



On March 30, 2009 The Centers for Medicare and Medicaid Services (CMS) issued the final 2010 Call Letter. The Call Letter provides guidance to Medicare Advantage organizations (MAO) and Part D plan sponsors on new regulatory requirements and statutory changes. The changes are important since they represent new guidance that plans must consider when preparing their Medicare Part D bids for Calendar Year (CY) 2010. The initial draft of the 2010 Call Letter was issued on January 8, and then withdrawn on January 22 to provide the new Obama administration a chance to review and provide further clarifications. The revised draft 2010 Call letter was re-issued on February 23, 2009. A total of 190 public comments on the Call Letter were accepted by CMS until March 6, 2009. Comments came from a variety of sources (e.g. plan sponsors, pharmaceutical manufacturers, pharmacy organizations, even members of Congress) and were taken into consideration by CMS to make both revisions and clarifications to the final document. In some instances (e.g. determination of medical-loss ratios, etc.) CMS will consider addressing the issue in future contract years. All Part D plans are required to submit CY 2010 drug formularies by April 20, 2009 and bids no later than June 1, 2009. The 2010 Call Letter is available at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf.

Summary of the 2010 CMS Call Letter

Page #:	Description of Significant Program Changes:
Cover Memorandum	Medical-Loss Ratios: CMS refrained from implementing its proposal to calculate and disseminate plans Medical-Loss ratios (MLRs) due to the issue's "complexity". CMS will continue to evaluate methodologies for possible future implementation.
11 - 12	Low Enrollment Plans: CMS instructs MAOs to eliminate plan offerings that are not easily distinguishable by beneficiaries and may cause beneficiary confusion. MAOs offering more than one plan in a given service area should ensure that plan differences are transparent and readily discernable to beneficiaries. CMS is concerned that certain plan options have concealed aspects, such as high cost sharing for certain services which are not advantageous to beneficiaries. CMS may elect to eliminate MAPD and Part D plans with little or no enrollment (e.g. < 10 members) for more than three years unless there are extraordinary circumstances.
13 - 14	Cost-Sharing Guidance: CMS' goal is to establish a more transparent process so that beneficiaries will be better able to predict their out-of-pocket (OOP) costs and therefore protect themselves from excessive or unexpected cost sharing. Plans with a plan level OOP maximum amount not greater than \$3,400 will face less review of benefits and cost-sharing amounts. Cost-sharing amounts for certain services such as renal dialysis, skilled nursing facilities, durable medical equipment, home health, Part B drugs, inpatient acute and psychiatric hospital, and outpatient hospital will face closer reviews if higher amounts for cost-sharing are charged when compared to original Medicare Part A and B.
14 - 17	Preventive Services Incentives: A limited preventive services incentive program will be allowed for 2010 that must meet 16 criteria (e.g. requirement that the program cannot be used in pre-enrollment advertising, may not be cash/gift cards, may not waive or lower co-pays, and must be of nominal value \$10/item/\$50 aggregate).
24 - 25	CAHPS surveys: CAHPS (Consumer Assessment of Healthcare Providers and Systems) surveys will be performed by Plans with at least 600 members as of 7/1/2010. Plans will select a vendor from a CMS approved vendor list. The survey will be conducted in early 2011 and plans will need to cover the \$8.00 approximate cost of each field survey.
25 - 26	Complaint Tracking Module (CTM): MA plans will be 'expected' to resolve 95% of complaints labeled as "immediate need" within two calendar days; "urgent need" within

	seven calendar days; and 95% of the remaining CTM complaints without an issue level within 30 calendar days.
26	Audit Approach: CMS's audit strategy in 2010 will reflect a move away from routine audits to more targeted, data-driven and risk based audits. CMS plans on utilizing performance profiles of MAOs and Part D sponsors and target organizations that demonstrate poor performance.
27 - 28	Part C and D data validation: Part C and D data validation audits for 2010 will focus on specific areas, such as appeals and grievances and agent compensation structures. MAOs and Part D sponsors are responsible for acquiring the data validation audit resources required by CMS through a contractor or by other means.
29	Mandatory use of on-line Enrollment Center (OEC): As of 2010 all MAOs (except for certain plans such as Medical Savings Account plans, 800 Series Employer plans, etc.) and Part D sponsors must accept enrollment elections made via the OEC maintained by CMS.
29 - 31	Payment: Payment of the Physician Quality Reporting initiative (PQRI) and e-prescribing bonuses are optional with respect to contracting providers in Part C. Non-contracted physicians bonus payments are required when a physician is determined by original Medicare to have satisfied the requirements and qualified for the incentive and has billed a MAO as a non-contracted provider.
56 - 58	Submission of a valid application, bid, or formulary submission: During the application, formulary, and bid review processes for CY 2010 and beyond, CMS will consider the completeness and accuracy of the submission as factors in determining whether an organization has in fact met a submission deadline. CMS also reminded Part D sponsors that they must ensure that all of their associated contracts are linked to an initial formulary submission on or before the formulary submission deadline.
58 - 61	Access to covered Part D drugs: The six "Protected classes" of medications (i.e. antidepressants, antipsychotic, anticonvulsants, anticancer, immunosuppressant, and HIV/AIDS drug classes) will remain unchanged for 2009. CMS also stated that a Part D sponsor's drug coverage determination process should begin with confirming that the prescription drug product NDC is properly listed (i.e. as FDA approved) with the FDA. Lastly, the CY 2010 Formulary reference File (FRF) is now available on the CMS website.
61	Specialty Tier Threshold: The threshold for determining medications to be included on a specialty tier for CY 2010 will remain at \$600.00 (i.e. Part D drugs with negotiated prices that exceed \$600 per month).
66 - 67	Description of Gap Coverage: Beginning in CY 2010, sponsors will be required to specify their gap coverage for both generic and brand name medications using CMS' defined standardized thresholds. For example, if 75% of generics on the formulary are covered by gap coverage then the description would be 'many generics'.
68 - 73	<p>Medication Therapy Management Program (MTMP) requirements: A 2008 CMS analysis of MTMP data focused on enrollment methods, targeting mechanisms, eligibility criteria, interventions, and outcomes. Based upon results of that review CMS has revised the following MTM program requirements for 2010:</p> <ul style="list-style-type: none"> ▪ Enroll targeted beneficiaries using an 'opt-out' method of enrollment only. Enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. ▪ Target beneficiaries for enrollment at least quarterly during each year. ▪ Sponsors cannot require more than three chronic diseases as the minimum number of multiple chronic diseases and sponsors must target at least four of the

	<p>following seven core diseases: a) hypertension, b) heart failure, c) diabetes, d) dyslipidemia, e) chronic lung disorders, f) bone disease/arthritis, and g) mental health disorders.</p> <ul style="list-style-type: none"> ▪ Sponsors may not require more than eight Part D drugs to define multiple covered drugs. ▪ Annual cost threshold has been lowered to \$3,000 (from \$4,000). ▪ Offer a minimum level of MTM services for both beneficiaries and prescribers, including a comprehensive medical review (CMR), person to person consultation, targeted medication reviews, etc. ▪ Measure and report details on an expanded number of program intervention activities.
74	<p>Reference-based pricing: Due to the complexity of reference based pricing formulas, inability to accurately calculate out of pocket expenses, and to promote greater program transparency, reference-based pricing will no longer be allowed in Part D individual and employer offerings. Only about 10% of PDP continued to utilize reference based pricing in 2009.</p>
78 - 79	<p>Coordination of benefits (COB) notification: Part D sponsors will be required to notify each beneficiary of his/her documented other payer information. Each beneficiary will be requested to review the information and report back only when the information presented is inaccurate or incomplete.</p>
80 - 81	<p>Quality and Performance Measures:</p> <ul style="list-style-type: none"> ▪ New Part D reporting requirements (e.g. network support of e-prescribing, etc.) as well as revisions to current reporting (e.g. MTMP reporting on enrollment, etc.) will be implemented for CY 2010. ▪ Part D sponsors must establish quality assurance measures and systems to reduce medication errors, adverse drug interactions, and improve medication use. For CY 2010 CMS will be adding new expectations from the following programs: a) Concurrent DUR, b) Retrospective DUR, and c) Medication Error Identification and Reduction (MEIR).
82	<p>Prompt Payment of Retail/LTC Pharmacy Claims: New prompt pay rules (MIPPA) go into effect for clean pharmacy claims.</p>
83 - 84	<p>Processing Out of Network reimbursement requests: CMS will allow out-of-network reimbursement requests to be processed within 14 days as opposed to the original 72 hour deadline.</p>
86	<p>E-Prescribing: CMS <i>requests</i> that information related to pharmacies or medical providers who support e-prescribing be listed in plan sponsor directories. CMS also provided clarification regarding requirements of the new Prescription Origin Code. The Prescription Origin Code will be required on Prescription Drug Events (PDEs) for new prescriptions submitted in standard NCPDP 5.1 format but remain optional for refills.</p>
88 - 94	<p>Marketing/Beneficiary communications:</p> <ul style="list-style-type: none"> ▪ Broker and agent referral fees may not exceed limits set forth in agent compensation regulations and the amount paid to an agent that enrolls a beneficiary may not, when combined with a referral fee exceed those limits. A referral fee may be paid only when the referral leads to actual enrollment. ▪ CMS requires both MAOs and PDPs to include the plan type (e.g. HMO, PPO, etc.) in their communications/literature using standard terminology as developed

	<p>by CMS.</p> <ul style="list-style-type: none">▪ Part D sponsors will be required to indicate in their EOC and SB which of their formulary cost sharing tiers are designated as their 'exception tier'.▪ CMS' enhanced monitoring of many marketing and sales practices (e.g. secret shoppers, outbound calling, online readiness assessment, etc.) started in 2008 and will continue into the future, especially during annual/open enrollment periods (i.e. 11/15 – 12/31, 1/1. – 3/31).
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