

To: Bonnie Harkless, OSORA
From: Lori Robinson, Director, CPC/MDBG/DPD
Date: January 7, 2010
Re: Response to TERMS OF CLEARANCE

TERMS OF CLEARANCE: As this ICR is associated with the 45 day advance notice and call letter, which are both issued annually, this ICR is approved for 18 months. This ICR is approved on the understanding that, going forward, this ICR is related to the 45 day advance notice and call letter and that, as such, CMS agrees to sync up the public comment period for this ICR with the public comment period for the 45 day advance notice and the call letter. Even if CMS believes that the policies contained in the 45 day advance notice and call letter do not impact burden, the public shall be provided an opportunity to comment on CMS's burden assessment. To facilitate meaningful public comment, CMS agrees to reference this ICR by OMB control number in the 45 day advance notice and call letter, as appropriate. To the extent that changes in the 45 day advance notice and the call letter impact burden, the burden estimates in this ICR should be revised accordingly. Previous terms of clearance remain in effect.

Response

In response to the "terms of clearance," CMS has thoroughly analyzed the contents of the combined Contract Year (CY) 2011 45 day Advance Notice and Call Letter document as it pertains to the CY 2011 Plan Benefit Package (PBP)/formulary PRA package. CMS has determined that the policies outlined in the Advance Notice/Call Letter are not relevant to the data entry/file upload requirements and corresponding burden covered by the PBP/formulary PRA package.

The payment policies and methodologies in the Advance Notice (e.g., normalization factors, frailty adjustments, and ESRD payment) do not inform or impact the PBP or formulary submission software. For CY 2011, the Call Letter is quite minimal in scope. While this section does present limited information on the formulary and Part D benefits, our analysis has determined that the PBP/formulary software is not dependent on the outcomes of these policies. In regard to these issues, the software has been designed to provide CMS with the flexibility to respond to changes in the policies without having to modify the software code or burden to the user.

CMS has determined that the contents of the CY 2011 Advance Notice/Call Letter are largely independent of the CY 2011 PBP/formulary PRA package. Likewise, where there are a few intersection points between the Call Letter and the PBP/formulary, CMS has proactively implemented strategies in the software design to mitigate any risk associated with potential changes to those particular Call Letter policies. In consideration of these factors, CMS has concluded that a simultaneous comment period is not required for CY 2011.

According to our respective timelines, there will be a one-week overlap in the comment periods for the PBP/formulary PRA package and the Advance Notice/Call Letter from February 1, 2010 through February 8, 2010.

Moving forward, CMS will continue to identify and address the potential interrelationships between the PBP/formulary PRA package and the Advance Notice/Call Letter in order to ensure that the public has the necessary information to assess burden related to these activities.
