DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: **September 6, 2012**

TO: **All Part D Sponsors**

FROM: **Cynthia G. Tudor, Ph.D., Director**
Medicare Drug Benefit and C&D Data Group

SUBJECT: **Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D**

Summary

This memorandum provides supplemental guidance regarding the section entitled, "Improving Drug Utilization Review Controls in Part D," of the Final CY 2013 Call Letter, which sets forth how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of prescribed covered Part D drugs. Specifically, in this memorandum we provide information in the following three categories, which we briefly summarize here and provide more detail below under the same headings:

1) Case Management Pilot: We describe a pilot implementation of Level Three: Improved Retrospective DUR Programming and Clinical Case Management ("Level Three"). We addressed implementation of Level Three in the HPMS memorandum entitled, "DRAFT Additional Guidance Related to Improving Drug Utilization Review Controls in Part D—Request for Comments" ("June 29, 2012 HPMS memo") and provided sample letters for comment. We share some observations made during this pilot that will be useful to sponsors as they are designing or supplementing their existing opioid overutilization programs for CY 2013.

2) June 29, 2012 HPMS Memo: In light of the case management pilot and comments that we received on the June 29, 2012 HPMS memo, we reiterate for ease of reference and modify some of the June 29, 2012 HPMS memo, including the sample letters. Thus, to the extent this memo does not change the June 29, 2012 HPMS memo, then the policy is the same. Modified versions of the sample letters are attached as Addendum A. We also include a Frequently Asked Questions (FAQs) document as Addendum B to further assist sponsors in understanding and complying with the opioid overutilization policy for 2013.

3) Analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program: As a result of our ongoing analysis of prescription drug event (PDE) data, we include an Addendum C, "*Analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program,"* which describes CMS' use of daily morphine equivalent dose (MED) and other factors to identify potential overutilization of opioids in the Part D program. We believe the analysis reflected in Addendum C may be useful to P&T committees in considering retrospective DUR clinical thresholds and targeting criteria to identify potential, non-borderline opioid overutilizers warranting case management. Targeting criteria, when properly set, will minimize the number of false positives. Based on the analysis we used in Addendum C, we believe that approximately 22,000 Part D beneficiaries are potential, non-borderline opioid overutilizers.

Again, these categories are each addressed in detail below under the same headings. We thank commenters for their feedback on the June 29, 2012 HPMS memorandum, particularly the sample letters. We encourage sponsors to carefully read this guidance, including the FAQs, as well as review the June 29, 2012 HPMS memo and applicable sections of the Final CY 2013 Call Letter again. We will work to consolidate these documents for easier reference in the near future. Any additional questions should be directed to PartDPolicy@cms.hhs.gov with the subject heading "Opioid Overutilization."

1) Case Management Pilot

During the summer of 2012, three sponsors volunteered to conduct a pilot implementation of Level Three as described in the June 29, 2012 HPMS memo with respect to potential opioid overutilization by a small sample of Part D beneficiaries. We wish to share some observations made during this pilot:

- This approach is effective to identify potentially unsafe and inappropriate use of opioids, and may inhibit the billing of fraudulent prescriptions to the Part D program.
- As noted in the June 29, 2012 HPMS memo, the CY 2013 Final Call Letter was intended to be and is, sufficiently flexible to accommodate different sponsor approaches to case management of potential opioid overutilization.
- There were three categories of prescriber reaction to case management to which we expect certain sponsor responses regardless of the design of the Level Three case management component of its opioid overutilization program:

PRESCRIBER REACTION	SPONSOR RESPONSE
Agreement that there is an opioid usage issue with the patient and cooperation with plan's case management to identify appropriate opioid use.	Sponsor may implement beneficiary-level POS opioid claim edit as appropriate and agreed to by prescriber(s) to assist in managing the beneficiary's opioid utilization after advance notice to beneficiary and prescribers in order to prevent ongoing opioid overutilization. Sponsor cannot lock-in beneficiary to a specific prescriber or pharmacy.
Assertion that patient's opioid usage is being actively managed and dose is appropriate.	No further action necessary. If the sponsor still has concerns about potential fraud, waste or abuse, the sponsor may report this case to the MEDIC.
Lack of response or no prescriber willing to manage patient's opioid usage going forward.	Sponsor may implement beneficiary-level POS opioid claim edit after advance notice to beneficiary and prescriber in order to prevent ongoing opioid overutilization. Sponsor cannot lock-in beneficiary to a specific prescriber or pharmacy.

- Clinical thresholds and prescription patterns, or targeting criteria, set by the P&T committee that trigger case management are of paramount importance in identifying potential, non-borderline opioid overutilizers and not generating false positives. In developing targeting criteria, in addition to Addendum C which uses a daily MED approach, P&T committees may also be interested in "*An Analysis of Heavy Utilizers of Opioids for Chronic Non-Cancer Pain."* (Journal of Pain Symptom Management, 2010 August; 40(2): 279-289).
- Cumulative daily MED is not currently being used as an automated safety measure, at least by the pilot sponsors, but appears to have potential value as a formulary management tool and for retrospective DUR. Drug-level Quantity Limits (QLs) based upon MED have to be submitted for approval by CMS. We are currently working on a submission mechanism for limits based upon cumulative daily MED.
- Cumulative daily acetaminophen (APAP) dose, which has a limit of 4gm/day as recommended by the FDA, is also important to monitor and manage in beneficiaries with high MEDs due to the APAP content of frequently-used opioid analgesics. We remind sponsors that in the Final CY 2013 Call Letter, we stated our expectation that all sponsors would implement edits in their systems that prevent the dispensing of unsafe daily doses of APAP to any beneficiary.

- There are alternatives to a beneficiary-level MED point-of-sale (POS) edit, such as limiting approvals at the beneficiary level to specific opioids and quantities. Two additional POS tools are a beneficiary-level prior authorization on every opioid or selective reduction in opioid MED over time, if warranted. These edits require beneficiary and prescriber advance notice.
- Sponsors should identify ER doctors, oncologists, and pain specialists in their preliminary reviews in order to appropriately target, intervene and communicate.
- Sponsors need up-to-date address, telephone, and fax numbers of beneficiaries and providers.
- Physician-to-physician calls are productive to get needed case information and are frequently well-received by prescribers.
- Some providers are open to receiving general information that assists them in properly managing opioid usage of their patients.
- Sponsors will need to train customer service representatives (CSRs), staff handling coverage determinations, and opioid case management staff, as appropriate, to ensure they are aware of each other's role in the sponsor's opioid overutilization program.

The pilot participants' results demonstrated to us that sponsors can use the approach outlined in the Final CY 2013 Call Letter to effectively address the most concerning cases of potential opioid overutilization in the Part D program, as detailed in the Government Accountability Office (GAO) report referenced in the Final CY 2013 Call Letter (GAO-11-699 September 2011 http://gao.gov/new.items/d11699.pdf). We sincerely appreciate the cooperation and diligence of the pilot sponsors, and their willingness to share their experiences and lessons learned with CMS.

2) June 29, 2012 HPMS Memo

As noted in the June 29, 2012 HPMS memo, we intend the features described in the 2013 Call Letter to be sufficiently flexible to accommodate different sponsor approaches to addressing opioid overutilization. However, there are certain components to Level Three that we believe are necessary to ensure that egregious opioid overutilization is effectively targeted and addressed in the Part D program through Level Three while beneficiaries' right to contest claim edits is protected. In light of the case management pilot and comments that we received on the June 29, 2012 HPMS memo, we set forth the expected components of Level Three:

A) Expected Components of Level Three

1. There is documentation of the program in written policies and procedures that are periodically reviewed, updated as necessary, and approved by the plan's P&T committee.

2. There is a methodology to identify potential opioid overutilizers based on drug claims data through clinical thresholds and prescription patterns that trigger case management. This methodology excludes as early as possible those beneficiaries who have legitimate diagnoses that may warrant high opioid use (e.g., cancer patients or others who need palliative care), or who are borderline cases.

3. There is a process that addresses the required contents of the case management files of potential opioid overutilizers, including what clinical content must be included in a file.

4. There is a process for communication during case management that provides for:

(a). Written inquiries to the prescribers of the opioid medications about the appropriateness, medical necessity and safety of the apparent high dosage for their patient.

(b). At least three (3) attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period (e.g., a ten (10) business day period) from the issuance of the written inquiry notification. These telephone conversations should comply with the following:

i. The personnel communicating with prescribers have appropriate credentials, as established by the P&T committee;

ii. The clinician-to-clinician communication includes information about the existence of multiple prescribers and the beneficiary's total opioid utilization, and the plan's clinician elicits the information necessary to identify any complicating factors in the beneficiary's treatment that are relevant to the case management effort; and

iii. There is appropriate documentation to record the telephone conversations with the prescribers.

5. There is a process to address cases of opioid overutilization that are identified through case management, as follows:

(a). After discussion or communication about the appropriate level of opioid use, the consensus reached by the prescribers is implemented by the sponsor, with a beneficiary-level claim edit, as appropriate.

(b). In cases of non-responsive prescribers, the sponsor implements a beneficiary-level claim edit to prevent coverage of an unsafe level of drugs.

6. There is a process to notify beneficiaries and prescribers of the results of case management, as follows:

(a). When a beneficiary-level claim edit is implemented, written notice is issued to the beneficiary and those prescribers who have requested information for their treatment purposes at least thirty (30) days in advance of this action, in order to give the beneficiary sufficient time to request a coverage determination before implementation of the edit, even though a coverage determination may be requested at any time. In addition, sponsors are required to send a copy of these notices to CMS for CMS's audit purposes in a secure manner to the CMS account manager and the central office mailbox PartDPolicy@cms.hhs.gov with the subject line "Notice of Pending Beneficiary POS Opioid Claim Edit." This e-mail should include the beneficiary's name, address, date of birth, and HICN number, as well as a description of the action taken by the sponsor.

(b). If the current level of opioids is determined to be medically necessary for the beneficiary, the prescribers who asked for such information for treatment purposes should also be promptly notified in writing.

7. With respect to beneficiaries with POS opioid claim edits who voluntarily disenroll from a plan, there is a method to track these beneficiaries in order for the existing sponsor to transfer information (including the case management file) to the new sponsor, if the new sponsor asks for such information for their care management or fraud and abuse purposes. There is also a method for sponsors to document and address incoming notifications from other sponsors.

8. There are policies and procedures for referrals to the appropriate agencies in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefits Manual, if the sponsor believes a beneficiary, prescriber, and/or pharmacy is involved in fraudulent activity.

B) Sample Letters

We received many comments on the June 29, 2012 HPMS memo, and especially on the sample letters to beneficiaries and prescribers as we requested. In this memo, we clarify that the sample letters are not required or can be modified to suit Level Three of the sponsor's opioid overutilization program.

For those sponsors who utilize the sample letters as is, or adapt them, we have included modified versions in Addendum A. The modifications are:

- The overall language of the sample letters is more neutral in order to more effectively communicate with prescribers.
- The initial beneficiary inquiry sample letter has been eliminated due to its limited value, particularly in light of its potential to alarm beneficiaries.
- The beneficiary and prescriber sample letter confirming no change in opioid coverage has been changed to a prescriber sample letter only, since the initial beneficiary inquiry sample letter has been eliminated.
- The sample letter of a pending beneficiary opioid POS claim edit has been broken into two versions for ease of use—one for use when there is full prescriber cooperation with case management and one for use when there is not.
- Some language has been modified or added to respond to comments about HIPAA requirements.

If a sponsor uses or adapts these sample letters, or creates its own, such letters do not have to be approved by us, as they do not constitute marketing letters but rather are *ad hoc* beneficiary communications.

C) Data Sharing Between Sponsors

We clarify that sponsors should transfer the records and actions relevant to a beneficiary-level POS opioid claim edit only when the new sponsor for the beneficiary requests the transfer, and only if all applicable federal and state laws permit the transfer, including privacy laws that address substance abuse and addiction. As noted in the June 29, 2012 HPMS memo, in order to coordinate transfers of beneficiary information and facilitate manual processes to do so, sponsors will be expected to provide an "overutilization" contact and attestation in HPMS when prompted by CMS. This contact and attestation will be made available to all sponsors to support these requests and transfers. We expect a sponsor to use the appropriate overutilization contact to offer to a new sponsor to transfer the applicable overutilization record and action within two (2) weeks of receiving the relevant TRR notice of the disenrollment and enrollment in a new plan of a beneficiary for whom the sponsor has implemented a beneficiary-level POS opioid claim edit.

If requested by the new sponsor, we would expect the actual transfer to be made within two (2) weeks of the request. Such offers and transfers must be done securely. We have accordingly modified the sample sponsor data transfer memorandum that is included in Addendum A with the sample letters to reflect that transfers of records and actions will occur only after an offer by the former sponsor and a request by a new sponsor to do so.

D) Coverage Determinations/Appeals/Grievances

Implementing an opioid overutilization program does not negate a sponsor's responsibilities to ensure that beneficiaries have access to comprehensive appeal and grievance processes. Opioid overutilization programs created by the sponsor are to fit within existing coverage determination, appeal, and grievance rules, as set forth at 42 CFR 423 Subpart M and Chapter 18 of the Medicare Prescription Drug Benefit Manual. If a sponsor determines that a beneficiary is overutilizing an opioid and implements a beneficiary-level edit to prevent overutilization, the beneficiary will have a right to request a coverage determination. Imposing an edit in this case does not constitute a coverage determination, but the plan must process the beneficiary or a prescriber dispute of the edit as a coverage determination. All such coverage determinations should be handled as exceptions requests. Sponsors must determine on case-by-case basis whether any additional outreach should be made to the prescriber(s), particularly when there is a new prescriber, based on the age of the existing clinical information used to implement the edit and the beneficiary's health condition.

If a beneficiary calls to complain about the opioid overutilization process, but is not disputing the new edit, the complaint should be handled through the grievance process. However, because enrollees affected by this program are currently using an opioid, plans must be diligent in obtaining sufficient information to determine whether the enrollee is actually requesting a coverage determination (for example, due to a change in condition). Sponsors must have in place adequate infrastructure and training of their overutilization program staff to ensure effective communication and coordination with staff responsible for customer service, coverage determinations, appeals and grievances.

3) Analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program

This analysis is attached as Addendum C and stands as a separate document.

Questions about this memorandum or the Part D overutilization policy should be directed to PartDPolicy@cms.hhs.gov using the Subject Line "Overutilization."

ADDENDUM A

Sample Part D Opioid Overutilization Initial Prescriber Inquiry Letter CY2013

Instructions: This sample could be used to notify opioid prescribers that the plan's record shows that one of their patients is being prescribed a drug(s) from the opioid class in a potentially unsafe high dosage, which has triggered a drug overutilization review to determine whether the patient's safety may be at risk.

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<PRESCRIBER NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: PRESCRIPTION FILE [###]>

Dear <PRESCRIBER>:

<Plan Name> is sending you this letter to request your assistance because we have determined your patient, <Patient Name>, is being prescribed a certain dosage of a medication(s) in the opioid class and/or has opioid prescriptions involving multiple prescribers and/or pharmacies.

<Plan Name> is the Medicare drug plan for your patient, <Patient Name>. As part of our responsibilities as a Medicare Part D sponsor, we provide certain case management services. We identify and follow up to obtain additional information when there are prescribing and dispensing patterns that could potentially be inappropriate and medically unnecessary.

We have <listed> <attached> the medication(s) in the opioid class prescribed for <Patient Name>, which includes all opioid medications of which we are aware, the dosage(s) prescribed, and the time period we are reviewing.

[List or attach the information just described].

We are requesting your confirmation that the opioid medication(s) <listed><attached> and the current cumulative dosage of opioid medications being prescribed for your patient are appropriate, medically necessary, and safe for <Patient Name>. When multiple prescribers are involved, our goal is to verify that there is a consensus among all prescribers as to the appropriate, medically necessary, and safe dosage for <Patient Name>, and if there is no consensus, to facilitate one.

We thank you for your assistance in addressing this matter and urge you to be responsive. If we are unable to establish through communication with the prescriber(s) that the current dosage of opioid medication(s) is appropriate, medically necessary, and safe for <Patient Name>, we may have to inform the beneficiary and deny coverage of some or all of these medications. Therefore, your input is imperative.

Should you have any questions, or if you need additional information for use in your treatment of this patient, please contact me at <Contact Information> during the hours of <LIST HOURS> and please refer to the file number above.

Sincerely,

<NAME>

[Insert beneficiary identifying information]

Sample Part D Opioid Overutilization Prescriber No Change Confirmation Letter CY2013

Instructions: This sample letter could be used if the sponsor confirms with a prescriber who requested information for use in their treatment of the patient, that an enrollee's opioid usage is appropriate and medically necessary.

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<PRESCRIBER NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: PRESCRIPTION FILE [###]>

Dear <PRESCRIBER>:

<Plan Name> wishes to thank you for confirming that the opioid medication(s) described below is/are appropriate, medically necessary and safe for your patient <Patient Name>.

[Insert description of opioid medication(s) and dose]

Based on your input, we will continue to cover this opioid medication(s) for <Patient Name> at this time. If you have any questions or concerns with this letter, or if you would like any further information about your patient's opioid prescriptions in the future for your treatment purposes, please contact <Name and Phone Number> and have ready the file number above.

Sincerely,

<NAME>

[Insert beneficiary identifying information]

Sample Part D Drug Overutilization Notice of Pending Beneficiary POS Opioid Claim Edit Letter/Prescriber Confirmation CY2013

Instructions: This letter could be used when the sponsor concludes that an enrollee's opioid usage is inappropriate and not medically necessary. It could be forwarded to prescriber(s) who have asked for information on their patient's opioid use for treatment purposes. The sponsor is expected to provide a copy of this letter to the CMS Account Manager and to the CMS Central Office via secure e-mail at PartDPolicy@cms.hhs.gov *with the subject line "Notice of Pending Beneficiary POS Opioid Claim Edit" for CMS' audit purposes.*

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<BENEFICIARY NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: PRESCRIPTION FILE [###]>

Dear <BENEFICIARY NAME>:

One of the most important care management services that a prescription drug plan can offer their enrollees is monitoring the safe and effective use of prescription drugs. We're writing you today to tell you the results of a medical necessity review. After communicating with your doctor(s), <Prescriber Name(s)>, who prescribed your opioid pain medication(s) for you, <only the opioid pain medication listed below> OR <no opioid pain medication> has been found to be appropriate and medically necessary for you.

WHAT YOU SHOULD DO IF YOU DISAGREE WITH THIS LETTER:
If you believe a mistake has been made and that you need more opioid pain medication than is described below, or you disagree with information provided to you by a pharmacist related to refills of your opioid pain medications, you or your prescriber have the right to request a **coverage determination** by contacting <Plan Name> Customer Service at XXX-XXX-XXXX or going to the <Plan Name> website at <Website address>. In addition, you may also contact the Centers for Medicare & Medicaid (CMS) Ombudsman program at 1-800-MEDICARE (1-800-633-4227).

If you do not request a coverage determination before thirty (30) days have passed from the date of this letter, as of <Date>, <only the opioid pain medication listed below> <no opioid pain medication> will be covered by <Plan Name>.

[When some opioid pain medication will continue to be received by the enrollee, sponsors should describe the POS opioid claim edit to be implemented by the plan. The following is an example of how a description of such a claim edit could be worded].

<Only <Dosage> of <Drug Name> will be covered every <Number> days for you subject to the plan's benefits. <Plan name> will deny any claim for opioid pain medication that is not described here. This dosage may be subject to <Plan Name's> standard quantity limits when they are dispensed.

This letter does not concern any non-opioid pain medications you may be taking, and you should not experience any changes with respect to any non-opioid pain medications, if you are taking any.

If you have any questions or concerns about this letter, please contact <Name and Phone Number> and have ready the file number above. Of course, if you have any questions concerning your pain medication, please contact the doctor(s) who prescribed it.

Sincerely,

<CLINICIAN NAME>

[Insert beneficiary identifying information]

Sample Part D Opioid Overutilization Notice of Pending Beneficiary POS Opioid Claim Edit Letter/No Prescriber Confirmation CY2013

Instructions: This letter could be used if the sponsor cannot confirm that an enrollee's opioid usage is appropriate and medically necessary due to lack of prescriber input. It could be forwarded to prescriber(s) who have nonetheless asked for information on their patient's opioid use for treatment purposes. The sponsor is expected to provide a copy of this letter to the CMS Account Manager and to the CMS Central Office via secure e-mail at PartDPolicy@cms.hhs.gov *with the subject line "Notice of Pending Beneficiary POS Opioid Claim Edit" for CMS' audit purposes.*

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<BENEFICIARY NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: PRESCRIPTION FILE [###]>

Dear <BENEFICIARY NAME>:

One of the most important care management services that a prescription drug plan can offer their enrollees is monitoring the safe and effective use of prescription drugs. We're writing you today to tell you the results of a medical necessity review. After multiple attempts, we weren't able to reach the doctor(s), <Prescriber Name(s)>, who prescribed your opioid pain medication(s) for you. Therefore, <only the opioid pain medication listed below> OR <no opioid pain medication> has been found to be appropriate and medically necessary for you.

WHAT YOU SHOULD DO IF YOU DISAGREE WITH THIS LETTER:
If you believe a mistake has been made and that you need more pain medication than is described below, or you disagree with information provided to you by a pharmacist related to refills of your opioid pain medications, you or your prescriber have the right to request a **coverage determination** by contacting <Plan Name> Customer Service at XXX-XXX-XXXX or going to the <Plan Name> website at <Website address>. In addition, you may also contact

the Centers for Medicare & Medicaid (CMS) Ombudsman program at 1-800-MEDICARE (1-800-633-4227).

If you do not request a coverage determination before thirty (30) days have passed from the date of this letter, as of <Date>, <only the opioid pain medication listed below> <no opioid pain medication> will be covered by <Plan Name>.

[When some opioid pain medication will continue to be received by the enrollee, sponsors should describe the POS opioid claim edit to be implemented by the plan. The following is an example of how a description of such a claim edit could be worded].

<Only <Dosage> of <Drug Name> will be covered every <Number> days for you subject to the plan's benefits. <Plan name> will deny any claim for opioid pain medication that is not described here. Changing dosages of opioid pain medication should be done with medical supervision. Please talk to the doctor(s) who prescribed this medication for you about this letter. This dosage may be subject to <Plan Name's> standard quantity limits when they are dispensed.

This letter does not concern any non-opioid pain medications you may be taking, and you should not experience any changes with respect to any non-opioid pain medications, if you are taking any.

If you have any questions or concerns about this letter, please contact <Name and Phone Number> and have ready the file number above. Of course, if you have any questions concerning your pain medication, please contact the doctor(s) who prescribed it.

Sincerely,

<CLINICIAN NAME>

[Insert more specific beneficiary identifying information]

Sample Part D Opioid Overutilization Sponsor Data Transfer Memorandum CY2013

Instructions: This cover memorandum could be used by a sponsor when an enrollee who is subject to a beneficiary-level POS opioid claim edit disenrolls from the sponsor's plan and enrolls in another in order to alert the new sponsor who has indicated their desire to receive such information for their care management use. It is intended to convey information about the former sponsor's findings about the enrollee's prior opioid overutilization, and to provide the new sponsor with the records and actions generated by the sponsor's overutilization review of the enrollee.

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

DATE: <Date>

TO: New Sponsor

FROM: Former Sponsor

RE: Enrollee Subject to a Beneficiary-Level POS Opioid Claim Edit

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The purpose of this memo is to highlight certain information that is being provided in response to a request that <Former Sponsor> received on <Date> from <New Sponsor> to receive information related to a POS opioid claim edit implemented by <Former Sponsor> for <Beneficiary Name> since <date>. <New Sponsor> received notice from <Former Sponsor> on <Date> that <Beneficiary Name> disenrolled from <Plan Name> and enrolled in <Plan Name> effective <Date>.

The POS opioid claim edit implemented by <Former Sponsor> is described below:

[*The following is an example of how a description of such a claim edit could be worded*].

<Only <Dosage> of <Drug Name> was covered every <Number> days>.

Accompanying this memorandum are copies of the records from the retrospective DUR review/case management that was conducted by <Former Sponsor> upon which the decision to implement the POS opioid claim edit was based. Specifically, the following minimum necessary records are permitted to be transferred under applicable law and include:

[List the records that are included. Examples of records that could be included are:

a) clinical threshold and/or prescription pattern that triggered case management;

b) copies of medical records;
c) beneficiary drug utilization history;
d) correspondence with prescribers and the beneficiary;
e) notes documenting telephone conversations; and
f) documentation of the decision arrived at through case management.

If you have any questions concerning this memorandum, please contact <Name> at <Contact Information.>

[*Insert beneficiary identifying information]*

ADDENDUM B

Improving Drug Utilization Controls in Part D

Frequently Asked Questions

LOCK-IN

1. Can we "lock-in" a beneficiary, who has been identified through our retrospective DUR programming and case management as an opioid overutilizer, to a specific provider and/or or pharmacy?

No. A beneficiary may not be "locked-in" to any specific provider or pharmacy. In this regard, claims should not be denied on the basis that they involve prescriptions written by a certain prescriber, unless the plan suspects fraud with respect to the prescriber. Rather, claims should be denied only after the appropriate opioid medication and dosage, if any, has been covered as determined through case management. As we noted in the Final CY 2013 Call Letter, in certain instances, this may appear to a beneficiary to be "lock-in" to a specific prescriber since claims that are not for the authorized opioid medication or dosage will be denied. However, this is not "lock-in," as the beneficiary would be entitled to coverage of the authorized medication and dosage regardless of which prescriber actually wrote the prescription.

CLINICAL SCENARIOS

2. What if all prescribers are prescribing opioids to a beneficiary within acceptable clinical limits, but the sum total of the opioids appears to be unsafe?

The Final CY 2013 Call Letter provided an example case, where retrospective DUR could identify possible opioid overutilization that would not be identified through use of normal utilization management and POS safety edits, as precisely the type of case that warrants monitoring by Part D sponsors of utilization reports to identify patterns of apparent duplicative drug use over sustained periods of time and/or across multiple drug products and engaging in case management as appropriate. CMS expects targeting criteria to combine opioid doses through some methodology such as MED.

3. What should a sponsor do in cases where there is a lack of prescriber response or no prescriber willing to provide input about medical necessity and appropriateness of the opioid usage by the patient going forward, such as in a case where the prescriptions are written by emergency room physicians, or the contacted prescribers state they no longer plan to treat the beneficiary?

A sponsor should make every attempt to identify a prescriber who is willing to provide input about medical necessity and appropriateness of the opioid usage by the patient going forward. This may require the sponsor to look at non-opioid claims, and specifically, at the prescribers of the non-opioid claims. Sponsors must determine for themselves the usefulness of attempting to call or contact all opioid prescribers when there are many, particularly when they are emergency room physicians. Whatever approaches a sponsor employs, if these approaches fail, the sponsor could implement a beneficiary-level POS opioid claim edit to prevent Part D coverage of opioids that cannot be determined to be appropriate, medically necessary and safe with input from its P&T committee.

4. What if a prescriber who agreed with a beneficiary-level POS opioid claim edit to help manage the beneficiary's health care wants to later increase the opioid dosage?

Sponsors' opioid overutilization programs should take into account that, in some cases, doses and/or opioid medications will change. We strongly encourage Part D sponsors to provide a proactive avenue for prescribers who are cooperative with the sponsors' opioid overutilization review program to contact appropriate clinical staff to revise a previously agreed upon dose limit.

5. What if the beneficiary only has one prescriber who is prescribing opioids in an unusually high dose for the beneficiary that appears to be unsafe, but during case management, the prescriber asserts that such dose is medically necessary? Is CMS instructing us to implement a beneficiary-level POS opioid claim anyway?

No. As noted in the Final CY 2013 Call Letter, a sponsor may implement a beneficiary-level POS opioid claim edit without prescriber cooperation only if the sponsor has been unable to work with the prescriber after multiple attempts due to the prescriber's unresponsiveness. In this case, the prescriber is responsive. The sponsor should carefully note the prescriber's explanation in its case management record for the beneficiary, and may also attempt to obtain the prescriber's opinion in writing. Additionally, the sponsor may want to investigate other claims involving prescriptions written by the prescriber. In this regard, we remind sponsors that they have responsibilities regarding fraud, waste and abuse as described in Chapter 9 of the Prescription Drug Benefit Manual, which include making appropriate referrals to the MEDIC.

6. After a beneficiary has been identified through our retrospective DUR as a potential opioid overutilizer as part of our case management, may a sponsor, in appropriate circumstances, send a written notice to the prescribers that the sponsor is monitoring the claims of the beneficiary before escalating to an actual phone call to the prescribers?

Yes. We have provided the expected components of an opioid overutilization review program in the Final CY 2013 Call Letter and this memo. Sponsors are not required to automatically contact prescribers telephonically. However, sponsors who employ a wait-and-see approach should consider that the Final CY 2013 Call Letter, the June 29, 2012 HPMS memo, and this guidance make clear that we expect sponsors to address the most egregious cases of opioid overutilization without unreasonable delay, and we do not believe that all such cases can be addressed through a prescriber letter campaign. However, to the extent that some cases can be addressed through written communication to prescribers only, we would acknowledge the benefit of not aggravating prescribers with unnecessary telephonic communications. At a minimum, to be effective, we believe such communications should include information about the beneficiary's total opioid utilization, such as through use of the MED methodology discussed in Addendum C.

7. If case management indicates that the beneficiary is an opioid overutilizer, must we implement a beneficiary-level POS opioid claim edit after thirty (30) days, or may we monitor claims for the beneficiary and determine if the overutilization resolves itself due to our outreach to the opioid prescribers?

Where prescribers are cooperative, the sponsor should use discretion in implementing such an edit. Where prescribers are not responsive, a sponsor should implement a beneficiary-level POS opioid claim edit promptly to ensure the opioid overutilization issue has been effectively addressed.

OPERATIONAL QUESTIONS

8. Our plan has quantity limits (QLs) on the opioid class for 2013. If one of these is triggered, do we have to send the sample beneficiary/prescriber notices?

No. The sample letters are intended for the Level Three retrospective DUR programming and case management component of an opioid overutilization program. Moreover, as answered above, the sample letters are not required as is and can be adapted to the sponsor's opioid overutilization program. However, whenever a claim is denied at POS, the "Medicare Prescription Drug Coverage and Your Rights" notice must be provided in accordance with existing procedure for all claims denied at POS.

9. Do beneficiary-level POS opioid claim edits have to be consistent with the criteria for hard edits we submitted with our formulary?

No. A QL for an opioid medication that was approved through formulary submission is used to ensure safe dosage of a specific opioid product for all beneficiaries unless an exception is granted. A beneficiary-level POS opioid claim edit is to prevent continuing coverage of a MED dose of an opioid(s) that case management has established as unsafe and not medically necessary or appropriate for a specific beneficiary.

10. How does the CMS policy on opioid overutilization intersect with the transition policy?

In general, for non-formulary opioid medications and formulary opioid medications subject to prior authorization or step therapy under the new plan's utilization management rules, a temporary supply must be provided during a transition period in accordance with established Part D transition policy. However, if a beneficiary-level POS opioid claim edit has been implemented, we would expect the beneficiary to only be able to receive during a transition period the opioid dosage that has been determined to be medically necessary and appropriate for him or her through the case management process.

MONITORING EFFORT

11. Will CMS provide us with a list of potential opioid overutilizers in our plans so we do not have to identify them ourselves?

No, we will not provide such a list. As noted in the Final CY 2013 Call Letter, 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. While we are developing monitoring tools which will identify outliers in opioid use, and we may ask the relevant sponsors to respond whether the beneficiaries' opioid use has already been investigated for those beneficiaries for whom no POS opioid claim edit is in place, this does not mean that CMS will identify for sponsors which beneficiaries should be subject to case management. Outlier checks that we are considering for these monitoring efforts include, but are not limited to, daily morphine equivalent dose (MED) greater than 120 mg for at least 90 consecutive days, number of prescribers, and/or number of pharmacies. See Addendum C for a report of CMS' Analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program, which includes a methodology to calculate the cumulative daily MED for Part D beneficiaries.

COVERAGE DETERMINATIONS/APPEALS/GRIEVANCES

12. Does an edit imposed pursuant to the plan's opioid utilization program override a previously approved exception request for a higher dose of the drug?

Yes, if the review conducted pursuant to the plan's opioid utilization program resulted in a determination that the previously approved dose is not medically necessary, appropriate or safe for the beneficiary. A beneficiary or a prescriber may request an exception to the claim edit dose. However, the beneficiary-level claim edit should continue to be applied unless an exception is granted to the edit.

13. Can beneficiaries appeal these decisions to the IRE? How should case files be compiled for the IRE, and what standards will the IRE use in overturning a plan's decision?

Yes. Beneficiaries will have all of their standard appeal rights, including appealing an adverse decision to the Independent Review Entity (IRE). Case files will be compiled using the same rules as all exception requests. Per the Part D QIC Reconsideration Procedures Manual, plans are provided with an exhaustive list of documents that must be included in the case file. These documents include, but are not limited to, medical records, plan materials, and a Case Narrative Form (which can be downloaded from the Part D QIC's website) in which the plan provides an overview of the issues on appeal, identifies arguments in favor of and against coverage, and explains the plan's reasons for denying coverage as requested by the appellant. For appeals involving exception requests, the plan must also include prescriber supporting statements. If the plan obtained an oral statement, the IRE will accept transcribed oral statements and phone logs documenting telephone conversations. In addition, the Part D QIC Reconsideration Procedures Manual instructs plans to include any other evidentiary information/documents that are relevant to the disputed drug benefit. Communications with prescribers and the enrollee regarding the enrollee's opioid use would be relevant in these cases. In addition, copies of the coverage determination and redetermination denial notices (which must be in the case file) should clearly explain why a higher dose has been denied by the plan.

14. Since a beneficiary-level edit is made only after outreach to a prescriber, how much additional outreach is necessary before responding to a beneficiaries' subsequent coverage determination?

A sponsor must review a coverage determination request pursuant to the requirements in 42 CFR 423 Subpart M. Sponsors must review any new evidence provided by either the beneficiary or the prescriber to determine whether the requested drug/dosage is medically necessary. Sponsors must consider existing clinical information as well as any new information provided at the time the coverage determination is requested when making their decision. Sponsors must determine on a case by case basis whether any additional outreach must be made to the physician based on the age of existing clinical information used to implement the edit, as well as the enrollee's health condition.

15. What steps must the sponsor take once a coverage determination to approve or deny the requested drug/dosage has been made?

The sponsor must follow the requirements in 42 CFR 423 Subpart M with respect to notification and effectuation of coverage determinations. If the sponsor denies the coverage determination request, it must timely notify the enrollee and prescriber(s) by sending a Notice of Denial of Medicare Prescription Drug Coverage (CMS-10146), which must state the specific reason(s) for the denial and include a description of the enrollee's appeal rights.

16. How can a sponsor determine whether an enrollee's request constitutes an inquiry, grievance or a request for a coverage determination?

Sponsors should use Chapter 18 of the Medicare Prescription Drug Benefit Manual to help them determine how to classify a beneficiary's request. When an affected enrollee contacts the plan because they disagree with the plan's decision to implement a claim edit, the plan should process that request as a coverage determination. Pursuant to 42 CFR 423.568(a), the plan must accept both oral and written requests for coverage determinations.

DATA TRANSFER

17. When a beneficiary under a beneficiary-level POS claim edit for opioid overutilization changes to a plan of another sponsor, how can a sponsor identify the new plan sponsor?

If a beneficiary enrolls in a new plan and as a result of that enrollment is disenrolled from his/her current plan, the transaction reply report (TRR) notifying the current plan of the disenrollment includes the identity of the successor plan. Once the current sponsor identifies the new sponsor, the current sponsor can refer to the overutilization contact provided by the new sponsor through HPMS to contact the new sponsor. Only in those infrequent instances when a beneficiary first disenrolls from his/her current plan and then in a separate transaction enrolls in a new plan would the current plan not be notified of the identity of the successor plan. In this latter circumstance, we would not expect the former sponsor to notify the new sponsor of a beneficiary-level POS opioid claim edit since the former sponsor will not be able to identify the new sponsor.

18. For a beneficiary with a POS opioid claim edit in place, must the former sponsor automatically transfer the record and actions generated by the overutilization review to the new sponsor?

No. The new sponsor must first request the record and actions. However, we do expect the former sponsor to notify any new sponsor that has indicated that it is interested in such records for purposes of its care management or fraud and abuse program, so the new sponsor has the opportunity to request the relevant records and actions.

19. The claim patterns that trigger case management may be proprietary. Must the former sponsor include this information in the record and action that it shares with the new sponsor?

No, as stated in the June 29, 2012 memo, sponsors are not expected to share proprietary business information with another sponsor.

20 We think privacy laws addressing substance abuse and addiction prevent us from sharing the record and actions with the new sponsor. What should we do?

Our guidance on opioid overutilization review programs should not be construed as recommending actions that conflict with applicable federal or state privacy laws. If a sponsor's counsel advises that a federal or state law prohibits the sponsor from sharing any particular record or action, the sponsor should not share that particular record or action.

OTHER

21. What if a sponsor wishes to implement the approach described in Level Three of the Final CY 2013 Call Letter, the June 29, 2012 HPMS memo and this guidance for non-opioid medications?

If a sponsor chooses to implement this approach for non-opioid medications, we would expect the sponsor to employ the same level of diligence and documentation with respect to non-opioid medications that we expect for opioid medications. However, sponsors should be clear that, at this time, our guidance applies only to opioid overutilization, and thus it should not be characterized as applying to non-opioid overutilization.

22. Are there any special considerations for long-term care ("LTC")?

No. There are no special considerations for LTC.

ADDENDUM C

Analysis of Morphine Equivalent Dose (MED) in the Medicare Part D Program

August 31, 2012

Statement of Issue

Prescription drug abuse has been recognized as an increasingly significant public health concern. After it was classified by the Joint Commission as a "vital sign" in 2001[1], pain management issues have been raised around prescribing and dosage levels, costs and risks associated with overutilization, and how to identify and respond to persons who seek out prescriptions for purposes that fall under fraud, waste, and abuse. People who abuse opioids have direct health care costs more than eight times those of nonabusers.[2] Opioid overdose is now the second leading cause of unintentional death in the United States, second only to motor vehicle crashes.[3] In September 2011, the United States Government Accountability Office (GAO) identified potential instances of fraud and abuse of opioids and other potent analgesics in the Medicare Prescription Drug Program (Part D), and recommended that The Centers for Medicare and Medicaid Services (CMS) improve its efforts to curb overutilization in the program.[4]

Given the significant increases in the number of patients seeking and receiving opioid prescriptions, risk of dose-related morbidity and mortality, and potential fraud, waste, and abuse, CMS is taking steps to improve the safe and effective use of opioids in the Medicare Part D Program. As described below, CMS developed a drug utilization review methodology to identify a narrowed target population of beneficiaries who are at risk due to high use of opioids for whom focused case management may be appropriate and for which the caseload would be manageable. These efforts are intended to keep the best interest and safety of beneficiaries as a primary focus, while helping to identify potential prescription drug abuse.

Background

In the fall of 2011, CMS proposed a beneficiary-centric approach to improve efforts to curb overutilization in Part D while maintaining beneficiary access to needed medications. This approach included solicitation of comments from Part D sponsors and other interested stakeholders on how to improve drug utilization controls in Part D, including comments on what resources and timelines are needed to implement a beneficiary-centric strategy to managing overutilization based on medically-

[1] Jeanmarie Perrone, M.D., and Lewis S. Nelson, M.D. Medication Reconciliation for Controlled Substances — An "Ideal" Prescription-Drug Monitoring Program N Engl J Med 2012; 366:2341-2343

[2] Unintentional drug poisoning in the United States [July 2010]. National Center for Injury Prevention and Control. Centers for Disease Control and Prevention. http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf.

[3] Volkow ND, McLellan TA. Curtailing Diversion and Abuse of Opioid Analgesics Without Jeopardizing Pain Treatment. *JAMA* 2011;305(13):1346-1347.

[4] GAO, *Medicare Part D, Instances of Questionable Access to Prescription Drugs*, GAO-11-699. (Washington, D.C.: Sept. 6, 2011).

accepted norms of dosing, preferably within the existing Part D statutory authority and without passing the responsibility onto other parties. Concurrently, CMS analyzed Part D data to gain a better understanding of the prescribing and dispensing of highly abused pain medications to Medicare beneficiaries. We concluded from Part D sponsors' feedback that: 1) safety edits and retrospective drug utilization review (DUR) at point-of-sale (POS) are insufficient for identifying beneficiaries who are at-risk for overutilization of opioid analgesics, and 2) analyzing beneficiaries' prescription drug data is a complex task, requiring careful clinical review or case management and consideration of multiple diverse factors. These efforts informed subsequent communications to Part D sponsors on an improved retrospective drug utilization review and case management approach, such as guidance in the draft and final 2013 Call Letter, and the memo accompanying this report.

As an extension of the analysis completed last fall, CMS looked for other tools that Part D plans could use to manage and assess potential patient safety risks as a result of overutilization. Recent studies demonstrate that a patient's cumulative, daily morphine equivalent dose (MED) of opioids is an indicator of potential dose-related risk for adverse drug reactions. Compared with patients receiving 1 to 20 mg MED per day, who had 0.2% annual overdose rate, patients receiving 100 mg MED or more daily had an 8.9-fold increase in overdose risk and a 1.8% annual overdose rate as compared to the lowest doses.[5] The studies suggest that the total daily dose of opioids should not be increased above 120 mg oral MED without either the patient demonstrating improvement in function and pain or first obtaining a consultation from a practitioner qualified in chronic pain management.[6] Further, beginning in 2011, the State of Washington implemented public policy requiring a patient's physician to consult or transfer the patient to a pain specialist based on a MED of at least 120 mg per day. CMS believes that the use of daily 120 mg MED calculations as a screening tool may be applicable to Part D and may help identify beneficiaries who are at risk for potential adverse effects or possible inappropriate use or diversion of opioids.

Study: Targeting Overutilization of Prescription Opioid Medications using Daily Morphine Equivalent Dose (MED) and Other Criteria

To support the improved retrospective DUR and case management approach to curb unsafe overutilization of opioid pain medications and determine the extent of the issue in Part D, CMS:

1. Evaluated the scope of the population at risk including how prescription opioids are being prescribed and dispensed within the Part D population,

[5] Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med 2010;152(2):85-92.

[6] Washington State Agency Medical Directors' Group, Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy, 2010 Update. Available at www.agencymeddirectors.wa.gov.

2. Determined segments of the Part D population that may be overutilizing prescription opioids or may be at risk for dose-related adverse effects, and
3. Developed a retrospective review methodology to identify a manageable, narrowed target population of high opioid users.

A daily MED above 120 mg was selected as a targeting criterion based upon the aforementioned findings in the literature and the State of Washington experience to determine whether or not a Medicare Part D beneficiary was potentially receiving unsafe doses of prescription opioids. After converting a beneficiary's opioid medications to their MED, a beneficiary's cumulative prescription opioid daily doses could be summed to determine if he/she exceeded 120 mg MED as well as the duration of consecutive days above this threshold. Further analysis examined the beneficiaries identified by the MED targeting criterion and determined the number of prescribers providing these prescriptions to detect potential "doctor shopping" behavior. Additionally, by tracking the number of pharmacies that a beneficiary uses, the potential for "pharmacy shopping" could be observed as a contributing factor to the overutilization of opioid analgesics. The use of multiple prescribers and pharmacies may increase the risk of adverse effects as well as indicate potential fraud, waste, and abuse. Finally, diagnoses and demographic characteristics of beneficiaries who use opioids were studied. The methodologies and results from these analyses are summarized in the following sections.

Methods

Contract year 2011 Medicare Part D prescription drug event (PDE) data as of June 2, 2012 were used to study potential overutilization of opioids. To mitigate disruption and reduce the number of false positive cases identified, beneficiaries with cancer were excluded from the analysis using Part D Hierarchical Condition Categories[7] (RxHCCs) 8, 9, 10, and 11 reported in the Risk Adjustment Processing System (RAPS), as well those beneficiaries under hospice care based on the Hospice indicator in the Enrollment Database (EDB)[8]. High MED values within this population are more likely to be cases of appropriate use of opioid medications.

Early analysis found that over 10% of the beneficiaries who had greater than or equal to 120 mg MED (referred to as the MED threshold) for at least a day had exactly 120 mg MED. Therefore, to identify a more focused and less resource intensive population, our analysis only included beneficiaries who exceeded the MED threshold.

The targeted opioid products, the amount of opioid in each dosage unit, and their MED conversion factors (see Appendix, Table A) were used to determine which PDE claim(s) exceeded the MED

[7] For a discussion of Part D Hierarchical Condition Categories, see the "Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter," February 19, 2010, available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2011CombinedCallLetter.pdf.

[8] Hospice beneficiaries are defined as those who have a hospice stay in the last quarter of 2010 and all months of 2011.

threshold. Generic Product Identifiers (GPI)-14 indicators in Medi-Span were used to identify unique opioid products for which a specific MED conversion factor applied. Table 1 lists the opioid products that were included in the calculation of the daily MED. Tapentadol was excluded from this analysis since an accepted conversion factor to determine an accurate morphine equivalent dose was not available.

Table 1: Opioid Products

ACETAMINOPHEN / BUTALBITAL / CAFFEINE / CODEINE PHOSPHATE	ASPIRIN / OXYCODONE HYDROCHLORIDE	MEPERIDINE HYDROCHLORIDE
ACETAMINOPHEN / CAFFEINE / DIHYDROCODEINE BITARTRATE	ASPIRIN / OXYCODONE HYDROCHLORIDE / OXYCODONE TEREPHTHALATE	METHADONE HYDROCHLORIDE
ACETAMINOPHEN / CODEINE PHOSPHATE	CODEINE SULFATE	MORPHINE SULFATE
ACETAMINOPHEN / HYDROCODONE BITARTRATE	FENTANYL	MORPHINE SULFATE / NALTREXONE HYDROCHLORIDE
ACETAMINOPHEN / OXYCODONE HYDROCHLORIDE	FENTANYL CITRATE	OXYCODONE HYDROCHLORIDE
ACETAMINOPHEN / PROPOXYPHENE HYDROCHLORIDE	HYDROCODONE BITARTRATE / IBUPROFEN	OXYMORPHONE HYDROCHLORIDE
ACETAMINOPHEN / PROPOXYPHENE NAPSYLATE	HYDROMORPHONE HYDROCHLORIDE	PROPOXYPHENE HYDROCHLORIDE
ASPIRIN / BUTALBITAL / CAFFEINE / CODEINE PHOSPHATE	IBUPROFEN / OXYCODONE HYDROCHLORIDE	PROPOXYPHENE NAPSYLATE
ASPIRIN / CAFFEINE / DIHYDROCODEINE BITARTRATE	LEVORPHANOL TARTRATE	

The initial analysis examined the number of days beneficiaries who exceeded the MED threshold, the range of daily MED used, and the percentage of opioid treatment days that exceeded the MED threshold. To identify beneficiaries with prescription opioids that exceeded the MED threshold, each claim was converted into the MED with the appropriate conversion factor associated with the opioid product of that prescription claim. The MED for each day's claims were summed to determine the total MED for that day.

The general algorithms used to determine the daily MED are below:

- $\#\ \text{Opioid Dosage Units per day} = (\text{Opioid claim quantity}) \div (\text{Opioid claim days supply})$
- $\text{Oral MED Daily Dose per claim} = \begin{pmatrix}\#\ \text{Opioid Dosage} \\ \text{Units per day}\end{pmatrix} \times \begin{pmatrix}\#\ \text{Mg Opioid per} \\ \text{dosage unit}\end{pmatrix} \times \begin{pmatrix}\text{MED} \\ \text{conversion} \\ \text{factor}\end{pmatrix}$

- ∑ Oral MED Daily Dose per claim

One limitation is that this analysis did not correct for early refills, overlapping fills of new prescriptions, dose changes or discontinuation of opioid prescriptions. Therefore, if a beneficiary has filled a prescription for a medication but only utilizes that medication for a portion of the days filled and then receives a new prescription to replace the existing one; this may cause the calculated daily dosage to exceed the MED threshold when in fact the patient is not utilizing an excessive amount.

Prescriber identifiers, such as the National Provider Identifier (NPI), were used to determine the number of prescribers providing opioid prescriptions for beneficiaries. However, there were some data limitations which may result in an overestimation of the number of prescribers. Prescriber information for approximately 200 beneficiaries in the analysis population was not available. That is, not all prescriber identifiers could be mapped into a common format to eliminate duplicates arising from different identifiers for the same prescriber or to identify different prescribers in the same practice setting. To overcome this limitation for future analysis, crosswalks are being built in an effort to account for this possible overestimation in data reporting.

The number of pharmacies associated with the opioid fills was also calculated. When possible, pharmacies were mapped into one common format (i.e., NCPDP) to ensure that unique pharmacies were counted. A matching pharmacy ID was associated with 100% of claims.

Lastly, we examined whether certain health conditions or demographic characteristics were more likely to be associated with high utilization of opioid medication among our populations of interest through logistic regression. This analysis focused on three beneficiary cohorts:

- **Part D Beneficiaries:** Beneficiaries enrolled in Part D at any time in 2011, excluding cancer patients and hospice beneficiaries.
- **Opioid Users:** Beneficiaries with at least one 2011 Part D claim for an opioid medication, excluding cancer patients and hospice beneficiaries.
- **Target Population of High Opioid Users:** Among opioid users, beneficiaries who exceeded 120 mg MED for at least 90 consecutive days.

We ran two sets of logistic regressions for the aggregate Part D and Opioid User populations, assessing the likelihood of these beneficiaries being in the High Opioid User population. The outcome variable (likelihood of being in the High Opioid User population) was regressed on the set of RxHCCs, demographic information (age, race, and gender), low-income subsidy (LIS) status, and Medicare Status Codes for both the Part D and Opioid User populations.

Findings

We found that there were 8.8 million beneficiaries (28% of all Part D beneficiaries) who used prescription opioids in 2011, excluding cancer and hospice patients. About 1.765 million (5.61% of Part D beneficiaries) of those beneficiaries exceeded the MED threshold for at least one day (Table 2). There were over 801,000 beneficiaries that had 10 or more consecutive days exceeding the MED threshold, and nearly 225,000 Part D enrollees that exceeded the MED threshold for 90 or more consecutive days. We determined that beneficiaries who exceeded the MED threshold for 90 or more consecutive days are at high risk for potential adverse effects and have a high likelihood of inappropriately using opioids. This group is referred to as the target population and represents 0.71% of all Part D beneficiaries.

Table 2: Number and Percentage of Beneficiaries Greater than the MED Threshold for at Least One Day by Number of Consecutive Days, 2011

Total Consecutive Days	Total Beneficiaries Greater Than the MED Threshold	Share of All Beneficiaries Greater Than the MED Threshold	Share of All Part D Beneficiaries
≥ 1	**1,765,444**	**100.0%**	**5.61%**
≥ 2	1,609,438	91.2%	5.11%
≥ 5	1,156,086	65.5%	3.67%
≥ 10	801,568	45.4%	2.55%
≥ 30	564,279	32.0%	1.79%
≥ 60	346,744	19.6%	1.10%
≥ 90	224,964	12.7%	0.71%

Table 3 compares the number of prescribers for the target population. Almost 64,000 beneficiaries in the target population (0.20% of Part D beneficiaries) filled opioid prescriptions written by least 4 prescribers, and 8,460 (0.03% of Part D beneficiaries) had at least 8 prescribers.

Table 3: Number and Percentage of the Target Population by Number of Prescribers, 2011

Number of Prescribers	Total Beneficiaries in the Target Population	Share of All Beneficiaries in the Target Population	Share of All Part D Beneficiaries
ALL	**224,964**	**100.0%**	**0.71%**
1	60,007	26.7%	0.19%
≥ 2	164,945	73.3%	0.52%
≥ 3	105,041	46.7%	0.33%
≥ 4	63,749	28.3%	0.20%
≥ 8	8,460	3.8%	0.03%

Further analysis showed that within the target population, nearly 75,000 (0.24% of Part D beneficiaries) used at least 3 pharmacies (Table 4). Over 40,000 beneficiaries used four or more pharmacies, and about 4,000 used eight or more pharmacies.

Table 4: Number and Percentage of the Target Population by Number of Pharmacies, 2011

Number of Pharmacies	Total Beneficiaries in the Target Population	Share of All Beneficiaries in the Target Population	Share of All Part D Beneficiaries
ALL	**224,964**	**100.0%**	**0.71%**
1	89,988	40.0%	0.29%
≥ 2	134,976	60.0%	0.43%
≥ 3	74,195	33.0%	0.24%
≥ 4	40,160	17.9%	0.13%
≥ 8	4,070	1.8%	0.013%

We then analyzed the distribution of the target population who received opioid prescriptions from at least 4 prescribers and at least 4 pharmacies by the number of consecutive days in which they exceeded the MED threshold (Table 5). In 2011, 22,222 beneficiaries (0.07% of Part D beneficiaries) met these criteria (referred to hereafter as the narrowed target population). Of the beneficiaries in the narrowed target population, 14,893 were on these high dosages for at least 120 days, 9,964 were for at least 150 days, and 2,653 were utilizing more than the MED threshold for at least 240 days.

Table 5: Number and Percentage of the Narrowed Target Population by Number of Consecutive Days Exceeding the MED Threshold, 2011

Total Consecutive Days	Total Beneficiaries in the Narrowed Target Population	Share of All Beneficiaries in the Narrowed Target Population	Share of All Part D Beneficiaries
≥ 90	**22,222**	**100.0%**	**0.071%**
≥ 120	14,893	67.0%	0.047%
≥ 150	9,964	44.8%	0.032%
≥ 180	6,592	29.7%	0.021%
≥ 210	4,273	19.2%	0.014%
≥ 240	2,653	11.9%	0.008%

Prescriber analysis revealed that within the narrowed target population, 16,104 filled prescriptions from at least five prescribers and 5,613 filled prescriptions from at least eight different prescribers (Table 6).

Table 6: Number and Percentage of the Narrowed Target Population by Number of Prescribers, 2011

Number of Prescribers	Total Beneficiaries in the Narrowed Target Population	Share of All Beneficiaries in the Narrowed Target Population	Share of All Part D Beneficiaries
ALL	**22,222**	**100.0%**	**0.071%**
≥ 5	16,104	72.5%	0.051%
≥ 6	11,509	51.8%	0.037%
≥ 7	8,051	36.2%	0.026%
≥ 8	5,613	25.3%	0.018%

Based on analysis of pharmacy utilization by this narrowed target population, 13,939 visited at least five different pharmacies to fill their opioid prescriptions, and 3,313 beneficiaries went to at least eight different pharmacies (Table 7).

Table 7: Number and Percentage of the Narrowed Target Population by Number of Pharmacies, 2011

Number of Pharmacies	Total Beneficiaries in the Narrowed Target Population	Share of All Beneficiaries in the Narrowed Target Population	Share of All Part D Beneficiaries
ALL	**22,222**	**100.0%**	**0.071%**
≥ 5	13,939	62.7%	0.044%
≥ 6	8,602	38.7%	0.027%
≥ 7	5,264	23.7%	0.017%
≥ 8	3,313	14.9%	0.011%

We next combined the number of pharmacies and number of prescribers to further isolate potential overutilizers. Of the narrowed target population, 2,927 had exactly four prescribers and used exactly four pharmacies, and 1,776 used eight or more prescribers and eight or more pharmacies (Table 8).

Table 8: Cross Tabulation for the Narrowed Target Population by Number of Prescribers and Number of Pharmacies, 2011

Number of Beneficiaries in the Narrowed Target Population (Total: 22,222 Beneficiaries)	4 Pharmacies	5 Pharmacies	6 Pharmacies	7 Pharmacies	≥ 8 Pharmacies
4 Prescribers	2,927	1,590	813	405	383
5 Prescribers	1,995	1,183	684	345	388
6 Prescribers	1,326	886	566	300	380
7 Prescribers	821	590	385	256	386
≥ 8 Prescribers	1,214	1,088	890	645	1,776

Our analysis that examined whether certain health conditions or demographic characteristics were more likely to be associated with high utilization of opioid medication showed that some categories consistently had large effects (i.e., a large significant odds ratio). Among Part D beneficiaries and opioid users, we observed that:

- The lowest age category had a very large odds ratio; those under 65 are about three times more likely to be in the target population of high opioid users than those between ages 75 and 85.
- LIS beneficiaries had higher odds of being high opioid users than non-LIS beneficiaries.
- Beneficiaries whose Medicare Status Code indicates they are disabled or have end-stage renal disease (ESRD) are more likely to be high opioid users than those who are aged but do not have ESRD or a disability.

Results of the logistic regression are available upon request.

Discussion

Cumulative daily MED correlates with the risk of dose-related morbidity and mortality. When combined with other criteria, MED may be used to develop an algorithm to identify possible overutilization of opioids and relative risk for adverse reactions, and to trigger additional patient-specific utilization review and case management. For this study, CMS also used consecutive days of opioid dose, the number of prescribers, and the number of pharmacies singly and in combination as potential thresholds for additional investigation of a beneficiary's utilization of opioids. We narrowed the target population of high opioid users to include 22,222 beneficiaries (0.07% of Part D) who exceeded 120 mg MED daily for at least 90 consecutive days, and who received those opioid prescriptions from more than 3 prescribers and more than 3 pharmacies. Through analysis of the data available, possible overutilization of prescription opioids is evident and requires additional review and case management in order to prevent the danger of serious adverse effects to the beneficiary.

As previously mentioned, a limitation that could account for overestimation in the data analysis could be that all prescriber identification information is not mapped at this time. Multiple prescribers located in a single practice also cannot be easily identified. Once crosswalks are established between these identifiers, a more accurate result can be produced, although we have no reason to expect this will significantly alter the results. Also, with adjustments for early refills or changes in therapy, other results could also differ from what has been described herein. If a beneficiary has filled a prescription for a medication but only utilizes that medication for a portion of the days filled and then receives a new prescription to replace the existing one, this may cause the calculated daily dosage to exceed the MED threshold when in fact the patient is not actually utilizing an excessive amount.

Our methodology excluded beneficiaries with cancer and those in hospice. Other conditions that could account for high daily dosages of opioid prescriptions drugs and therefore be candidates for exclusion

are still being determined. Demographic analysis indicated that certain categories of Part D beneficiaries are more likely to be high opioid users, including those under age 65, LIS beneficiaries, and beneficiaries who are disabled or have end-stage renal disease (ESRD).

Another limitation is that RxHCC data are not concurrent. Therefore, new enrollees or beneficiaries newly diagnosed with cancer may not have been excluded from the analysis. The case management approach should properly identify and exclude these cancer patients.

Conclusions

As an effective treatment for management of non-cancer pain, prescription opioid medications are useful tools in helping patients. Over time, patients often develop increased tolerance and as a result, are prescribed escalating dosages of opioids, which give rise to patient safety concerns with increased risks for serious adverse events. It is evident that Medicare Part D Plan sponsors could use this methodology to identify beneficiaries who are at the highest risk of adverse reactions from overutilization of opioid medications as part of their quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

As established by this analysis along with the standards set by Washington state, MED can be utilized as a tool to determine whether or not a beneficiary is exposed to potentially unsafe dosages of prescription opioids. By establishing methods using cumulative, daily MED, duration, number of prescribers, and number of pharmacies, it is possible for Part D sponsors to focus on a manageable number of beneficiaries for the initial implementation of improved retrospective drug utilization review and case management. With these methods, along with progressive expansion of screening criteria as needed, patient safety and overall health outcomes can be monitored and improved, keeping the best interests of the beneficiary at the forefront of CMS' initiatives, while identifying and curbing overutilization and "doctor shopping" as recommended by the GAO.

APPENDIX

Table A – Opioid Drug Products, Opioid Content, and MED Conversion Factors *

This table is based on the CONSORT (CONsortium to Study Opioid Risks and Therapeutics) classification of opioid medications and morphine equivalent conversion factors per milligram of opioid (see Table B), with modifications to the fentanyl MED conversion factors for analysis of PDE data in this study.

Product Name	Dosage Form	Dosage Unit	Mg Opioid/ Dosage Unit	MED Conversion Factor
ACETAMINOPHEN 325 MG / BUTALBITAL 50 MG / CAFFEINE 40 MG / CODEINE PHOSPHATE 30 MG	ORAL CAPSULE	1 CAP	30	0.15
ACETAMINOPHEN 356 MG / CAFFEINE 30 MG / DIHYDROCODEINE BITARTRATE 16 MG	ORAL CAPSULE	1 CAP	16	0.25
ACETAMINOPHEN 713 MG / CAFFEINE 60 MG / DIHYDROCODEINE BITARTRATE 32 MG	ORAL TABLET	1 TAB	32	0.25
ACETAMINOPHEN 24 MG/ML / CODEINE PHOSPHATE 2.4 MG/ML	ORAL SOLUTION	1 ML	2.4	0.15
ACETAMINOPHEN 24 MG/ML / CODEINE PHOSPHATE 2.4 MG/ML	ORAL SUSPENSION	1 ML	2.4	0.15
ACETAMINOPHEN 300 MG / CODEINE PHOSPHATE 15 MG	ORAL TABLET	1 TAB	15	0.15
ACETAMINOPHEN 300 MG / CODEINE PHOSPHATE 30 MG	ORAL TABLET	1 TAB	30	0.15
ACETAMINOPHEN 650 MG / CODEINE PHOSPHATE 30 MG	ORAL TABLET	1 TAB	30	0.15
ACETAMINOPHEN 300 MG / CODEINE PHOSPHATE 60 MG	ORAL TABLET	1 TAB	60	0.15
ACETAMINOPHEN 650 MG / CODEINE PHOSPHATE 60 MG	ORAL TABLET	1 TAB	60	0.15
ACETAMINOPHEN 500 MG / HYDROCODONE BITARTRATE 5 MG	ORAL CAPSULE	1 CAP	5	1
ACETAMINOPHEN 21.7 MG/ML / HYDROCODONE BITARTRATE 0.5 MG/ML	ORAL SOLUTION	1 ML	0.5	1
ACETAMINOPHEN 33.3 MG/ML / HYDROCODONE BITARTRATE 0.5 MG/ML	ORAL SOLUTION	1 ML	0.5	1
ACETAMINOPHEN 21.7 MG/ML / HYDROCODONE BITARTRATE 0.67 MG/ML	ORAL SOLUTION	1 ML	0.666666667	1
ACETAMINOPHEN 20 MG/ML / HYDROCODONE BITARTRATE 0.67 MG/ML	ORAL SOLUTION	1 ML	0.666666667	1

ACETAMINOPHEN 500 MG / HYDROCODONE BITARTRATE 2.5 MG	ORAL TABLET	1 TAB	2.5	1
ACETAMINOPHEN 300 MG / HYDROCODONE BITARTRATE 5 MG	ORAL TABLET	1 TAB	5	1
ACETAMINOPHEN 325 MG / HYDROCODONE BITARTRATE 5 MG	ORAL TABLET	1 TAB	5	1
ACETAMINOPHEN 400 MG / HYDROCODONE BITARTRATE 5 MG	ORAL TABLET	1 TAB	5	1
ACETAMINOPHEN 500 MG / HYDROCODONE BITARTRATE 5 MG	ORAL TABLET	1 TAB	5	1
ACETAMINOPHEN 300 MG / HYDROCODONE BITARTRATE 7.5 MG	ORAL TABLET	1 TAB	7.5	1
ACETAMINOPHEN 325 MG / HYDROCODONE BITARTRATE 7.5 MG	ORAL TABLET	1 TAB	7.5	1
ACETAMINOPHEN 400 MG / HYDROCODONE BITARTRATE 7.5 MG	ORAL TABLET	1 TAB	7.5	1
ACETAMINOPHEN 500 MG / HYDROCODONE BITARTRATE 7.5 MG	ORAL TABLET	1 TAB	7.5	1
ACETAMINOPHEN 650 MG / HYDROCODONE BITARTRATE 7.5 MG	ORAL TABLET	1 TAB	7.5	1
ACETAMINOPHEN 750 MG / HYDROCODONE BITARTRATE 7.5 MG	ORAL TABLET	1 TAB	7.5	1
ACETAMINOPHEN 300 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 325 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 400 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 500 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 650 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 660 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 750 MG / HYDROCODONE BITARTRATE 10 MG	ORAL TABLET	1 TAB	10	1
ACETAMINOPHEN 500 MG / OXYCODONE HYDROCHLORIDE 5 MG	ORAL CAPSULE	1 CAP	5	1.5
ACETAMINOPHEN 65 MG/ML / OXYCODONE HYDROCHLORIDE 1 MG/ML	ORAL SOLUTION	1 ML	1	1.5
ACETAMINOPHEN 300 MG / OXYCODONE HYDROCHLORIDE 2.5 MG	ORAL TABLET	1 TAB	2.5	1.5
ACETAMINOPHEN 325 MG / OXYCODONE HYDROCHLORIDE 2.5 MG	ORAL TABLET	1 TAB	2.5	1.5
ACETAMINOPHEN 400 MG / OXYCODONE HYDROCHLORIDE 2.5 MG	ORAL TABLET	1 TAB	2.5	1.5
ACETAMINOPHEN 300 MG / OXYCODONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	1.5
ACETAMINOPHEN 325 MG / OXYCODONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	1.5
ACETAMINOPHEN 400 MG / OXYCODONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	1.5
ACETAMINOPHEN 500 MG / OXYCODONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	1.5
ACETAMINOPHEN 300 MG / OXYCODONE HYDROCHLORIDE 7.5 MG	ORAL TABLET	1 TAB	7.5	1.5
ACETAMINOPHEN 325 MG / OXYCODONE HYDROCHLORIDE 7.5 MG	ORAL TABLET	1 TAB	7.5	1.5
ACETAMINOPHEN 400 MG / OXYCODONE HYDROCHLORIDE 7.5 MG	ORAL TABLET	1 TAB	7.5	1.5
ACETAMINOPHEN 500 MG / OXYCODONE HYDROCHLORIDE 7.5 MG	ORAL TABLET	1 TAB	7.5	1.5

ACETAMINOPHEN 300 MG / OXYCODONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	1.5
ACETAMINOPHEN 325 MG / OXYCODONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	1.5
ACETAMINOPHEN 400 MG / OXYCODONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	1.5
ACETAMINOPHEN 500 MG / OXYCODONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	1.5
ACETAMINOPHEN 650 MG / OXYCODONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	1.5
ACETAMINOPHEN 650 MG / PROPOXYPHENE HYDROCHLORIDE 65 MG	ORAL TABLET	1 TAB	65	0.23
ACETAMINOPHEN 325 MG / PROPOXYPHENE NAPSYLATE 50 MG	ORAL TABLET	1 TAB	50	0.23
ACETAMINOPHEN 325 MG / PROPOXYPHENE NAPSYLATE 100 MG	ORAL TABLET	1 TAB	100	0.23
ACETAMINOPHEN 500 MG / PROPOXYPHENE NAPSYLATE 100 MG	ORAL TABLET	1 TAB	100	0.23
ACETAMINOPHEN 650 MG / PROPOXYPHENE NAPSYLATE 100 MG	ORAL TABLET	1 TAB	100	0.23
ASPIRIN 200 MG/ BUTALBITAL 50 MG/ CAFFEINE 40 MG/ CODEINE PHOSPHATE 30 MG	ORAL CAPSULE	1 CAP	30	0.15
ASPIRIN 325 MG / BUTALBITAL 50 MG / CAFFEINE 40 MG / CODEINE PHOSPHATE 30 MG	ORAL CAPSULE	1 CAP	30	0.15
ASPIRIN 356 MG / CAFFEINE 30 MG / DIHYDROCODEINE BITARTRATE 16 MG	ORAL CAPSULE	1 CAP	16	0.25
ASPIRIN 325 MG / OXYCODONE HYDROCHLORIDE 4.84 MG	ORAL TABLET	1 TAB	4.8355	1.5
ASPIRIN 325 MG / OXYCODONE HYDROCHLORIDE 4.5 MG/ OXYCODONE TEREPHTHALATE 0.38 MG	ORAL TABLET	1 TAB	4.88	1.5
CODEINE SULFATE 15 MG	ORAL TABLET	1 TAB	15	0.15
CODEINE SULFATE 30 MG	ORAL TABLET	1 TAB	30	0.15
CODEINE SULFATE 60 MG	ORAL TABLET	1 TAB	60	0.15
FENTANYL 0.012 MG/HR	TRANSDERMAL PATCH	1 PATCH	0.864	100
FENTANYL 0.025 MG/HR	TRANSDERMAL PATCH	1 PATCH	1.8	100
FENTANYL 0.05 MG/HR	TRANSDERMAL PATCH	1 PATCH	3.6	100
FENTANYL 0.075 MG/HR	TRANSDERMAL PATCH	1 PATCH	5.4	100
FENTANYL 0.1 MG/HR	TRANSDERMAL PATCH	1 PATCH	7.2	100

FENTANYL 800 MCG	SUBLINGUAL SPRAY	1 UNIT	0.8	125
FENTANYL 100 MCG	SUBLINGUAL SPRAY	1 UNIT	0.1	125
FENTANYL 400 MCG	SUBLINGUAL SPRAY	1 UNIT	0.4	125
FENTANYL 1600 MCG	SUBLINGUAL SPRAY	1 UNIT	1.6	125
FENTANYL 200 MCG	SUBLINGUAL SPRAY	1 UNIT	0.2	125
FENTANYL 600 MCG	SUBLINGUAL SPRAY	1 UNIT	0.6	125
FENTANYL 1200 MCG	SUBLINGUAL SPRAY	1 UNIT	1.2	125
FENTANYL CITRATE 0.2 MG	BUCCAL FILM	1 FILM	0.2	125
FENTANYL CITRATE 0.4 MG	BUCCAL FILM	1 FILM	0.4	125
FENTANYL CITRATE 0.6 MG	BUCCAL FILM	1 FILM	0.6	125
FENTANYL CITRATE 0.8 MG	BUCCAL FILM	1 FILM	0.8	125
FENTANYL CITRATE 1.2 MG	BUCCAL FILM	1 FILM	1.2	125
FENTANYL CITRATE 0.2 MG	LOZENGE	1 LPOP	0.2	125
FENTANYL CITRATE 0.4 MG	LOZENGE	1 LPOP	0.4	125
FENTANYL CITRATE 0.6 MG	LOZENGE	1 LPOP	0.6	125
FENTANYL CITRATE 0.8 MG	LOZENGE	1 LPOP	0.8	125
FENTANYL CITRATE 1.2 MG	LOZENGE	1 LPOP	1.2	125
FENTANYL CITRATE 1.6 MG	LOZENGE	1 LPOP	1.6	125
FENTANYL CITRATE 0.1 MG	BUCCAL TABLET	1 TAB	0.1	125
FENTANYL CITRATE 0.2 MG	BUCCAL TABLET	1 TAB	0.2	125
FENTANYL CITRATE 0.3 MG	BUCCAL TABLET	1 TAB	0.3	125
FENTANYL CITRATE 0.4 MG	BUCCAL TABLET	1 TAB	0.4	125

FENTANYL CITRATE 0.6 MG	BUCCAL TABLET	1 TAB	0.6	125
FENTANYL CITRATE 0.8 MG	BUCCAL TABLET	1 TAB	0.8	125
FENTANYL CITRATE 0.1 MG	SUBLINGUAL TABLET	1 TAB	0.1	125
FENTANYL CITRATE 0.2 MG	SUBLINGUAL TABLET	1 TAB	0.2	125
FENTANYL CITRATE 0.3 MG	SUBLINGUAL TABLET	1 TAB	0.3	125
FENTANYL CITRATE 0.4 MG	SUBLINGUAL TABLET	1 TAB	0.4	125
FENTANYL CITRATE 0.6 MG	SUBLINGUAL TABLET	1 TAB	0.6	125
FENTANYL CITRATE 0.8 MG	SUBLINGUAL TABLET	1 TAB	0.8	125
HYDROCODONE BITARTRATE 2.5 MG / IBUPROFEN 200 MG	ORAL TABLET	1 TAB	2.5	1
HYDROCODONE BITARTRATE 5 MG / IBUPROFEN 200 MG	ORAL TABLET	1 TAB	5	1
HYDROCODONE BITARTRATE 7.5 MG / IBUPROFEN 200 MG	ORAL TABLET	1 TAB	7.5	1
HYDROCODONE BITARTRATE 10 MG / IBUPROFEN 200 MG	ORAL TABLET	1 TAB	10	1
HYDROMORPHONE HYDROCHLORIDE 1 MG/ML	ORAL SOLUTION	1 ML	1	4
HYDROMORPHONE HYDROCHLORIDE 8 MG	EXTENDED RELEASE TABLET	1 TAB	8	4
HYDROMORPHONE HYDROCHLORIDE 12 MG	EXTENDED RELEASE TABLET	1 TAB	12	4
HYDROMORPHONE HYDROCHLORIDE 16 MG	EXTENDED RELEASE TABLET	1 TAB	16	4
HYDROMORPHONE HYDROCHLORIDE 2 MG	ORAL TABLET	1 TAB	2	4
HYDROMORPHONE HYDROCHLORIDE 4 MG	ORAL TABLET	1 TAB	4	4

HYDROMORPHONE HYDROCHLORIDE 8 MG	ORAL TABLET	1 TAB	8	4
IBUPROFEN 400 MG / OXYCODONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	1.5
LEVORPHANOL TARTRATE 2 MG	ORAL TABLET	1 TAB	2	11
MEPERIDINE HYDROCHLORIDE 10 MG/ML	ORAL SOLUTION	1 ML	10	0.1
MEPERIDINE HYDROCHLORIDE 50 MG	ORAL TABLET	1 TAB	50	0.1
MEPERIDINE HYDROCHLORIDE 100 MG	ORAL TABLET	1 TAB	100	0.1
METHADONE HYDROCHLORIDE 1 MG/ML	ORAL SOLUTION	1 ML	1	3
METHADONE HYDROCHLORIDE 2 MG/ML	ORAL SOLUTION	1 ML	2	3
METHADONE HYDROCHLORIDE 10 MG/ML	ORAL SOLUTION	1 ML	10	3
METHADONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	3
METHADONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	3
METHADONE HYDROCHLORIDE 40 MG	ORAL TABLET	1 TAB	40	3
MORPHINE SULFATE 10 MG	EXTENDED RELEASE CAPSULE	1 CAP	10	1
MORPHINE SULFATE 20 MG	EXTENDED RELEASE CAPSULE	1 CAP	20	1
MORPHINE SULFATE 30 MG	EXTENDED RELEASE CAPSULE	1 CAP	30	1
MORPHINE SULFATE 45 MG	EXTENDED RELEASE CAPSULE	1 CAP	45	1
MORPHINE SULFATE 50 MG	EXTENDED RELEASE CAPSULE	1 CAP	50	1
MORPHINE SULFATE 60 MG	EXTENDED RELEASE	1 CAP	60	1

	CAPSULE			
MORPHINE SULFATE 75 MG	EXTENDED RELEASE CAPSULE	1 CAP	75	1
MORPHINE SULFATE 80 MG	EXTENDED RELEASE CAPSULE	1 CAP	80	1
MORPHINE SULFATE 90 MG	EXTENDED RELEASE CAPSULE	1 CAP	90	1
MORPHINE SULFATE 100 MG	EXTENDED RELEASE CAPSULE	1 CAP	100	1
MORPHINE SULFATE 120 MG	EXTENDED RELEASE CAPSULE	1 CAP	120	1
MORPHINE SULFATE 200 MG	EXTENDED RELEASE CAPSULE	1 CAP	200	1
MORPHINE SULFATE 2 MG/ML	ORAL SOLUTION	1 ML	2	1
MORPHINE SULFATE 4 MG/ML	ORAL SOLUTION	1 ML	4	1
MORPHINE SULFATE 20 MG/ML	ORAL SOLUTION	1 ML	20	1
MORPHINE SULFATE 15 MG	EXTENDED RELEASE TABLET	1 TAB	15	1
MORPHINE SULFATE 30 MG	EXTENDED RELEASE TABLET	1 TAB	30	1
MORPHINE SULFATE 60 MG	EXTENDED RELEASE TABLET	1 TAB	60	1

MORPHINE SULFATE 100 MG	EXTENDED RELEASE TABLET	1 TAB	100	1
MORPHINE SULFATE 200 MG	EXTENDED RELEASE TABLET	1 TAB	200	1
MORPHINE SULFATE 15 MG	ORAL TABLET	1 TAB	15	1
MORPHINE SULFATE 30 MG	ORAL TABLET	1 TAB	30	1
MORPHINE SULFATE 20 MG / NALTREXONE HYDROCHLORIDE 0.8 MG	ORAL CAPSULE	1 CAP	20	1
MORPHINE SULFATE 30 MG / NALTREXONE HYDROCHLORIDE 1.2 MG	ORAL CAPSULE	1 CAP	30	1
MORPHINE SULFATE 50 MG / NALTREXONE HYDROCHLORIDE 2 MG	ORAL CAPSULE	1 CAP	50	1
MORPHINE SULFATE 60 MG / NALTREXONE HYDROCHLORIDE 2.4 MG	ORAL CAPSULE	1 CAP	60	1
MORPHINE SULFATE 80 MG / NALTREXONE HYDROCHLORIDE 3.2 MG	ORAL CAPSULE	1 CAP	80	1
MORPHINE SULFATE 100 MG / NALTREXONE HYDROCHLORIDE 4 MG	ORAL CAPSULE	1 CAP	100	1
OXYCODONE HYDROCHLORIDE 5 MG	ORAL CAPSULE	1 CAP	5	1.5
OXYCODONE HYDROCHLORIDE 1 MG/ML	ORAL SOLUTION	1 ML	1	1.5
OXYCODONE HYDROCHLORIDE 20 MG/ML	ORAL SOLUTION	1 ML	20	1.5
OXYCODONE HYDROCHLORIDE 10 MG	EXTENDED RELEASE TABLET	1 TAB	10	1.5
OXYCODONE HYDROCHLORIDE 15 MG	EXTENDED RELEASE TABLET	1 TAB	15	1.5
OXYCODONE HYDROCHLORIDE 20 MG	EXTENDED RELEASE TABLET	1 TAB	20	1.5
OXYCODONE HYDROCHLORIDE 30 MG	EXTENDED RELEASE TABLET	1 TAB	30	1.5
OXYCODONE HYDROCHLORIDE 40 MG	EXTENDED RELEASE	1 TAB	40	1.5

	TABLET			
OXYCODONE HYDROCHLORIDE 60 MG	EXTENDED RELEASE TABLET	1 TAB	60	1.5
OXYCODONE HYDROCHLORIDE 80 MG	EXTENDED RELEASE TABLET	1 TAB	80	1.5
OXYCODONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	1.5
OXYCODONE HYDROCHLORIDE 7.5 MG	ORAL TABLET	1 TAB	7.5	1.5
OXYCODONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	1.5
OXYCODONE HYDROCHLORIDE 15 MG	ORAL TABLET	1 TAB	15	1.5
OXYCODONE HYDROCHLORIDE 20 MG	ORAL TABLET	1 TAB	20	1.5
OXYCODONE HYDROCHLORIDE 30 MG	ORAL TABLET	1 TAB	30	1.5
OXYMORPHONE HYDROCHLORIDE 5 MG	EXTENDED RELEASE TABLET	1 TAB	5	3
OXYMORPHONE HYDROCHLORIDE 7.5 MG	EXTENDED RELEASE TABLET	1 TAB	7.5	3
OXYMORPHONE HYDROCHLORIDE 10 MG	EXTENDED RELEASE TABLET	1 TAB	10	3
OXYMORPHONE HYDROCHLORIDE 15 MG	EXTENDED RELEASE TABLET	1 TAB	15	3
OXYMORPHONE HYDROCHLORIDE 20 MG	EXTENDED RELEASE TABLET	1 TAB	20	3
OXYMORPHONE HYDROCHLORIDE 30 MG	EXTENDED RELEASE TABLET	1 TAB	30	3
OXYMORPHONE HYDROCHLORIDE 40 MG	EXTENDED RELEASE TABLET	1 TAB	40	3

OXYMORPHONE HYDROCHLORIDE 5 MG	ORAL TABLET	1 TAB	5	3
OXYMORPHONE HYDROCHLORIDE 10 MG	ORAL TABLET	1 TAB	10	3
PROPOXYPHENE HYDROCHLORIDE 65 MG	ORAL CAPSULE	1 CAP	65	0.23
PROPOXYPHENE NAPSYLATE 100 MG	ORAL TABLET	1 TAB	100	0.23

Table B[9]

CONSORT (CONsortium to Study Opioid Risks and Therapeutics) classification of opioid medications and morphine equivalent conversion factors per milligram of opioid. [1]

Major Group	Type of Opioid	Morphine equivalent conversion factor per mg of opioid
Short-acting Less potent (Schedule III/IV)	Propoxyphene (with or without aspirin/acetaminophen/ibuprofen)	0.23
	Codeine + (acetaminophen, ibuprofen or aspirin)	0.15
	Hydrocodone + (acetaminophen, ibuprofen, or aspirin) Hydrocodone and Homatropine	1.0
	Butalbital and codeine (with or without aspirin, ibuprofen, acetaminophen)	0.15
	Dihydrocodeine (with or without aspirin, ibuprofen, acetaminophen)	0.25
Short-acting, More Potent (Schedule II)	Morphine sulfate	1.0
	Codeine sulfate	0.15
	Oxycodone (with or without aspirin, acetaminophen, ibuprofen)	1.5
	Hydromorphone	4.0
	Meperidine hydrochloride	0.1
	Fentanyl citrate transmucosal[2]	0.125
	Oxymorphone	3.0
Long-acting (Schedule II)	Morphine sulfate sustained release	1.0
	Fentanyl transdermal[3]	2.4
	Levorphanol tartrate	11.0
	Oxycodone HCL controlled release	1.5
	Methadone	3.0

[1]Opioids delivered by pill, capsule, liquid, transdermal patch, and transmucosal administration were included in CONSORT data. Opioids formulated for administration by injection or suppository were not included.

[2]Transmucosal fentanyl conversion to morphine equivalents assumes 50% bioavailability of transmucosal fentanyl and 100 micrograms transmucosal fentanyl is equivalent to 12.5 to 15 mg of oral morphine.

[3]Transdermal fentanyl conversion to morphine equivalents is based on the assumption that one patch delivers the dispensed micrograms per hour over a 24 hour day and remains in place for 3 days.

[9] Von Korff M, Saunders K, Ray GT, et al. De Facto Long-term Opioid Therapy for Non-cancer Pain. Clinical Journal of Pain: July/August 2008 - Volume 24 - Issue 6 - pp 521-527