MANATT HEALTH SOLUTIONS

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Key Elements of DRAFT 2009 Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Cost-Based Plan, and Prescription Drug Plan (PDP) Sponsors Call Letter (Part D Section)

On January 16, 2008, the Centers for Medicare & Medicaid Services (CMS) released through HPMS and posted on its website the draft 2009 Call Letter for Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Cost-Based Plan, and Prescription Drug Plan (PDP) Sponsors. Comments must be submitted to *2009CallLetter@cms.hhs.gov* no later than 5 PM EST January 30, 2008 via the excel spreadsheet provided by CMS and available at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf.

Like the 2007 Call Letter, CMS did not summarize the instructions issued over the past year. Rather, it discussed information believed to be especially useful as Part D Plans prepare for the upcoming contract year. It references current CMS guidance and directs Part D Plans to the documents or web sites where they can locate in-depth information. Below are key elements of the Prescription Drug Plan Sections of the Call Letter. The Part C Sections of the Call Letter will be analyzed separately.

1. Six Classes of Clinical Concern. There will be no change in CMS's six classes of clinical concern policy for contract year 2009. However, as of 2009, Part D Plans may no longer apply prior authorization to the HIV drug Fuzeon and should generally not employ any utilization management tools for HIV/AIDS drugs.

2. Prior Authorization.

    a. In order to streamline the CMS formulary review and provide a uniform format that will allow greater transparency when comparing formularies, CMS is standardizing the submission of Part D Plan prior authorization (PA) requirements. CMS will release details about the new standardized PA file as part of the CY2009 Formulary Submission Module and Reports Technical Manual in March 2008.

    b. Part D Plans must also post their approved PA criteria on their websites by November 15, 2008, augmenting their ability to rapidly provide this information, improve transparency and allow plan comparison during enrollment. Part D Plans must make the information available for viewing either from a link when the drug is displayed or from a general ink on the formulary page. All of the PA criteria in the new standardized PA file must be displayed.

3. Formulary Submission Timeline. CMS is proposing to deny bids in instances where Part D Plans have failed to meet their formulary submission and re-submission deadlines during the formulary approval process.

4. Specialty Tiers

    a. CMS proposes to maintain the $600 threshold for the specialty tier.

    b. CMS also clarifies that if a drug is available in multiple strengths, package sizes and formulations, it will only allow inclusion on the specialty tier of those strengths, packages sizes and formulations that would reasonably exceed the $600 threshold.

5. Limited Access Drugs. CMS notes that additional education or counseling alone does not qualify a drug for limited distribution with a Part D Plan's overall pharmacy network.

6. Supplemental Formulary File Submissions. CMS is implementing a new process for Part D Plans to submit supplemental formulary files. Details will be released as part of the CY2009 Formulary Submission Module and Reports Technical Manual in March 2008.

7. e-Prescribing.

    a. CMS is soliciting comments on additional Part D formulary information that CMS could obtain from Part D Plans to reflect in the Formulary Reference File (FRF), which would then be included in the CMS Public Use File (PUF) used by e-prescribing vendors in the design of eRx systems. Specifically, CMS asks whether it should request that Part D Plans provide a Formulary Status identifier, such as the Formulary Status identifier specified in the NCPDP Formulary and Benefit Standard Version 1.0.

    b. CMS is also considering requiring that Part D Plans report on the source of prescriptions filled, and other elements described in the reporting requirements section of this summary, that will allow CMS to evaluate the increase in e-prescribing within Part D. Also under consideration is the addition of a new field to the PDE record that would capture the Prescription Origin Code.

8. RxNorm. CMS is introducing the RxNorm nomenclature for FRF drugs. For each CY 2009 FRF proxy code, the RxNorm semantic names and RxNorm concept unique identifier (RXCUI) code (when available) will be included. CMS is exploring RxNorm as a potential alternative to proxy NDCs for formulary submissions in future years.

9. Steps to Complete When a Part D Sponsor Changes its PBM. CMS indicates that for those Part D Plans changing PBMs mid-year, the formulary and benefits must be administered as approved for the current contract year. Formulary category/class changes are not permitted. For those changing PBMs for January 1, 2009, the formulary and benefits must be administered as approved for the 2009 contract year.

10. Limiting Co-payments to a Part D Plan's Negotiated Price. CMS is revising previous guidance such that for CY2009, Part D Plans are required to charge beneficiaries the lesser of a drug's negotiated price or applicable co-payment amount when a drug's negotiated price is less than its applicable co-payment amount.

11. Prohibition of Limiting Coverage to Mail-Order Only Drugs in the Coverage Gap. CMS clarifies that Part D Plans offering enhanced alternative coverage that includes coverage in the gap as a supplemental benefit may not limit access to drugs for which they provide coverage in the gap to mail-order pharmacies. If a Part D Plan provides coverage of drugs in the coverage gap when obtained from mail-order pharmacies, the plan also must provide coverage of those drugs when obtained from retail pharmacies.

12. Best Available Evidence (BAE) to Correct a Beneficiary's Low-Income Status. CMS is requiring that Part D Plans accept BAE at point-of-sale and update their systems within 48 to 72 hours of their receipt of the documentation. Prior to this, CMS had not mandated a specific timeframe. In addition, Part D

Plans must have a process in place to permit beneficiaries to receive an emergency supply if they are in immediate need.

13. Benefit Structure in the Coverage Gap. CMS indicates it is considering methodologies for determining what is sufficient gap coverage or limited gap coverage, including an analysis of the percentage of beneficiaries who potentially would benefit from a proposed benefit offering in the coverage gap.

14. Timely Delivery of Home Infusion Drugs. CMS is requiring Part D Plans to provide delivery of home infusion drugs within 24 hours of discharge from an acute setting or later if so prescribed. CMS expects to finalize its policy and technical corrections regulation, in which this policy was first proposed, in spring 2008.

15. Interoperability Standards for Health Information Technology. CMS is asking that Part D Plans take steps to implement provisions in Executive Order 13410: "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs," which directs federal agencies that contract with health plans, insurers, and providers to require, as feasible, that health IT systems acquired include recognized interoperability standards. CMS will be providing further guidance to assist Part D Plans in doing so.

16. Part D Plan Ratings/Quality and Performance Metrics. CMS is proposing a number of new quality measures which may include but are not limited to Medication Therapy Management services, prescription drug utilization, and patient safety.

17. 2009 Reporting Requirements. CMS will reflect changes in reporting requirements in its CY 2009 reporting requirements memo. Part D Plans will be required to report on the number and source of prescriptions processed by network pharmacies on a quarterly basis and on the number of prescriptions that are immediately filled at the point of sale versus the number delayed due to the need for an exception request, prior authorization activity etc.

18. Vaccines. The draft Standardized Model Combined ANOC/EOC contains information about vaccine access and administration under Part D, including a chart that sets out a beneficiary's required payments in various circumstances. See page 199.

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