DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-15

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CENTER FOR MEDICARE

DATE: September 21, 2012

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D.

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SUBJECT: Review of Part D Sponsors' Transition Policies

The Centers for Medicare & Medicaid Services (CMS) conducted a review of a sample of the contract year (CY) 2013 transition policies. During our review, we found several sponsors' policies to be non-compliant with current Part D transition requirements. As a result, we are requiring that all Part D sponsors re-review their most recently submitted CY 2013 transition policies to ensure that they meet the requirements set forth in 42 CFR § 423.120(b)(3) and are consistent with the attestations that they completed within the CY 2013 Health Plan Management System (HPMS) Formulary Submission Module. A list of the requirements for which sponsors' policies most often failed to demonstrate compliance are provided below.

To conduct the review CMS randomly selected CY 2013 transition policies that were submitted by current Part D sponsors. In many instances, CMS was unable to determine whether the stated policies were consistent with the submitted transition attestations. As a result, CMS is concerned that many sponsors may not have in place the policies and procedures necessary to properly administer the transition coverage to which their members are entitled. Therefore, we are sharing these findings with all sponsors to serve as a guide in their review of their own transition policies to ensure that they can meet the requirements stated at 42 CFR § 423.120(b)(3).

The following were the most common attestations for which CMS determined that a sponsor failed to provide an adequate implementation discussion, did not address the attestation or only partially addressed the attestation:

- 1. Part D Sponsors did not address attestation #4, "Sponsor will have systems capabilities that allow them to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescriber to make 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 reasons."
- 2. For attestation #7, many Part D Sponsors did not address the regulatory changes to the revised Long Term Care transition requirements in which sponsor will ensure that in the long-term care setting the transition policy provides for a 91-to 98-day fill consistent with

- the dispensing increment (unless the enrollee presents with a prescription written for less), with refills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.
- 3. Part D Sponsors only partially met the elements addressed in attestation #11 which states, "Sponsor will send written notice via U.S. first class mail to enrollee within three business days of adjudication of a temporary fill. The notice must include (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the enrollee's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. For long-term care residents dispensed multiple supplies of a Part D drug in increments of 14 days or less, consistent with the requirements under Chapter 6 Section 30.4 of the Medicare Prescription Drug Benefit Manual, the written notice must be provided within 3 business days after adjudication of the first temporary fill. Sponsor will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review. Sponsor will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice."
- 4. Part D Sponsors did not address attestation #13, "Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, Sponsor will promptly implement either: (1) appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim (see the 5.1Editorial Document), or (2) alternative approaches that achieve the goals intended in the messaging guidance."

If, after your review, you determine that your policy requires revisions, you must submit an email to partdtransition@cms.hhs.gov requesting that your transition policy submission gate be opened. The email must be sent prior to **5:00 pm EDT on September 28, 2012**. In your email, please include the Transition Policy ID, the associated contracts, and what modifications are needed to the transition policy. You will then be required to resubmit your updated policy to HPMS. When resubmitting, the transition policy must contain track changes from your most recent version indicating the specific attestation your change reflects as a comment.

CMS reserves the right to request and review the Part D sponsor's current or future transition policy at any time. Failure to correct any errors may subject your organization to compliance actions. Further questions regarding our transition policy should be directed to June Page at June.page@cms.hhs.gov.