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**PLAN OVERSIGHT & ACCOUNTABILITY GROUP**

**DATE:** May 9, 2006

**TO:** Prescription Drug Plan and Medicare Advantage Prescription Drug Plan Sponsors

**FROM:** Cynthia E. Moreno /s/
Director

**SUBJECT:** Part D Audit Guide – Response to Industry Comments

On November 23, 2005, the Centers for Medicare & Medicaid Services (CMS) provided the draft Medicare Part D Audit Guide (the Guide) to all contracted Prescription Drug Plan and Medicare Advantage Prescription Drug Plan sponsors for review and comment. We understand this is an extremely busy time for everyone and greatly appreciate the time taken to review and provide feedback. CMS carefully reviewed all comments submitted.

The attached document contains a summary of the comments pertaining to the Guide elements and our responses. Comments and policy questions outside the scope of the Guide elements were forwarded to the appropriate CMS personnel for review and consideration.

The final versions of the "Medicare Advantage Prescription Drug Plan Sponsors Part D Audit Guide" and "Prescription Drug Plan Sponsors Part D Audit Guide" will be posted to the Plan Reporting and Oversight section of the CMS Website this summer.

## Background

On November 23, 2005, CMS provided a DRAFT document titled "Medicare Part D Audit Guide" to all contracted Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PD) sponsors for their review and comment. The following is a summary of the comments received that pertain to the Guide elements, and CMS responses.

## General Comments

The following responses address general comments regarding the overall draft Medicare Part D Audit Guide.

1. CMS received requests to provide the Method of Evaluation (MOE) for each of the elements in the Audit Guide.
   - **Response:** Unlike the MA Audit Guide, the Part D Audit Guide does not include MOEs. CMS will provide sponsors with general guidance regarding how the agency will undertake audit work. This information will be disclosed to industry prior to CMS beginning its audit activity.

2. CMS received requests to define the audit "types" listed in the first column of the audit guide (desk, onsite, sample).
   - **Response:** CMS will be conducting randomized desk and onsite audits within the 3 year audit cycle as described in the "Part D Audit Strategy" located on CMS' website at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/OversightStrategy_10.24.05.pdf. As a result of this new randomized auditing strategy, there is no longer a need to identify an element as "desk" or "on-site," so this information has been deleted from the Part D Audit Guide. Regarding the designation of "sample," CMS will notify sponsors prior to an audit regarding the need to provide CMS with universes from which samples are selected. Therefore, this designation has been deleted from the Guide as well.

3. CMS received a recommendation to merge the Part D Audit Guide elements into the Medicare Advantage Monitoring Guide to assist MA-PD sponsors in complying with auditing requirements.
   - **Response:** CMS' long-term goal for Medicare Advantage Organizations (MAO) is to incorporate applicable Part D Audit Guide elements directly into the Medicare Advantage Monitoring Guide. In the interim, CMS audit staff will carry separate audit tools for Parts C and D and will utilize separate HPMS modules. CMS Account/Plan Managers will work with MAOs to coordinate Part C and D audit activities and minimize burden on Sponsors.

4. CMS received a request to define the precise requirements for each element, rather than use general language, such as "as specified in CMS instructions." CMS also received a request to specify the applicable section of the reference document(s).
   - **Response:** CMS has provided a substantial amount of detail in each element; however, due to their length, some requirements are not fully described in the element language. Each element in the Part D Audit Guide provides corresponding references from the Part D Final Regulations, guidance documents, and the Solicitation for Applications to indicate the specific requirements that apply. Part D sponsors must comply with all of the requirements and instructions provided in these references in order to meet the requirements for each element. Other than for the Final Regulations, CMS has not provided the applicable section of the reference documents for each element because those section references will change as these documents are updated.

5. CMS received a request to indicate which model letters are required for each element, where applicable.
   - **Response:** CMS has not indicated the specific model letter required for each element, where applicable, because Part D sponsors are not required to use the CMS-provided model letters (e.g., they may alter the model language with CMS approval), and because those references and their location will likely change as guidance documents are updated.

## Deleted Elements

CMS has deleted the following elements from the final version of the Medicare Part D Audit Guide. The reasons for the deletions are also provided.

*ER13 Enrollment Process – File and Retaining Requests*

CMS has deleted this element and combined its requirements with Element CN01 Maintenance of Records.

*DN04 Voluntary Disenrollment Process – File and Retaining Requests*

CMS has deleted this element and combined its requirements with Element CN01 Maintenance of Records.

*DN05 Inappropriate Involuntary Disenrollment or Encouragement to Disenroll*

CMS has deleted this element because the requirements for compliant mandatory and operational involuntary disenrollment procedures are currently satisfied by Elements DN06-DN12.

*MR01 Submission of Pricing and Pharmacy Network Information (www.medicare.gov)*

CMS has deleted this element because Part D sponsor compliance with the requirements for submitting pricing and pharmacy network information to CMS for posting on www.medicare.gov will be monitored as part of ongoing CMS contractor management activities.

*MR11 Formulary Education*

CMS has deleted this element because the requirements for educating enrollees concerning a Part D plan's formulary are currently satisfied by providing the marketing and beneficiary information materials required by Elements MR04 Requirements for Pre-enrollment Marketing Materials, MR10 Provision of Notices Regarding Formulary Change, MR13 Requirements for Post-enrollment Materials, MR14 Information Provided to Beneficiaries Upon Request, and MR16 Internet Website.

*MR12 Card or Other Technology to Access Negotiated Prices*

CMS has deleted this element because the member ID cards are reviewed under the marketing material review process to ensure they have all pertinent and required information displayed in accordance with CMS Marketing Guidelines. This requirement is satisfied by Element MR02 Submission and Distribution of Marketing Materials and Element PR02 Use of SSN/HICN.

*MR18 Disclosure of Price Differential*

CMS has deleted this element and combined its requirements with Element CN04 Required Contract Provisions: Other First-Tier and Downstream Entities

*PH03 Long-Term Care Pharmacy Contracting Terms and Conditions*

CMS has deleted this element as a result of combining its requirements with Element PH04 Access to Long-Term Care Pharmacies and the new Element CN05 Required Contract Provisions: Long-Term Care Pharmacies.

*PH05 I/T/U Pharmacy Contracting Terms and Conditions*

CMS has deleted this element as a result of combining its requirements with Element PH06 Access to I/T/U Pharmacies and the new Element CN06 Required Contract Provisions: I/T/U Pharmacies.

*PH08 Pharmacy Network Contract Requirements*

CMS has deleted this element and combined its requirements with Element CN04 Required Contract Provisions: Other First-Tier and Downstream Entities.

*PH12 Pharmacy Access Reporting Requirements*

CMS has deleted this element and combined its requirements with Element MR14 Information Provided to Beneficiaries Upon Request.

*MT04 Coordination of MTMP with Chronic Care Improvement Programs*

CMS will delete this element for MA-PD Sponsors, as this requirement is not applicable to MA-PD Sponsors, because beneficiaries enrolled in Part C plans cannot enroll in a CCIP, as defined in Section 1807 of the Social Security Act.

*CL03 Paper Claims Processing System*

CMS has deleted this element and combined its requirements with Element CD05 Coverage Determinations Concerning Payment.

*CL04 Mail Order Processing System*

CMS has deleted this element because the turnaround time processing requirements for a Part D sponsor offering mail order pharmacy services depend on the Sponsor's contractual arrangement with its mail order pharmacy.

*CL07 Coordination of Claims with Chronic Care Improvement Programs (CCIPs)*

CMS will delete this element for MA-PD Sponsors, as this requirement is not applicable to MA-PD Sponsors, because beneficiaries enrolled in Part C plans cannot enroll in a CCIP, as defined in Section 1807 of the Social Security Act.

*GV03 Access to Grievance Records*

CMS has deleted this element and combined its requirements with Element CN02 Access to Facilities and Records.

*CD03 Access to Exceptions and Appeals Records*

CMS has deleted this element and combined its requirements with Element CN02 Access to Facilities and Records.

*LS02 Temporary State License Waiver for Regional Plans*

CMS has deleted this element and combined its requirements with Element LS01 State Licensure or Waiver Status.

**Added Elements**

CMS has added the following elements to the Medicare Part D Audit Guide. The reasons for the additions are also provided.

*ER13 Confirmation of Enrollment for Members of Employer Group/Union Receiving Employer Subsidy*

CMS has added this element to the Enrollment and Disenrollment chapter in order to verify compliance with the requirement in Section 10.4 of the PDP Guidance Eligibility, Enrollment and Disenrollment and Section 40 of Chapter 2 of the Medicare Managed Care Manual.

*CN05 Required Contract Provisions: Long-Term Care Pharmacies*

CMS has added this element to the First-Tier and Downstream Contracts/Maintenance of Records chapter in order to verify compliance with the requirement that all written contracts with network long-term care pharmacies must include the CMS-specified performance and service criteria for long-term care pharmacies, as required by 42 CFR § 423.120(a)(5), the Solicitation for Applications, and the Long-Term Care Guidance. This requirement was previously part of Element PH03 Long-Term Care Pharmacy Contracting Terms and Conditions.

*CN06 Required Contract Provisions: I/T/U Pharmacies*

CMS has added this element to the First-Tier and Downstream Contracts/Maintenance of Records chapter in order to verify compliance with the requirement that all written contracts with network I/T/U pharmacies must contain standard contracting terms and conditions conforming to the model addendum that CMS provides, as required by 42 CFR § 423.120(a)(6), the Solicitation for Applications, and the Information for Part D Sponsors on Contracting with Indian Health Care

Providers Guidance. This requirement was previously part of Element PH05 I/T/U Pharmacy Contracting Terms and Conditions.

*PA04 Claims Processing and Payment Reporting Requirements*

CMS has added this element to the Claims Processing and Payment chapter in order to verify compliance with the requirement in 42 CFR § 423.514(a), the Solicitation for Applications, and the Final Medicare Part D Reporting Requirements document (updated 4/19/2005).

*LS04 Significant Business Transactions*

CMS has added this element to the Licensure and Financial Solvency chapter of the "Prescription Drug Plan (PDP) Sponsors Part D Audit Guide" in order to verify compliance with the requirement in 42 CFR § 423.514(b), § 423.514(c)(1-3), and the PDP Solicitation for Applications.

**Other Changes**

CMS made changes to the language of the following elements in the Medicare Part D Audit Guide.

*MR15 Toll-Free Customer Call Center*

CMS added the requirement for the Part D sponsor to report to CMS information related to the operations of its customer call center. This requirement is described in the Final Medicare Part D Reporting Requirements document (updated 4/19/2005).

*PH10 Out-of-Network Pharmacy Access*

CMS revised the requirement in this element to make it consistent with the regulation in 42 CFR § 423.124(a) and (c). Specifically, CMS deleted the reference to CMS-required out-of-network pharmacy access guarantees.

*TP01 Transition Process for Enrollees*
*TP02 Transition Process for Residents of Long-Term Care Facilities*

CMS clarified that both of these elements require that the Part D sponsor's transition process address situations where enrollees are prescribed Part D drugs that are not on its formulary or that are on its formulary but require prior authorization or step therapy.

*CD04 Timely Notification of Coverage Determination Concerning Drug Benefit*
*CD05 Timely Notification of Coverage Determination Concerning Payment*
*CD10 Timely Notification of Expedited Coverage Determination*
*RE05 Timely Notification and Effectuation of Standard Redetermination Concerning Covered Drug Benefit*
*RE06 Timely Notification and Effectuation of Standard Redetermination Concerning Payment*
*RE07 Timely Notification of Expedited Redetermination and Request for Medical Information*

CMS added to each of these elements the requirement that the Part D sponsor inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when a coverage determination or redetermination case is forwarded to the Independent Review Entity (IRE). This requirement is described in the *Prescription Drug Benefit Manual, Chapter 18, Part D Enrollee Grievances, Coverage Determinations and Appeals*.

*CD05 Timely Notification of Coverage Determination Concerning Payment*

CMS added the following requirement to this element:
For favorable determinations, the Part D sponsor must authorize payment and notify the enrollee within 72 hours after receiving the request, or, for an exceptions request, after receiving the physician's supporting statement. The Part D sponsor must also make payment (i.e., mail the payment) within 30 calendar days of the request, or, for an exceptions request, after receiving the physician's supporting statement. This requirement is described in the *Prescription Drug Benefit Manual, Chapter 18, Part D Enrollee Grievances, Coverage Determinations and Appeals*.

*RE10 Timely Transfer to IRE Upon Reconsideration Request*

CMS clarified the requirement that the Part D sponsor transfer the case file to the IRE, when requested, within 24 hours (expedited requests) or 48 hours (standard requests) from the time it receives the IRE's request for the case file. This requirement is described in the *Prescription Drug Benefit Manual, Chapter 18, Part D Enrollee Grievances, Coverage Determinations and Appeals*.

**Chapter/Element Specific Comments**

The following sub-sections provide responses to comments on a specific chapter/element of the Medicare Part D Audit Guide.

**Chapter 1: Enrollment and Disenrollment**

1. Notice Acknowledging Receipt of Completed Enrollment Election (ER04)
   A comment requested clarification on when the Part D sponsor must send an acknowledgment of completed enrollment request.
   - **Response:** CMS has revised the element to be consistent with the Enrollment Guidance. Part D sponsors must provide the acknowledgement letter prior to the effective date of enrollment, or if late in election period within 7 business days of receipt of the completed enrollment request.

2. Cancellation of Enrollment and Disenrollment Requests (ER05 and DN03)
   A comment requested clarification on when the Part D sponsor must send a cancellation notice.
   - **Response:** CMS has revised the element to clarify that Part D sponsors must send the cancellation notice within 7 business days of the receipt of the cancellation request.

3. Denial of Disenrollment Requests (DN02)
   A comment requested clarification on when the Part D sponsor must send the denial of disenrollment notice to the enrollee.
   - **Response:** The Part D sponsor must notify the enrollee of its denial of a voluntary disenrollment request within 7 business days of the receipt of the request.

4. Involuntary Disenrollment for Nonpayment of Premium, Disruptive Behavior, and Fraud and Abuse (DN06, DN07, and DN08)
   A comment requested clarification on the definition of the word "optional" in these elements.
   - **Response:** These elements are considered "optional" since a Part D sponsor has the choice of disenrolling or not disenrolling its Part D plan members for the reasons stated. Although a Sponsor is permitted to have different policies for different plans, it must maintain the same policy for any single plan for the entire contract (calendar) year. Additionally, the Part D sponsor must apply the same policy in a consistent manner to all members of the same plan. If the Part D sponsor has a policy to not disenroll its Part D plan members for one of the reasons stated, then the respective element does not apply for that Sponsor.

5. Required Disenrollment for Loss of Part D Eligibility (DN10)
   A comment recommended that the element language be changed to state that the Part D sponsor must disenroll an individual who loses "entitlement to Medicare Part A and Part B," rather than "eligibility for Part D."
   - **Response:** The language used in this element is consistent with the Part D Final Regulations and will not be revised.

6. Enrollment and Disenrollment Reporting Requirements (DN13)
   A comment requested clarification on whether this element applies to MA-PD sponsors.
   - **Response:** This element is derived from the Final Medicare Part D Reporting Requirements document (updated 4/19/2005). MA-PD organizations are required to comply with all Part D reporting requirements specified in this guidance document with the exception of those provided in Section XI titled "Licensure and Solvency, Business Transactions and Financial Requirements." Therefore, this element is not waived for MA-PD sponsors.

**Chapter 2: Provider Communication**

1. Toll-Free Call Center (PC01)
   A comment requested clarification on whether there are certain requirements that need to be met to demonstrate compliance for this element.
   - **Response:** The specific requirements that must be met to demonstrate compliance with this element are described in the Solicitation for Applications.

**Chapter 3: Marketing and Beneficiary Information**

1. Plan Responsibility for Persons Employed or Contracted to Perform Marketing (MR07)
   A comment recommended that the first sentence of this element be deleted.
   - **Response:** CMS has not changed the element language. Part D sponsors must meet the CMS requirements described in the Marketing Guidelines for compensation structures.

2. Marketing to the Disabled (MR09)
   A comment requested clarification on whether there are certain requirements that need to be met to demonstrate compliance for this element.
   - **Response:** The specific requirements for this element are described in the Marketing Guidelines. CMS has added the Marketing Guidelines document as a reference for this element.

**Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing**

1. Electronic Prescribing (EP01)
   A comment requested clarification on the electronic prescribing standards and the time requirements for their implementation.
   - **Response:** Effective January 1, 2006, Part D sponsors must comply with the adopted electronic prescription drug program standards as described in 42 CFR § 423.159 of the Part D Final Regulations. This first set of e-prescribing standards described in 42 CFR § 423.160 were published in separate Final Regulations on November 7, 2005 (E-prescribing and the Prescription Drug Program), and does not represent the full set of standards and functionalities that will be necessary to effectively implement an electronic prescription drug program. The standards apply to electronically transmitted prescriptions for covered Part D drugs and other related information (such as eligibility and benefits checking) for Part D eligible individuals. The requirement to use the standards applies to Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) Organizations offering Medicare Advantage Prescription Drug (MA-PD) plans, and other Part D sponsors, which are required by the MMA to implement an electronic prescription drug program.

**Chapter 6: Pharmacy Access**

1. Level Playing Field Between Mail Order and Retail Network Pharmacies (PH09)
   A comment recommended that the element title be changed to indicate that this element is "optional."
   - **Response:** CMS has changed the element language to indicate Part D sponsors must permit its enrollees to receive this benefit at "some" instead of "any" of its retail network pharmacies, in order to be consistent with CMS guidance. However, compliance with this element is not optional for Part D sponsors. CMS expects that if extended supplies of drugs are available at mail order, then enrollees will be permitted to receive those benefits at a retail pharmacy that has contracted with a Part D sponsor to provide an extended supply of drugs. CMS further expects that Part D sponsors will contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order.

**Chapter 10: Compliance Plan**

1. Effective Compliance Training and Effective Lines of Communication (CP04 and CP05)
   A comment requested that the term "agents" be defined.
   - **Response:** For these elements, the term "agents" refers to contracted persons, whether the person contracts directly with the Part D sponsor or is a downstream contractor. Part D sponsors must have and implement a compliance plan that includes effective training and effective lines of communication for all persons who are directly employed or contracted to perform Part D-related functions.

**Chapter 13: Grievances, Coverage Determinations, and Appeals**

1. General comment on forthcoming guidance from CMS (all elements in this chapter, except GV04, Grievance Process Training)
   A comment questioned whether the *Prescription Drug Benefit Manual, Chapter 18, Part D Enrollee Grievances, Coverage Determinations and Appeals* was the "forthcoming guidance" referenced in several of this chapter's elements.
   - **Response:** Yes—The *Prescription Drug Benefit Manual, Chapter 18, Part D Enrollee Grievances, Coverage Determinations and Appeals* is the "forthcoming guidance" referenced in several of the elements in this chapter. CMS has added Chapter 18 of this manual as a reference for each applicable element in this chapter.

2. Approval of Tiering and Non-Formulary Exceptions Requests (CE03)
   A comment requested clarification on whether a Part D sponsor must place approved non-formulary exceptions in the same cost-sharing tier as preferred drugs.
   - **Response:** CMS has revised the element to clarify that a Part D sponsor that approves an exception request for a non-formulary drug has the flexibility to determine what level of cost-sharing applies to the approved non-formulary drug, so long as the designated level is one of its existing cost sharing tiers. It is not required to apply the same cost-sharing level as preferred drugs. For an approved tiering exception request for non-preferred drugs, the Part D sponsor must permit enrollees to obtain an approved non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier.