



Via Electronic Submission

December 15, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory Development
Attention: Document Identifier CMS-10417
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**Re: Centers for Medicare and Medicaid Services [Document Identifier CMS-10417]
Emergency Clearance: Public Information Collection Requirements Submitted to the Office of
Management and Budget (OMB) AGENCY: Center for Medicare and Medicaid Services¹**

The American Association for Homecare (AAHomecare) submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS) request for comments on the above referenced collection of information. CMS has asked the Office of Management and Budget (OMB) for emergency clearance under the Paperwork Reduction Act (PRA), reasoning that the information collection is necessary to prevent "public harm."

AAHomecare is the national association representing the interests of durable medical equipment (DME) providers and manufacturers. Our members make quality products that meet all applicable regulatory requirements and function safely and effectively when used properly by patients in their homes. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the emergency clearance request.

According to the Agency's submission, public harm is reasonably likely to result if the normal clearance procedures are followed because the data collection in question is "essential to ensuring that Medicare claims are paid properly." CMS asserts that without emergency clearance, claims will not be reviewed to ensure compliance with §1862(a)(1)(A) of the Social Security Act (SSA), which provides that Medicare may only make payment for services which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. AAHomecare opposes the request for emergency clearance because the Agency has not established a valid reason in support of its request. The Association urges OMB to deny CMS' request for emergency clearance of expanded prepayment review and pilot authority.

¹ 76 Fed Reg. 76737 (December 8, 2011)

I. COMMENTS

AAHomecare strongly supports vigorous program integrity actions to protect Medicare and its beneficiaries. We agree that Medicare must be vigilant to ensure that benefit dollars are not diverted to abusive or fraudulent providers. We agree that the Social Security Act (SSA) requires the Secretary to pay only for covered items and services that are “‘reasonable and necessary’ for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member [.]”² However, Congress also intended that the Secretary comply fully with statutory and regulatory requirements that limit the unfettered use of her authority. These authorities include the PRA, which was designed to protect the public from burdensome paperwork and data collection activities imposed by administrative agencies.

Specifically, the PRA is designed to ensure that agencies scrutinize the paperwork burdens they impose on the public in order to minimize them. These include: the need for the information collection and its usefulness in carrying out the agency’s specific functions; the accuracy of the agency’s estimate of the documentation burden; the quality, utility and clarity of the information to be collected; and recommendations to minimize the information collection burden on the public. Importantly, the PRA and its implementing regulations also seek to promote greater public participation in government by requiring agencies and OMB to publish proposed data collections for a minimum 60-day public comment period. The comment period ensures that an information request is, in fact, clear, necessary, useful and not overly burdensome as required under the law.

A. CMS Has Not Established a Basis for Emergency Clearance

As we noted above, CMS bases its request for emergency clearance on an undefined assertion that “public harm” will result if it is required to follow the notice and comment rules prescribed under the PRA. The Agency does not address the nature of the public harm. CMS requests that OMB approve the data collection on an emergency basis after allowing for a ten-day public comment period.

CMS’ position is disingenuous. First, the Agency already has the authority to prevent improper payments through the use of complex pre-payment medical review. Moreover, that authority exists and can be exercised independently of any data collections that are subject to PRA review. Next, the Agency had OMB approval for these types of data collection requests under OMB control number 0938-0969, which expired 18 months ago in May 2010.³ It simply is not persuasive for CMS to say it faces an emergency today given the 18-month gap in seeking approval for OMB control number 0938-0969 or requesting approval for a new information collection as it is doing now. More importantly, CMS’ request for emergency clearance circumvents public scrutiny of a broad, poorly and vaguely defined data collection that is open to precisely the type of abuse Congress intended to prevent.

Specifically, the data collection would apply to all providers and services, permitting CMS free rein to perform wide scale prepayment complex medical review on claims for any provider, item, or service covered by Medicare. Although CMS does not state this explicitly, a careful reading of its submission to OMB reveals the breathtaking scope of what CMS is requesting. CMS’ submission cites §402 of the SSA,

² §1862, Social Security Act.

³ It is AAHomecare’s understanding that OMB denied CMS request for an extension of OMB control number 0938-0969 and that CMS did not file any new requests up to now.

which authorizes the Secretary to perform demonstrations as the legal basis for this data collection. Assuming without conceding that CMS' reliance on §402 is valid, the Secretary has nonetheless failed to comply with its requirements, which include, among others, consultation with the public and health care sector experts. Clearly, that has not happened here. Importantly, §402 does not exempt the Agency from seeking OMB approval for data collections such as this one.

It is impossible to overstate the impact that prepayment reviews can have on health care providers. They give rise to special hardships by significantly disrupting providers' cash flow. Service-specific wide-scale complex prepayment reviews, moreover, tend to disproportionately affect small providers and providers who furnish only the item(s) or service(s) under review. AAHomecare has many examples of providers who were forced to close or layoff staff because prepayment complex medical reviews cut-off their cash flow. These wide-scale pre-payment reviews, in turn, eventually impede beneficiary access to items and services that are indeed "reasonable and necessary," contrary to Congress' fundamental mandate under the SSA that the Secretary pay these claims.

Further, this emergency clearance request would grant CMS the authority to conduct pilot project requiring prior authorization for Medicare claims without properly vetting this concept through input from the public and other industry stakeholders. Mandatory prior authorization would place a significant burden on DME providers and physicians and significantly restrict beneficiary access to medically necessary items and services.

B. OMB Should Not Allow CMS to Avoid a Genuine Public Comment Period

Given the grim consequences of the proposed data collection and its broad applicability to all Medicare providers, items or services, it would be a public disservice if OMB were to permit only ten days for public comments. This is especially true considering that the Secretary already has authority to prevent improper payments and her dubious assertion of "public harm" following an 18-month gap in submitting the data collection to OMB for approval. Under the circumstances, **every** Medicare stakeholder, including providers and beneficiaries, has the right to demand that CMS explain how it would administer the data collection to minimize any adverse impact on the public.

As an example, CMS recently announced a "demonstration" involving *100 percent* prepayment complex medical review of power mobility device (PMD) claims in seven states beginning on January 1, 2012. CMS made the announcement *via* a press release just six weeks prior to implementation and so far has failed to furnish any guidance to providers or beneficiaries in those states. The PMD "demonstration" highlights the questions CMS is dodging by requesting emergency approval of this data collection. For example:

1. CMS is proposing 100 percent prepayment complex medical review of PMD claims in seven states, but has not provided any assurance to providers or beneficiaries that contractors can timely review and process those claims.
2. CMS has not identified the data to support its action. A recent Office of Inspector General Report found a high payment error rate for Medicare PMD claims, but the report relied on 2007 data that did not reflect recent program changes; the use of current data would likely show a lower payment error rate.

3. CMS has not provided a valid estimate of the paperwork burden associated with the data collection. The PRA submission asserts that the burden estimate would be no more than 30 minutes for providers because the information is already in the provider's files. However, many local and coverage determination policies state that documentation must be available "upon request." Collecting documentation after-the-fact challenges providers' time and resources far beyond the Agency's 30-minute estimate.
4. CMS has failed to explain whether it considered any alternatives to the data collection that would achieve the same goals with fewer burdens.

Although CMS does not say its PRA submission is related to the data collection in the PMD "demonstration," the relationship between the two is obvious. CMS is using this request for emergency clearance in order to bootstrap OMB's approval as way to engage in more demonstrations without the bother of seeking additional OMB approval for those data collections or public scrutiny of its "demonstrations." In other words, by requesting emergency clearance of what is a broad but ill-defined data collection for prepayment reviews today, CMS would be free to engage in any number of such "demonstrations" without undergoing OMB approval or consulting with the public under §402 in the future. In our view, the request for emergency clearance for this data collection is a bold attempt to skirt its obligations under the PRA, which OMB should deny.

C. CMS Has Not Met the Criteria for Emergency Clearance under 5 C.F.R. §1320.13

CMS has also not met the criteria for emergency process enumerated under §1320.13. That provision authorizes an agency head to seek emergency approval for a data collection when the agency provides a written determination that:

(2) The agency cannot reasonably comply with the normal clearance procedures under this Part because:

(i) Public harm is reasonably likely to result if normal clearance procedures are followed;

(ii) An unanticipated event has occurred; or

(iii) The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed.

5 CFR § 1320.13

CMS has not shown that public harm will result if OMB denies its approval, especially because the Agency can conduct complex prepayment medical reviews for individual suppliers or providers under its existing authority, providing adequate protection for program dollars. The Agency has not advanced a single reason for why OMB should allow it to perform wide scale prepayment review across all healthcare sectors and providers without first informing OMB and the public of what it intends do. Consequently, OMB should deny CMS's request.

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II. CONCLUSION

For all of the foregoing reasons, OMB should deny CMS' request.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Walter J. Gorski".

Walter J. Gorski

Vice President of Government Affairs