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December 29, 2008

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1403-FC, Mail Stop C4-26-05
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Final Rule; 73 Fed. Reg. 69,726 (Nov. 19, 2008)

Dear Acting Administrator Weems:

The American Medical Association (AMA) appreciates the opportunity to provide our comments regarding *Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Final Rule*; 73 *Fed. Reg.* 369,726 (Nov. 19, 2008).

The AMA appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) physician payment final rule with comment period for calendar year 2009. We discuss below our views on various provisions in the final rule, including continued strong concerns with certain provisions, along with recommendations to address these concerns.

ESRD PROVISIONS: APPLICATION OF HEALTHCARE ASSOCIATED CONDITIONS TO OTHER SETTINGS

In the final rule, CMS continues to suggest that the Medicare non-payment policy for healthcare associated conditions (HACs) in the hospital inpatient setting could be applied more broadly to other Medicare providers, including physician practices, hospital outpatient departments, ambulatory surgical centers, skilled nursing facilities, home health care, and end-stage renal disease facilities.

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CMS acknowledged in the final rule that it received many public comments raising concerns about the HAC policy, as well as about extending this policy to outpatient settings, including physicians' offices. We are disappointed that CMS merely acknowledged these concerns in the final rule, and failed to take them into serious consideration. It is critical that CMS address these concerns, particularly because private payers are adopting this non-payment policy, thereby further compounding the complications raised by this ill-conceived policy. In an Office of Inspector General (OIG) of the Department of Health and Human Services report, *Adverse Events in Hospitals: Overview of Key Issues* (OEI-06-07-00470), the OIG found that HAC nonpayment policies are increasingly popular among payers, and that these policies have drawbacks and may "limit access to care, increase hospital costs, and reduce hospital revenues."

CMS held a listening session regarding the HAC policy on December 18, 2008, and is accepting comments on this matter through December 31, 2008. The AMA submitted extensive comments to CMS in response to the listening session. We summarize these comments below.

The AMA strongly opposes non-payment for HACs in the inpatient or in any payment setting that are not reasonably preventable through the application of evidence-based guidelines, developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies. Because the current inpatient HACs do not meet that criteria, we have grave concerns about this policy and about extending it to other payment settings, including physician practices.

Our main concerns with the HAC policy and its potential extension to physician practices are:

- **CMS does not have the statutory authority to extend the inpatient HAC policy to other settings, including physician office practices.** Under the Deficit Reduction Act of 2005, Congress specifically provided CMS with the authority to begin applying the HAC policy to the hospital inpatient setting. If CMS were to extend this policy to other settings, it would likewise need similar statutory authority granted by Congress.

- **In developing the HAC policy, CMS confuses events that should never happen in a hospital, like wrong-site surgery, with often unavoidable conditions, like surgical site infections.** Medical conditions covered by the HAC policy should be reasonably preventable through the application of evidence-based guidelines. To be reasonably preventable, there should be solid evidence that by following guidelines, the occurrence of an event can be reduced to zero or near zero. Yet, there is <u>strong, unequivocal disagreement</u> with CMS throughout the medical community that the conditions covered under the inpatient HAC non-payment policy are "reasonably preventable." The AMA continues to work aggressively to improve quality and

efficiency for patients, but simply not paying for complications or conditions that, while extremely regrettable, are not entirely preventable is not effective or good for patients or the Medicare program.

- **The HAC policy will increase Medicare spending on tests and screenings with questionable benefit to patients.** The HAC policy requires hospitals to ensure that certain medical conditions are not present on admission. To determine whether a condition exists when the patient enters the hospital will increase Medicare spending on tests and screenings with questionable benefit to patients. This could also delay needed care, with possible increased risk for patients due to the delay.

- **Expanding the inpatient HAC nonpayment policy to other settings would be extremely problematic, especially in physician offices, because the payment approach is completely different from the hospital setting.** For example, in the inpatient setting, Medicare denies the portion of payment associated with care complications when the complications are associated with a condition on the HAC list. However, there is no clear way to determine some portion of a physician's payment that would be denied due to presumed mismanagement of a reasonably preventable condition. The appropriate level of an evaluation and management service is based on the conditions managed at a given encounter and the time and intensity of the work associated with those conditions. Because the presence and severity of additional conditions present during the visit will vary greatly among patients, identifying and valuing the work attributable to a preventable condition managed by the physician at a visit would be very difficult.

  In addition, the lack of adequate risk adjusters is an even greater problem in physician practices than in hospitals because some physicians specialize in treating the riskiest patients and do not have the ability to make up for losses on these patients through care of patients with below-average risks. Further, patient compliance outside of the physician office setting would be extremely difficult to assess and monitor, which also could seriously hamper any risk adjustment techniques. **Since many factors outside of a physicians' control could cause a patient to acquire various conditions while under a physician's care, CMS should instead encourage compliance with evidence-based guidelines rather than extending the HAC policy.**

- **CMS should conduct an analysis of the current inpatient HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers. This analysis must occur before extending this approach to other settings.** It is unacceptable that CMS is considering expansion of the inpatient HAC policy when the agency has not yet conducted any analysis of: (i) the impact of the current HAC inpatient policy with regard to such concerns as: impact on the quality of care delivered to patients, especially in proportion to the additional costs to the Medicare program required to comply with the HAC requirements; (ii) the need for appropriate risk adjustment techniques; (iv) how to determine attribution issues

with respect to when, where and why a condition has occurred; and (iii) the reasonable number of expected incidences in which these conditions will occur in individual hospitals, especially with regard to high-risk patients, when evidence-based guidelines are followed.

It defies any logical rationale to extend an approach to other settings when it is not clear that the approach achieves its quality improvement goals and, in fact, may cost significantly more money in proportion to overall program benefits and delay or deny access to needed care for patients.

PHYSICIAN QUALITY REPORTING INITIATIVE

The AMA expressed strong concerns regarding implementation problems with the 2007 Physician Quality Reporting Initiative (PQRI) in our comments to CMS regarding the Medicare physician fee schedule proposed rule. We are extremely disappointed that CMS failed to address these concerns in the final rule.

According to CMS data, approximately 16 percent of physicians attempted to report on measures in the 2007 program, but only half of them received bonus payments. **Further, feedback reports and bonus payments were not disseminated until 7 months after the reporting period ended, well after this information could be used by physicians to correct reporting procedures for either 2007 or 2008.**

There is widespread confusion and no clear direction from CMS regarding why so many physicians were unsuccessful in reporting during the first year of the program. Without clearly understanding how physicians and eligible professionals can successfully report under the PQRI, it is nearly impossible to improve success rates. Yet, CMS is about to launch the third year of the PQRI program, and in the near future will make publicly available information about whether physicians' successfully participated in the PQRI. The AMA wants to help physicians succeed in participating in the PQRI, but as the program is currently operating, that is nearly impossible. CMS must make changes now to assist physicians in successful PQRI participation. In a November 2008 letter to CMS, the AMA set forth to CMS our 2007 PQRI concerns and recommendations. We have attached that letter to these comments, and we reiterate to CMS those recommendations, which relate to (i) early education and outreach to physicians and Medicare contractors; (ii) the need for interim and final confidential feedback reports; (iii) easier access to feedback reports; (iv) CMS relief in the absence of a formal appeals process; and (v) provision of the 2007 PQRI data set file to the AMA to better understand possible barriers and stimuli to physician reporting.

The letter also discusses the insurmountable hurdles to successful participation in the 2007 PQRI, as reported to the AMA in a September 2008 survey. **With such a troublesome start of the PQRI program, we urge CMS to further monitor and analyze the program to address and resolve ongoing problems before expanding it further.**

The AMA also is disappointed that CMS continues to lack transparency in the PQRI measure selection and implementation processes. CMS failed to include certain measures recommended by the AMA-convened Physician Consortium for Performance Improvement (PCPI) in the 2009 PQRI and certain measures will only apply to registry-based reporting. Yet, CMS did not adequately explain its rationale for not including these measures or limiting application of some measures to registries only. **We reiterate our comments on the proposed physician fee schedule rule urging CMS to ensure greater transparency in all aspects of developing the PQRI program, especially regarding the measure and implementation processes.**

We acknowledge that CMS is re-examining whether some participants might have been erroneously determined to be unsuccessful, and, if so, CMS will pay a bonus (in 2009) to these physicians and other eligible professionals for successful 2007 participation. We support CMS in this effort and look forward to working with the agency regarding our concerns about how and when these payments will be distributed.

PHYSICIAN RESOURCE USE FEEDBACK PROGRAM

MIPPA requires the Secretary of the Department of Health and Human Services to implement by January 1, 2009, a Physician Resource Use Feedback Program (Physician Feedback Program) using Medicare claims data and other data to provide confidential feedback reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. If appropriate, the Secretary may also include information in the reports on quality of care furnished to Medicare beneficiaries by the physician. CMS has already begun implementing Phase I of this program at pilot sites in Baltimore, Maryland and Boston, Massachusetts.

The AMA appreciates CMS's decision to phase this requirement in over a period of time beginning with a limited demonstration in Boston and Baltimore that CMS has previously stated will now to be expanded to 12 sites. We further agree with CMS that in the initial stages, participation in the demonstration should be voluntary and changes should be implemented through notices in the *Federal Register*. We look forward to continued progress reports and discussions with CMS and its Mathematica Policy Research contractor regarding the demonstration and the findings from the initial sites.

Many of the questions that CMS has posed in the final rule may be answered through the demonstration. In some cases—such as preference for paper versus electronic reports and/or the pros and cons of per capita versus per episode reports—the results may vary by location, size of practice, and physician specialty. Thus, even after expansion to the additional sites, further experimentation and/or flexibility with approach may be appropriate. As a result, we are reserving judgment on several of the questions posed in the rule and offer the following over-arching principles:

- **The Physician Feedback Program should be completely transparent.** For example, the software used to calculate physicians' resource use should be open public scrutiny. This ensures that the program is constructive and is accurately measuring appropriate indicators of physicians resource use. The current "black box" does not meet this criteria and is widely believed to discriminate against physicians with subspecialties that lead to treatment of patients with complex conditions and comorbidities for which the software does not adequately adjust. This limits the credibility of reports based on this software, and in the most egregious cases can penalize patients by requiring high copayments when they are treated by the very physicians who are most qualified to deal with their condition. Only with a more transparent process can the resource reports serve the end goals of educating physicians about resource use patterns and improving quality of care for patients.

- **In order to have a significant impact on physicians' practice patterns, feedback must be timely and easily accessible.** As demonstrated by physicians' extreme frustration with the PQRI's initial year, data that is 18 months old and takes hours of time to access creates extreme frustration, increases physician costs at a time when payments for many services already fail to cover costs, decreases physicians' ability and desire to make meaningful changes in their practices, and delays such changes unnecessarily.

- **Physicians should have the ability to verify the accuracy of physician feedback reports is in the Physician Feedback Program. This includes access to patient-identified data to determine whether patients have been appropriately assigned and/or whether various comorbidities or other extenuating circumstances that affect resource use have been identified and adjusted for in the software. Physicians must also have the opportunity for prior review and comment, along with the right to appeal and reconsideration.**

  As demonstrated by the CMS-funded Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Project, unless physicians can review and verify the accuracy of the data, physician feedback programs will not be actionable and meaningful for either patients or physicians. As part of a quality improvement organization (QIO) special project, the Delmarva Foundation for Medical Care piloted the BQI in six communities to test methods to aggregate Medicare claims data with data from commercial health plans and, in some cases, Medicaid, in order to calculate and report quality measures for physician groups and, in some cases, individual physicians.

  Shortcomings in the BQI Project have included problems with how to verify and accurately assign the quality reporting scores generated from the data. Much of the data generated from the six pilot-sites could not be reviewed for accuracy by participating physicians because CMS would not provide patient identification information to physicians to assist with verification of the data behind their scores.

Overall, quality reporting entities must be able to trust the data generated from quality reporting initiatives. **CMS must apply lessons learned from the BQI Pilots to the Physician Feedback Program. Specifically, active physician input is required if efforts are to be viewed as credible. Further, physicians must be able to review and validate the data behind the feedback reports, and request a reconsideration process if necessary. CMS must also provide physicians with patient identification information so that physicians can verify the data being used. This also advances the educational and quality improvement purposes of the program.**

- **The Physician Feedback Program must use a well-developed risk adjustment methodology.** Without adequate risk adjustment, the feedback reports cannot be meaningful or actionable. If, for example, additional resources are needed to deliver quality of care to a higher-risk patient, the data must be risk-adjusted to show proper resource use for that patient. Otherwise, the feedback reports could encourage patient de-selection for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics that make them less adherent with established protocols.

  Current risk adjusters do not generally adjust for factors such as obesity and smoking, and are not precise enough to identify certain complex patients. While the law of averaging may mitigate these weaknesses in payment systems applied to hospitals and health plans, they do not work as well at the individual physician level and have the potential to label physicians who specialize in treating the most difficult patients as inefficient. **To overcome these barriers, we urge CMS to fund research and consult with the medical community to identify and collect the data that will be necessary to develop risk adjusters that are meaningful at the individual physician level.**

  For the purposes of a pilot, data aggregated to the MSA or hospital service area may provide valuable lessons. **Yet, physicians should not be compared to unrealistic benchmarks that do not account for variation in resource availability and patient populations even within a given MSA or hospital service area.** In emergency rooms at the various hospitals in the Baltimore-Washington HSA, for instance, typical patients at a private hospital in upper northwest vary greatly from patients seen in some of the area's inner city hospitals. Education, income, diet, insurance coverage, and a variety of other features affect patient compliance and progress, and feedback programs should not expect to see the very same treatment patterns in both areas.

ENROLLMENT

The AMA urges CMS to place a moratorium on the changes to the physician enrollment, eligibility, billing, and appeals processes contained in the physician fee schedule final rule. The AMA is deeply concerned by CMS's decision to move forward

with significant changes to these Medicare processes in 2009. Our concern has only deepened as the country's rapid and ongoing economic downturn has been felt by physicians across the nation, particularly small practices. Over fifty percent of physician practices have five physicians or less. These practices, like other small businesses, are struggling to remain afloat and will remain extremely vulnerable for the foreseeable future as their access to lines of credit have disappeared. These small practices account for 80 percent of outpatient visits and their survival is inextricably tied to access and health care for Medicare's beneficiaries.

The sweeping changes in the physician Medicare eligibility, enrollment, billing, and appeals process seriously compromise the ability of any number of physicians even in the best of economic times to remain viable, but as the bottom has fallen out of the financial markets and the country is hemorrhaging job losses, these changes will be financially devastating for physicians impacted by these new rules. The consequences are not likely to be isolated nor limited. These changes come on top of serious existing problems stemming from the transition to the National Provider Identifier (NPI) number. We strongly urge the agency to consider the Administration's acknowledgment in the past month that all businesses (which obviously include small physician practices) face significant changed financial circumstances and an economic recovery is highly unlikely in the foreseeable future. **The precipitous deterioration in the economic environment, which magnify the adverse financial consequences of the implementation of these rules, combined with the current strains placed on the system following the transition to NPI, constitute "*good cause*" for placing a moratorium on these final rules.**

Strained Contractor Capacity: National Provider Identifier & Other Enrollment Changes

Even prior to the significant downturn in the economy, many of CMS's contractors were already strained beyond capacity and incapable of handling workloads. The transition to the NPI magnified these problems. Because Medicare was unable to appropriately match enrollment data with the new NPI numbers, countless physicians across the country—even those who have been enrolled for decades—are required to re-enroll in the program. This has further burdened an already backlogged process. It is troubling, given the systemic problems that have resulted from a series of changes that began in 2006 and have continued unabated through the NPI transition, that CMS is making even more changes, particularly in the current economic climate, rather than devoting its limited resources to the current problems at hand.

The AMA has repeatedly documented these problems for CMS, and weekly shares individual physician issues with the agency. CMS has made so many changes to the process that neither Medicare contractor staff nor physicians are able to keep up. In some cases, physicians have reported to the AMA that attempting to re-enroll during the

transition to the NPI was such a fruitless exercise that these physicians are no longer taking Medicare patients.[1]

In addition, the ongoing Medicare Administrative Contractor (MAC) transition has also exacerbated enrollment delays and communication problems. The consolidation of carrier workload and transition to MACs have increased the enrollment backlog. In turn these backlogs have contributed to customer service problems. The new contractors have inherited old problems, struggled to adequately train staff, and are unable to allocate a sufficient number of staff to enrollment and customer service because of limited resources. Physicians report having to wait several hours to get through on customer service lines. These overloaded customer service lines will receive even higher rates of use as the disposition of enrollment applications and the proper processing will have significant and far reaching financial ramifications for physician practices. While the volume of calls will, undoubtedly, increase, the resources to field such calls will remain static. We recognize and appreciate that CMS has increased the number of staff handling enrollment but, as evidenced by the continuing problems, more are needed.

Physician Financial Crisis: Current Economic Downturn

The existing enrollment application processing delays are contributing to serious cash flow problems for physicians. These problems have been amplified by the current economic crisis. Physicians are reporting that they are unable to secure revolving loans to help them while they await processing of their enrollment applications. This process can take several months during which time physicians who have been required to re-enroll due to NPI "matching" issues, have been unable to bill and thus receive reimbursement for services rendered to Medicare patients. As the availability of credit and revolving loans for small businesses has shrunk dramatically, there has been a pronounced increase in the number of physician practices reporting that they are unable to meet their payroll, are late on payroll taxes, cannot make timely mortgage payments, are unable to pay their liability insurance, and have had to stop paying other key bills like phone service. In addition to a recent account of financial difficulties faced by physician practices in California, Nevada, and Hawaii by the *Los Angeles Times*, the AMA has

[1] Since May, when the NPI became mandatory and physicians saw payment interruptions, the AMA has urged physicians to submit advance payment requests to their contractor. Unfortunately, all too often Medicare contractors are not aware of this option. Although CMS provided assurances to publicize widely the advance payment option, to date this has not happened. Only a handful of Medicare contractor websites contain any information about advance payments, and when some physicians requested an advance payment from their contractor, they were told this option does not exist. Even in cases where contractors are familiar with advance payments, many physicians are denied this option because they have not been billing in the past several months. Reportedly, the foregoing is a key criterion in establishing a physician's eligibility for advance payments. **Yet, the precise reason physicians are having cash flow problems is because they are unable to bill while they wait to become re-enrolled.**

learned that a growing number of physicians, especially in New York and Connecticut, are struggling financially.

Despite the foregoing serious and financially debilitating problems faced by physicians under the existing regulatory regimen, the final rule contains yet more sweeping changes to the enrollment, eligibility, and appeals process. Instead of easing the administrative paper work requirements and financial burdens that physicians are shouldering, these changes will create additional obligations and increase financial uncertainty and pressure on physician practices. While we appreciate that CMS has assured us that the changes will not be phased in until the Spring, we believe it is incumbent upon CMS: 1) not to adopt any of these changes until it is evident that there are no further backlogs: 2) that Medicare contractors are meeting the timeframes required for processing applications; and, 3) that the new internet-based PECOS web system is working free of glitches.

Retroactive Billing

The most draconian change in the final rule is the dramatically shortened timeframe in which physicians may retroactively bill the program once a physician is approved to participate in the Medicare program. In addition to creating significant financial risk for physicians, there is ambiguity as to what the actual final rule is since it is described in seemingly conflicted terms in the preamble and the comment section of the *Federal Register* notice.

Following successful enrollment in Medicare, physicians have up until now been able to submit claims up to 27 months. In the comment section of the final rule, it states that starting January 1, physicians will only be allowed to submit claims the later of: 1) the "date of filing" of a Medicare enrollment application that was subsequently approved by a Medicare contractor or; 2) the date they first began furnishing services at a new practice location. However, further in the comment section (and the language amending the relevant regulation) provide that the new enrollment requirements permit physicians to retrospectively bill 30 days prior to the filing effective date "if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries." (An expanded window for filing claims of 90-days is provided for physicians called to work in statutorily prescribed national disaster areas.) The rule must be clarified. Are physicians allowed to bill up to 30 days prior to the filing effective date? If yes, it is unclear what "circumstances" constitute those that "preclude enrollment" in advance of providing services to Medicare beneficiaries. The foregoing areas of ambiguity constitute "good cause" for placing a moratorium on the implementation of this new rule. While we adamantly oppose removing the 27 month retroactive billing period while the above outlined backlogs exist, should CMS elect to truncate the retroactive billing period, we strongly urge that at a minimum all physicians, irrespective of circumstance, be permitted to bill back as far as 30 days prior to their filing effective date.

The agency has good cause to not implement the modification to retroactive billing final rule for a host of additional reasons.

We believe the agency has good cause to not implement this final rule since the serious deficiencies of the existing enrollment process have not been remedied since it was issued. As outlined above, a significant number of physicians have experienced serious problems and barriers to enrollment. Physicians have experienced backlogs as long as 180 days over the past three years. Systemic issues such as poorly trained customer service agents and inadequate enrollment staff combined with ongoing changes to the process have contributed to delays in processing enrollment as well as large application backlogs. While this often led to financial stress and administrative burdens for physicians, the lack of additional resources for contractors means that existing problems will only increase.

Contractors frequently do no alert physicians to missing information. CMS requires contractors to alert physicians within 15 days concerning missing information. However, this requirement is frequently unmet and despite physicians' repeated attempts to obtain status information from CMS, their inquiries go ignored. Physicians can wait hours to speak to a customer service representative, or they are provided with misinformation. The contractors' customer service shortcomings have not been remedied since the final rule was issued and therefore good cause exists to not implement this final rule.

There is no evidence to suggest that the vast majority of physicians who apply to participate in the Medicare program do not meet key eligibility criteria prior to enrollment. The justification in the final rule for significantly truncating the retroactive billing timeframe is because, "it is not possible to verify that a supplier has met all of Medicare's enrollment requirements prior to submitting an enrollment application." This belies the current reality where physicians regularly submit enrollment applications that are rejected numerous times as a routine matter where, for the most, part it is likely that physicians have met the Medicare participation requirements and would have been approved had the enrollment process functioned properly. CMS has not presented any data or evidence to demonstrate that physicians who have been able until now to submit claims as far back as 27 months are not meeting Medicare's enrollment criteria prior to enrollment in the program. CMS has said, "that physician and NPPs must meet all State licensing requirements before Medicare can convey billing privileges," however, its unclear under what situations a physician would be practicing medicine if they did not meet these basic criteria.

This new rule will create a significant (and in some cases an insurmountable) barrier to entry for new practices. Because physicians as small business owners must pay for rent, salaries, and other expenses in order to become operational, many must obtain loans, financing, and lines of credit. The limitations on the time they may bill retroactively significantly hinders new practices and could serve as a barrier to entry into the marketplace. This requirement will be further magnified by the credit crunch. Some physicians have already reported being unable to secure credit lines to keep their practices afloat while Medicare resolves NPI / enrollment or MAC transition problems that preclude them from billing.

CMS contractors are not meeting the current paper processing requirements. CMS states in the final rule that the agency, "expect that Medicare contractors will fully process most complete Internet-based PECOS enrollment applications within 30 to 45 calendar days compared to 60 to 90 calendar days in the current paper-based enrollment process." However, the internet-based PECOS web was only recently rolled out in certain states and the performance of the new system has not yet been established. The PECOS web has been a long awaited system CMS has been promising for years and CMS has repeatedly represented that PECOS web will solve many of the problems with the current enrollment system. Yet, the agency asserts in the final rule that it does not "believe a change to the effective date of Medicare billing privileges has a nexus to the implementation of the Internet-based PECOS." Until it has been clearly established that PECOS web is running efficiently and is significantly ameliorating the current backlogs and other documented, physicians' ability to recover payments for care provided to Medicare beneficiaries cannot be ignored. Not surprisingly, CMS's own Provider Satisfaction Survey found that contractors received a dismal satisfaction score that averaged 4.23 on a 6 point scale for satisfaction with the enrollment process, also the lowest score for any of the topics surveyed. (See page 21, http://www.cms.hhs.gov/MCPSS/downloads/MCPSS_Report.pdf).

The final rule provides that the application filing date would be the date the contractor receives a signed enrollment application *that it is able to process to approval*. This could have disastrous financial consequences for physicians who routinely receive inaccurate or incomplete guidance from contractors or physicians whose contractor misplaces their original enrollment application and/or supporting documentation and requires the filing of a new enrollment application. In the past, this would create financial pressure, but the new rule will constitute a significant and substantial reduction in payment and also exacerbate tensions between physicians and contractors that have misplaced or otherwise provided inadequate guidance on the enrollment application process. These problems also will only grow because contractors: (i) do not meet application processing standards; (ii) have scored the lowest among all categories in the Medicare Provider Satisfaction survey, clearly demonstrating physician dissatisfaction with contractors; and (iii) the MAC transition is still underway, and more transition challenges lie ahead.

Enrollment Data

CMS states in the final rule that while the agency monitors contractor enrollment processing timeliness, the agency does not currently calculate an average length of time for initial enrollments, changes, and reassignments. The agency states that it will consider calculating the average length of time for initial enrollment applications, changes of information, and reassignments and making this information available to the public." For years the AMA has requested CMS make publicly available contractor specific data that provides information on how many enrollment applications are in the queue. CMS has never made this data available. Physicians are frequently informed by the contractor it could be months before their application is processed. To the extent that

the agency maintains that systemic enrollment problems are due to incomplete or incorrect submissions by physicians, public release of this data will provide much needed information on whether particular contractors have an inadequate enrollment capacity, or, if all contractors are starved of resources to meet the ever changing enrollment requirements.

Appeals Process and Denied Applications vs. Rejected Applications

CMS has said that they will deny rather than reject applications when information is missing. Contractors will provide physicians 30 days to supply the missing information. CMS states that by denying billing privileges for enrollment in the Medicare program or to establish a new practice location, rather than rejecting an enrollment application, physicians will be afforded appeal rights which will preserve the original date of filing the application. While we appreciate CMS has established an appeals process for denied applications which preserves the original date of filing an application, we are concerned that that the focus should remain on curing the actual problem of chronic enrollment backlogs and ensuring the communication between the contractors and physicians is strengthened, thereby averting the need to engage in a lengthy appeals process.

Voluntary Re-enrollment / Mandatory Revalidation

Pursuant to the April 21, 2006 final rule on enrollment, CMS stated physicians that enrolled in Medicare prior to 2003 (the time when the PECOS enrollment system went into affect) who have not completed a Medicare enrollment application since that time, may voluntarily re-enroll. CMS has said physicians who choose not to voluntarily come into compliance will be asked to do so through a revalidation process. CMS reiterated this in the final fee schedule rule. Once CMS initiates revalidation efforts, physicians will only be provided 60 days to respond to a contractor's request. Physicians who do not re-enroll or revalidate their information face revocation of their billing privileges. Despite the seriousness of the consequences associated with this requirement, CMS has done little to no outreach on this effort to communicate these requirements to physicians. While the agency considers publication of the April rule and the notice in the current rule to constitute sufficient, it is not. CMS must take reasonable steps to communicate directly with the medical community and make a reasonable effort to provide actual notice to individual physicians. Failure to provide such notice as matter of policy is neither reasonable nor an appropriate way to run a health care program that requires open communication. Furthermore, CMS should not institute any widespread revalidation effort until all backlogs are removed, the PECOS web system has been rolled out to physicians in every state, and it has been established that the new online system is working efficiently.

Reporting Requirements for Providers and Suppliers

The final rule includes more stringent reporting requirements for physicians. CMS now requires physicians to alert Medicare within 30 days of a: 1) change in ownership; 2)

final adverse legal actions, and; 3) change in practice location. Previously, physicians had 90 days to report changes. Failure of a physician to comply in 30 days can result in revocation of Medicare billing privileges and Medicare recoupments for overpayments from the date of the reportable change. Billing privileges could be revoked for no less than a year. Some exceptions apply in disaster areas. Many physicians are unaware they must report a change to Medicare within an allotted time. Publication of this final rule does not constitute outreach nor is it an adequate vehicle for communicating directly to physicians. This final rule will lock physicians out of the Medicare program including physicians who have done nothing wrong other than failing to report a change in a short time. This could lead to more physicians dropping out of Medicare and we urge CMS to allow physicians the current 90 days to report a change in ownership or practice location.

Oddly enough, while the agency indicates that it will recoup payments from physicians who move from a higher reimbursement geographic area to a lower one, it appears that Medicare is taking the position that it will not pay underpayments for physicians moving from a lower reimbursement area to a higher one. CMS has said physicians who move from less costly areas to areas where reimbursement rates are higher, they are not entitled to underpayments if the change in location is not filed. This is inconsistent with the law and is inconsistent with the agency's position on overpayments. No legal authority or rational basis was provided to support the distinction for recovering overpayments, but refusing to provide pay physicians for underpayments.

Revoking a Physician's Billing Privileges in Certain Situations

In the final rule, physicians convicted of felonies, license suspensions or revocations, or **no longer at the location contained on the enrollment application**, can have their billing privileges revoked immediately. In the case of physicians who have moved, many physicians may need more than 30 days to alert Medicare that they are moving. Furthermore, there are well-documented problems with the contractors losing information submitted by physicians and this alone substantiates the need for a 90 day reporting period, as is afforded for other changes. This requirement poses significant problems for physicians in good standing who aside from moving are in full compliance with Medicare's requirements. If they do not meet the 30 days however they are facing revocation and thus could be locked out of Medicare for a year. (According to June 27, 2008, final regulation on contractor determinations on enrollment, reenrollment and revalidations, failure to respond to a revalidation request may warrant a 1-year ban.) These are extreme penalties for what are easy to overlook change of address paperwork requirements, particularly when the agency's communication of these changes to physicians is particularly lackluster. And, this could also contribute to more physicians opting out of the program.

The foregoing changes to the eligibility, enrollment, and appeals process are ill-considered and timed. We strongly urge the agency to place a moratorium on these far reaching changes that will be imposed with no outreach or actual notice to physicians.

For the physicians caught up in the current administrative quagmire, these final rules will only further tax the rapidly evaporating resources they have to maintain their practices and meet their patient needs. The financial consequences for physicians are real. The current economic crisis and the dramatic deterioration in the business environment since the above final rules were finalized and issue, warrant decisive action by the agency to avoid further weakening of the health care infrastructure that physicians who serve Medicare patients provide.

COMPUTER-GENERATED FACSIMILE TRANSMISSIONS EXEMPTION

We agree with CMS' decision to reinstate, on January 1, 2009, the exemption for computer-generated facsimile transmissions in its entirety from the requirement to use the NCPDP SCRIPT standard in transmitting prescriptions or prescription-related information. Allowing prescribers and dispensers to continue to transmit prescriptions or prescription-related information by means of computer-generated facsimiles will enable the ongoing adoption of e-prescribing without significantly impeding existing prescription workflows at both the prescriber and dispenser ends. CMS has decided to eliminate the exemption for computer-generated facsimiles in all instances other than transient/temporary network transmission failures when the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA) e-prescribing program disincentives take effect on January 1, 2012. **We recommend that CMS assess whether the 2012 sunset of the computer-generated facsimile transmissions exemption is appropriate or whether the deadline should be further extended.**

E-PRESCRIBING INCENTIVE PAYMENT PROGRAM

MIPPA authorizes a new incentive program that begins on January 1, 2009 for eligible professionals who are deemed to be successful e-prescribers. Given the limited adoption and use of e-prescribing by physicians and other health care professionals who prescribe medications, we strongly recommend that CMS undertake an aggressive education and outreach program for physicians on the e-prescribing reporting requirements so that physicians can take advantage of the incentive program as soon as possible. **Given recent experiences with the PQRI, we recommend that CMS provide interim feedback reports and an appeals process to ensure that physicians who make a good faith effort to report on e-prescribing receive incentive payments. We urge CMS to establish an Advisory Panel, comprised of both public and private stakeholders, to closely monitor e-prescribing adoption rates and the capabilities of the NCPDP SCRIPT standard with respect to all prescribers and dispensers, to provide solutions for further facilitating and encouraging the rapid adoption of e-prescribing, and to provide a recommendation for the timing of lifting the computer-generated facsimile transmissions exemption.**

ASP ISSUES

Medicare Part B covers a limited number of prescription drugs and biologicals (hereafter both referred to as drugs) that are physician administered. The AMA is deeply troubled that many physicians, particularly those in small practices and certain specialties, already facing financial strain as a result of the economic turmoil roiling the country will not recover all of their acquisition, inventory and carrying costs for Part B drugs. As finances in these offices become increasingly strained, particularly in light of the changes to enrollment, eligibility, and appeals, outlined in this letter, the capacity of physicians to continue to absorb even small loses on Part B drugs will evaporate. We urge CMS to consider again more fully the comments and data we cited in our comment letter to the proposed rule.

We noted that in addition to small practices, according to MedPAC, certain specialties have been particularly hard hit, including oncologists, urologists, and infectious disease specialists by the current payment methodology. MedPAC reported urologists and infectious disease specialists provided fewer physician-administered drugs in their offices in 2005 than in 2004. Physicians, particularly oncologists, report spending considerable time and staff resources seeking to secure patients' drugs at ASP payment rates. The foregoing remain unchanged, but the consequences and impact are growing as practices are experiencing financial difficulty.

Our concern is only heightened by the failure of the Competitive Acquisition Program (CAP) for fiscal year 2009. CAP was an alternative program to payment for Part B drugs under ASP. For some physicians who are not in the position to face the financial risks associated with ASP CAP was a lifeline, albeit for a very small number of physicians given the inflexibility and copious administrative requirements of the CAP program. **We strongly urge CMS to invoke all administrative authorities and exercise its discretion to protect physicians who administer Part B drugs—many who are struggling to maintain access for their patients.**

CAP ISSUES

As required by Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), in 2005 CMS developed and implemented the Competitive Acquisition Program (CAP). CAP was designed to be an alternative to payments based on the ASP plus 6 percent. CMS was not able to secure the participation of a CAP vendor for fiscal year 2009. As a result, the CAP option is not available to physicians. In light of the collapse of CAP, CMS seeks comments concerning CAP including any on the procedural changes that may increase the program's flexibility to potential vendors and physicians. We urge CMS to consider again the previous comments that the AMA submitted concerning administrative barriers to physician participation. We have commented extensively on how the CAP program has proven to be overly restrictive and administratively burdensome.

We had previously strongly urged CMS to exercise its discretion to allow physicians to transport CAP drugs including to satellite offices or to administer to patients in their

homes or other placements because the prohibition is overly restrictive and has an adverse impact on rural clinics and other physician satellite offices in underserved areas. **It would be reasonable and sufficient for physicians to certify that drugs will "not be subjected to conditions that will jeopardize their integrity, stability or sterility while being transported" and the appropriate steps will be taken "to keep transportation activities consistent with all applicable laws and regulations."** We believe any additional requirement laid out in regulation will only create additional administrative burdens with little attendant benefit.

As other commenters noted during the prior rule-making process, physicians and their staff are knowledgeable and capable of ensuring the proper transport and maintenance of the covered drugs. **We urge the agency to require CAP vendors to allow those physicians who elect to transport CAP drugs (and file the necessary certification described above) to do so.** This takes on particular importance where there is only one vendor. If a CAP successor is not willing to voluntarily allow physicians to transport the covered drugs, then physicians cannot shop around to find a vendor who will permit such transport. The end result is the same: physicians in underserved and rural areas are likely to be the most adversely impacted. CMS should take steps to ensure that a physician's ability to provide necessary care is not impaired, because such a restriction is a significant deterrent to greater physician interest in the CAP as an alternative to ASP.

In addition to the foregoing, we incorporate by reference the August 2007 comments that we previously offered to CMS concerning needed flexibility in the CAP program. The August letter contained recommendation concerning the post-payment review process used in CAP, the transportation of CAP drugs, CAP election agreements, and contractual provisions with CAP vendors, among others issues. All of these recommendations would provide much needed flexibility to CAP and likely produce greater physician participation.

MIPPA UPDATE TO PHYSICIAN CONVERSION FACTOR

In the final rule, CMS implemented section 131 of MIPPA, which provided a 1.1 percent increase to the calendar year 2009 physician conversion factor. **We applaud CMS for using the 2008 conversion factor as the base rate for the 1.1 percent increase in 2009.** We believe this fulfills the statutory intent, as Congress clearly stated that the 1.1 percent is intended to be consistent with Medicare Payment Advisory Commission's recommendation of a 1.1 percent physician update to the 2008 conversion factor. Further, use of any earlier base year in establishing the 2009 update would have inherently built in a payment rate cut that Congress intended to avoid.

POTENTIALLY MISVALUED SERVICES UNDER THE PHYSICIAN FEE SCHEDULE

CMS had requested that the RUC review potentially misvalued CPT codes, including a review of: (i) the fastest growing procedure codes; (ii) Harvard-valued codes; and, (iii)

practice expense RVUs. The RUC has aggressively reviewed nearly 500 potentially misvalued codes since October 2006, and has made recommendations to CMS concerning many of these codes. **We appreciate that CMS has accepted all of the RUC's recommendations for reduced payments for services reviewed as misvalued in 2008. The RUC is continuing its review of potentially misvalued codes and we hope that recommendations from future reviews will achieve the same result as the 2008 RUC recommendations. Further, in the final rule, CMS raised concerns relating to the RUC's methodology in reviewing these codes. We urge CMS to work with the RUC in addressing these concerns.**

MISSING CODES

CMS has identified various codes that it has apparently mistakenly not included in SGR calculations going back in some cases to 1998. CMS announced in the final rule that it will revise SGR actual spending to reflect spending on these codes. It is ironic that CMS finds it has the authority to retroactively revise SGR calculations to account for these codes. Yet, CMS has repeatedly declined to revise SGR calculations to retroactively remove spending on physician-administered drugs on the basis that CMS does not believe it has the authority to do so. The AMA has provided sound legal analysis showing that CMS has the authority to remove these drugs from SGR calculations back the SGR's base year. We urge CMS to exercise its authority to remove physician-administered drugs from SGR calculations back to the base year, just as CMS has done with respect to the missing codes.

The AMA appreciates the opportunity to provide our views on these critical issues, and we look forward to working with CMS to achieve consensus in moving forward on the foregoing matters.

Sincerely,

Michael D. Maves, MD, MBA