

Summary of the 2011 Centers for Medicare & Medicaid Services (CMS) Call Letter

On April 5, 2010, the Centers for Medicare & Medicaid Services (CMS) issued the final calendar year (CY) 2011 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 CY 2011. All Part D plans are required to submit CY 2011 drug formularies by April 19, 2010, and bids no later than June 7, 2010. The 2011 Call Letter is available at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/>.

Page(s)	Description of significant program changes
53	<p>How to use this Call Letter: Over the past year CMS worked on a number of issues intended to improve the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage and prescription drug plans (PDPs). As part of that effort, CMS:</p> <ol style="list-style-type: none"> published a proposed regulation on October 22, 2009 that made revisions to the Part C and D regulations to ensure meaningful differences among plan offerings, strengthened beneficiary protections, and improved data for CMS oversight and quality assessment released new or revised Medicare Part D manual chapters did not renew a number of plans for CY 2010 due to little or no enrollment conducted listening sessions for industry and advocacy groups to give them an opportunity to communicate their concerns about procedural or operational issues they would like CMS to address in the CY 2011 Call Letter.
57–58	<p>Potential new B versus D coverage determination for beneficiaries with end stage renal disease (ESRD): CMS published a notice on September 29, 2009 that implemented a case mix bundled prospective payment system (PPS) for Medicare outpatient ESRD dialysis facilities beginning January 1, 2011. In accordance with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the new rule proposes to include erythropoiesis-stimulating agents, other drugs and biologicals, and their oral equivalents, furnished to individuals for the treatment of ESRD in the new bundled payment as “renal dialysis services.” Any such drugs or biologicals would no longer be eligible for coverage under an individual’s Part D drug plan but would instead be covered under his or her Medicare Part B benefit.</p>
58–60	<p>Encouragement of sponsor practices to curb waste of unused drugs dispensed in a retail setting: In the draft CY 2011 Call Letter, CMS encouraged Part D sponsors to consider allowing beneficiaries in the community setting the option of requesting a trial supply (e.g., no more than a seven-to-14 day supply) of a chronic Part D medication when first prescribed. As part of the proposal, Part D plans would be expected to prorate cost-share amounts associated with that prescription. As might be expected, CMS received numerous comments on this proposed regulation change asserting that a number of issues (e.g., multiple dispensing fees, increased administrative costs, decreased utilization of manufacturer samples, etc.) would possibly offset the proposed savings of such a program. In the end CMS decided further discussions were needed before implementing such a program and opted instead to make this a voluntary program for 2011.</p>

60–61	<p>Reassignment: In the draft Call Letter, CMS requested comments on policy issues related to the annual reassignment of certain low-income subsidy (LIS) beneficiaries in standalone PDPs. All reassignments are done on a random basis to PDPs in a region with premiums below the LIS benchmark. The issue was whether these “choosers” should be allowed to remain in Part D plans if their premium liability (i.e., the difference between their LIS subsidies and actual plan premiums) was \$10 or less. Opposing views included concerns about disruption of drug regimens, loss of beneficiary choice, and CMS’s inability to discern if beneficiaries wanted to stay in their plan. Due to these and other concerns as well as lack of evidence that this population was failing to pay its premiums, CMS decided not to expand the reassignment process to this population in 2011.</p>
72	<p>Specialty tier threshold: For CY 2011, CMS will maintain the threshold for determining medications to be included on a specialty tier at \$600 (i.e., Part D drugs with negotiated prices that exceed \$600 per month). This means the specialty tier threshold would be unchanged from CY 2009.</p>
72–73	<p>Medicare Enrollment Assistance Demonstration Project: In late 2009, CMS announced it was considering the implementation of an Enrollment Assistance Demonstration Project. However, due to a lack of strong stakeholder support of the demonstration project, CMS has decided to re-evaluate its intended approach to the project and does not anticipate implementation for plan year 2011.</p>
73	<p>Release of Part C and Part D payment data: In the draft Call Letter, CMS announced it was considering the public release of Part C and Part D payment data after risk adjustment and Part D payment reconciliation has been completed. As might be expected, numerous plans objected to the proposed release of payment data on the grounds that the data was confidential and commercially sensitive, and therefore protected from public disclosure under FOIA. Plans also asserted that release of the information may violate the Uniform Trade Secrets Act in the absence of specific regulatory authority authorizing its release. CMS intends to publish a proposed regulation that authorizes the release of Part C and D data in the near future.</p>