



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

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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

Dear Dr. Berwick:

In response to President Obama's January 18 executive order aimed at reducing federal regulatory burdens, the American Medical Association (AMA) asked our member organizations and surveyed individual physicians to identify the most burdensome regulations they deal with along with any recommendations for how the regulations could be improved upon. More than 2,000 physicians and many medical specialties responded with a long list of suggestions dealing primarily with Medicare. Unfunded federal mandates, elimination of Medicare payment for physician consultations, and incompatible and inconsistent quality initiatives topped the list. Survey findings are catalogued and discussed in more detail below.

UNFUNDED MANDATES

Over the years, Medicare has demanded that physicians take on a panoply of duties aimed at achieving social justice and protecting Medicare from potential fraud by other providers. While these requirements generally have laudable goals, costs frequently exceed benefits and are simply unrealistic in a program which fails to recognize the cost of practice changes implemented after 1973 and which threatens physicians with cuts of nearly 30 percent next year. Because of the broad nature of the care they provide, the primary care physicians you and the President have pledged to support to protect are particularly disadvantaged by these mandates. Three out of five physicians responding to our survey put this at the top of their list of regulatory grievances and provided a number of examples, including:

- ***Translators:*** Since 2000, physicians have been required to provide translators for Medicare and Medicaid patients with hearing impairments or limited English proficiency. The AMA agrees that physician-patient communications are critical to good health care and we have a number of initiatives underway to improve communications. We also recognize that the Centers for Medicare and Medicaid Services (CMS) did not promulgate this regulation and that it does not apply when a physician participates only in Medicare and not in other programs such as Medicaid where government payment is direct to the provider rather than assigned by the patient. It affects a large number of physicians, nonetheless, and consequently has significant implications for both Medicare and Medicaid patients.

An AMA survey at the time this guidance was issued revealed that costs of \$150 or more for translator services were not uncommon and that the price of these services frequently exceeded the physician's payment for the visit where they were provided. Yet neither Medicare nor Medicaid compensates physicians for the translators and the physician also cannot bill patients even when they cancel the visit on short notice. With Medicare payments that today are only 3 percent higher on average than in 2001, the cost of these services is a significant hardship that discourages physicians from participating in Medicaid and/or practicing in areas with large minority populations. We note that Medicare Advantage plans are required to cover the cost of translator services for their enrollees and we believe that **CMS should also allow interpreters to bill Medicare and Medicaid for translator services and if applicable treat this as a change in law and regulation for purposes of the physician payment update formula.**

- ***Drug Plan Authorizations:*** Despite their ongoing support for Medicare drug coverage, physicians have many complaints about associated burdens, including formulary changes and time-consuming pre-authorization requirements of drug and Medicare Advantage plans. A separate AMA survey found that drug pre-authorizations also delay care with 69 percent of physicians waiting several days for approval and 10 percent waiting more than a week. Suggested improvements include: **(1) requiring plans to pay physicians for prior authorizations that exceed a specified number or that are not resolved within a set period of time; (2) prohibiting repeated prior authorizations for ongoing use of a drug by patients with chronic disease; (3) prohibiting prior authorizations for certain standard or inexpensive drugs; and (4) enforce the requirement that plans use a standard form.**
- ***Emergency Medical Treatment and Labor Act (EMTALA):*** Over the years, expansion of the requirements of this act beyond its original intent have increased the financial and legal liability for providing emergency care to poor and uninsured patients, reduced physician on-call availability and reportedly contributed to closures of some emergency departments and trauma units. Now, CMS is considering another expansion to inpatient hospital units and hospitals with specialized capabilities. As we have previously communicated, the AMA believes such a move is unwarranted and counterproductive and we strongly urge **CMS to work with hospitals and physicians to find alternative strategies to protect against inappropriate discharges and transfers.**
- ***Documentation and Certification:*** The vast majority of physicians are honest people who want to take care of patients and have little time to waste on unnecessary administrative details. A significant number of survey respondents identified Medicare documentation requirements as a major imposition that delays care with redundant requirements for verifying physician orders and voluminous medical records where the salient patient information is buried in reams of purposeless, formulaic language.

To make matters worse, Medicare is not content with requiring physicians to over-document what they themselves do. Now, they are also expected to keep other providers honest by certifying and recertifying the need for virtually any other service the patient requires—from power wheel chairs, to repeat orders of glucose strips or diapers for patients with chronic ongoing conditions, to physical therapy plans, home health and hospice services.

What is needed is a more targeted approach that focuses on the individual providers who are repeat offenders, who could be initially identified for government auditors through

contractor claims analysis rather than imposing “mother may I” certificates signed by physicians. In addition, CMS should reexamine its policies for recertifying orders items like glucose strips or diapers for patients with chronic ongoing conditions.

Recently, CMS responded to our complaints about several potential documentation and certification requirements by suspending a rule requiring physicians to sign every lab requisition and delaying another rule requiring documentation of a face-to-face physician visit as a condition of payment for home health services. The AMA greatly appreciates both of these decisions. As detailed later in this document, however, we do not think three months is an adequate lead time for implementation of major new program requirements and we are extremely disappointed that CMS has refused to further delay the home health requirement despite pleas from both beneficiary and provider groups.

Both of these requirements illustrate a troublesome tendency by Congress and CMS officials to impose new policing policies on physicians with inadequate timelines and little to no consideration of the need for such policies or the impact on physicians and patients. **It is our hope that CMS will reconsider its decision not to further delay the home health requirement and that in the future, imposition of policies such as the lab signature requirement would be discussed with the medical profession BEFORE they turn up in a proposed rule. In addition, CMS needs to significantly improve its education efforts for physicians.**

- ***Impact on the Medicare Economic Index (MEI):*** Each of these regulations has added to physicians costs as they are forced to hire additional types of staff, expand their information technology, and pay practice management companies, legal firms and billing services to keep up with the regulatory tsunami and adhere to the fine print of the Medicare law. None of these costs existed in 1973. Yet the MEI that purports to measure practice cost inflation includes only those inputs that were present at that time and therefore undervalues actual medical cost increases. Data from the Medical Group Management Association show an increase of 18.8 percent the number of people employed in physician offices between 1992 and 2002 and data from the Department of Labor shows a similar increase of 18 percent from 2001 to 2009. As a result, the MEI significantly understates the true cost of medical practice, registering cost increases of just 18 percent between 2000 to 2006 compared to the 79 percent growth indicated by AMA survey data. **In the 2010 physician fee schedule rule, CMS promised to examine the need for modernizing and increasing the MEI to reflect 21st century medicine. It is time to put that promise into practice and we stand ready to work with the agency in this effort.**

PHYSICIAN CONSULTATIONS

A second concern expressed by nearly half (48 percent) of those who responded to the administrative burden survey involves Medicare’s decision to prohibit the use of consultation codes in Medicare and force physicians to bill for these services with lower-valued visit codes. This puts Medicare at odds with the policies of most private payers and creates considerable confusion and administrative complications when physicians bill secondary payers for consultations. The policy also flies in the face of Health Insurance Portability and Accountability Act (HIPAA) administrative simplification provisions that require all payers to use a common set of codes based on the AMA’s Current Procedural Terminology (CPT).

As revealed in an earlier AMA survey conducted with 17 medical specialty societies, Medicare's elimination of payment for consultations also had far greater consequences for many physicians than CMS projected. Specifically, although the agency predicted that no specialty would see Medicare revenues fall by more than 3 percent, nearly three-quarters of the 5,500 consultation survey respondents (72 percent) had seen decreases of more than 5 percent, and 30 percent had seen a decline of more than 15 percent. This disconnect creates questions as to whether CMS has met the President's directive that "each agency must...propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs."

In promulgating this regulation, CMS also ignored the executive order's call for identification and assessment of "available alternatives to direct regulation." As a rationale for the new policy, CMS claimed that ongoing problems with the consultation codes were creating confusion and inappropriate use of the codes. This claim completely ignored a newly-adopted CPT "transfer of care" definition that was intended to address CMS' concerns and which was developed after two years of work by the CPT Editorial Panel, where CMS is a voting member. Ironically, the new CPT definition, a readily available alternative that CMS had appeared to find acceptable, took effect on the same day as the burdensome new regulatory policy.

As expressed in various communications to your staff (attached), we also believe that elimination of the consultation codes has highlighted differences between CMS' and CPT's definitions of a "new patient." Recovery Audit Contractors (RAC) audits related to this issue have exacerbated the problem and exposed errors in physician specialty data. Most important of all, our consultation survey indicates that the current policy has reduced Medicare patients' access to consultative services and threatens to undermine your goal of improving care coordination.

To date, CMS has rejected our concerns as "hypothetical." We submit that the views of 5,500 survey respondents should not be dismissed so lightly. **Payment for consultations should be reinstated, CMS should work with the AMA and other physician groups to address problems with its new patient definition, and RAC and other audits of new patient visits should be suspended until this work is completed.**

INCOMPATIBLE INCENTIVE PROGRAMS AND COMPETING PRIORITIES

There are three incentive programs available to physicians today: Physician Quality Reporting System (PQRS), e-prescribing, and meaningful use of electronic health records (EHR). However, each program was created under separate laws and has separate reporting requirements. More than one out of five physicians in our administrative burden survey identified this as a problem and called on CMS to eliminate inconsistencies between the incentive programs. While physicians are eligible to receive incentives concurrently under PQRS and the EHR program or the PQRS and the e-prescribing program, they are not permitted to receive incentives concurrently under the e-prescribing and Medicare EHR programs. While these parameters are established in law, as are the years when penalties begin, there are many other issues where CMS has discretion that would permit great consistency among the programs. **For example, the quality reporting measures established under PQRS vary from those physicians must meet in order to be a "meaningful user" of a certified EHR under Stage 1. This is not required and we urge CMS to align the quality measure requirements for both of these programs to reduce the reporting burden on physicians.**

Another significant issue lies with the e-prescribing incentive program and the EHR program. While the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which established the e-prescribing program calls for penalties to begin in 2012, CMS decided to require physicians to report data from the first six months of 2011 rather than 2012 data in order to avoid a 2012 penalty even though no specific reporting period was named in the law. Because the decision to use 2011 data was announced in a physician fee schedule final rule in November of 2010, there was virtually no time to educate physicians on this unexpected requirement. In addition, the policy presents a significant problem for those physicians who planned on waiting until 2012, the second year of the Stage 1 EHR program, to purchase a comprehensive EHR. In essence, many of these physicians will be forced to purchase a stand-alone e-prescribing system in 2011 simply to discard it for a complete, certified EHR in 2012 just to avoid an e-prescribing penalty. Further, CMS' own outreach and education for the past year made it clear that physicians were not permitted to participate in both the e-prescribing and EHR programs so many physicians continue to believe they may only participate in one of these programs when in fact they must participate in both simply to avoid an e-prescribing penalty. We recognize that CMS is reviewing some of these concerns and strongly urge you to: **1) establish an additional reporting period in 2012; 2) extend the current 2011 reporting period through the end of the year; 3) establish additional exemption categories; and 4) establish a better mechanism for recouping money based on penalties rather than applying the 1 percent cut to physician's Medicare reimbursement by using separate payment schedules and limiting charges reflecting the application of the penalty.**

In addition, we cannot overemphasize the importance of considering the aggregate impact of the unprecedented scope of changes physicians are being ordered to absorb over a very short period of time. Provisions of one law have not even been implemented before additional requirements are mandated in the next one. Along with the ACA provisions, physicians are coping with earlier mandates, including most notably the upcoming Health Insurance Portability and Accountability (HIPAA) deadlines for 5010 on January 1, 2012 and ICD-10 on October 1, 2013. To date, there has never been a return on investment for physicians for the implementation of any HIPAA administrative simplification requirement. The human and technological investments needed to participate in quality incentives are competing for physician time and resources needed to move to an enormous new set of diagnosis codes in ICD-10. The struggle to keep up leaves little time to get engaged in the practice redesign and payment and delivery reforms envisioned in the ACA and detracts from patient care just as the ACA is promising access to millions of uninsured Americans. **We strongly urge the Administration and CMS to carefully consider the impact the collision of these compliance deadlines will have on physicians, patients and the ACA's promise of better care for more people.**

INCONSISTENT AUDIT POLICIES

We ask CMS to consider that physicians are already subject to claims review by multiple contractors including Medicare Parts A and B (FFS) RAC Medicare Administrative Contractors (MAC), Medicaid Integrity Contractors (MIC), Comprehensive Error Rate Testing Contractors (CERT), and Zone Program Integrity Contractors (ZPIC). In addition, physicians will soon be subject to Medicaid RAC audits. These audits, identified as a problem by 19 percent of our survey respondents, present a paramount example of the redundant, inconsistent or overlapping administrative burdens that President Obama's recent executive order asked CMS to identify, streamline, and, if appropriate, repeal. At the very least, the regulations that control these programs should be coordinated to maximize net benefits.

CMS recently issued a proposed rule on Medicaid RAC audits. During the RAC Medicare pilots, the AMA worked extensively with CMS to reduce the burden and to ensure that the RAC program was equitable. CMS' proposed rule on Medicaid RAC did not reflect these improvements.

Also, in the event that CMS requires Medicare Parts C and D RAC to conduct claims review similar to the model already employed by the Medicare FFS RAC program, **we urge the agency to establish clear criteria and require Medicare Parts C and D plans to compensate physicians for the office staff time required to pull, review, copy, and re-file medical records, as well as photocopying and postage charges. Further, we ask CMS to utilize notices that ensure that physicians can identify the entity that is requesting information, the reason for the request, and the reason for any deadline that is given for responding to the request. Lastly, we urge CMS to implement policies in the Medicaid RAC program which are consistent with the Medicare RAC audits.**

ADMINISTRATIVE SIMPLIFICATION

Section 1104 of the ACA contains several administrative provisions that require the implementation of standards and operating rules for the electronic exchange of information. They are intended to reduce the burden physicians and other stakeholders face with billing and other administrative health care functions and would address: patient eligibility and financial responsibility; timely acknowledgment, response, and status reporting to support a transparent claims and denial management process; and the unambiguous description of administrative data such as reasons and remark codes that tell a physician when a service has been denied and why. The law also specifically calls for promulgation of rules for a unique health plan identifier, electronic funds transfer, and claims attachments. Taken together, the standards and operating rules, if adopted appropriately, have a significant potential for reducing the administrative complexity physicians face today in the claims processing cycle.

Repeatedly, physicians have asked for more streamlined approaches to getting all the information they need, when they need it, to process claims. **One area, for example, where CMS has the latitude to create a far more workable process for physicians is with the unique health plan identifier (HPID). This requirement stems from HIPAA, which was passed in 1996, but there is still no HPID.** Without an HPID, physicians still do not get the information they need to process claims in the most efficient manner due to the fact that the term "health plan" can mean different things to different entities. Today there are numerous entities acting in the health plan role, and without a unique health plan identifier that clearly informs the physician which role each entity is playing, the physician is left scrambling to identify the health insurance product. The reason this is so important is that this information helps them understand the identity of the health insurance product/benefit in force with a specific patient, which in turn gives them the information necessary to determine a patient's eligibility for benefits, deductible amount, co-insurance percentage, prior authorization requirements, and the patient's in or out-of-network status. **If implemented by HHS with the needed level of granularity, the complexity in determining this information will be reduced significantly for physicians. Furthermore, a more streamlined health care billing system has the potential to result in significant costs savings.** The costs of health care billing, payment and claims reconciliation process are high. For instance, the costs associated with verifying eligibility and benefits alone are estimated at \$2.3 billion per year, and studies have indicated that as much as \$210 billion could be saved through standardization and simplification of the health care billing, payment and claims reconciliation process.

Another area ripe for streamlining is the National Correct Coding Initiative (NCCI) edits which Medicare has used for years and the ACA extended to state Medicaid programs. Because it is transparent,

downloadable and free, the NCCI offers a vast improvement over inconsistent, constantly-changing black box private payer edits that make it costly and nearly impossible for physician offices to reconcile their claims payments. However, the AMA is deeply concerned that CMS' current plan for implementing NCCI in Medicaid will result in the use of two different NCCI edit contractors. This is likely to lead to inconsistencies between Medicare and Medicaid, further complicate a landscape that is already littered with competing claims edit programs and subvert the ACA's and the President's goal of administrative simplification. **We firmly believe that a single contractor should oversee both edit programs and we believe it is critical that there is consistency among the programs. Anything less than that will create even more administrative complexity with payer edits which already presents an onerous burden to physicians.** We also believe that a single contractor will provide efficiency to CMS.

MEDICARE ENROLLMENT PROCESS

Over the past few years, physicians have experienced tremendous problems with CMS' enrollment program. These difficulties have led to serious cash flow disruptions for many practices. Some 12 percent of our administrative burden survey respondents found this to have been a problem and one physician told us it "took me eight months to get a Medicare number. I still haven't been paid and will have to take bankruptcy soon." In fact, according to CMS' own Provider Contractor Satisfaction Survey, physicians' experience with the Medicare enrollment process has ranked at the bottom and essentially amounts to a score of "C-." Enrollment has perennially been an area where CMS contractors have struggled to implement agency changes with limited resources and within artificially short deadlines.

We fully recognize and appreciate the recent steps the new Administration has taken to mitigate and correct some of these concerns. We also recognize that these problems were not created overnight, nor will they be solved overnight. Nonetheless, physicians continue to express serious concerns with the overall process finding it extremely burdensome and time consuming. In many cases physicians wait months longer than the time allocated the contractors to have their applications processed resulting in financial hardships for their practices. Also, in many cases when physicians are informed they are missing information, they submit it only to have it lost by the contractor. **We believe that the past volume and frequency of changes made to the enrollment process by CMS have made it hard for the contractors to keep up.**

We appreciate that CMS has indefinitely postponed the requirement stemming from ACA which calls for all physicians who refer or order services to be enrolled in the Provider Enrollment, Chain, and Ownership System (PECOS) so that CMS has the adequate time to work with the contractors to the above referenced problems and to streamline the PECOS process. We also strongly support CMS' decision, in creating more robust enrollment requirements also pursuant to ACA, to place physicians in the lowest risk tier. The vast majority of physicians are honest and law abiding, and 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. We remain concerned, however, with the decision to subject physician suppliers to more intense screening, which could include fingerprinting and background checks, as well as a screening fee of \$505. **To the best of our knowledge, the vast majority of physician suppliers do not pose an increased program integrity risk and absent any evidence to the contrary, we urge CMS to move physician suppliers to the lowest risk tier and remove the application screening fee.**

We furthermore appreciate CMS' decision not to place physicians who have been the victim of identity theft in a higher risk tier and instead to place them in the lowest risk tier. **We continue to urge CMS and**

other agencies with jurisdiction to create a single ombudsman to guide physicians through the reporting process and assist them in reclaiming their identity.

PQRS FEEDBACK REPORTS

Section 3002(e) of the ACA requires the Secretary to provide timely feedback to physicians on their performance with respect to satisfactorily submitting data on quality measures. CMS has not taken any steps to implement this timely feedback requirement, and the AMA is disappointed that CMS' feedback program for 2011 is merely consistent with current practices, which are extremely problematic. Issuing feedback reports 7-10 months after the reporting period has ended is not timely. Physicians cannot improve their understanding of program criteria or participation in a timely manner when there is such significant lag time between participation and distribution of feedback reports. To be effective, reports must be distributed during the reporting period to allow physicians to assess their reporting and performance status, and if needed, revise their reporting practices to be a successful participant. These reports should be confidential and can be a first step toward promoting internal quality improvement within a practice and ensuring that physicians are reporting correctly early in the program. The reports should also provide physicians with actionable information on potential problems in their PQRS reporting.

We urge CMS to immediately implement this provision of the ACA. **Current practices are unacceptable and fall well short of the statutory requirement and intent; we urge CMS to take steps to ensure that the feedback process improves successful participation in the PQRS program, as is intended by section 3002(e).**

EDUCATION AND OUTREACH

In our significant experience with educating physicians about federal policies, the **AMA has found that it usually takes at least six months to adequately reach out and inform physicians about new requirements.** Lawmakers' growing propensity for cramming hundreds of program changes into massive legislative vehicles with retroactive effective dates and inadequate lead time has greatly complicated things for both CMS and physicians and we sympathize with the agency's struggle to provide adequate notice and education in the current environment. Nonetheless, the critical mass of regulatory change in any given year has become so great that something has to give. Keeping up with the swelling number of Medicare rules has become a full time job that is an enormous challenge even for large practices and can be almost impossible for smaller practitioners. The problem is compounded when, as has happened with increasing frequency, they are confronted with a host of new rules contained in a voluminous physician fee schedule rule published in November and effective on January 1 of the next year. A large number of physicians thus are completely unaware of the requirements because there has been so little opportunity to educate them before the requirement begins. Moreover, in many instances, details needed to implement the policy are lacking until well into the new year and in some cases new information comes out in a corrective regulation that never becomes widely available.

The consultation policy, lab signature and home health requirements mentioned earlier are good examples of policies where considerably more time to think through the potential problems and conduct outreach to physicians would have been appropriate. **Physicians in our survey also asked that CMS create more specialty-tailored list serves; be more selective about what it sends out on list serves; prohibit contractors from limiting the number of items that can be discussed in a single phone call; strive for**

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prompter replies to e-mail and phone queries; and provide more specific examples of proper documentation.

NURSING HOME PAIN MANAGEMENT

CMS regulations for skilled nursing facilities define as a Severity Level 4 consideration “Immediate Jeopardy to Resident Health or Safety for a resident with pain or potential for pain.” The facility can be judged to have not met the conditions of participation for Medicare if its noncompliance “results, or has the potential to result, in expressions (verbal and/or non-verbal) of severe, unrelenting, excruciating, and unrelieved pain; pain has become all-consuming and overwhelms the resident.” Long-term care medical directors are generally on-site at facilities for only a portion of each day, but severe or excruciating pain can emerge at any time. Until 2009, the standard practice if patients experienced severe pain when the medical director was not on-site was for the nursing staff to contact the physician and then transmit the physician’s verbal prescriptions to the facility’s pharmacy. In 2009, however, the Drug Enforcement Administration (DEA) suddenly began enforcing rules that require pharmacists to either have signed, written prescriptions or to orally confirm the prescription through direct contact with the DEA-registered prescriber. These enforcement actions have led to serious delays in dispensing urgently needed controlled substances. Delays in dispensing controlled drugs are causing needless suffering for long term care patients, including those in hospice care. Patients who are admitted to nursing homes to receive palliative care need to be able to count on getting that palliation, whether or not the severity of their pain has been accurately anticipated prior to their admission or during the physician’s face-to-face visit following admission. The conflict between the DEA and CMS regulations has persisted for two years now and is preventing the delivery of compassionate and high quality care. **The AMA urges CMS to work with the DEA to secure a change in the DEA policy to allow nurses at long term care facilities to act as agents of physicians in communicating with pharmacists.**

We appreciate CMS’ ongoing effort to listen to our suggestions or ways to improve the implementation of new Medicare policies and ease regulatory burdens on physician practices. If you have any questions on this letter please contact Sharon McIlrath, Assistant Director, Federal Affairs at: sharon.mcllrath@ama-assn.org.

Sincerely,



Michael D. Maves, MD, MBA

Attachment