CMS Response to Public Comments Received for CMS-10302

The Centers for Medicare and Medicaid Services (CMS) received comments from two individual submitters. This is a reconciliation of their comments.

Comment:
One commenter stated that the estimate of 5.7 hours per response significantly undercounts the hours required for compendia publishers to audit, verify and publicly disclose financial conflicts of interest across panels with multiple members. This commenter stated that this process requires 15-25 hours per submission cycle.

Response:
Based on the estimates presented in the supporting statement, the hourly burden of a compendium to meet transparency requirements per response (which refers to the number of requests a compendium receives per year for inclusion of a therapy in their publication) is 26 hours (calculated by the range from 1950 hours per compendium with 75 responses to 2600 hours per compendium with 100 responses described in the supporting statement). As the estimates capture the maximum burden, as described in the supporting statement, the commenter's suggested estimated hours specific to a compendium's transparency regarding the financial conflicts of interest of panel members falls within our burden estimates.

Comment:
The other commenter requested more significant changes to the information collection, reevaluation of the burden estimates and identification of how CMS uses the collected information.

Response:
There have been no statutory or regulatory changes to the publicly transparent processes for evaluating therapies and for identifying potential conflicts of interest which are subject to this PRA package. CMS also has not received information to support or justify changes to the burden estimates originally calculated based on the statutory and regulatory requirements. Therefore, we disagree that the information collection and burden estimates currently require significant changes and reevaluation. Statutory provisions requiring transparent processes for evaluating therapies and identifying conflicts of interest were implemented by amending 42 CFR 414.30 so this PRA package extension cannot change the information collection requirements which are specified in the CFR. Additionally, the collection does not result in data being submitted to CMS. Rather, the collection of information is specific to the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interest that are required of compendia under the statute and regulation. The information collected is used by each compendium to have specific information available to the public for at least five years on the compendium's process for evaluating therapies and process for identifying potential conflicts of interest of individuals who substantively participate in the development or disposition of compendia recommendations. By collecting the information and making it publicly available consistent with provisions in 42 CFR 414.30, compendia meet the statutory and regulatory transparency requirements.