



CENTER FOR MEDICARE

DATE: December 19, 2012

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director
Medicare Drug Benefit and C&D Data Group

SUBJECT: CY 2014 Formulary Submission Deadline

On September 18, 2012 the Centers for Medicare & Medicaid Services (CMS) sought feedback from Part D sponsors regarding a possible change in the formulary submission deadline for Contract Year (CY) 2014. We received comments from approximately 40 organizations and very much appreciate their efforts. The comments provided valuable insight into how the proposed changes would affect Part D sponsors. The majority of organizations that submitted comments were supportive of a change in the formulary submission deadline for CY2014. These organizations noted that the later date would provide additional time to analyze their current formulary designs and to better develop their formulary strategies for CY 2014. Others noted that coordinating the formulary submission with the bid submission would enable sponsors to better align the formulary with the Part D benefits. Several organizations added that the proposed change would allow for more time to negotiate rebates with manufacturers. After consideration of all submitted comments, CMS is announcing that the CY 2014 Health Plan Management System (HPMS) formulary submission window will be open from 12:00 AM PDT on May 13, 2013 to 11:59 PM PDT on May 31, 2013. However, as discussed below, we will not be moving forward with all proposals outlined in the September 18, 2012 memo.

We initially proposed that the limited summer formulary update window would be eliminated with a submission deadline change. However, we received many comments that did not support such a change. We understand from these comments that this update window is important for plan sponsors with respect to cost-effective formulary design, as it enables them to make important formulary changes such as generic substitutions. Other organizations stated that the summer update window enables them to market the most up-to-date formulary information to prospective members. Finally, others noted that the elimination of the summer window would likely result in an increase in the number of midyear negative formulary changes. CMS must weigh the benefits of a summer update window versus the need to meet formulary review and approval timelines, as well as the timelines that Part D sponsors must adhere to in order to meet marketing deadlines. In doing so, we believe that we can continue to offer the summer formulary update window but with some additional limitations as compared to previous contract years. Part D sponsors should not need to make significant changes to their formularies after the bids are submitted. Therefore, only drugs that are new to the summer release of the formulary

reference file (FRF) will be permitted to be added to conditionally approved formularies. In addition, negative changes will only be permitted to brand drugs if the equivalent generic is added to the summer FRF and corresponding formulary file. In order to streamline the submission and review of formulary changes for the summer update, we will be releasing an abbreviated formulary negative change request (NCR) module within HPMS in advance of the window. We believe that this solution will strike a balance between enabling sponsors to provide for a more current and cost-effective formulary while also ensuring that CMS will be able to complete its review of formularies in time for sponsors to prepare for marketing activities. Please note that CMS will continue to strictly enforce the summer update window with respect to the allowable formulary changes and will provide additional detailed guidance on this revised process prior to the summer update.

Some organizations submitted comments that were not supportive of the proposed change in submission timelines. These comments generally related to how the later deadline would affect Part D out-of-pocket cost (OOPC) modeling and calculations. CMS agrees that additional consideration is necessary in order to determine how best to coordinate FRF release dates, formulary submission windows, and OOPC analyses. As a result, we will outline an approach in the draft CY 2014 Call Letter so that Part D sponsors and other stakeholders will have an opportunity to comment.

We again thank those organizations who provided comments regarding the formulary date change. We look forward to working with Part D sponsors in the implementation of these new processes.