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December 14, 2011

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

Re: Emergency Clearance: Public Information Collection Requirements Submitted to the
Office of Management and Budget (OMB) [CMS-10417]

The American Medical Association (AMA) is writing to express our strong concern with a so-called "emergency" request that would provide just seven days for public comment on a substantial new regulatory burden that the Centers for Medicare and Medicaid Services (CMS) proposes to impose on physicians and other providers. In our view, the proposal completely eliminates the opportunity for meaningful public input and makes an absolute mockery of President Obama's Executive Orders 13563 and 13579, which call for improved transparency and reduced regulatory burden in government.

The plan in question calls for a 50 percent increase in pre-payment reviews by the growing cadre of contractors that pay and review claims submitted by physicians, hospitals and other providers treating Medicare patients. As required by the Paperwork Reduction Act of 1995, CMS on December 6 requested clearance from the Office of Management and Budget (OMB) to proceed with the plan and sought "an emergency review." Specifically, CMS said, public comment should be required by December 15 and OMB approval by December 19, leaving just seven working days for stakeholder comments and two days for OMB review. As a rationale for this alleged emergency, the agency says only that "public harm is reasonably likely to result" if the normal 60 day comment period is allowed.

We submit that "public harm" is even more "likely to result," if CMS proceeds with its current plan and timeline. Based on announcements the agency and its contractors have made regarding a series of new "demonstrations" and audits that will impose mandatory pre-payment reviews and/or prior authorization for certain types of claims in a dozen states, we surmise that the real reason CMS is pressing for expedited OMB approval lies in its

desire to start these “demonstrations” on January 1. (See <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4176&intNumPerPage=10&checkDate=&checkKey=&srchType>) In fact, the background materials submitted with the emergency request indicate that the original plan was to allow for a 60-day comment period as is generally done and as is strongly encouraged in the Presidential orders.

In its announcement of the new demonstrations, CMS cited a desire to reduce payment error rates. The AMA agrees that this is an important goal but we do not accept that broad brush pre-payment review is the best or only way to achieve that goal. Nor do we believe that a two-month delay in these programs would lead to any program harm since contractors in the interim could still conduct post-payment review and recover any erroneous payments. To the contrary, as we have often pointed out, implementing new program policies without at least six months lead time only creates confusion for physicians and problems for Medicare patients.

In another violation of the Presidential order, CMS and its contractors do not appear to have consulted with those who could be adversely affected in the design of these demonstrations. There is no mention of such consultations in the background document submitted to OMB, and the lack of adequate input from physicians, hospitals and beneficiaries is evident in some of the projects about to come on-line.

Of direct interest to OMB, the paperwork burden that CMS envisions is substantial. Even by the agency’s conservative estimate, physicians, hospitals and other providers will spend 1.35 million hours and \$90.1 million a year chasing down, copying and submitting requested medical records associated with pre-payment reviews. For physicians, this will come on top of a confusing and time-consuming array of other paperwork requirements that require their certification of the need for everything from diapers and colostomy bags to hospice care. Associated administrative costs to physician practices have soared but thanks to the discredited Sustainable Growth Rate (SGR), Medicare has not recognized these increases and threatens instead to reduce payments for physician services by 27.4 percent next year.

While the OMB review is centered on the paperwork, however, the CMS policies will also have substantial consequences for patients that should not be ignored. Post-payment reviews associated with short hospital stays already have driven hospitals to bill some stays that for all intents and purposes are inpatient admissions as observation care. There are well-documented accounts of the serious problems this has presented for patients who need follow-up care in a skilled nursing facility. In fact, CMS is now about to launch another demo intended to reduce the financial incentive for hospitals to shift patients into observation care. At the same time, however, the agency is proposing pre-payment audits of short hospital stays in four states, potentially increasing the number of patients who are shifted into observation care and are therefore ineligible for Medicare SNF coverage.

A point that is also not addressed in the CMS clearance request, is pre-payment review’s potential to delay or reduce access to care. In a demo involving power mobility devices, the agency heard on a stakeholders call that there is a significant risk that beneficiaries will be

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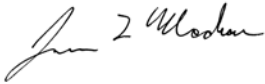
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hit, after the fact, with large bills for equipment they expected Medicare to cover. A contractor's proposal to require 100 percent pre-payment review for 15 cardiology and orthopedic procedures performed on Medicare inpatients in Florida raises similar concerns, especially since, unlike the mobility device demo, it does not appear to have an exception for emergencies. Providers might be able to avoid non-payment by using an advance beneficiary notice and billing patients when the contractor rejects the claim. Ironically, however, this presents additional paperwork burdens that are not even mentioned in CMS's submission to OMB.

To be clear, the AMA understands the pressure that CMS is under to contain Medicare costs and we are in complete agreement with the goal of ensuring that care provided to Medicare patients is reasonable and necessary. In his Executive Orders 13563 and 13579, President Obama also ordered all federal agencies to consider regulatory alternatives that reduce regulatory burdens and maintain flexibility. With that in mind, OMB should reject CMS's request for emergency clearance for expanded pre-payment reviews and direct the agency to work with patients, physicians and other stakeholders on less burdensome options to deter inappropriate care and reduce Medicare error rates.

Should you have any questions regarding our comments, please contact Margaret Garikes, Director, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim L. Madara".

James L. Madara, MD

cc: OMB, Office of Information and Regulatory Affairs