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CENTER FOR BENEFICIARY CHOICES

May 26, 2006

Memorandum to: All Part D Sponsors

Subject: Review of Important 2007 Plan Requirements

From: Abby L. Block, Director, Center for Beneficiary Choices

Since the initial start-up of the Medicare prescription drug benefit, we have provided information on additional procedures and best practices that plans should implement in 2006 to meet our requirements. As summarized below, we expect these procedures and practices to be used in 2007. As we update our manuals and requirements, and prepare to receive plan bids for 2007, I wanted to take the opportunity to remind plans when constructing your bids to carefully review the requirements outlined in our previously issued 2007 Call Letter, and in the 2007 Formulary, Transition, and Reporting requirements documents.

In addition, we also want to alert plans to some policies for 2007 that will be reflected in upcoming guidance that will be issued in draft form in the next few weeks. Although not fully developed as of the date of this letter, we wanted to ensure that plans have as much information as possible in advance of bid submission. We have developed the attached list so that, in preparing bids for the 2007 contract year, plans can appropriately allocate administrative costs as needed to implement these likely requirements. This list is not intended to be completely inclusive of all 2007 requirements, but is provided in order assist plans in focusing on important requirements and ensuring their proper consideration in bid development.

1. Plan Performance Metrics

In 2007, we are building in measures of Part D plan performance in four areas to help purchasers and consumers assess plans based on quality:

- Effective Data Systems
- Effective Customer Service
- Effective Exceptions and Appeals
- Effective Pharmacy Management

We plan to continue to use various data sources in the development of these measures including CMS complaint tracking information, Medicare Prescription Drug Plan Finder data, prescription drug event information submitted by plans, and call center statistics. Plans should consider

these measurement areas to ensure their call centers meet the requirements outlined in the 2007 call letter, to ensure appropriate capacity for exceptions and appeals, and to ensure effective data systems, with the understanding that CMS is planning to post performance metrics.

2. Standardized Messaging

Consistent with the 2006 requirement outlined in a May 22, 2006 letter to Part D plans, CMS will require in 2007 the adoption and use of new standardized messaging procedures approved by National Council for Prescription Drug Programs (NCPDP) in order for Part D plans to effectively coordinate with any other payers in real time. This requirement will address issues that have arisen at point of sale that indicate the need to clarify certain claims messaging situations that are specific to Part D. These include claims rejections for drugs excluded from Part D coverage and for drugs that are covered under Medicare Part B for the particular beneficiary. We previously notified you that a work group of the NCPDP has approved a process for using structured reject "coding" in the message field of the billing transaction response to provide additional information clarifying the specific reason for rejection in these two situations. This process is consistent with the current NCPDP 5.1 standard. As part of the 2007 Coordination of Benefit (COB) Guidance, CMS will require Part D plans to adopt and use this new standardized procedure until such time as transactional reject codes can be implemented in a new version of the HIPAA standard.

3. Exceptions and Appeals Website Requirements

The 2007 Medicare Marketing Guidelines will clarify the requirements for plan web pages relating to exceptions and appeals reflecting the practices that plans have already widely adopted. We expect that Part D organizations will be required to include the following information on their exceptions and appeals web pages:

- A summary of the plan's grievance, coverage determination (including exceptions), and appeals processes.
- Instructions for filing a grievance, including:
  - The telephone number designated for receiving oral grievances; and
  - The mailing address and fax number designated for receiving written grievances.
- A link to the Request for Medicare Prescription Drug Determination Request Form (for use by enrollees).
- A link to the Medicare Part D Coverage Determination Request Form (for use by providers).
- A link to the plan's redetermination request form, if the plan has developed one.
- Any form developed by the plan to be used by a physician or enrollee to satisfy a prior authorization or other utilization management requirement.
- Any form developed by the plan to be used by physicians when providing a supporting statement for an exceptions request.

- Contact numbers that enrollees and physicians can use for process or status questions.
- Instructions about how to appoint a representative and a link to CMS's Appointment of Representation form (Form CMS-1696).
- A link to the plan's Evidence of Coverage (EOC) and a reference to the sections to EOC that discuss the grievance, coverage determination (including exceptions), and appeals processes.
- A link to the plan's or CMS's coverage determination request form.

In addition, use of the Request for Medicare Prescription Drug Determination Request Form (for use by enrollees) and the Medicare Part D Coverage Determination Request Form (for use by providers) is being clarified in the next revision to Chapter 18 of the Prescription Drug Benefit Manual on Part D Enrollee Grievances, Coverage Determinations, and Appeals.

4. Mandatory 4Rx Files

In our COB guidance, we expect to address the issue of mandatory 4Rx data reporting at the time of the enrollment transaction. As you know, plans submit enrollments to the Medicare Advantage – Prescription Drug (MARx) system. When MARx accepts an enrollment and transmits a successful reply to plans, plans are required to follow up with a 4Rx data transaction that is submitted to the Medicare Beneficiary Database (MBD). If MBD accepts the 4Rx data, it is then sent to the TrOOP facilitation contractor to support the eligibility (E1) transaction from pharmacies, which is needed anytime a beneficiary shows up for the first time at a pharmacy and does not have a plan-issued card for drug benefits. While plans have worked with us to reduce the time between enrollment and complete 4Rx information, the time lag between enrollment transactions and 4Rx submissions can be 7-14 days. In order to better facilitate access at point of sale, we expect to significantly reduce this time lag by revising the enrollment transaction process to require 4Rx data on every enrollment transaction received from plans. We expect to implement this process no later than April 2007. Plans may need to make programming and business process changes to expedite enrollment in PBM systems and allow more frequent processing of CMS transactions.

5. Bundling Home Infusion Payments by MA-PDs

In our 2007 COB Guidance, we expect to clarify that certain home infusion drugs which are bundled into per diem payments made by MA-PDs for home infusion services are not considered Part D drugs. As such, MA-PDs will have the option to cover home infusion drugs as part of a bundled service as a supplemental benefit under Part C, provided the plan consistently applies the option (i.e., always covered under Part C or always covered under Part D for the plan year). Based on this guidance, interested Medicare Advantage plans will have to appropriately apportion costs between the Part D and C components of their bid to account for these drugs, describe such changes in the notes section of the PBP and be given an opportunity to revise formularies so that CMS can appropriately identify the drugs for benefit, CMS plan finder tool, marketing, auditing, and oversight purposes.

6. Transfer of TrOOP and Gross Drug Spending Balances between Plans

In 2007, CMS will be implementing a process to automate the transfer of a Part D beneficiary's true-out-of-pocket (TrOOP) and total gross drug spending balances between plans that a beneficary is enrolled in during the year. Part D rules require plans to track the beneficiary's TrOOP and correctly apply these costs to the TrOOP limit in order to provide the catastrophic level of coverage at the appropriate time. The TrOOP threshold is calculated on an annual basis and must be transferred between Part D plans if a beneficiary disenrolls and re-enrolls at any time before the end of a coverage year. Plan collection, and transfer if appropriate, of the TrOOP and gross covered drug spending balances are essential for plans to correctly manage the Part D benefit. CMS is considering options that range from plans transmitting the total figures only upon a beneficiary mid-year disenrollment to routine monthly reporting of totals for all beneficiaries when explanation of benefits (EOB) reports are created. Programming may be required to accommodate this automation of the TrOOP and Gross Drug Spending Balance transfer.

7. N1 Transactions

CMS is also working with the TrOOP Facilitation Contractor to develop two additional uses of the N1 transaction. These would permit:

1. The exchange of drug-specific information between plans and patient assistance programs (PAPs) operating outside the Part D benefit to automate the communication of this information to the Part D plan, and

2. The exchange of information about drug purchases outside the plan's contracts (e.g., through a discount card vendor) that count toward gross covered drug costs and TrOOP to ensure the accurate tracking of these balances by the Part D plan.

Results of this information from an expanded N1 transaction would require plans to incorporate information from PAPs into their drug utilization review programs and ensure any claims submitted for the drug(s) provided by PAPs outside the benefit are denied for payment, or that prescription drug purchases made by the beneficiary using a non-Medicare discount card are added to a beneficiary's TrOOP balance.

8. Plan to Plan Reconciliation during Transition periods

The opportunity for beneficiaries to change their Part D plan enrollment during the coverage year creates situations in which, due to lags associated with the enrollment process and information systems updates, the plan from which a beneficiary has transferred makes payment for covered prescription drug costs incurred after the effective data of the beneficiary's enrollment in the new plan of record. To provide further support for payment reconciliations that are required to resolve these enrollment transition issues, CMS will continue to develop the plan-to-plan reconciliation and reimbursement process in 2007. As such, plans will likely follow the special prescription drug event submission and reimbursement processes established this year.

9. Submission of drug pricing and pharmacy network data

For the 2007 plan year, CMS will again require all Part D plans to submit drug pricing and pharmacy network data for their plans on a bi-weekly basis and will post this data on the Medicare Prescription Drug Plan Finder on www.medicare.gov. However, we anticipate requiring all plans to submit their drug pricing information based on the NDCs contained in the "Formulary Reference NDC File for CY 2007 Formulary Submissions" (http://www.cms.hhs.gov/Pharmacy/07_Formulary%20Guidance.asp). Thus, the unit cost submitted for each drug on a plan's formulary in the pricing data files for the Medicare Prescription Drug Plan Finder must be for the specific NDC listed in the "Formulary Reference NDC File." Further guidance regarding the data file layout and submission of drug pricing and pharmacy network data will be made available to all plans in early June 2006.

10. Medication Therapy Management Program and Medicare Health Support Organization Coordination

We will be issuing a draft chapter for the Prescription Drug Benefit Manual addressing plan requirements related to medication therapy management programs (MTMP) and quality improvement. Included in the discussion will be a description of the required coordination between a plan's MTMP and any care management plan established for a targeted individual under a chronic care improvement program, now known as a Medicare Health Support Organization (MHSO). The description of the coordination will specify the minimum data exchange that CMS will require between the Part D plans and the MHSO for individuals participating in both programs, which will minimally require Part D plans to indicate whether certain beneficiaries are enrolled in the plan's MTMP program and whether elements of the plan's MTMP program overlap with the MHSO intervention.

We look forward to continuing to work with you as you prepare bids for the 2007 contract year and hope you find this list useful. Please feel free to contact your account manager if you have additional questions.