Improving Drug Utilization Review Controls in Part D (Excerpt from Final 2013 Call Letter 04-02-2012)

Introduction

Part D sponsors are, and have been, responsible for establishing reasonable and appropriate drug utilization management programs that assist in preventing overutilization of prescribed medications. Through discussions with the industry, CMS has determined that sponsors need to employ more effective concurrent and retrospective drug utilization review (DUR) programs to address overutilization of medications in order to protect beneficiaries, to comply with drug utilization management (DUM) requirements at 42 CFR §423.153 et seq. and to reduce fraud, waste and abuse in the Part D program. While stakeholders need not wait for our input, we would be amenable to working with them to achieve consensus on consistent metrics to identify overutilization of medications, particularly opioid analgesics ("opioids"), but the health and safety of Medicare beneficiaries cannot wait for such consensus. Part D sponsors either already have, or should have, the existing expertise to address significant patterns of overutilization, and we are setting forth in this section how sponsors can use that expertise in ways some may not have thought permissible, have not previously considered, or have not implemented adequately.

We believe that, for many sponsors, several improvements to formulary management processes are necessary to curb overutilization. We are delineating specific, but sufficiently flexible, features such as a minimum standard for compliance for CY 2013. In particular, while we expect to see Improved Use of Concurrent Claim Edits (Safety Controls at POS) and Improved Use of Formulary Utilization Management Designs (QLs at POS), as described in detail below, applied to all medications to ensure dispensing at safe dosages, we expect to see Improved Retrospective DUR Programming and Case Management, also described in detail below, applied at a minimum to opioids in CY 2013. If these levels of DUR do not prove effective at establishing medical necessity, which we believe would be a rare occurrence, the sponsor may implement beneficiary-level POS edits under certain conditions.

As a matter of general clarification, the improvements we describe below do not change our existing policy on QLs, prior authorizations, step therapy and protected class drugs, and are in fact intended as improvements to formulary management processes that we expect sponsors to implement. We will provide further guidance to sponsors as needed and appropriate on the implementation of these improvements, and we remind sponsors that we will be monitoring their performance in appropriately implementing these improvements.

We are also outlining how sponsors may share beneficiary-level data about overutilization under HIPAA when a beneficiary changes plans. Further, we emphasize sponsors' ability to make referrals to the appropriate agencies when they suspect fraudulent activity in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefit Manual.

Finally, CMS is committing to undertaking a communication and educational campaign about medication overutilization, particularly opioids, for physicians and pharmacies in the fall of 2012 to support sponsors' strengthened efforts to address this issue in the Part D program. To encourage further dialogue between CMS and Part D sponsors about overutilization, we will also be offering a session on overutilization at the Medicare Advantage and Part D Spring Conference in April 2012, during which

illustrative examples will be presented and reviewed, and we encourage sponsors to have representatives attend.

Background

A recent Government Accountability Office (GAO) report highlighted evidence that effective concurrent DUR has not been fully implemented across the Part D program (GAO-11-699 September 2011 http://www.gao.gov/new.items/d11699.pdf). This report summarized findings of egregious overutilization of medications by Part D beneficiaries who were obtaining medications from a minimum of five different prescribers and a maximum of fifty prescribers, with the vast majority of beneficiaries receiving medications from between five and ten providers. The medications most often identified as being potentially overprescribed were those opioid products containing hydrocodone followed distantly by oxycodone containing products. Therefore, we are focusing on addressing overutilization of opioids beginning CY 2013.

Overview of Improvements to Formulary Management Processes

On September 28, 2011, we issued a memorandum through the Health Plan Management System ("HPMS") ("September memo") relating to inappropriate overutilization of drugs and solicited comments from industry stakeholders regarding methods to improve DUR controls. Based on comments that were received for the September memo, we learned that we needed to first clarify and reinforce current Part D policy relating to utilization management strategies available to Part D sponsors to combat inappropriate overutilization of prescription drugs. Therefore, as described in our December 13, 2011, memorandum entitled "Clarification of Medicare Part D Policies with Respect to Overutilization," and issued through HPMS, Part D sponsors must first ensure that they are fulfilling the current regulatory requirements with respect to DUR. Effective formulary DUM programs, when layered on concurrent DUR systems, should strongly diminish the likelihood of inappropriate overutilization. Thus, the processes described in the September memo were not meant to be a substitute for, but rather be a supplement to, effective DUR and DUM programs that should currently be implemented by sponsors.

As detailed in Chapter 7 of the Prescription Drug Benefit Manual, the regulations at 42 CFR 423.153(c)(2) require that each Part D sponsor have concurrent DUR systems, policies, and procedures designed to ensure that a review of prescribed drug therapy is performed before each prescription is dispensed to an enrollee, typically at point of sale (POS) or point of distribution. The Part D sponsor's concurrent DUR program must include a number of checks each time a prescription is dispensed, including one for overutilization.

Sponsors are in a unique position to identify potential medication overutilization and engage the involved prescribers. Sponsors are a central data collection point for beneficiary medication dispensing events, which may be generated from multiple providers and pharmacies, who may be unaware that a beneficiary is receiving the same drug (or therapeutic equivalent) simultaneously from different providers and pharmacies.

An adequate system to assist in preventing overutilization of prescribed medications, including opioids, includes several levels of improved formulary management. We have termed the first level "Improved Use of Concurrent Claim Safety Edits (Safety Controls at POS)." We believe that if safety edits, such as "therapeutic duplication," "maximum dose exceeded," and "refill too soon," had been appropriately

implemented, and not routinely overridden, much of the egregious overutilization noted in the GAO report described above would have been averted. In addition to these POS edits, sponsors should apply safety edits that minimize the risk of overutilization of individual medications contained in combination products, such as opioid products containing acetaminophen ("APAP"), which does have maximum dosing limits when the ingredient APAP is considered across all unique combination products. The second level is "Improved Use of Formulary Utilization Management Designs (QLs at POS)," such as quantity limits (QLs) applied to medications that do not have a clear maximum dose, such as opioids that do not contain APAP, or QLs applied below the Food and Drug Administration ("FDA") labeled maximum dose. The third level is "Improved Retrospective DUR Programming and Case Management" to identify patterns that suggest drug overutilization based on number of prescribers and doses, patterns of prescribing, and cumulative dosing, and then employment of clinical case management intervention strategies.

We discuss each level in detail below, using opioids as the example. However, as noted above, we expect to see the improvements outlined in Level One and Two applied to all medications for CY 2013, and Level Three applied to opioids. As also noted above, it should be clear in reviewing these levels that we will continue to approve QLs and other required formulary and DUM submissions as per our current policy described in the applicable Part D manuals. Finally, we will develop monitoring protocols to ensure sponsors are implementing effective but appropriate controls against overutilization. Sponsors that establish inappropriate controls may be subject to a compliance action.

Level One: Improved Use of Concurrent Claim Edits (Safety Controls at POS)

Part D sponsors, through the appropriate use of concurrent DUR systems, have the ability to substantially improve patient safety by facilitating a reduction in the incidence of inappropriate overutilization. As long as they are consistent with FDA labeling, the safety edits described in this level can be implemented without submission to or approval by us (e.g., edits that prevent the dispensing of a drug when the labeling clearly identifies the dispensing as unsafe). Therefore, all drugs (including the six protected classes and controlled substances) should be subject to DUR safety controls at POS, such as early refill edits, therapeutic duplication edits (i.e., patient receiving same drug or drug within the same class two days prior), and dose limitations at or above the maximum dose (as described in the Food and Drug Administration (FDA) approved label for most drug products and addressed again in more detail in Level Two (A) below). Further, these safety controls at POS should not be suppressed during beneficiaries' transition periods. Based on their experience with the use of these edits, sponsors should use their discretion in implementing such edits as soft edits, or pharmacy messaging only, or hard edits, such as those requiring an authorization to resolve the edit.

However, based on the comments submitted in response to our September memo, it is evident that not all sponsors are fully utilizing available concurrent DUR tools. For example, while opioid analgesics do not always have a clearly defined approved maximum daily dose, those products that contain acetaminophen (APAP) do. Thus, we would expect all sponsors to consider the APAP content of opioid analgesics and implement edits in their systems that prevent the dispensing of unsafe daily doses of APAP (greater than 4gm/day as recommended by the FDA). Yet, comments on the September memo indicated that some sponsors believe our existing formulary guidance restricts their ability to implement such safety edits. Consequently, we are taking this opportunity to clarify that we consider safety edits to prevent dispensing of unsafe dosing of drugs to be part of the concurrent DUR requirements for all Part

D drugs. Also, while POS edits provide a broad first level of beneficiary safety, more sophisticated levels of formulary management need to be employed by Part D sponsors to prevent overutilization, as discussed in further detail below.

Level Two: Improved Use of Formulary Utilization Management Designs (QLs at POS)

A) QLs/ At or Above FDA Maximum Dose

For ease of reference (by consolidating our review of QLs in relation to FDA maximum doses in one place in this Call Letter), we are repeating the guidance just above on QLs at or above the FDA maximum dose here. So again, Part D sponsors are permitted to apply QLs at or above the FDA maximum approved dosing to covered Part D drugs, including drugs within a protected class, in order to promote safe use (by not allowing dosages beyond maximum dose or unsafe dosages) and to decrease fraud, waste and abuse. Again, QLs at or above the FDA labeled maximum daily dose do not have to be included as part of the HPMS formulary submission and do not require our approval, even if they are implemented as hard edits. We note that 42 CFR §423.120(b)(2)(vi)(B) permits exceptions to the protected classes requirement for "utilization management processes that limit the quantity of drugs due to safety."

B) QLs/No FDA Maximum Dose

Part D sponsors may also apply QLs to drugs, as appropriate, for which there is no clearly defined maximum dose in the approved labeling, such as most opioid analgesics, to ensure safety, promote cost-effectiveness through dose optimization, and to decrease fraud, waste and abuse. When developing QLs in such cases, sponsors' Pharmacy and Therapeutic (P&T) committees should consider existing best practices to control overutilization through formulary management and document their conclusions. Sponsors are reminded that QLs where there is no FDA labeled maximum daily dose must be included as part of the HPMS formulary submission and are subject to our approval. Again exceptions to the protected classes requirement are permitted for utilization management processes that limit the quantity of drugs due to safety.

C) QLs/Below FDA Maximum Dose

Finally, Part D sponsors may apply QLs, as appropriate, below the FDA maximum approved dosing to promote cost-effectiveness through dose optimization, and to decrease fraud, waste and abuse, if the approved maximum dose is accessible on the plan formulary. An example of dose optimization would be to promote the use of one 80mg controlled release (CR) tablet rather than two 40mg CR tablets to achieve an 80mg CR tablet dose through QL restrictions on the 40mg CR tablets. Sponsors are reminded that QLs below the FDA labeled maximum daily dose also must be included as part of the HPMS formulary submission and are subject to our approval. In addition, this example would only be permitted so long as the 80mg CR tablet is also on formulary; however, it would not be permitted for protected class drugs unless such QLs are due to safety.

Level Three: Improved Retrospective DUR Programming and Case Management

All Part D sponsors must have retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate use of specific drugs or groups of drugs, or of medically unnecessary care, among

enrollees in a Part D plan (42 CFR §423.153(c)(3)). As noted above, in the September memo, we outlined additional retrospective DUR processes that Part D sponsors should adopt to address potential overutilization. The primary intent of this guidance was to provide sponsors with additional DUR level processes, e.g., retrospective DUR programming and case management, to detect and prevent inappropriate overutilization should an event go undetected by claim level controls. Thus, the approach described in this level is based on multifaceted beneficiary-level clinical assessment, and its effectiveness will be highly dependent upon P&T committees and clinical case managers. While some sponsors felt that implementing such a process would be resource-intensive, the overall comments did not suggest that such an approach is unreasonable and acknowledged that drug overutilization is a significant concern. The following paragraphs outline the processes in more detail, and address the comments that we have received.

For CY 2013, for those sponsors who are not already employing this type of approach, or are not doing so with respect to opioids, we expect these sponsors to implement this level to address opioid overutilization, at a minimum. This will allow these sponsors to gain experience in using this approach while addressing the most commonly overutilized medications according the GAO report. Although we recognize that some beneficiaries may require high doses of opioids for appropriate indications to maintain analgesia, these medications may pose significant safety hazards to beneficiaries when overprescribed and not appropriately monitored.

Indeed, we recognize that the opioid class of medication presents many challenges for sponsors to ensure beneficiary safety and prevent fraud, waste and abuse. The application of current utilization management tools, such as safety controls at POS and QLs, may not be as effective in identifying overutilization of opioids when compared to other classes of medications. For instance, therapeutic duplication safety edit software at POS may not be currently programmed to the level of sophistication to prevent overutilization for opioids, and edits are often soft edits overridden at the pharmacy. These POS edits may not distinguish between drugs within a therapeutic class, or may be overly sensitive and identify regimens that are commonly used for pain management. Challenges such as concurrent use of long-acting with short-acting products, titration of dose, switching agents within the class, and new prescriptions written monthly for Schedule II drugs (often by different doctors) highlight the need for sponsors to implement effective retrospective DUR programs to identify beneficiaries who are at risk for overutilization of these medications.

In light of this, sponsors should have DUR programming (that is, retrospective report-generation criteria as opposed to POS claim edits) that identifies patterns which suggest that the identified patients may be at risk of overutilization, so that these cases may be further analyzed clinically for possible fraud, waste and abuse. Moreover, beneficiaries receiving multiple products, from multiple providers, dispensed from multiple pharmacies, may be at risk for harm and overutilization. Other examples are beneficiaries for whom a sponsor has authorized quantities in excess of the normal QL set by the sponsor, or beneficiaries for whom soft edits are consistently overridden, could trigger a referral for retrospective review/case management.

CMS conducted an informal survey of five Part D sponsors that demonstrated the limits of current utilization edits for beneficiaries receiving controlled substances and the need for retrospective DUR programs to identify patients at risk which have case management and prescriber communication as included features. The following example illustrates a case where retrospective DUR could identify

possible overutilization that would not be identified through use of normal utilization management tools and POS safety edits:

> A beneficiary is receiving care from thirteen different physicians over the course of one year. Nine of these providers are writing for controlled substances. The patient is receiving methadone 30mg/day from one provider routinely each month, while receiving oxycodone SR 80mg three tablets/day routinely each month from a second provider. It is conceivable that they are each unaware the patient is on both of these Schedule II controlled substances. In addition, the patient is receiving #90 hydrocodone 10mg/APAP 650mg each month from a third provider with five refills while receiving #90 hydrocodone 7.5mg/APAP 750mg also with five refills within one week from a fourth provider. In total, the patient appears to be taking 4.2 gm of APAP per day (which is over the FDA maximum recommended dose due to risk of hepatic toxicity).

We note several observations about this case:

- Use of multiple prescribers for multiple controlled substances places the beneficiary at risk for harm and suggests overutilization of medications;
- Normal safety edits at the POS or formulary management tools, such as quantity limits, would not be triggered since dosing for each product was within the FDA maximal dosing limits;
- Patterns of scheduled maintenance opioid therapy (both long and short duration medications) that repeat from month to month, from different providers, need to be investigated to ensure patient safety and prevent overutilization;
- Schedule III narcotics, unlike Schedule II narcotics, are not required to be rewritten each month allowing up to five refills and can more easily pose a threat of recurrent overprescribing
- Daily APAP exposure can be dangerous, and the intent of each prescriber above was to provide a lower quantity of a hydrocodone/APAP containing product, and to that end, a limited quantity of opioid exposure;
- The FDA daily maximum dose of 4gm of APAP across all scheduled substances should be implemented by sponsors and is found at http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm;
- Sponsors should develop effective DUR programs which include case management, outreach to providers, and if necessary, beneficiary-level controls to prevent overutilization of opioid therapy and ensure beneficiary safety.

Using variables such as those outlined above, Part D sponsors should create and monitor Part D utilization reports to identify patterns of apparent duplicative drug use over sustained periods of time and/or across multiple drug products.

When warranted by review of the retrospective DUR programmed reports and the beneficiaries' medication histories, clinical staff, such as case managers, should communicate with prescribers and beneficiaries to ascertain medical necessity. This clinician-to-clinician communication should include information about the existence of multiple prescribers and the beneficiary's total opioid utilization, as well as elicit any complicating factors, as necessary and appropriate features of such communication.

We expect that merely sharing information about multiple prescribers and the beneficiary's total opioid utilization by sponsors with the prescribers involved in most cases will result in adjustments to future opioid medication regimens that are mutually agreeable to the prescribers and the sponsor. However, if necessary, more involved discussions around the beneficiaries' medical conditions and opioid

prescriptions should occur. Our expectation is that these discussions will result in clinical decision-making about the appropriate level of opioid utilization for the beneficiary. Results of case management may confirm that the current level of opioids is medically necessary, or in some cases, that a lower level or no opioids, are warranted. In the latter cases, our expectation is that all, or some prescribers involved in the health care of the beneficiary, will agree to alter their level of prescribing going forward to achieve the medically necessary level and will be made aware of any beneficiary-level edits to be put in place to ensure this level.

We would expect the bases for the opioid overutilization thresholds or patterns that trigger reports to be documented by the P&T committee. Indeed, our expectation is that the opioid overutilization review program will be reviewed and have documented approval by the P&T committee. In addition to the clinical thresholds and prescription patterns established for triggering retrospective reports to identify beneficiaries that need further evaluation, expected components of the program would be a written policy and procedure that addresses (for beneficiaries who were further evaluated):

1) the required clinical contents of the case file, such as the threshold or pattern triggering the review, as well as the beneficiary medication history;

2) communication with prescribers and beneficiaries, such as the credentials of personnel conducting the communication, the number of attempts at communication to be made; and the documentation required of the communication;

3) the results of the communication with prescribers and beneficiaries, such as any case management plan that is mutually agreed to and the documentation required;

4) in the case of non-responsive prescribers, any action taken by the sponsors, such as beneficiary-level claim edits and the documentation required;

5) copies of the written notices issued to the beneficiary and prescriber(s) informing them of a pending beneficiary-level claim edit to be implemented. (We note that CMS will develop model notices for pending beneficiary-level claim edits, and that sponsors can expect us to ask for the case file when we receive a complaint).

Some sponsors have stated that this level of review and monitoring will be resource-intensive. However, as we have indicated above, the improved overutilization reviews are meant to complement existing, sound DUM and DUR. As such, we expect sponsors to implement programs in a manner that eliminates the need to review borderline cases of inappropriate opioid overutilization. More effective implementation of concurrent DUM, as described above, should minimize the incidence of cases that will need to be reviewed at this more resource-intensive level, as we noted that comments on the September memo demonstrate that many sponsors are not currently applying tools, such as QLs and safety edits as effectively as they could be.

In response to the September memo, we also received comments suggesting that prescribers are currently non-responsive to retrospective DUR requests, and that this non-responsiveness and the sponsors' lack of authority over providers would reduce the impact of overutilization review activities. Therefore, under this process, to the extent that a Part D sponsor has identified a bona fide safety concern about a beneficiary's opioid utilization triggered through thresholds or patterns established in an overutilization review program, the sponsor may move forward with an overutilization protocol;

provided, the sponsor has made reasonable efforts to contact the prescriber and beneficiary in accordance with the policy and procedure of the program and has taken complicating factors of which it is aware into account. More specifically, in the event that a beneficiary's prescription drug claims for opioid analgesics cannot be established as medically necessary for the level of prescribing from the information or documentation received from prescribers, if any, during case management, the sponsor may implement beneficiary-level edits at POS at all network pharmacies that will result in the rejection of claims, or rejection of quantities in excess of plan established limits of opioid analgesics, for the beneficiary. We would expect the sponsor to notify the prescriber(s) and beneficiary in writing that the rejections will begin after a reasonable period of time. In other words, if despite multiple attempts, a sponsor has been unable to work with prescribers to adjust prescribing to a safe level of dosing, the sponsor may prevent the dispensing of unsafe level of drugs. However, we note again that proper implementation of the several improvements to formulary management processes described above will significantly limit the cases requiring such edits.

We received comments from the draft Call Letter asking us to confirm that case management can address physician or pharmacy "shopping" by restricting the beneficiary to selected physicians and pharmacies, but we are not certain exactly what the commenters meant. To clarify our expectation, while the end result of a case management approach may be that prescriptions from certain prescribers who do not communicate with the sponsor may be denied, and the beneficiary is unable to fill them at any pharmacy, this is not the same thing as the sponsor restricting (or "locking-in") the beneficiary to certain providers in advance. If prescribers respond to sponsor outreach to discuss beneficiary case management, again, we expect clinician-to-clinician consultations to arrive at appropriate prescribing patterns going forward. Part D sponsors should limit denial of drug claims only to those prescribed by providers who do not work with the sponsor to assess the appropriate level of dosing.

As stated in the September memo, any such denials would be subject to routine exceptions and appeals processes. Furthermore, we would not expect the Improved Retrospective DUR Programming and Case Management Level to be implemented in a manner that pharmacy providers are put at financial risk (i.e., sponsors would not retroactively recoup prescriptions for prescribers who determined that a particular prescription is no longer medically necessary). Rather, we envision the process described here to be a going-forward collaborative effort between sponsors and prescribers to improve patient safety and reduce fraud, waste and abuse, and not to consist of reviewing past claims for retroactive recoupment unless there is credible evidence of a pharmacy's participation in fraud related to opioid misuse.

Data Sharing Between Sponsors

Some organizations also expressed concerns that once they have implemented these edits for a beneficiary, the beneficiary could disenroll from their plan and enroll in another organization's plan and re-engage in overutilization of medications. They suggested that we should restrict the enrollment rights of dually-eligible beneficiaries who were identified through overutilization efforts. Section 1860D-1(b)(3)(D) of the Act permits LIS beneficiaries access to special election periods, and we will review our guidance in this area.

In the meantime, however, we are making clear that for CY 2013, a sponsor could share the record and actions generated by overutilization review, e.g., the record from the retrospective DUR review/case management, as well as beneficiary-specific POS edits, with the successor sponsor. That is, if a Part D sponsor implemented POS edits for a beneficiary based on retrospective review, and that beneficiary

then voluntarily disenrolled and enrolled in another plan, the initial sponsor may share this information with the subsequent sponsor, who may immediately implement similar beneficiary-level edits if the new sponsor is satisfied that the documentation supports such edits. Again, however, we expect that proper implementation of the improvements described above should minimize the instances requiring such transfers of information. Nevertheless, when such transfers of information on specific beneficiaries are warranted, we expect Part D sponsors to promptly coordinate them. With respect to such transfers, we will welcome additional comments, as well as those already received, on how best to trigger and/or securely exchange this information and will take these under consideration for further guidance. However, in the absence of established automated processes, we expect sponsors to facilitate manual processes when necessary to convey their documented case files. In cases where such transfers result in the imposition of beneficiary-level edits for a beneficiary that has changed plans, denials by the subsequent sponsor would also be subject to routine exceptions and appeals processes.

It is our view that HIPAA permits such data sharing between sponsors. For example, subject to the "minimum necessary" requirements at 45 CFR §164.502(b), a covered entity is permitted under 45 CFR §164.506(c)(3) to disclose protected health information (PHI) to another covered entity for the payment activities of the entity that receives the information. The definition of "payment" in §164.501 includes "review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care …" as long as they relate to the individual to whom health care is provided if it related to medical necessity or appropriateness of care. Thus, a sponsor may share a beneficiary's PHI with a subsequent sponsor for payment activities if the PHI related to medical necessity or appropriateness of care.

In addition, subject to the "minimum necessary" requirements at 45 CFR §164.502(b), if a subsequent sponsor were interested in obtaining information from the initial sponsor in advance of receiving a first prescription request for payment processing, it could do so under a fraud and abuse program (a kind of "health care operation" in HIPAA parlance) for new enrollees that seeks to identify beneficiaries for whom added oversight of prescriptions is needed. We note that this kind of program would be in keeping with sponsors' obligations to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse pursuant to 42 C.F.R. § 423.504(b)(4)(vi)(H) so long as the three requirements for a health care operations "fraud and abuse" disclosure under 45 CFR 164.506(c)(4) were met. However, such a program is not necessarily a part of a comprehensive fraud, waste, and abuse plan.

Thus, as we have described above, there are several avenues by which HIPAA may permit an initial sponsor to share a beneficiary's PHI with a subsequent sponsor. However, we would encourage sponsors to seek guidance from their own legal counsel to determine whether the specific facts, or any other applicable legal considerations, such as state privacy provisions, may place further limits on their options for sharing information for these purposes.

Reporting Suspected Fraudulent Activity

Finally, sponsors are reminded that if a sponsor believes a beneficiary, prescriber, and/or pharmacy is involved in fraudulent activity, they should make referrals to the appropriate agencies in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefit Manual. Please note that MEDIC may be reached at the following number 1-877-7SAFERX (1-877-772-3379).

Summary

In order to more effectively address overutilization in CY 2013, we are delineating several improvements to formulary management processes that should be employed by Part D sponsors to comply with the drug utilization management (DUM) requirements at 42 CFR §423.153 et seq. Specifically, we would consider implementation of these levels by a sponsor to be a minimum standard for compliance with 42 CFR §423.153 with respect to overutilization of opioids beginning CY 2013. Should these levels of DUR not prove effective at establishing medical necessity, which we believe would be a rare instance, the sponsor may implement beneficiary-level POS restrictions under certain conditions. We are also clarifying that sponsors may share beneficiary-level data about overutilization when a beneficiary changes plans. Finally, sponsors are cautioned that we will be monitoring the use of these tools to ensure that they are appropriately implemented.