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CENTER FOR MEDICARE

TO: All Medicare Part D Sponsors

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SUBJECT: Part D Transition Requirements and Monitoring Programs

DATE: January 14, 2014

The Part D transition requirements, as outlined in 42 CFR § 423.120 (b)(3), are an important protection under Medicare Part D. The provision of a temporary fill of a non-formulary drug and accompanying notice affords enrollees the opportunity to work with prescribers to switch to formulary alternatives, or to pursue necessary prior authorizations or formulary exceptions. In spite of the criticality of the transition benefit, some Part D sponsors continue to not adequately administer transition processes. CMS identified numerous transition errors during the CY 2012 Program Audits, as detailed in the July 30, 2013 Health Plan Management System (HPMS) memo entitled "Best Practices and Common Findings Memo #2 from 2012 Program Audits". We also found non-compliance with our transition requirements through other program analyses. For CY 2012, CMS implemented the transition monitoring program analysis (TMPA). The purpose of the TMPA was to evaluate point-of-sale (POS) rejected claims to ensure that Part D sponsors were adequately administering Medicare Part D formulary transition requirements. The results of this analysis revealed that sponsors continued to not provide required transition supplies. The TMPA was repeated for CY 2013, and as detailed later in this memo, transition errors continued to occur.

Given that we are entering into the ninth year of the Part D program, we are very concerned that some Part D sponsors have not fully complied with our transition requirements. As a result, we held a Parts C & D User Call on December 11, 2013 to review Part D transition requirements, the TMPA, and to answer industry questions related to transition requirements. The purpose of this memo is to provide Part D sponsors with an overview of the CY 2013 TMPA results and details regarding the CY 2014 TMPA, and to supply policy clarification questions and answers that were developed as the result of the December 11th User Call (Appendix I). We also

encourage sponsors to review the aforementioned July 30, 2013 HPMS memo since it contains useful information regarding the successful implementation of Part D transition requirements. If you have questions relating to transition processes, please email PartDTransition@cms.hhs.gov.

CY 2013 TMPA

For the CY 2013 TMPA, CMS conducted two analyses on rejected claims data provided by all contracts that utilize a formulary for Part D (with the exception of National PACE, Medicare-Medicaid Plans, and Non Employer- Direct 800 series employer group waiver plans) to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2013 for a drug that qualified for a transition fill, and 2) rejected POS claims for Part D drugs for new members from January 1, 2013 to January 21, 2013. Sponsors responded to each claim in question, providing explanations as to whether the claim was rejected correctly or incorrectly. After analyzing the results of all of the contracts included in the sample, approximately 22% of contracts exceeded the protected class and/or non-protected class drug failure threshold. The following information details some common areas of concern regarding universe submissions and areas of non-compliance identified during the CY 2013 TMPA.

Concerns Identified in Universe Submissions:

1. Submission of early refill rejections in the POS rejected claims universe, which should be limited to non-formulary, prior authorization (PA, including both administrative and clinical), and step therapy (ST) rejects.
2. Inclusion of HICNs for continuing beneficiaries in the new enrollee universe.
3. Errors in reporting rejected claims for compounded drugs.
4. Incorrect formatting and/or values were reported within the universes.

Common Areas of Non-Compliance:

1. Transition fills were provided for only some drugs that were subject to a cross-contract year formulary change. Similar to CY 2012, sponsors noted that this type of error was often the result of not providing claims processors with accurate information, or errors on the part of claims processors in loading the new formulary.
2. PAs for drugs that were part of the high risk medication measure were inappropriately treated as safety edits and thus maintained during transition.
3. Various errors occurred in processing enrollments resulting in the failure to recognize beneficiaries as new enrollees.
4. Errors occurred in the look-back into claims histories, which resulted in the failure to provide transition fills for members affected by a cross-calendar year formulary change.

CY 2014 TMPA

The TMPA will again be performed for CY 2014 on all Part D sponsors. Please note that employer group waiver plans (EGWPs) and Medicare-Medicaid Plans (MMPs) are eligible for inclusion in the CY 2014 analysis, but PACE organizations will be excluded. Part D sponsors that are selected for analysis will be notified and provided additional information.

The methodology below describes how CMS will complete the CY 2014 TMPA. Although sponsors should have the ability to provide the following information to us within 48 hours of request at any time during the plan year, for the purpose of this monitoring program, data will be required to be submitted in the timeframes outlined below:

- Sponsors will be required to submit all rejected POS claims for dates of service from January 1, 2014 through January 21, 2014 for the following 3 categories: 1) non-formulary status; 2) Prior Authorization (PA); and 3) Step Therapy (ST).
- Sponsors will provide electronically a list of new enrollees with a January 1, 2014 effective date.
- Sponsors will upload the POS rejected claims and a list of new enrollees as a .txt file between February 3, 2014 and February 7, 2014 (11:59 PM EST).
- Selected EGWPs will upload two formulary files: 1) Last formulary file effective December 2013 and 2) first formulary file effective January 2014. Additional details regarding the file formats will be provided upon notification of selection.

HPMS formulary file extracts for CY 2013 and CY 2014 will be used to identify drugs that were deleted from the formulary or had an addition of PA and/or ST. A list of drugs that were subject to a formulary change will be selected. Once this list is identified, CY 2013 Prescription Drug Event (PDE) data will be used to identify beneficiaries taking the affected drugs. We will then conduct two analyses to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2014 for a drug that qualified for a transition fill and, 2) rejected POS claims for Part D drugs for new members from January 1, 2014 to January 21, 2014.

Part D sponsors will use a secure website to upload the required POS rejected claims and the list of new enrollees, following the format outlined in the attachment titled **"**Rejected Claims Template and New Members file layout." The Formulary and Benefits Monitoring Website (formerly known as the Benefit Administration Website) will serve as a secure centralized collaboration tool between CMS, Acumen, LLC (Acumen), and selected Part D sponsors. Medicare Compliance Officers will have access and authority to designate access to the secure website. Please ensure contact information is up to date in HPMS. Only authorized users will have access to the secure website which is separately secured from all other Part D Sponsors.

In order to standardize the rejections across all sponsors, the Rejected Claims Template includes

a field relating to the reject category that sponsors must populate. The possible values include: 1= non-formulary, 2= PA, 3= ST.

We will apply a failure threshold when reviewing the rejected claims sample. We will calculate an overall score to determine if the Part D sponsor is compliant with Part D transition requirements. For non-protected class drugs, the number of failures (numerator) will be divided by the number of claims sampled (denominator) to calculate an overall compliance score. If the number of failures results in more than a 20% failure rate, an overall failure will have occurred for this area. For protected class drugs, the number of failures (numerator) will be divided by the number of claims sampled (denominator) to calculate an overall compliance score. If the number of failures results in more than a 10% failure rate, an overall failure will have occurred for this area. Sponsors who meet or exceed the failure threshold will receive a notice of non-compliance, at a minimum, along with a report containing the details regarding each failed sample. Additional samples from the sponsor may be required in order to demonstrate compliance. CMS will require Part D sponsors to work aggressively to promptly address problems identified by this monitoring program. Failure to correct any confirmed errors may subject your organization to additional compliance actions.

Part D sponsors will be notified with instructions for completing the user authorization process and additional details regarding the CY 2014 TMPA in a separate communication. Please see the schedule of events below that describes the expected actions and corresponding deadlines for this analysis.

CY 2014 TMPA Schedule of Events:

The following table summarizes expected actions and timelines for the 2014 Part D Transition Monitoring Program Analysis.

Action	Date
Medicare Compliance Officer (MCO) will identify up to five authorized users for Acumen's Formulary and Benefits Monitoring website. For each user, verify and authorize access permissions through Acumen's User Security Website – MCOs will be notified with instructions for completing the user authorization process in a separate communication.	New user requests and current user validation due by 5:00 PM EST on 1/21/14
Authorized users will receive a welcome email with their username and a User Guide with detailed instructions for submitting data and downloading reports. Letters containing login passwords will arrive separately via USPS.	On or about 1/24/14

Participating sponsors can upload Rejected Claims Files and Transition-New Members Files – see attachment titled **“**Rejected Claims Template and New Members file layout.”	On or about 2/3/14 through 2/7/14 (11:59 PM EST)

For questions related to data extraction, submission or the secure website, please contact Acumen at FormularyBenefits@acumenllc.com. For questions regarding the TMPA, please contact June Page at june.page@cms.hhs.gov or Jeannettee Joyner at jeannettee.joyner@cms.hhs.gov.

Thank you.

Appendix I: Medicare Part D Transition Requirements Questions and Answers

EDITS DURING TRANSITION:

1. **Question:** Can a sponsor impose a claim edit to determine whether the drug (such as Cialis® or a Transmucosal Immediate Release Fentanyl product) is being dispensed for a medically-accepted indication during transition?
   Answer: Yes. As stated in Chapter 6, Section 30.4.8- Edits for Transition Fills, a Part D sponsor must ensure that a new enrollee is able to leave a pharmacy with a temporary supply of non-formulary Part D drugs [emphasis added] without unnecessary delays. Part D sponsors may only apply certain drug utilization management edits during a beneficiary's transition period. Drug utilization management edits that are appropriate during a beneficiary's transition period include the following:
   - Edits to help determine Part B vs. Part D coverage;
   - Edits to prevent coverage of non-part D drugs (such as excluded drugs); and
   - Edits to promote safe utilization of a Part D drug (such as quantity limits based on FDA maximum recommended daily dose; early refill edits).

   Claim edits to prevent coverage of non-Part D drugs include those which prevent coverage of formulary and non-formulary drugs that are being dispensed for an indication that is not medically accepted (see definition of medically-accepted indication §1860D-2(e)(4) of the Social Security Act). Edits should be applied to drugs that are likely to be used for indications that are not medically accepted in the sponsor's experience or as directed by CMS. While we would not expect edits to be universally applied to check whether every drug or most drugs are being used for medically accepted indications, Part D sponsors remain responsible for ensuring that all covered Part D drugs are prescribed for medically-accepted indications only. Except for point-of-sale claim edits to promote safe utilization of a Part D drug, Part D sponsors must submit all prior authorization requirements to CMS for approval to implement point-of-sale claim edits for B vs D and Part D drug determinations for formulary drugs.

2. **Question:** Are drug claim edits based upon dose, age, or gender considered safety edits?
   Answer: As noted in Chapter 6 cited above, an edit to promote safe utilization of a Part D drug (safety edit) can be applied during transition (see section 30.2.2.1 for examples of safety edits). Thus, if a drug has a maximum dose of 50mg, and the FDA approved label states that doses above 25mg should be avoided in patients $\geq$ 65 years of age, a dose related safety edit can be administered during transition which prevents the dispensing of doses above 25 mg. The key is that the safety edits must be based upon FDA labelling and must be tailored to reflect such labelling. Thus, the example safety edit should not be applied to an enrollee who is under the age of 65.

3. **Question:** Will CMS expect plans to override APAP and Opioid QL restrictions during Transition?
   Answer: It depends. 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 the established Part D transition policy. However, if a beneficiary level point-of-sale opioid claim edit has been implemented, CMS expects 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. Please refer to Question 10 in the FAQ section of the September 6, 2012 memorandum "Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D."

30-DAY TRANSITION SUPPLY:

4. **Question:** Chapter 6, Section 30.4.4.1 states that in the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs – including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules – must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days. Part D sponsors should note that, outside the long-term care setting, such a temporary fill may be a one-time fill only. If the prescription is written for less than a 30-day supply with additional refills on the same prescription or a new prescription is presented to continue therapy, does the request also fall under a transition fill?
   Answer: Yes. The Part D sponsor must allow multiple fills to provide up to a total of 30 days of medication. See 42 CFR §423.120(b)(3)(iii)(A).

BRAND vs. GENERIC:

5. **Question:** If a patient has been taking a brand drug that is no longer on the formulary and is thus eligible for a transition fill, must a temporary fill be provided for the brand, or would the generic drug satisfy the transition requirements?
   Answer: The purpose of the Part D transition policy is to promote continuity of care. If a patient received a fill for the brand name, then the patient should receive a transition fill for the brand name if requested, not the generic.

ENROLLMENT:

6. **Question:** If a beneficiary is still within the first 90 days of enrollment in a Medicare Part D plan and there is a gap in coverage-for example, the beneficiary leaves the plan for one month and then re-enrolls in the same plan-will the beneficiary be considered to be within the first Transition period?

Answer: No. A beneficiary's transition period begins with the date of each enrollment. We remind Part D sponsors that the purpose of the transition policy is to promote continuity of care. Thus, the policy requires that Part D sponsors accommodate the immediate needs of the enrollee, which gives the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity. See Ch. 6, Section 30.4.1 of the Medicare Prescription Drug Benefit Manual.

7. **Question:** If the member stays with the same contract number but changes their PBP, is it appropriate that this member be considered new and therefore eligible for transition benefits as a new member?
   Answer: Yes. A member that stays with the same contract number but changes PBPs is eligible for a transition benefit. However, we point out that just because a member is eligible for a transition period does not mean that the member will necessarily receive a transition fill. In this example, for instance, the formulary may not have changed (which means there have also been no addition of utilization management edits). Also, the sponsor may have the claims history for the member from the just prior PBP. In both of these scenarios, the sponsor may be able to determine that the member is not taking a non-formulary medication or one that was not subjected to utilization management edits. In other words, the sponsor may be able to determine that there will be no interruption in medication therapy for the member, and therefore the member does not warrant a transition fill.

COST-SHARING:

8. **Question:** Regarding Chapter 6, Section 30.4.9 on cost-sharing considerations, is it acceptable for plans to charge member cost share based on the drugs' tier (charge the amount for the generic tier or brand tier as applicable), which could be less than what is charged when a coverage exception is approved?
   Answer: No. Consistent with Chapter 6, Section 30.4.9, the cost-sharing that should be applied should be that of non-formulary drugs approved under a coverage exception. However, CMS recently issued a notice of proposed rule making that would change this requirement beginning in 2015.

TRANSITION NOTICES:

9. **Question:** If a patient completes his or her transition supply in several fills (10 days + 5 days +15 days), is it CMS' expectation that the sponsor sends a letter with every "partial" fill?
   Answer: No. The sponsor should send the required notice only with the first transition fill.