DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: September 18, 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

Through this memorandum, the Centers for Medicare & Medicaid Services (CMS) is seeking feedback from Part D sponsors regarding a possible change in the formulary submission deadline for Contract Year (CY) 2014. Please utilize the following link to submit any comments or concerns regarding the formulary submission deadline change: http://comments.cms.fu.com/Formulary2013_DateChange/Formulary_datechange_start.asp. The comment period will run from September 19, 2012 through September 28, 2012.

Since the start of the Part D program, the initial formulary submission deadline has been in April, which has provided us with ample time to review and approve formularies prior to the execution of Part D contracts for the following contract year. Since formularies have been due nearly nine months prior to the start of the plan year, CMS has provided an update window, typically during July or August of each year, during which sponsors could modify their submissions to reflect final formulary drug updates. While we have followed this general submission calendar for the CY 2006 – 2013 review seasons, we feel that these timeframes create several challenges as outlined below. In addition, because of accumulated staff expertise and process improvements that CMS implemented as the Part D program matured, we are now able to review formularies in a much more expeditious manner. Because of this, we are considering moving the formulary submission deadline to one week prior to the statutory bid submission deadline of the first Monday in June of each year and are seeking input from sponsors regarding this change. Generally, each year, this deadline has been the third Monday in April.

The reason for the change in deadline includes a number of issues. First, CMS reviewed almost 400 proposed formularies for 2013 which were ultimately deleted. Thus, we devoted a large number of resources to reviewing formularies that were eventually withdrawn from our system. While CMS deletes a few formularies annually in response to organizations' withdrawals of applications or contracts, most deletions each year occur shortly after the annual bid submission deadline when we identify formularies that sponsors have not associated with one of their proposed Part D Plan Benefit Packages (PBP). The submission and review of these formularies creates unnecessary work for both CMS and Part D sponsors. To address this issue, CMS believes that formularies must be better

integrated into the annual bid submission and review process, an objective supported by the Part D authorizing statute at section 1860D-11(e)(2)(D) of the Social Security Act which requires that CMS evaluate formulary designs as part of our drug plan approvals. Second, moving the submission deadline to the week prior to the bid submission deadline would afford plan sponsors time to negotiate contracts with pharmaceutical manufacturers and develop formularies that better match their final proposed plan benefit packages, eliminating sponsors' need to submit placeholder formularies prior to the Part D bid submission deadline and reducing the need for subsequent formulary modifications. Finally, we also believe that a later submission window would better align the Medicare formulary submission and review schedule with those of the non-Medicare lines of business that many sponsors also offer, reducing the annual formulary development burden on their pharmacy and therapeutics (P&T) committees.

In order to operationalize this change, we would also modify our review processes. For example, CMS would incorporate additional flexibilities in the formulary reference file (FRF) releases. We would publish a draft FRF in early April, well in advance of the new formulary submission deadline. In addition, we would also incorporate the most up-to-date FRF information much closer to the submission deadline (for example, five days prior). This would give sponsors the best opportunity to include newly approved drugs on their initial formulary submissions. We would also provide Part D sponsors, as part of our annual formulary training, a more detailed staged review calendar, which would include the weeks that the staged reviews would be released.

The later formulary submission date would mean that CMS would not make the summer update window available to sponsors to modify their proposed formularies. However, we believe that a more dynamic FRF, coupled with the additional time allotted for sponsors to better establish contracts with pharmaceutical manufacturers, would substantially reduce any benefits to offering this submission window. As part of the modified formulary review process, we could also provide sponsors with an enhancement-only submission window in the fall to align the Health Plan Management System (HPMS) formulary files with any formulary enhancements that sponsors made subsequent to the July formulary approvals. However, under this scenario, no negative formulary changes could be made once the initial file was submitted for review.

We would appreciate the submission of comments from Part D sponsors via http://comments.cms.fu.com/Formulary2013_DateChange/Formulary_datechange_start.asp.

Thank you.