

## **Response to OMB Comments CMS-1810-F Paperwork Collection Burden**

**Issue 1:** Per OMB, CMM needs to provide specifics about the changes discussed within section A15 of the SS. This can be presented as a separate attached or by providing old and new forms with mark-ups. The decrease in burden hours for this request totals over 300,000 burden hours, which is a significant amount.

**Response 1:** In the exception for professional courtesy (§411.357(s)), we eliminated §411.357(s)(5) which had required that the insurer be informed in writing, "If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction." This Phase II provision required that any entity that reduced any coinsurance obligation had to a one-time burden of preparing a model letter and notifying affected insurance companies of this provision. Also, in subsequent years, the entities were required to notify any additional affected insurance companies. (Taken together, these requirements had a total burden of 103,096 hours.) Because the model letter and notification to insurance companies affected in 2004 through September 4, 2007 had occurred already, that burden was not included in the request for approval for Phase III. In addition, because Phase III eliminated the requirement for notification to insurers, we eliminated the associated annual paperwork burden.

After further consideration of our Phase II rule, we determined that, with respect to the exception for personal service arrangements, the burden incurred by the requirement that all separate arrangements incorporate each other by reference or that a master list of all separate arrangements be created and maintained (§411.357(d)), is not subject to the PRA because the information would be kept in the normal course of business (5 CFR 1320.3(b)(2)). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal action, or during the conduct of an administrative action, investigation, or audit, decreasing the number of hours we are requesting. In Phase II, we had estimated that this requirement would create a one-time burden on entities for preparing new personal service arrangements and an annual updating burden of 127,000 hours. Because the one-time burden for of incorporation by reference or a master list had occurred already, that burden was not included in the request for approval for Phase III. (See Response 3, also.)

The reduction in the burden hours noted above with respect to professional courtesy and personal service arrangements amounts to 230,096 hours. We cannot explain our original burden estimate of 422,008, which may have been an error.

**Issue 2:** Per the supporting statement, only vague descriptions are discussed. "In general, the numbers of physicians and hospitals have changed since the last information collection request (in CMS-1810-IFC); therefore, the information collection burden has changed for some sections. (What specifically has changed?)

**Response 2:** Calculations used in the March 2004 Phase II rule were based on then up-to-date data from the 2003 CMS Statistics booklet, which showed 581,108 physicians and 6,018 hospitals. Since that time, the numbers of physicians, hospitals, and other health care entities have changed. For example, the 2007 CMS Statistics booklet shows 660,819 physicians (Table 22) and 6,177 hospitals (Table 15).

However ever, after further consideration of Phase II, we believe that the information requested in Phase III is not subject to the PRA because the information is kept in the normal course of business (5 CFR 1320.3(b)(2)). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal action, or during the conduct of an administrative action, investigation, or audit.

**Issue 3:** For §411.357, the Phase II interim final rule assumed that a master list for §411.357(d) would be created to comply with the requirements. We believe that the master list would now need only updates, so we have reduced the estimated time required for this burden. (What exactly were the updates?)

**Response 3:** As explained above, an entity may choose to incorporate by reference all contracts that an entity has with a physician or a member of the physician's immediate family or create a master list of these contracts. The one-time burden is in creating an incorporation by reference statement in each contract or by creating a master list of contracts. The "updates" refer to adding information to master list to identify -- (a) all new contracts, (b) all revised contracts, and all terminated contracts.

However, as stated above in response to Issue 1, we believe that §411.357(d) is not subject to the PRA because the information is kept in the normal course of business (5 CFR 1320.3(b)(2)) and making the information available to the Secretary should occur rarely and would be exempt from the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal action, or during the conduct of an administrative action, investigation, or audit.