DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

TO: All Part D Sponsors

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

SUBJECT: Part D Transition Policy Reminder

DATE: August 27, 2010

This memorandum is in response to recent compliance findings regarding Part D sponsors' administration of the Part D prescription drug benefit transition policies. The Centers for Medicare & Medicaid Services (CMS) has found several Part D sponsors non-compliant with our current transition policy, in particular, when a plan's current enrollees are affected by changes to their plan's formulary. This memorandum reminds Part D sponsors of their obligation to adequately administer transition policies consistent with regulation and manual requirements.

CMS has identified a number of Part D sponsors who were not in compliance with Part D transition requirements. We believe it is important to share this information with all sponsors in order to avoid replication of these errors, especially if those errors were a result of Part D sponsors and processors failing to perform necessary quality assurance checks, such as running test claims for all the types of scenarios on the adjudication system prior to the start of the plan year in order to avoid these errors. Below are examples of these non-compliant practices:

1. A Part D sponsor intended to prospectively transition all members whose drugs were subject to a formulary change prior to January 1. However, they were unable to complete this task for all current enrollees in time for the new plan year. Rather than provide the remaining enrollees with a temporary fill, the sponsor rejected these required fills at the point-of-sale (POS).

2. Sponsors improperly relied on the Annual Notice of Change (ANOC) to effectuate the transition. One Part D sponsor changed their formulary from a very broad formulary to a more restrictive formulary between contract years and decided that providing the formulary with the ANOC was sufficient notice. Thus, the sponsor did not provide continuing members with the required transition fills at the POS. Another sponsor only processed transition fills if the beneficiary called the plan in advance for authorization.

3. Sponsors processed transition fills for only some of the drugs that were subject to a cross-contract year formulary change. This type of error was the result of either the sponsor

not providing a complete list of drugs to the processor for transition fills, or coding errors on the processor's part when implementing the new formulary.

4. Sponsors (or their processors) denied claims with a "hard edit" that required the dispensing pharmacist to enter an override code prior to paying the claim for the non-formulary drug. This type of processing required the rejected claim to be overridden by the pharmacist in order to effectuate the coverage of a transition fill, but no controls were in place to ensure this happened at the point of sale.

5. Sponsors denied beneficiary access to transition fills as a result of errors in enrollment dates. For example, a beneficiary who left the plan for a year to enroll in a different plan decides to re-enrolls in the plan. This beneficiary should be recognized by the enrolling plan as a new member. One sponsor relied on the beneficiary's original enrollment date of two years ago, thus failing to recognize the beneficiary as a new enrollee who would be eligible for a transition fill.

As stated in regulation at 42 CFR 423.120(b)(3) and the current version of Chapter 6 of the Medicare Prescription Drug Benefit Manual D, Part D sponsors must provide for an appropriate transition process for new enrollees and current enrollees prescribed Part D drugs that are not on its formulary. Specifically, a sponsor must provide for an appropriate transition process with respect to:

- The transition of new enrollees into prescription drug plans following the annual coordinated election period;

- The transition of newly eligible Medicare beneficiaries from other coverage;

- The transition of individuals who switch from one plan to another after the start of the contract year;

- Enrollees residing in LTC facilities; and,

- In some cases, current enrollees affected by formulary changes from one contract year to the next.

Also, sponsors should consider how to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.

The majority of compliance actions regarding the proper administration of our transition policies were with current enrollees affected by changes to their plan's formulary. As stated in our guidance, CMS expects sponsors to select one of two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary. Sponsors may provide a transition process for current enrollees consistent with the transition process required for new enrollees, or effectuate a transition for current enrollees prior to the start of the new contract year. Additional guidance regarding the two options is further discussed in section 30.4.5 of Chapter 6.

CMS believes the crux of the problem with many sponsors' non-compliance may lie with the messaging sponsors and/or their processors are adopting when adjudicating claims at the point-of-sale. Part D sponsors must have systems capabilities that allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are subject to prior authorization or step therapy) in order to accommodate the immediate needs of an enrollee, as well as to allow 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 reasons. This policy means that an enrollee eligible for a transition supply of a drug must leave the pharmacy with a filled prescription. Part D sponsors are required to ensure that this policy is enforced.

However, CMS has found that sponsors adopting the "hard edit" approach in example #4 above are at the most risk for being found non-compliant because the sponsor's administration of the transition policy is reliant on the pharmacist effectuating the coverage of a transition supply by inputting an override code. When sponsors and/or their processors adopt the "hard edit" approach, sponsors must either ensure that their contracted pharmacies apply the override code or put in place other internal controls to ensure the beneficiary does not leave the pharmacy without the transition supply required under Medicare rules.

Further questions regarding our transition policy should be directed to Keely Ireland on (410)786-7160 or keely.ireland@cms.hhs.gov .