



Michael D. Maves, MD, MBA, Executive Vice President, CEO

November 16, 2010

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: Proposed Rule concerning Medicare, Medicaid, Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions, and Compliance Plans for Providers and Suppliers [CMS-6028-P] RIN 0938-AQ20

Dear Dr. Berwick:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments regarding the Centers for Medicare and Medicaid Services' (CMS) *Proposed Rule concerning Medicare, Medicaid, Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions, and Compliance Plans for Providers and Suppliers* [CMS-6028-P] RIN 0938-AQ20. While we generally support key elements of the proposed rule, there are a number of areas of concern where beneficiary access to care could be seriously undermined. We urge CMS to adopt alternative and modified rules that comport with the statutory language, enhance program integrity, and do not impose excessive administrative costs and burdens on honest and legitimate health care providers. Our detailed comments are set forth below.

PROVIDER SCREENING UNDER MEDICARE, MEDICAID & CHIP AND FEES

The health system reform law requires CMS to establish procedures whereby enrollment (or re-validation) screening in the Medicare program is conducted according to the risk of fraud, waste, and, abuse (referred to as risk-based screening hereafter) posed by health care practitioners and entities. CMS is also required by the Affordable Care Act (ACA) to impose a \$500 enrollment fee on institutional providers.

Harmonization

In the proposed rule, CMS has requested input on whether the agency should harmonize enrollment screening across Medicare, Medicaid, Medicaid managed care entities, Children's Health Insurance Program (CHIP) and Medicare Advantage Organizations (MA).

Harmonization would be beneficial only to the extent that Medicare, Medicaid, and MA have enrollment and re-validation reciprocity and only where adequate resources and time were allocated to ensure that harmonization does not wreck havoc among state Medicaid programs and MA plans. Reciprocity would ensure that physicians are not subject numerous times to the same or similar onerous requirements and reviews once physicians have undergone screening (whether it was undertaken by Medicare, Medicaid, CHIP, or MA plans). This would also represent significant savings for federal health care programs. However, we believe that efforts to harmonize MA and Medicaid enrollment screening should include adequate lead time and resource allocation to build the capacity to effectively and expeditiously conduct the requisite level of screening and enrollment. Currently, we are surveying state enrollment and screening practices. We will have additional comments on future CMS proposals. The AMA agrees that it would be inefficient and costly to require entities that administer other federal health care programs to conduct the same screening undertaken by Medicare.

Risk-Based Screening & Tiers

CMS has proposed differentiating the intensity of enrollment (and re-validation) screening based on risk posed by the category of provider or supplier type. CMS criteria for risk assignment appear to be based on a number of factors including: (1) recent studies that indicate elevated risk; and (2) provider or supplier state licensure or other significant government regulatory oversight. The AMA supports conceptually the creation of low (Tier I), medium (Tier II), and high (Tier III) risk tiers where provider and supplier types are placed in a tier based on the agency's assessment of relative risk of fraud, waste, and abuse. **We strongly support the proposal to assign physicians to Tier I, which is designated as the lowest risk.** It is well-documented that the vast majority of health care fraud is not perpetrated by physicians. Physicians are already subject to rigorous oversight and state licensure requirements. As a result, additional scrutiny would be duplicative, time-consuming, and of limited value. Tier I enrollees would not be subject to additional requirements beyond current screening practices which are already extensive for physicians.

CMS has requested input on the process that the agency should utilize to modify the assignment process and criteria. The AMA urges CMS to utilize public notice and comment prior to modifying the process or revising tier assignments based on new criteria. The AMA does not support agency updates to the risk categories without notice and comment because, as demonstrated by this proposed rule, there are likely to be a number of significant and unintended consequences not contemplated by CMS. Stakeholder input is essential. We generally support changes to the risk screening and assignments based on *documented* evolving risk after notice and comment. We strongly recommend that the criteria used by

CMS to make assignments should reflect reports on fraudulent schemes as documented in government reports and fraud statistics.

However, based on the currently proposed categories and tier assignments, CMS has requested comment on whether re-assignments to a higher risk tier would be warranted based on “geographical circumstances.” We strongly oppose “geographical circumstances” as a possible criterion for adjusting a providers or suppliers from one risk category to another. Such a move would deny all providers and suppliers in the specified geographic area basic due process and could seriously damage beneficiary access to health care providers and services in the impacted area. In short, such a re-assignment is not in the interest of beneficiaries and violates basic notions of fairness.

Tier II and Tier III - Office-Based Physician and Non-Physician Practitioners DMEPOS Suppliers

There are physicians and certain non-physician practitioners, *e.g.*, podiatrists, optometrists, physical and occupational therapists, physician assistants (collectively referred to hereinafter as “non-physician practitioners”), who provide their own patients with durable medical equipment prosthetics, orthotics, and supplies (DMEPOS). At best, the proposed rule is ambiguous with regard to how CMS would assign to a particular tier these individuals who are required to submit an application to become DMEPOS suppliers. Unfortunately, a plain reading of the proposed rule appears to assign office-based physicians of DMEPOS to Tier II (if currently enrolled [re-validating]) or Tier III (if prospective [newly enrolling]). **This will create a significant disincentive to office-based physicians to continue offering DMEPOS. Furthermore, such office-based practices offering DMEPOS do not pose a heightened risk of fraud and abuse to the program and we are not aware of any studies that indicate otherwise.** If office-based physicians terminate offering DMEPOS, it will adversely impact the delivery of quality care, undermine the patient-physician relationship, and, ironically, could increase the potential for fraud, waste, and abuse.

While there have been numerous government reports, investigations, and audits concerning fraud and abuse perpetrated by commercial DMEPOS, the record is scant with regard to physician office-based DMEPOS. (In fact, the most widely reported DMEPOS fraud has involved physicians as the victims of identity theft as opposed to perpetrators of fraud.) There are some specialty practices, such as ophthalmologists, where this will dramatically impact access to their patients, despite the fact that there has been little to no documentation of fraud, waste, or abuse in this category of DMEPOS. Furthermore, the proposed rule does not account for the existing Stark Law restrictions applicable to physicians vis-à-vis DMEPOS. Under the Stark Law, there are a litany of requirements physicians must meet in order to provide DMEPOS to their patients and the law significantly limits the universe of DMEPOS office-based physicians can provide. In addition, referring patients to an unknown commercial DMEPOS could actually increase the risk of fraud and abuse.

For the subset of physicians offering office-based DMEPOS, they do so to ensure that: (1) a particular item of DMEPOS meets the “size and fit” specifications for that particular patient; and (2) the patient is properly instructed concerning the use of that DMEPOS. This improves the quality of care, enhances patient compliance, reduces risk of further injury, and averts liability concerns, as well. For example, if a patient is diagnosed with a foot fracture, a walking boot and crutches may be required upon leaving the physician’s office. If the patient is unable to acquire the item from the treating physician and must obtain the item from another supplier, serious adverse consequences could result, including a delay in care, continuous or exacerbated pain, or the patient could be at risk for additional, increased injury, which would increase costs to the Medicare program. This could also contribute to fragmented care, which could disrupt the patient-practitioner relationship. Moreover, in some cases, Medicare allows only one item of DMEPOS per patient. In this event, if the item is not initially properly fitted and sized, the patient may later have to pay out-of-pocket for a replacement item. Further, the clinical judgment and expertise of the treating practitioner in selecting a particular item is essential and should be based on the evaluation of the patient at the time of dispensing. This would also be the appropriate time to instruct the patient and address any questions, or concerns on the utilization of the item. If a patient is sent elsewhere to obtain an item and the fit is incorrect, or the patient receives insufficient information about an item, the patient will likely return to the practitioner’s office with questions or for assistance. This will result in increased costs to the Medicare program and will increase utilization under the sustainable growth rate (SGR). **For quality and continuity of care reasons alone, the proposed rule should include an exception for physician office-based DMEPOS.**

In light of the foregoing, we urge CMS to place physician and non-physician practitioner office-based suppliers in the lowest risk tier. We recommend that CMS create an exception for office-based physicians and non-physician practitioners who enroll as DMEPOS suppliers. Such an exception would be consistent with the exception explicitly established in the proposed rule for DMEPOS suppliers that are publicly traded on the New York Stock Exchange (NYSE) or the NASDAQ. CMS has proposed categorizing such DMEPOS suppliers in the low risk tier. The rationale provided by the agency for this NYSE/NASDAQ exception, that such entities are already subject to significant regulatory oversight, is equally apt for physicians and non-physician practitioners who are subject to significant state oversight.

Re-Assignment to Tier III - Identity Theft

The AMA strongly opposes the proposal to re-assign physicians from the “limited” or “moderate” risk tier to the “high” risk tier when CMS has evidence from or concerning a physician that another individual is using their identity within the Medicare program. Re-assigning physicians who have been the victims of identity theft to the high risk tier (Tier III) would stigmatize the physician and create a presumption that he/she has engaged in conduct warranting heightened scrutiny. We agree with CMS added scrutiny is needed where a new enrollment application (as opposed to re-validation) is submitted that includes a compromised

identity. Nonetheless, simply re-assigning physicians to Tier III with other categories of providers and suppliers would be punitive to the victim of identity theft and it does not adequately address the risk to federal health care programs. We urge CMS to establish a fourth tier (Tier IV) which signifies a heightened level of risk to federal health care programs as a result of compromised physician identity or identity theft. This would diminish significantly the possibility of stigmatizing further a victim of identity theft. In addition, it would enhance the ability of CMS and other federal and state programs and law enforcement to quickly identify identity theft victims, track them, and then coordinate and work together to address the particular challenges and threat to health care programs when a physician's identity has been stolen. Creating a fourth tier would also assist contractors and others tasked with implementing the screening requirements to ensure that physicians who are the victims of identity theft will not be subject to fingerprinting or other biological or biometric requirements. We urge CMS to provide contractors with sufficient and targeted resources to handle identity theft screening to ensure that the additional screening precipitated by identity theft will not delay processing of new enrollment applications. We anticipate that as federal and state regulators combat outright fraud and limit enrollment into federal health care program, fraudsters will increase efforts to steal the identities of legitimate and honest health care providers and physicians. We urge CMS to move quickly to reach out to, and work with, other federal and state agencies to develop resources and protocols to decrease the current identity theft vulnerabilities faced by physicians and to mitigate harm to the victims of identity theft and federal health care programs.

Re-Assignment to Tier III - Billing Privileges Revoked

The AMA has significant concern with the proposal to re-assign physicians (and other providers/suppliers) from the "limited" or "moderate" risk levels to the "high" risk level if a physician has had billing privileges revoked by a Medicare contractor within the previous ten years and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier. Billing privileges can be revoked for a number of reasons unrelated to fraud, waste, or abuse. One of the more common reasons includes failure to respond to a request for revalidation documentation within stringent contractor imposed deadlines. This latter scenario has not been, unfortunately, uncommon. Contractor revalidation notices and processing has been fraught with nearly as many problems as the enrollment process for new applicants. Over the years, AMA has fielded and shared with CMS concerns that evidenced a systemic failure among certain contractors to provide reasonable, comprehensible, and timely revalidation notices to physicians. In addition, some contractors have been consistent poor performers with regard to handling re-validation paperwork. Unfortunately, physicians do not control which contractor they are assigned and do not control how resources are allocated to contractors. Problems with Medicare contractor enrollment are evidenced by a recent CMS' Medicare Contractor Provider Satisfaction Survey which found only 55 percent of physicians and other healthcare providers who bill Part B are satisfied with the enrollment process. Nonetheless, physicians have borne the consequences of contractor poor performance including instances where physician billing privileges were temporarily revoked because of paperwork snafus outside of the physician's control. The

AMA has significant concerns with re-assignment of physicians from a low risk category to the highest risk category as a result of poor performance of contractors. (The AMA does recognize and commend the new CMS leadership which has made significant strides recently to address many of these problems.) Nonetheless, we urge CMS to differentiate between a temporary revocation of billing privileges and revocations based on actual misconduct by a provider or supplier.

Re-Assignment to Tier III – Temporary Moratorium

As discussed in the section below concerning the proposed rules interpreting CMS's authority to impose temporary moratorium, the AMA urges CMS to exercise this authority judiciously and to exempt physicians from re-assignment from Tier I to Tier III if physicians are ever subject to the temporary moratorium. Based on the factors CMS has proposed for consideration prior to imposition of a moratorium, it appears exceedingly unlikely that physicians would be subject to moratoria. Nonetheless, physicians and other health care practitioners who offer office-based DMEPOS could be caught-up, unless carved out, to a moratorium placed on commercial DMEPOS. Even in those instances where physicians were the subject of a moratorium, it is exceedingly improbable that physicians as a group pose a heightened risk to federal health care programs simply based on their geographic location. As a result, we urge CMS to establish an exception for physicians vis-à-vis re-assignment from Tier I to Tier III following a temporary moratorium.

Enrollment Fee for Institutional Providers

The AMA has significant concerns that physicians and non-physician practitioners who offer office-based DMEPOS will be subject to a \$500 enrollment fee because the proposed rule and existing regulations would define such physicians and non-physician practitioners as "institutional providers." Imposition of the fee on physicians is unambiguously beyond the scope of CMS's statutory authority, would frustrate congressional intent, and is not warranted since the vast majority of physicians would not be subject to additional screening. Section 6401 of the Affordable Care Act (ACA) as amended requires CMS to impose a \$500 fee on "institutional provider[s]" enrolling in the Medicare program. Congress mandated the imposition of the fee to defer the government's administrative costs associated with more rigorous screening procedures. Though early versions of Section 6401 would have required HHS to impose a \$200 application fee on physicians who provide "medical or other items or services," the final version included an amendment that struck the \$200 application fee in ACA Section 10603. Congress and stakeholders fully anticipated that CMS would not have to subject physicians to heightened and costly screening measures. As discussed above, we have urged CMS to re-assign physician and non-physician practitioner office-based DMEPOS suppliers to Tier I because there are not any reports or documented patterns of fraud perpetrated by them. Imposition of the \$500 fee would have a similar result as placing such practices in Tier II or Tier III—it will cause these practices to stop offering DMEPOS to their patients. As discussed in detail above, this will have a significant impact on the quality of

care provided, continuity of care, and could, actually increase the potential for fraud, abuse, and waste.

TEMPORARY ENROLLMENT MORATORIA

The ACA confers HHS with the authority to impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers, including categories of providers and suppliers, if it is determined that it is necessary to prevent or combat fraud, waste, and abuse. The imposition of a temporary moratorium is an extreme measure since it casts a wide net that will cause hardship for potential fraudsters and legitimate and honest providers alike. The AMA is deeply concerned with the general nature of the proposed rule because it could easily lead to an abuse of discretion or arbitrary and capricious decision-making with little recourse beyond the internal review process. In addition, the AMA is particularly concerned with the one area where the proposed rule is very specific. Specifically, the proposed length of the “temporary” moratorium is inconsistent with a reasonable interpretation of the authorizing statutory language.

First, the AMA strongly urges CMS to specify that a moratorium will not be imposed unless: (1) there is significant risk of widespread fraud, waste, or abuse in a specified and discrete geographic region; and (2) clear and documented agency analysis substantiates that the moratorium will not exacerbate health disparities, create additional barriers for underserved communities, and will not have a disparate adverse impact on racially and ethnically diverse beneficiaries and physicians. Congress did not intend that tools to combat fraud and abuse would be used in a fashion that broadly undermined the delivery of care and creates additional barriers where many already exist. Unfortunately, the blunt force nature of a moratorium is likely to result in significant collateral damage among individuals who have engaged in no wrongdoing. CMS should include greater specificity as to what conditions would warrant the imposition of a moratorium and what factors would be considered to ensure that the harm does not outweigh the benefit. The AMA does support the proposed rule language specifying that re-validating providers and suppliers would not be covered nor would change of practice locations once a moratorium was imposed.

Second, the length of the proposed moratorium—six months—and the ability to extend the moratorium in perpetuity cannot be reasonably inferred from Congress authorizing “temporary” moratoria. It is hard to envision under what conditions and circumstances six months could be considered “temporary.” A half year moratorium would have significant consequences for new physicians interested in enrolling in the Medicare program. We urge CMS to revise the proposed rule so that the length of the temporary moratorium would be for no more than 30 days. In addition, the proposal to allow HHS to continue authorizing an extension of the moratorium without limit is beyond the authority conferred by Congress. If congressional intent was to confer HHS with the open ended discretion to impose a moratorium, “temporary” would not have been included in the statutory language. Regardless of the length of the moratorium, HHS does not have the authority to extend it beyond a temporary period of time.

PAYMENT SUSPENSIONS

Medicare – Generally

As CMS notes in the proposed rule, the agency, under prior grants of general statutory authority, has already promulgated regulations and guidance specifying the basis and process for suspending payments. Despite the foregoing, there was widespread misinformation among Members of Congress that CMS lacked the authority to suspend payments. We strongly urge CMS, at a minimum, to maintain the current evidentiary basis and standards used by the agency to suspend payments. Further, we note that the current authorized length of suspension can essentially constitute a termination for many physician practices, and this problem will be exacerbated by CMS's proposal to allow for the prolonged duration of suspensions. Physicians and patients can ill afford such an outcome. Therefore, we also strongly urge reconsideration of the authorized and proposed length of time allowed for suspensions.

Medicare – Evidentiary Standard for Suspension

Section 6402 of the health system reform law provides that “the Secretary may suspend payments to a provider of services or supplier. . . pending an investigation of a credible allegation of fraud against the provider of services or supplier.” The proposed rule would define “a credible allegation of fraud” as an allegation identified through any source, including fraud complaint hotlines, claims data mining, provider audit patterns, civil false claims cases, and law enforcement investigations. These informational sources, while useful in identifying actual fraudulent activity, will undoubtedly also be avenues for unfounded allegations. The proposed rule also provides that allegations will be considered “credible” when they have a mere “indicia of reliability.” This standard is too low and is inconsistent with the actual statutory standard. We note that, currently, CMS employs fraud suspensions when there is “reliable information that fraud or willful misrepresentation exists,” a higher, and more reliable, evidentiary standard. **Accordingly, we urge CMS to define the new evidentiary standard for payment suspension, a “credible allegation of fraud,” as consistent with CMS’s longstanding standard of “reliable information that fraud or willful misrepresentation exists.”**

Medicare – Length of Suspension

The AMA is concerned that the exception of some Medicare payment suspensions from the established time limits may create a scenario whereby onerously lengthy investigations are the norm. Currently, a number of physicians are undergoing suspensions of virtually unlimited duration. The HHS Office of Inspector General's (OIG) November 2010 report on payment suspensions found that, in 2007 and 2008, CMS “extended more than half of payment suspensions,” and “extended 46 of 145 (32 percent) [of] suspensions for indefinite time periods.” According to the OIG report, in 2007 and 2008, the suspensions CMS removed lasted a median of 267 days. OIG makes clear that CMS's current guidance on extending

payment suspensions is contradictory. We are concerned that extending suspensions beyond the current time limits further compounds the *status quo*: non-fraudulent physicians are essentially being terminated by lengthy suspensions. We commend CMS's acknowledgment in the proposed rule that "a speedy overpayment determination" may be needed in the case of an overpayment suspension, and CMS's intent to apply the existing time constraints to those suspensions. Correspondingly, we ask that all suspensions be given a timely resolution, and we oppose the further exception of any suspensions from the current specified time limits.

Medicare – Exceptions to Suspension

The AMA agrees that there should be a good cause exception not to suspend payments if CMS determines that beneficiary access to necessary items or services may be jeopardized. Similarly, we are encouraged that CMS suggests that a good cause exception should be considered, on a case-by-case basis, when a suspension has been prolonged, although we believe that a suspension period lasting two or three years, the scenario CMS invokes, is clearly too long. When payments are suspended for even a brief period of time, it compromises a physician's ability to care for his/her patients and maintain their practice. This is particularly true for the many small physician practices. Such suspensions—particularly lengthy ones of six months or more—will lead to *de facto* terminations. The foregoing has real consequences for patients who will need to identify a new physician or who may forgo care. Good cause exceptions to ensure care delivery are especially necessary in the physician practice setting, and the AMA urges CMS to specify that exceptions for physician practices should be a standard consideration and given heavy weight.

Medicaid

The AMA has significant concerns with provisions of the proposed rule as they relate to Medicaid suspensions. These concerns track those outlined above vis-à-vis Medicare suspensions. In brief, there is no evidence that the existing suspension regulations have limited the ability of government agencies and law enforcement to suspend payments. To the contrary, there is ample evidence that both state and federal governments have adequate authority and the ACA language merely creates explicit statutory authority. In addition, to the extent states or the federal government were unable to move quickly to suspend payments historically, it has not been because the evidentiary burden was so high, but rather it has been caused by a lack of funding and coordination capacity among state and federal agencies and law enforcement.

First, states have long had authority to suspend payments "upon receipt of reliable evidence of fraud." There is not any discussion in the proposed rule that states have been hamstrung by existing standards nor or any reports cited. The proposed changes expand broadly the discretion to impose suspensions in a manner that can easily constitute a *de facto* termination from the Medicaid program without any meaningful due process. The proposed rule would lower the evidentiary standard required prior to suspending payments and also create a nearly open ended period for such suspensions. The OIG report cited above underscores that CMS

has imposed lengthy suspensions so our concern is not without basis. The AMA strongly disagrees that it was Congress' intent to lower the existing evidentiary standard by utilizing the term credible allegation of fraud. It is clear that "pending an investigation of a credible allegation" of fraud is consistent with "reliable evidence" of fraud. A change to the existing regulation is neither warranted nor authorized by ACA or congressional intent. Furthermore, neither statutory authority nor sound policy support the proposed rule specifying that "investigations" by state agency units rise sufficiently to the level of "pending investigation of credible allegation of fraud." CMS notes that "state agency investigations may be preliminary in the sense that they lead to a referral to a law enforcement agency for continued investigation, [and] are adequate vehicles by which it may be determined that a credible allegation of fraud exists sufficient to trigger a payment suspension...." For the most part, these investigations are focused on overpayments and underpayments, not necessarily **fraudulent** behavior. Yet, providers could still have their payments suspended. Lowering the evidentiary standard is contrary to the assertion that CMS expects that suspensions will be imposed judiciously.

Second, the AMA strongly urges CMS to either shorten substantially the length of suspensions, or, in the alternative, maintain the current permitted duration without extension. The length of suspensions specified in the proposed rule will essentially push small physician practices out of the program. This is particularly the case with regard to Medicaid, where the low reimbursement rates mean that small practices will have very little capacity or reserves to make up for lost reimbursements for even a three-month period. It is hard to fathom how a small practice could remain operational after six months (or more) unless it stopped taking Medicaid patients.

The AMA supports the various proposed rule provisions that confer states with the discretion to forgo imposition of suspension of payments. We strongly support a good cause exception where a State determines that a suspension would have an adverse impact on beneficiary access to necessary items and services. In addition, we strongly support conferring states with the discretion to impose partial suspensions of payments.

REQUEST FOR INFORMATION: COMPLIANCE PLANS FOR PROVIDERS AND SUPPLIERS

We urge CMS to consider the unique nature of physician practices when establishing a compliance program for physicians. Section 6401 of the health system reform law requires HHS to establish core elements for a compliance program "for providers or suppliers within a particular industry or category." We were pleased that Congress acknowledged that the Secretary should not employ a 'one size fits all' approach when establishing compliance program guidelines. Most physician practices are vastly different from other health care providers in size and structure, and have fewer resources. The majority of office-based practices are very small: 78 percent of office-based physicians work in practices with nine physicians or less, and few administrative staff. **Therefore, we recommend that, because**

physicians are a unique category of providers, the Secretary establish core elements of a compliance program specific to physicians.

CMS seeks comment on the compliance and ethics program described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual as the model for compliance programs for Medicare, Medicaid and CHIP. The elements noted in the Manual are, in summary:

- (1) written policies, procedures, and standards of conduct to prevent and detect inappropriate behavior;
- (2) designation of a chief compliance officer or corporate compliance committee;
- (3) reasonable efforts not to include individuals who have engaged in illegal activities in positions of authority;
- (4) regular employee education and training programs;
- (5) a complaint hotline and procedure to protect whistleblowers from retaliation;
- (6) a system to respond to allegations of improper conduct and enforcement of disciplinary action;
- (7) audits and/or evaluation techniques; and
- (8) the investigation and remediation of systemic problems.

While some of these elements may not appear overly burdensome on their face, we urge CMS to consider both the expertise and resources necessary to implement the aforementioned elements as part of a physician compliance program. For example, a physician would likely have to retain outside legal counsel to craft and maintain written policies, procedures, and systems to identify, deter or respond to improper conduct; legal counsel and guidance would be necessary to avoid running afoul of state and federal law. Similarly, a physician would likely have to engage the services of a pre-employment screening company to perform background checks, and a human resources company to develop, teach, and maintain employee training programs. And, because most states do not require physicians to have a compliance program, most physicians would need to newly implement these core elements, creating a surge in demand for such services, and, likely, increased costs. **We urge CMS to consider the depth and complexity of the core elements of a physician compliance program in relation to their burden on most physician practices.**

In particular, we strongly urge CMS to consider the investment of resources and costs associated with comprehensive audits and evaluations. Generally, physician practices do not have the capacity to perform exhaustive audits themselves, or the funds to retain outside consultants to do so. We note the approach taken by the OIG in the “OIG Compliance Program for Individual and Small Group Physician Practices,” issued in 2000. That guidance noted the “financial and staffing resource constraints faced by physician practices,” and suggested an approach to voluntary compliance programs for small physician practices. In particular, that guidance discussed internal reviews, or self-audits, that OIG believed physician practices could perform, given their limited resources. OIG suggested the use of data samples, or “snapshots,” of a very limited number of claims, to allow physicians to benchmark general trends within their practice. Specifically, that guidance recommended

“five or more medical records per Federal payor, or five to ten medical records per physician,” as a guide for a periodic audit. The AMA does not endorse the approach taken by OIG, which would be too onerous for many small physician practices. Rather, we point out that CMS’s proposed rule purports to go beyond even the OIG’s requirements. **We submit that, generally, audit requirements that may be appropriate for other health care providers are beyond the capacity of most physician practices, and request that CMS carefully review the burden on physicians if comprehensive audits were to be required as a core element of a physician compliance program.**

We are concerned that many physicians will have difficulty staying abreast of the myriad of new rules and regulations regarding program integrity, generally, and compliance program requirements, in particular. As program integrity becomes a central initiative in federal and state health care systems, we anticipate that additional requirements will be forthcoming. We suggest that the federal agencies with jurisdiction collaborate on a single resource for physicians seeking information on new program integrity regulations, including compliance program requirements. A detailed website, a hotline for questions, and supplementary notifications are all possible means of informing physicians of new program integrity regulations. **We ask that CMS delay the required implementation of physician compliance programs until an appropriate infrastructure is in place to educate physicians regarding new program integrity regulations.**

Finally, we ask that CMS consider the time and intra-office systems needed to implement a physician compliance program, and request that CMS allow for a multi-tier or step-by-step approach to implementation. To ensure that physicians are able to effectively implement each of the core elements of a compliance program, it is important that the process is not required to be completed in haste. Rather than mandate that every core element be instituted at once, with only sufficient time to satisfy the basic regulatory requirements, we suggest that CMS allow physicians to focus on one core element at a time, so as to allow for the attention that each requires.

CONCLUSION

We are committed to working closely with federal and state agencies to develop and implement program integrity measures that safeguard scarce federal health care dollars. The ACA confers CMS, state agencies and federal and state law enforcement with significant new authorities and greatly expanded resources. We strongly urge CMS to continue the collaboration with organized Medicine it has initiated since the passage of ACA to ensure that the new requirements and changes do not cast the net so wide as to entangle honest and legitimate physicians, exacerbate physician shortages, interrupt physician-patient relationships, or impose crushing administrative burdens and costs on small physician practices. While the AMA appreciates that none of the foregoing outcomes are intended by state and federal health programs and law enforcement, we know that the rapidly evolving health care regulatory environment has the potential without stakeholder input to do all of the

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foregoing. The AMA appreciates this opportunity to provide our views on these critical issues, and we stand ready to work with CMS to achieve resolution in each of the foregoing matters. Should you have any questions on this letter please contact Mari Savickis at mari.savickis@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA