



**American Hospital
Association**

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Submitted Electronically

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

**RE: CMS-6028-P Medicare, Medicaid, and Children's Health Insurance Programs:
Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria,
Payment Suspensions and Compliance Plans for Providers and Suppliers**

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) implementation of several of the program integrity provisions in the *Patient Protection and Affordable Care Act* (ACA).

In the ACA, Congress enacted a combination of new provisions and refinements to existing provisions, intended to enhance the ability of CMS to reduce fraud, waste and abuse in Medicare, Medicaid and Children's Health Insurance Program (CHIP). In this rulemaking, CMS is proposing rules to implement some of those provisions. The AHA's comments focus on the following key items:

- Provider Screening
- Application Fee
- Temporary Moratoria on Enrollment
- Suspension of Payments

The AHA is also responding to CMS' request for input – prior to issuing a proposed rule – on another new provision mandated by Congress: mandatory compliance programs for providers and suppliers.



Our comments on the specific provisions follow. As a general matter, we urge that as CMS rolls out implementation of the many program integrity provisions, it look at the cumulative effect for hospitals and others and not issue each in a vacuum. As CMS is very aware, there are multiple and overlapping program integrity activities that affect hospitals, each making specific demands on hospital personnel and resources. Hospitals are committed to supporting CMS and HHS in fraud-fighting efforts. Our concern is to protect against having mistakes treated as fraud and hospital resources diverted away from patient care unnecessarily.

PROVIDER SCREENING

Risk categorization and screening. CMS proposes to create three risk categories to evaluate and screen providers and suppliers: limited, moderate and high risk. The AHA supports CMS' placement of hospitals in the limited risk category and, as such, to retain screening requirements that are largely consistent with what is currently included in the Medicare enrollment process.

We believe that the providers and suppliers that CMS proposes to designate as "high risk" or "moderate risk," and that are members of, operate as a part of, or are owned by a hospital or a health system, should instead fall under the same risk categorization that CMS proposes for hospitals. That is, they should also be designated as "limited risk." Hospitals and health systems, in the interests of offering a broader and more comprehensive range of services to meet the needs of their communities, may own, or otherwise be affiliated with, a wide variety of Medicare recognized health care providers, such as those offering home health, hospice, rural health clinic, rehabilitation or ambulance services. This trend will increase as hospitals organize to meet the goals of ACA for delivery system reform to provide more coordinated care. These service providers become part of the larger mission of the hospital or health system with which they are affiliated and effectively become part of their parent hospital or health system. Unlike the free-standing providers that CMS proposes to designate as high or moderate risk, hospital owned/affiliated entities are part of larger established organizations that have high levels of accountability to their internal governance structures and have longstanding relationships with and responsibility to their local communities. These health care providers and suppliers also pose a limited level of risk to the Medicare program by virtue of the oversight provided through their parent or affiliated hospitals or health systems. Therefore, the AHA recommends that these types of entities should be designated as "limited risk" and accorded the same level of screening that CMS proposes for hospitals.

In the event that CMS does not accept the AHA's recommendation to accord hospital or health system owned or affiliated providers/suppliers with a "limited risk" designation, the AHA has two other comments and recommendations related to CMS' proposed screening criteria for "moderate" and "high" risk entities:

- (1) CMS proposes fingerprinting and criminal background checks for owners, authorized or delegated officials or managing employees of any provider or supplier that is designated as "high-risk." While all these roles are defined in current regulation, we seek greater specificity regarding what level of managing employees would be subject to these requirements. In larger provider organizations, in addition to those high-level managers or directors who oversee the operation of the overall organization, such as the chief

executive officer, chief financial officer, and chief medical officer, there are many middle- and low-level managers who oversee only a department or a particular function within the larger organization, such as engineering, infection control, pharmacy services or housekeeping. These managers have limited areas of responsibility within the organization and report up to higher level managers. We recommend that CMS clarify that the additional proposed screening measures of fingerprinting and background checks apply to only the highest-level managing employees who operate or manage, or who oversee the operation of the entire healthcare organization, and not to lower-level managers of individual departments or functions.

(2) CMS proposes unscheduled, unannounced site visits for moderate- and high-risk providers/suppliers. The AHA supports site visits as a tool to improve program integrity. However, given the disruption and administrative burden that a CMS site visit could cause for a legitimate provider or supplier's business operations, we recommend that CMS limit the purpose of these site visits to verifying that the provider/supplier exists and is operational. Other matters that would require significant management and clinical staff time should be handled through separate scheduled site visits.

Geography. In several places in the proposed rule, CMS contemplates treating all providers and suppliers in a specific geographic location in a different way due to concerns about potential fraud, waste or abuse. For instance, in its discussion about the criteria appropriate to re-categorize entities from low or moderate risk to high risk, CMS indicates it is considering the applicability of geographic circumstances as a possible criterion. Further, in its proposal for temporary moratoria on enrollment, CMS proposes that a moratorium may be imposed in any particular geographic area if the agency, in consultation with the Department of Health and Human Services Office of the Inspector General (OIG) and/or the Department of Justice (DOJ), identifies the area as having a significant potential for fraud, waste or abuse. We believe that geography is too blunt an instrument with which to make such decisions and that it is inappropriate to penalize all providers and suppliers in a particular geographic location. Instead, we recommend that CMS adopt a more targeted approach that takes other relevant factors into consideration, such as the history or trend in proven fraud and/or abusive practices for specific types or categories of providers or suppliers. To paint all providers and suppliers in a particular geographic area with the same broad brush is too extreme a measure to be considered reasonable and would arbitrarily and inevitably penalize many providers and suppliers that are compliant with Medicare and Medicaid rules and regulations.

De-activation of Enrollment under Medicaid. The Agency proposes at §455.418 to de-activate the enrollment number of providers not submitting claims to Medicaid for a consecutive 12-month period. We note that this time frame is consistent with Medicare de-activation policy; however, under Medicare, there are special considerations around re-activation of billing privileges in those circumstances. We urge CMS to add the same special considerations for Medicaid at §455.420 "Reactivation of provider enrollment." That is, if the only reason for de-activation of the provider's Medicaid enrollment number was non-submission of claims or no referrals for a period of 12 consecutive calendar months, then re-activating the enrollment number should not require a re-screening of the provider or the re-submission of the enrollment

form. Instead, consistent with Medicare policy, providers whose Medicaid enrollment numbers were de-activated under these circumstances should merely be required to re-certify that the enrollment information currently on file with Medicaid is correct and furnish any missing information as appropriate.

Also, consistent with the recommendation the AHA makes for the Medicare rule (see discussion below regarding Application Fee), we urge that the proposed Medicaid rule be revised so that the newly created enrollment fee will not apply to re-activations that result from non-submission of claims or referrals for a 12-month period. This will address concerns from providers or practitioners who may not serve Medicaid enrollees in a 12-month period, e.g., pediatricians or pediatric subspecialists.

APPLICATION FEE

Congress has mandated a \$500 enrollment application fee for institutional providers to support the administrative costs of program integrity. The AHA finds it inequitable that those institutional providers in the “limited risk” category are still subject to the same \$500 application fee as “high risk” providers whose screening requirements CMS is proposing be greatly enhanced. While we recognize that this is a matter of statute, we believe that a more equitable policy would link the application fee amount to the assigned level of risk, with a zero or minimal fee applicable to “limited risk” facilities and higher scaled fees applied to the “moderate risk” and “high risk” categories.

However, as the fee is mandated by statute, the AHA recommends that CMS use the application fee collected from “limited risk” providers to develop prioritized and expedited processes and time frames for contractor review and approval of initial enrollment applications and revalidations for the providers in the “limited risk” category. As the AHA has noted on many previous occasions, there are growing delays and backlogs in Medicare contractor processing of paper-based and online enrollment applications as more physicians and other eligible professionals and organizations respond to calls from CMS and their national associations to establish an enrollment record. These delays will have an increasingly significant and adverse effect on the ability of hospitals to organize their services to better coordinate care, which is a goal of health reform. Using the enrollment fee collected from “limited risk” providers to develop and implement prioritizations and expedited processes for completing the enrollment and revalidation of “limited risk” providers will be welcomed.

Further, the AHA is concerned about the impact of CMS’ decision not to allow Medicare contractors to begin processing an enrollment application until after the fee is received and credited to the U.S. Treasury. As noted above, currently there are significant concerns about the often extended period of time it takes for new enrollment applications to be processed and for new providers and suppliers to receive their billing number. Hospitals are concerned that this fee provision will only lengthen the enrollment application and revalidation processing times and contribute to the current backlogs and delays, another stumbling block for hospital efforts to achieve the goals of health reform. CMS should identify and use an electronic funds transfer mechanism for the enrollment fee in order to facilitate the timely processing of enrollment applications and revalidations.

At proposed §422.514 (a) and (b), CMS would require prospective institutional providers and revalidating institutional providers to submit an application fee. The AHA requests that CMS clarify that *routine* updating of changes in enrollment information, as required by CMS in §424.520(b) and §424.550(b), and as distinct from new applications or revalidations, will not be subject to the \$500 fee. The current Medicare requirements for updating of enrollment information include reporting changes to ownership or control, practice location, a change in any managing employee, and a change in billing services, among others. These types of changes can occur frequently and it would be burdensome and costly to hospitals and health systems if CMS were to require that the fee apply each time such routine updating of information occurs.

Further, the AHA recommends that CMS state in the final rule and revise §424.540 *Deactivation of Medicare billing privileges* to clarify that the reactivation of Medicare billing privileges that had been deactivated as a result of non-submission of a claim for a consecutive 12-month period will not result in the imposition of an enrollment fee, since such an action is not considered to be a new enrollment application, the establishment of a new practice location, or a contractor requested revalidation of enrollment information. This clarification will address concerns from certain types of providers and suppliers who primarily serve pediatric populations and who therefore rarely submit claims under Medicare or whose involvement in Medicare is otherwise limited to infrequent referrals that result in Medicare claims.

TEMPORARY MORATORIA ON ENROLLMENT

CMS proposes that it may lift a temporary moratorium if there is a Presidentially-declared disaster under the Stafford Act. The AHA recommends that, in addition, CMS also be permitted to lift a moratorium if the Secretary of HHS declares a public health emergency in an area.

Further, as discussed in connection with screening, CMS should not use geography, by itself, as a determining factor in imposing a temporary enrollment moratorium on all providers and suppliers.

SUSPENSION OF PAYMENTS

The ACA lowered the standard for suspending payments to providers and suppliers in cases involving allegations of fraud. The AHA is concerned that the combination of the lower standard and the procedures related to initiating and continuing a suspension do not adequately protect against investigations and related suspensions continuing with no charges in sight.

In particular, for cases that are deemed to involve credible allegations of fraud, CMS proposes to eliminate the current 180-day limit for a suspension and the one-time extension, and replace it with a requirement for CMS to merely “evaluate” every 180 days whether there is good cause to discontinue the suspension. This effectively means that a provider’s payments could be continuously suspended without any meaningful opportunity to challenge the allegation. While there is technically an opportunity to submit a written rebuttal at the time of the initial suspension, it is rarely available in advance of the suspension, provides only the most minimal of due process protections, and does not create a right to challenge the ongoing validity of a payment suspension.

The AHA recommends that a higher standard be applied for continuation of a suspension beyond one year. There should be a presumption against an extension unless OIG or DOJ certify quarterly that the initiation of a proceeding is anticipated. There should also be a reordering of the regulatory text defining “credible allegation of fraud.” The last sentence, which defines credible, should become the first sentence (“Allegations are considered to be credible if...”). As drafted, the definition begins with a list of potential sources for a credible allegation that, implicitly and inappropriately, appears to favorably prejudice the merits of an allegation from these sources.

COMPLIANCE PROGRAM

Section 6401 of the ACA mandates that a provider or a supplier must, as a condition of enrollment in Medicare, Medicaid or CHIP, establish a compliance plan that includes the core elements established by the Secretary in consultation with the Inspector General. Instead of issuing a proposed rule, CMS has included in this Federal Register Notice a request for input on potential core elements of a compliance program and information related to current compliance activities. A proposed rule will follow separately.

Core Elements. CMS asks three questions in connection with the core elements of a compliance program:

- (1) Whether the U.S Sentencing Commission Guidelines for an effective compliance program should be adopted as the core elements;
- (2) Whether any additional requirements should be included; and
- (3) Specifically, whether a requirement for external and/or internal quality monitoring should be added for hospitals and long-term care facilities.

The AHA supports the adoption of the sentencing guidelines as the core elements of a compliance plan under Section 6401. We believe no additional requirements are warranted or should be imposed on hospitals. We would oppose any mandate to include the oversight of the quality of care provided by a hospital as a function of program integrity.

Hospitals have been actively engaged in voluntary compliance activities for more than ten years. This includes providing input to HHS on the development of voluntary guidelines. Hospitals adopted compliance programs to demonstrate their good-faith efforts to comply with complex and continually changing legal and regulatory requirements they must meet as a condition of receiving payment for serving beneficiaries and program enrollees. Since their inception, these plans have been based on the seven elements of effective compliance programs in the U.S. Sentencing Commission Guidelines and the adaptation of those for hospitals in the OIG’s voluntary compliance program guidance (the version of the Guidelines listed in the Federal Register Notice). The Guidelines have stood the test of time and continue to be the

foundation for hospital programs. Imposing any new requirements would only add unnecessary burdens and costs for hospitals with no additional benefit.

The AHA specifically opposes adding a requirement to the Guidelines for external and/or internal quality monitoring for hospitals. Putting patients first – ensuring their care is centered on the individual, rooted in best practices and utilizes the latest evidence-based medicine – is a priority for America’s hospitals. It’s what guides the actions and decisions of nurses, physicians and other caregivers every day. Quality oversight should remain with the clinical staff that has the required special knowledge and expertise. Hospitals have significant systems and processes in place to assess and enhance quality (e.g., peer review, credentialing, quality review protocols such as LEAN or Six Sigma, evidence-based medicine, and root cause analyses). Quality improvement and patient safety are already subject to extensive outside reviews, including by CMS (e.g., central and regional office survey and certification, QIOs, and state surveyors) as well as accrediting bodies, state licensing agencies, health departments and FDA. In addition, hospitals provide quality reporting to CMS, state agencies and accrediting bodies.

If the Guidelines are adopted as the core elements, CMS should modify or clarify the second element in the HHS adaptation of the Guidelines for hospitals -- reporting to the Board -- to conform with the Sentencing Guidelines. Instead of focusing on the function of the compliance officer, it appears to dictate to whom the compliance officer has a “direct report” relationship. The Guidelines are met if the compliance officer periodically provides information on compliance activities to high-level personnel and, as appropriate, to the Board. The Board should have the latitude to determine what structure will best enable it to meet its oversight responsibilities.

Effectiveness. CMS asks several questions related to the effectiveness of programs and states that it anticipates requiring providers to evaluate the effectiveness of their programs using electronic data. Taken together, the questions suggest that hospitals may be required to put an infrastructure in place specific to this requirement. As CMS is aware from its own efforts to measure effectiveness, there are many open questions about what effectiveness means, what to measure, and how to measure it. At this point it makes most sense to stay with the evaluation and monitoring already required under the Sentencing Guidelines that create accountability while allowing the particulars to be determined based on the circumstances of the individual hospital.

We note that CMS’ request for information asks whether the organization has tracking systems, data capturing systems and electronic claims submission systems in place. As CMS knows, hospitals are already subject to multiple and overlapping efforts to oversee the accuracy of claims submitted through electronic systems (e.g., RAC, MIC, MAC, MFCU, PERM, CERT, and ZPIC). Before considering the addition of another layer to the oversight of claims submission, including payment accuracy, we urge CMS to carefully review what is already occurring and what, if any, gaps exist. As the AHA has separately presented to CMS, there is a serious need for coordination and evaluation of the already existing program integrity activities to avoid duplicating and unnecessarily increasing demands on providers’ systems and resources.

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Timeline. CMS also asks what amount of lead time will be needed for establishing a required compliance program. That will depend on the specifics of CMS requirements. Hospitals are diverse in size, location and complexity and, hence, the formality and sophistication of their programs will be dictated by those characteristics. In making its proposal, CMS should keep in mind that there is no one-size-fits-all program, and any requirements should be scalable to the size and resources of the individual hospital.

Thank you for the opportunity to submit comments. If you have any questions regarding these comments, please do not hesitate to contact Roslyne Schulman, director, policy development, at (202) 626-2273 or rschulman@aha.org, or Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

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cc: Peter Budetti
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CMS