, et al. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. *BMJ* 2015;350:h2698.
[6] http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

durations so as to not subject beneficiaries who are in need of these therapies to unnecessary hurdles or lapses in treatment. Part D formulary and plan benefit designs that hinder access, either through overly restrictive utilization management strategies or high cost-sharing, will not be approved.

Under current statute, methadone, an FDA-approved medication for the treatment of opioid use disorder, is not covered by Part D for substance use disorder treatment because it does not meet the Part D requirement that it "may be dispensed only upon a prescription" since it must be dispensed in an opioid treatment program and cannot be dispensed upon a prescription at a pharmacy when used for this purpose. We appreciate comments submitted on whether or not this statutory requirement is a barrier to treatment. Absent a change in law, Medicare is unable to cover methadone for MAT under Medicare Part B or Part D. However, under Part C, MA organizations may cover methadone for MAT as a supplemental benefit.

A Note about the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain

The CDC prepared a guideline for opioid prescribing to assist primary care providers in delivering safer, more effective chronic pain management for patients with pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline, which was published on March 15, 2016, was developed through a rigorous scientific process using subject matter experts, the most recent scientific evidence, and public comment. Topics include 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use, including the use of opioids in patients age 65 and older. In the guideline, CDC identifies 50 mg MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing dosage to 90 MME per day. The guideline also presents tapering methodology for long-term, high opioid dose users, which may be useful to reduce high opioid doses. We encourage sponsors' P&T committees to carefully review and consider CDC's recommendations, and to share the CDC guideline with opioid prescribers. The CDC Guideline for Prescribing Opioids for Chronic Pain is available on the CDC website at http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

During 2016, we will consider potential revisions to CMS overutilization guidance and the OMS opioid overutilization methodology based on the CDC guideline, for presentation in the 2018 Call Letter. In addition, we will consider recommendations set forth in the guideline during the CY 2017 formulary and benefits review. For example, CDC notes that methadone has been associated with a disproportionately high number of overdose deaths relative to its prescribing frequency for pain management. As a result, the guideline states that methadone should not be used as a first line agent for pain management when an extended-release/long-acting opioid is indicated, and that only providers who are familiar with the complexities of methadone's pharmacokinetic and pharmacodynamics properties should prescribe it for pain. Part D sponsors should evaluate their utilization management strategies and eliminate processes that may lead to

inappropriate utilization of methadone in pain management. Submitted Part D benefit packages and formularies will be reviewed to ensure that methadone is not the sole preferred opioid analgesic within a plan design.