



**James L. Madara, MD**  
Executive Vice President, CEO

**American Medical Association**  
515 N. State Street  
Chicago, Illinois 60654  
  
ama-assn.org  
  
(p) 312.464.5000  
(f) 312.464.4184

September 23, 2011

Donald Berwick, MD  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Off-cycle Revalidation of Physicians

Dear Administrator Berwick:

On behalf of the physician and medical student members of the American Medical Association (AMA), I write regarding the Centers for Medicare and Medicaid Services (CMS) initiative to require an off-cycle revalidation of nearly all Medicare providers and suppliers between now and March 23, 2013.

We appreciate CMS' efforts to lessen the impact of the off-cycle revalidation on physicians, including CMS' plan to streamline the internet-based Medical Provider Enrollment, Chain, and Ownership System (PECOS) in January 2012. However, in light of the problems physicians have had with enrollment and revalidation efforts in the past, we do have serious concerns about the feasibility of this off-cycle revalidation effort and the additional burden that it will create for physicians.

We thank you for taking the time to review our comments on the legal basis for the revalidation effort and our specific recommendations on how CMS might reduce the burden of the revalidation effort on physicians.

#### Legal Background

As a preliminary matter, we ask that CMS reexamine its belief that it is statutorily required to apply the new screening procedures to all physicians by March 23, 2013, and, therefore, must revalidate all physicians by that date.<sup>1</sup> By our reading of Section 6401(a) of the Affordable Care Act (ACA), CMS is not required to revalidate and screen all physicians under the new screening procedures by March 23, 2013. Further, we believe that the ACA excludes physicians enrolled at the time of enactment from the new screening procedures until March 23, 2012, unless the physician is due for a regularly-scheduled revalidation. We think that this reading of the statute may afford CMS some leeway in its implementation of Section 6401(a), and request that CMS explore how this flexibility may be utilized to decrease the burden on physicians and CMS.

---

<sup>1</sup> CMS. *Further Details on the Revalidation of Provider Enrollment Information*, MLN Matters® Number: SE1126 Revised. Available at <https://www.cms.gov/MLN MattersArticles/downloads/SE1126.pdf>

*No statutory requirement that all physicians be screened by March 23, 2013.*

We urge CMS to consider that, by our reading of the ACA, all enrolled physicians are not required to be screened pursuant to the new screening procedures by March 23, 2013. Rather, we read the ACA to require that, from March 23, 2013 onward, no physician may be initially enrolled or revalidated without going through the new screening procedures. Section 1866(j) of the Social Security Act, as amended by the Section 6401(a), provides:

(iv) LIMITATION ON ENROLLMENT AND REVALIDATION OF ENROLLMENT.—In no case may a provider of medical or other items or services or supplier who has not been screened under this paragraph be initially enrolled or reenrolled in the program under this title, title XIX, or title XXI on or after the date that is 3 years after such date of enactment.<sup>2</sup>

We read the language above to mean that, going forward, no physician may initially enroll or revalidate without undergoing the new screening procedures. We do not read this section as requiring CMS to undergo the enormous effort of revalidating and screening every physician by March 23, 2013. We think the statute affords CMS the flexibility to implement the new screening procedures, from March 23, 2013 onward, during the normal course of enrollment and revalidation.

*Physicians enrolled at time of enactment generally immune under statute until March 23, 2012.*

We urge CMS to consider that, by our reading of the ACA, physicians that were enrolled at the time the enactment of the ACA are generally not subject to the screening until March 23, 2012. Section 6401(a) provides:

(ii) CURRENT PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is enrolled in the program under this title, title XIX, or title XXI as of such date of enactment, on or after the date that is 2 years after such date of enactment.<sup>3</sup> (emphasis added)

In our view, the section above plainly excludes physicians who were enrolled at the time of the enactment of the ACA from the new screening procedures until March 23, 2012. This reading is consistent with CMS' discussion in the final rule, where CMS stated: "these new procedures will be applicable to currently enrolled Medicare, Medicaid, and CHIP providers and suppliers beginning on March 23, 2012, in accordance with section 1866(j)(2)(ii) of the Act."<sup>4</sup>

*Statutory authority to screen revalidating physicians limited to regularly-scheduled revalidations.*

We are cognizant that the ACA does allow CMS to screen revalidating physicians beginning 180 days after enactment. However, we read the statute as providing that until March 23, 2012, CMS may only screen physicians revalidating pursuant their regular revalidation schedule. This view is harmonious with CMS' own interpretation in the final screening regulation, where CMS stated the following:

---

<sup>2</sup> Social Security Act Sect. 1866(j)(2)(iv)

<sup>3</sup> Social Security Act Sect. 1866(j)(2)(ii)

<sup>4</sup> 76 FR 5872

These new screening procedures will [also] be applicable beginning on March 25, 2011 for those providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information. For Medicare, this will impact those providers and suppliers whose revalidation cycle results in revalidation occurring between March 25, 2011 and March 23, 2012.<sup>5</sup> (emphasis added)

CMS' discussion in the final screening regulation clearly recognizes that already-enrolled physicians are not subject to the new screening procedures until March 23, 2012, unless they undergo an already-scheduled revalidation:

The ACA specifies the effective dates for the new screening provisions. For newly enrolling providers and suppliers, and for those currently enrolled whose revalidation is scheduled between March 25, 2011 and March 23, 2012, the effective date is March 23, 2011 or the date scheduled for the revalidation...For all other currently enrolled providers and suppliers, the statute established an effective date of March 23, 2012.<sup>6</sup> (emphasis added)

We think the final screening rule set clear guidelines, based on the statute, regarding when already-enrolled physicians would be subject to the new screening procedures. We think that CMS' discussion of the statutory timeline in the final screening rule led many physicians to believe that they would not be subject to the new screening procedures until March 23, 2012, or until their regularly-scheduled revalidation. We ask that CMS review the statutory language to confirm whether CMS has flexibility in implementing Section 6401(a).

*Regulatory authority to require off-cycle revalidations does not apply until March 23, 2012.*

Further, we urge CMS to consider that it may not have the regulatory authority to require the proposed off-cycle revalidations until March 23, 2012. CMS expressly promulgated new regulatory authority to conduct off-cycle revalidations in its final screening rule, codified at CFR 424.515(e), but that authority does not apply until March 23, 2012. That new authority provides:

(e) Additional off-cycle revalidation. On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).<sup>7</sup> (emphasis added)

CMS' communications on the off-cycle revalidation now cite CMS' pre-existing authority to conduct off-cycle revalidations, codified at CFR 424.515(d).<sup>8</sup> But, by our reading, that part of the Code only allows CMS to conduct off-cycle revalidations for particular providers and suppliers based on particular circumstances.<sup>9</sup> CMS' assessment of the bounds of its pre-existing authority to conduct off-cycle revalidations was included in the final screening rule preamble:

We have existing authority at § 424.515(d) to require off-cycle validations in addition to the regular 5 year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment

---

<sup>5</sup> 76 FR 5872

<sup>6</sup> 76 FR 5891

<sup>7</sup> 42 C.F.R. § 424.515(e)

<sup>8</sup> CMS. *Further Details on the Revalidation of Provider Enrollment Information*, MLN Matters® Number: SE1126 Revised. Available at <https://www.cms.gov/MLN/MattersArticles/downloads/SE1126.pdf>

<sup>9</sup> 42 C.F.R. § 424.515(d)

information when warranted to assess and confirm the validity of the enrollment information maintained by us. Such off-cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause us to question the compliance of the provider or supplier with Medicare enrollment requirements...The new authority to conduct off-cycle validations of providers and suppliers will enable us to apply the new screening requirements to all currently enrolled providers and suppliers by the statutory effective date.<sup>10</sup> (emphasis added)

We think that CMS' initial analysis concluding that the pre-existing authority to conduct off-cycle revalidations was insufficient to revalidate all providers and suppliers, prompting the inclusion of the new authority in the final rule. However, that authority does not attach until March 23, 2012. We urge CMS to review the regulatory language and explore whether CMS may have reason to delay the off-cycle revalidation effort.

### Recommendations to Reduce the Burden on Physicians

We are pleased that CMS has scheduled the launch of improvements to internet-based PECOS in January 2012. We understand that these improvements will include batch uploading of information, a "summary screen," a one-click revalidation button, and other streamlining measures. We also understand that CMS has directed the Medicare Administrative Contractors (MACs) to implement new follow-up procedures in relation to the revalidation effort, including phone calls and alternate address mailings, to facilitate provider and supplier compliance.

We look forward to the launch of these new improvements to PECOS, and strongly support CMS' decision not to require an off-cycle revalidation of physicians until these new improvements are in place and working properly. We also urge CMS to consider adopting the following recommendations to further minimize the burden of the revalidation effort on physicians:

#### **1. CMS should exempt physicians from the revalidation effort because they are of limited risk.**

According to CMS' discussion in the final screening rule, CMS chose to place physicians in the limited risk screening category because CMS concluded, based on its own analysis of historical trends and experience, that physicians pose a limited risk to the Medicare program.<sup>11</sup> To now require all physicians to revalidate is a sweeping measure that will burden all physicians, regardless of risk level assignment. This approach is inconsistent with CMS' initiative to move from a "one size fits all" approach to program integrity to a risk-based approach.<sup>12</sup>

We also urge CMS to consider that the revalidation effort is contrary to the goals of the Obama Administration's Campaign to Cut Waste.<sup>13</sup> CMS has already expended resources and time to delineate which providers and suppliers are more risk prone, and which are not. We suggest that, to avoid an unnecessary and duplicative use of CMS' resources, the more prudent course would be for CMS to exclude limited risk providers, including physicians, from the revalidation effort.

---

<sup>10</sup> 76 FR 5891, 5892

<sup>11</sup> 76 FR 5868

<sup>12</sup> *Public and Private Sector Efforts to Detect Fraud in the Health Care System*. Hearing before the U.S. House Committee on Ways and Means, Subcommittee on Oversight. (March 2, 2011). Statement of Peter Budetti, MD, JD, Director, Center for Program Integrity, pg. 18. Available at <http://waysandmeans.house.gov/UploadedFiles/Budetti.pdf>

<sup>13</sup> See <http://www.whitehouse.gov/photos-and-video/video/2011/06/13/campaign-cut-waste>

**2. CMS should screen physicians pursuant to their regular revalidation schedule.**

As discussed previously, in our view, there is no statutory deadline by which CMS must screen all already-enrolled physicians under the new screening procedures. The revalidation effort will therefore impose an unnecessary burden on physicians, CMS, and CMS contractors. Complying with the revalidation effort will also further compound the regulatory requirements for physicians, who are currently facing a multitude of new challenges as a result of health system reform, in addition to the implementation of health information technology and the transition to ICD-10-CM and ICD-10-PCS codes.

Physicians are already on a schedule for revalidation. To avoid undue confusion, we think that risk-based screening would most appropriately and seamlessly take place at the time of a physician's initial enrollment or regularly-scheduled revalidation. We strongly urge CMS to employ the flexibility afforded by the ACA and screen physicians at the time of initial enrollment or regularly-scheduled revalidation.

**3. CMS should delay the revalidation effort until March 23, 2012.**

By our reading, CMS is statutorily authorized to screen already-enrolled providers and suppliers on March 23, 2012. Correspondingly, CMS is authorized under the Code of Federal Regulations to commit off-cycle revalidations for screening purposes on March 23, 2012. Therefore, if CMS intends to go forward with the revalidation effort, we think that an implementation date of March 23, 2012 would be most appropriate.

We believe that a delay of the revalidation effort until March 23, 2012 would allow physicians more time to be educated about the revalidation effort, and would dovetail with CMS' plan to streamline internet-based PECOS functionality beginning in January 2012. We also think that a delay would allow CMS more time to fine-tune the new screening procedures, award the new screening contract,<sup>14</sup> and prepare the MACs for additional enrollment volume.

**4. CMS should allow physicians to revalidate at any time before March 23, 2013.**

CMS' communications state that between now and March 23, 2013, MACs will intermittently send out revalidation notices to providers and suppliers requiring that they revalidate within 60 days. CMS has said that providers and suppliers may only submit the revalidation after being asked by their MAC to do so.

We strongly urge CMS to consider the confusion that this process will cause. Because CMS is allowing a lengthy eighteen month period for MACs to transmit these requests, physicians have no certainty regarding when they might receive their request. We are concerned that the requests may be easily lost in the shuffle of MAC communications to physician offices. We are also concerned that if a physician revalidates before they receive the MAC request, that they may have to revalidate again once they receive the MAC request, and request clarification from CMS on that issue.

---

<sup>14</sup> HHS. Solicitation Number: RFP-CMS-2011-8A-0029, Provider Screening. Available at <https://www.fbo.gov/index?s=opportunity&mode=form&id=f46fa91439df184bcda78d057560e888&tab=core&cvview=1>

CMS has expressed that the lengthy window of time in which a physician may receive a revalidation request is necessary to allow the MACs flexibility in managing their workload. While we are generally supportive of CMS' efforts to monitor the workload of the MACs, as over-burdened MACs often result in hassles for physicians, we suggest that CMS equitably consider the increased physician workload that the revalidation effort will cause. Some physician practices may have to bring on temporary staff or increase current staff hours to accommodate the additional administrative burden of complying with the revalidation effort. We think CMS should afford physicians the discretion to manage the burden of the revalidation effort by allowing physicians to revalidate at a time of their choosing before March 23, 2013.

#### **5. CMS should publish a prospective revalidation schedule.**

Physicians who would like to plan in advance to have the additional resources in place to comply with the revalidation effort cannot do so because there is no way for a physician to anticipate when their MAC will require them to revalidate. This lack of advance notice will prove particularly problematic for large physician practices, who may be tasked with revalidating numerous physicians within a short period of time.

While we understand that CMS means to publish the names of providers and suppliers who have been sent a revalidation request from their MAC, we submit that this list is unlikely to be referenced by most physicians. Furthermore, listing the physicians who have been contacted by their MACs after the fact will do little to minimize the uptick in unanticipated physician workload.

This problem seems preventable considering that CMS and the MACs have, we believe, already decided on a "phased-in" approach for the revalidation effort, and an attendant schedule. Therefore, we request that CMS publish a prospective schedule, either by particular provider and supplier or by sub-group, so that physicians may know in advance when they will be required to revalidate.

#### **6. CMS should extend the revalidation period from 60 days to 90 days.**

Because the revalidation effort will be off-cycle and may catch many physicians by surprise, and because even those physicians who are aware of the revalidation effort have no means by which they may anticipate at what time they may be asked to revalidate by their MAC, we suggest that CMS extend the amount of time a physician has to revalidate from 60 days to 90 days.

We anticipate that many MAC revalidation requests may "fly under the radar" of physicians as they arrive amongst other communications from the MACs. Further, we think it is likely that when a physician does receive and become aware of the requirement to revalidate, that the physician may be stymied by ongoing problems with the enrollment system. CMS should consider their experience with problems regarding provider enrollment in PECOS in the past,<sup>15</sup> and how those issues may further complicate provider adherence to the 60 day timeframe.

We understand that CMS intends to deactivate physicians who do not revalidate within the 60 day window, rather than revoking their enrollment. We appreciate CMS' effort to anticipate problems that physicians may have with the revalidation effort, and to try to prospectively alleviate the

---

<sup>15</sup> The AMA has commented extensively on issues regarding CMS' enrollment process. While some of these issues have been addressed, many troubling issues still persist. See <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/medicare-enrollment-process.page>.

potential harm of non-compliance. CMS has communicated that deactivated physicians would still be able to file claims for services performed during the period of deactivation. We request that CMS provide further information on the deactivation period pursuant to the revalidation effort. Specifically, we ask that CMS provide clarity regarding whether the one year claims submission period will be stayed for the deactivation period.

We also understand that CMS has instructed the MACs to conduct outreach when a physician fails to revalidate within the 60 day period, including phone calls and correspondence by mail to an alternate address. We support CMS' effort to increase outreach to physicians regarding the revalidation effort, and appreciate CMS' willingness to take extra steps to aid physician compliance. We request more information on these new processes, and suggest that a longer time period for response, of at least 90 days, would aid MACs in their follow-up with physicians.

In spite of CMS' improvements, we think that a longer compliance time period is appropriate. Because this is an irregular and off-cycle revalidation, CMS must ensure that physicians are given ample opportunity to comply. We strongly suggest that CMS revise the off-cycle revalidation period from 60 days to 90 days.

**7. CMS should not require physicians to print, sign, date, and mail a certification statement.**

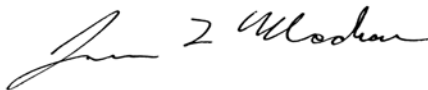
CMS' directives concerning the revalidation effort currently require a physician to print, sign, date, and mail a certification statement and any required supporting documentation to their MAC, even though they are to submit their enrollment information via internet-based PECOS.<sup>16</sup> CMS has said that once the new internet-based PECOS system edits are operational, physicians will no longer be required to print out, sign, date, and mail a paper copy of the enrollment form to their MAC. We support CMS' plan to make this change, and we request that this change become effective now. Physicians should not have to mail paper copies of information submitted to CMS through internet-based PECOS, especially in this case, where the revalidation effort is off-cycle.

Conclusion

We request that CMS consider each of our recommendations, as we believe that their adoption could make the revalidation effort less arduous for physicians. While we commend CMS for its efforts to improve the enrollment process, we request that CMS consider that the revalidation effort is an additional burden on physicians who are already struggling to meet regulatory demands.

We hope that our comments are helpful and look forward to working with you further on this issue. Should you have any questions about this letter, please contact Margaret Garikes, Director, Division of Federal Affairs, at [margaret.garikes@ama-assn.org](mailto:margaret.garikes@ama-assn.org) or 202-789-7409.

Sincerely,



James L. Madara, MD

---

<sup>16</sup> CMS. *Further Details on the Revalidation of Provider Enrollment Information*, MLN Matters® Number: SE1126 Revised. Available at <https://www.cms.gov/MLN MattersArticles/downloads/SE1126.pdf>