



December 29, 2008

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-FC; CMS-1270-F2
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Final Rule [Docket Nos. CMS-1403-FC; CMS-1270-F2]: 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; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule

Dear Mr. Weems:

The Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) write to address several issues raised by the Centers for Medicare and Medicaid Services (CMS) Physician Fee Schedule Final Rule for Calendar Year 2009.

IDSA represents over 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the U.S. and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms and new and emerging infections, such as severe acute respiratory syndrome (SARS) and influenza. Housed within IDSA is HIVMA, which represents more than 3,600 physicians working on the frontline of the HIV/AIDS pandemic. HIVMA members conduct research, administer prevention programs and provide clinical services to individuals with HIV disease. Together, IDSA and HIVMA are the principal organizations representing ID and HIV physicians in the United States.

While the Final Rule seeks to implement many of the provisions included in the 2009 Physician Fee Schedule Proposed Rule [Docket No. CMS-1403-P], it goes farther. Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA) earlier this year. The final rule seeks comments on many of the MIPPA-related provisions; including a requirement that CMS develop a plan to transition to a value based purchasing (VBP) program for physicians and other professional services. Efforts to transition from pay-for-reporting to pay-for-performance as well as plans to publicly report physicians' quality and efficiency data are among a few of the VBP initiatives currently being considered by CMS staff. Given the

need for further discussion of these initiatives, IDSA and HIVMA commend CMS for its decision to invite all affected stakeholders to a VBP Listening Session earlier this month. We are hopeful that this listening session was the first among many Agency efforts to seek stakeholder input followed by rigorous testing and analysis of individual VBP initiatives.

IDSA and HIVMA continue to support efforts to establish an exception to the physician self-referral prohibition that would allow incentive payments and shared savings program under Medicare. Given the extended comment period for this provision, IDSA and HIVMA will respond to CMS' request for additional information in a separate letter.

At this time, IDSA and HIVMA will comment on the following issues raised by the final rule:

- Application of the Hospital-Acquired Conditions (HAC) Payment Policy for IPPS Hospitals to other Settings.
- Physician Quality Reporting Initiative (PQRI): Decision not to finalize the measure group or the claims-based reporting option for the HIV measures.
- E-Prescribing Incentive Program: Comments on Eligibility Requirements
- Physician Resource Use Feedback Program: Requests for comments on how best to implement physician resource use feedback reports.
- Competitive Acquisition Program (CAP) for Part B Drugs: Decision to postpone the Program and request for additional comments or suggested changes that will make it more viable in the future.

APPLICATION OF THE HAC PROVISION IN THE PHYSICIAN OFFICE SETTING

In the Final Rule, CMS reiterated its interest in applying the Hospital-Acquired Conditions (HAC) Payment Policy to other settings of care, including physician practices. While the Agency acknowledges that such a move would require additional statutory authority, it appears increasingly likely that the Congress will consider an overhaul of the Medicare payment systems that would, among other things, expand the reach of the HAC provision to other settings.

IDSA and HIVMA continue to believe that CMS should first conduct a retrospective analysis of the impact of the current HAC payment policy before working with Congress to expand its scope to other settings. Additionally, a thorough prospective analysis of the challenges inherent with implementing an HAC-like provision in other settings should be conducted before moving forward. Such analyses should also demonstrate improved quality and efficiency of care resulting from application of the HAC provision.

A sound risk adjustment methodology is critical before implementing the HAC provision to other settings. This is especially true in the outpatient setting where patient compliance, socioeconomic status, a supportive family unit, and other factors beyond physicians' control

may influence the effectiveness of prescribed treatments. Examples of infectious diseases where these factors might lead to poor outcomes include HIV/AIDS and Hepatitis C.

Moreover, there is currently no cost effective way for providers in the outpatient setting, including the physician office, to distinguish between healthcare-acquired versus community-acquired conditions. While most hospitals may be able to absorb the cost of performing pre-admission tests for present on admission conditions, this is not the case for small and medium sized physician practices. Multiple years of stagnant or reduced Medicare payment updates have already forced many physicians to lay-off staff, reduce services, or stop accepting Medicare beneficiaries.

Perhaps most troubling, CMS proposes to require providers who “failed to prevent the occurrence of a preventable condition in one setting to pay for all or part of the necessary treatment in a second setting.” Taking application of an HAC-like provision to this extreme could be the “straw that broke the camel’s back” with respect to the survivability of many physician practices. Not only would applying the HAC provision in this fashion prove extremely costly to some providers but it also would be grossly unfair. Given that a team of providers is often responsible for treating Medicare beneficiaries, including those with serious infection, it is virtually impossible to attribute the occurrence of preventable conditions to specific providers. Even assuming that an appropriate attribution methodology could be devised, a serious and negative unintended consequence could be the emergence of a culture of mistrust in the medical community as individual providers reverse trends to coordinate care and work in medical teams for fear of being penalized for their colleagues’ mistakes.

If CMS remains intent on moving forward with application of an HAC-like provision to other settings, it should consider adjusting payments based on rates of risk-adjusted complications rather than implementing a zero tolerance policy. However, for the reasons stated above, **IDSA and HIVMA continue to urge the Agency to exercise caution and to carefully consider the implications and unintended consequences of applying the HAC provision to other settings, particularly physician practices.**

PHYSICIAN QUALITY REPORTING INITIATIVE

IDSA and HIVMA recognize CMS’ efforts to include additional reporting options and quality measures in the 2009 Physician Quality Reporting Initiative (PQRI) in an attempt to increase participation among eligible providers. However, the old adage that “more is not always better” may be relevant given the multitude and complexity of the PQRI reporting options.

Physicians and their staff will have little time to analyze the various reporting options to determine how best to qualify for the 2.0 percent incentive payment under the PQRI. This is especially the case given CMS’ inability to release the 2009 PQRI Measure Specifications prior to December 16th. While speciality societies can help with education and outreach to their members, these efforts will go only so far given the complexity of the available reporting options combined with the Agency’s decision to limit the number of reporting options available to certain measures.

IDSA and HIVMA are disappointed that CMS decided not to finalize the claims- and group-based reporting options for the four HIV/AIDS measures. This decision means that eligible providers who choose to report on these measures must pay to submit quality data through a “qualified” registry under the PQRI. In explaining its decision not to finalize the HIV/AIDS measures group, the Agency stated “*while these are meaningful individual quality measures, we believe that the issues as stated make it impractical to use these measures as measure groups.*” **IDSA and HIVMA respectfully request that CMS officials further clarify their decision to limit the HIV/AIDS measures to one reporting option.**

ID physicians are primarily recognized for their roles as inpatient consultants and infection control practitioners. The expertise ID physicians’ bring to these roles is crucial to managing the treatment of highly complex immune-compromised patients, such as those with multiple chronic conditions or organ failures, and in reducing the prevalence of hospital-acquired infections. Unfortunately, CMS appears completely disinterested in pushing for the development of physician-level accountability measures for the inpatient setting. **Such measures should be a priority for CMS and measure developers especially given the renewed interest in gainsharing arrangements between hospitals and physicians as well as efforts to increase care coordination and decrease hospital readmission rates.**

ID physicians generally did not participate in the 2007 PQRI. However, other specialists’ experiences with the Program suggest that the PQRI Feedback Reports need substantial modifications before physicians can use them for quality improvement. In the future, it is critical that the Agency deliver both provider-level and group-level feedback reports that are timely and readily understandable by physicians and their staff. Additionally, given Medicare’s interest in also reporting physicians’ resource use, it would be preferable to incorporate physicians’ quality and efficiency scores into a single, risk-adjusted feedback report. Such reports would give physicians the opportunity to promptly correct identifiable problems—CMS may want to even consider developing interim feedback reports so that physicians may correct problems before the reporting period ends.

IDSA and HIVMA believe that CMS has underestimated the cost and time to physicians of participating in the PQRI. For example, CMS estimates that preparing one’s practice for PQRI participation will take on average three hours at a cost of \$50 per hour. According to the Department of Health and Human Services (DHHS) safe harbor methodologies for calculating medical directors’ hourly payment rates, ID physicians’ infection control services were valued at approximately \$100 per hour. These safe harbor calculations did not take into account the overhead costs required to maintain an ID practice, which is one reason why DHHS was pressured to repeal these methodologies last year. However, they remain useful in their ability to demonstrate that for every hour an ID physician spends in preparing for PQRI participation, he or she loses money for their practice. Moreover, given the number and complexity of reporting options, IDSA and HIVMA believe that CMS has drastically underestimated the time necessary to prepare one’s practice for participation.

CMS estimates that it will take 1.75 minutes of additional time (median) for providers to report a quality data code on Medicare claim. Essentially this means that if an ID physician submits claims to Medicare for twenty office visits per day (Medicare will pay approximately

\$65 for a 99213 established office visit in 2009), he or she could increase their per-claim payments by approximately \$1.30 through successful participation in the PQRI. This would result in an increase of \$26 per day. As an alternative to PQRI participation, if the same ID physician increases their Medicare volume by billing one additional 99213 per day, he or she would realize a \$65 per day increase in Medicare payments (a \$39 difference). **This calculation is not done to criticize CMS' efforts to incentivize quality but rather to demonstrate that systemwide costs are unlikely to be reduced as long as quality incentives are not, at a minimum, on par with incentives for increasing the volume and intensity of Physician Fee Schedule Services**

Finally, and perhaps most important to HIVMA members, the Final Rule makes no allowances for the additional costs associated with registry reporting. Given that the HIV/AIDS measures must be reported through a "qualified" registry, this cost will drastically undermine ID physicians' ability to earn a 2 percent incentive payment under the PQRI. **We would appreciate CMS' help in publicizing a list of "qualified" registries that ID physician can use to report these measures at no cost.**

E-PRESCRIBING INCENTIVE PROGRAM

IDSA and HIVMA believe strongly in the promise of electronic-prescribing (e-prescribing) to improve quality by enabling providers to send an error-free and understandable prescription directly to a pharmacy from the point-of-care. However, our support of e-prescribing must be tempered by the realization that many ID physicians will not qualify for the 2 percent incentive payment under Medicare.

In order to qualify for the e-prescribing incentive payment, physicians' must generate at least 10 percent of their total Medicare charges from the outpatient CPT codes specified in the measure specifications. It is reasonable to assume that many ID physicians are unlikely to meet this threshold given their primary role as inpatient consultants. However, it is unreasonable for CMS to assume that these physicians have the time or the analytic tools necessary to accurately estimate the percentage of their Medicare charges realized from billing the listed codes. As such, **IDSA and HIVMA request that CMS make available to individual physicians the percentage of their prior year's Medicare charges that resulted from these codes.**

While e-prescribing will result in fewer medication errors, the steps necessary to fill an e-prescription are more cumbersome and take longer than a written prescription. These steps include log-in time, input and submission time, and log-off time for each e-prescription—when taken together over the course of a day, these small steps could add up to a substantial amount of additional time for physicians whose time is already stretched to the limit. A separate but no less important step occurs when pharmacies misplace or are unaware that physicians have submitted prescriptions electronically. This often results in phone conversations between the pharmacist and the prescribing physician as well as follow-up faxed prescriptions. **IDSA and HIVMA would like clarification from CMS as to**

whether their 1.75 minute time and \$0.90 cost estimates to report the e-prescribing measure take into account all of these cumbersome steps.

PHYSICIAN RESOURCE USE FEEDBACK PROGRAM

MIPPA statutorily requires CMS to begin measuring physicians' resource use in 2009. Given the significant cost growth in the Medicare program and the wide geographic variations in the volume of services per beneficiary, CMS ultimately plans to make physician resource use data publicly available on a Physician Compare Website at www.medicare.gov. While IDSA and HIVMA support these efforts, if CMS treats the first rendition of the Physician Resource Use Reports (RURs) as a testing opportunity, similar to the 2007 PQRI Feedback Reports, providers' and beneficiaries' confidence in the Medicare program could be severely undermined.

Keeping the above points in mind, IDSA and HIVMA will respond to several RUR-related questions included in the Final Rule. First and foremost, similar to the PQRI feedback reports, physician-level RURs could be a valuable tool to both providers and beneficiaries if they are timely and readily understandable. This is especially true given the probability, as the Medicare Payment Advisory Commission stated, that RURs "could encourage physicians to reduce the volume and intensity of services they provide without sacrificing quality of care." However, as previously stated, IDSA and HIVMA believe that physician-level quality and efficiency data should be combined into a single, risk-adjusted feedback report.

Similarly, IDSA and HIVMA believe that episode-based RURs are valuable tools as long as attribution is assigned to multiple physicians (using a team-based approach) as opposed to one physician. Additionally, it is critical that episode grouper software be open for analysis by stakeholders. This has not been the case during the pilot phase of the RUR program in which Mathematica Policy Research used private sector and proprietary episode grouper products.

IDSA's and HIVMA's responses to the above questions assume, of course, that CMS will employ a RUR risk adjustment methodology that includes multiple demographic variables. Ideally, an RUR risk adjustment methodology should take into account patients' age, sex, severity level, health status, and local area characteristics. Moreover, risk adjustment methodologies must be publicly released with the RURs and readily understandable by both providers and beneficiaries.

Finally, as was stated in our comments to the 2009 Physician Fee Schedule Proposed Rule, IDSA and HIVMA do not believe that physician-level quality or efficiency data should be publicly released as long as significant gaps in the existing set of quality and efficiency measures remain. **These measure gaps should be addressed before CMS releases quality and efficiency data on individual physicians.**

TRANSPORT OF CAP DRUGS BETWEEN MULTIPLE PRACTICE LOCATIONS

IDSA and HIVMA are disappointed that CMS decided to postpone the Competitive Acquisition Program (CAP) for Part B Drugs and biologicals but recognize that this step was necessary given the low number of participating physicians. Given that most of the challenges and solutions to CAP participation have been previously stated and restated, we will not repeat them at this point.

However, if CMS decides to reinvent the CAP, it must minimize the administrative burden to providers who elect to receive drugs in this fashion. As examples, the requirement that participating providers must order and track patient-specific doses of CAP drugs as well as the separate inventory requirement must be addressed if the CAP is to succeed in the future. Please reference IDSA's previous CAP-related comment letters for specific suggestions on how to improve the Program in the future.

Finally, it is noteworthy to mention that when CMS staff hosted a conference call on December 3rd to solicit feedback about the CAP, very few participants offered suggestions. This scant level of participation may suggest a level of apathy on the part of stakeholders with respect to whether CMS has the ability to transform the CAP into a viable program that is accepted by physicians.

CONCLUSION

IDSA and HIVMA appreciate CMS' consideration of our comments to the 2009 Physician Fee Schedule Final Rule. We believe that many of the Agency's proposals as well as many of the recommendations outlined in our comments would pave the way for meaningful healthcare reform as a new Administration and a new Congress take office next year.

If you have any questions or comments, please feel free to contact Jason A. Scull, IDSA's Program Officer for Clinical Affairs, at 703/299-0200. We look forward to working with CMS as it finalizes this regulation.

Sincerely,



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President, IDSA



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Chair, HIV Medicine Association