American Hospital Association

Regulatory Advisory

January 21, 2009

Medicare Physician Fee Schedule Final Rule for 2009

AT A GLANCE

The Issue:

Late last year, the Centers for Medicare & Medicaid Services (CMS) released the 2009 final physician fee schedule and other Medicare Part B revisions regulation. The final rule was published in the November 19, 2008 *Federal Register* and took effect January 1. Major provisions of the rule are highlighted below:

- While CMS did not finalize its proposed new exception to the physician self-referral regulations for incentive payments and shared-savings programs, it will reopen the comment period until February 17, and requests comments on 55 specific questions.
- Payment rates for physician fee schedule services will be increased by 1.1 percent in 2009, rather than being reduced by 5.4 percent, as proposed.
- The rule implements a new electronic prescribing (e-Rx) initiative that will provide an incentive payment equal to 2 percent of total Medicare allowed charges for physicians who adopt and use qualified systems to transmit prescriptions to pharmacies in 2009. More about the CMS e-Rx initiative can be found at http://www.aha.org/aha/advisory/2008/081209-regulatory-adv.pdf.
- Entities furnishing mobile diagnostic services are required to enroll in the Medicare program as an independent diagnostic testing facility (IDTF), comply with IDTF performance standards and bill directly for the services they furnish. However, the direct billing requirements do not apply to services provided by mobile entities that are part of a hospital service and furnished under arrangement with that hospital.
- CMS revises the effective billing date for physicians and non-physician practitioners enrolling in the Medicare program and makes other changes to the enrollment rules.

Our Take:

We welcome CMS' decision not to move forward with its proposed exception to the physician self-referral regulations for incentive payments and shared-savings programs. In filed comments, the AHA expressed support for creating a new exception, but cautioned that the proposal was "so complex, costly and limiting that it will not realistically advance the goals for health care delivery." We called for an exception that was "simple, straightforward and not so costly as to negate its value or become prohibitive to implement." CMS acknowledged that its starting proposal was narrowly drafted and expressed interest in expanding it in a "meaningful way" if sufficient safeguards to protect against abuse can be developed. We welcome your input by February 4 to assist us as we develop our response to CMS.

What You Can Do:

- ✓ Share this advisory with your executive team, in particular your legal counsel, chief financial officer, chief medical officer and key physician leaders.
- ✓ **Consider providing the AHA with input on CMS' proposed exception to the physician self-referral regulation**. E-mail your comments, including examples or illustrations, about selected questions described in this advisory to AHA staff (mmudron@aha.org) by January 30. Go to http://www.aha.org/aha/advocacy/compliance/self-referral-stark.html to get information about the physician self-referral regulation.

Further Questions:

For issues regarding physician self-referral, please contact Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org, and for other issues contact Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

AHA's Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. A 12-page, in-depth examination of this issue follows.

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BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) on October 30, 2008 released the physician fee schedule and other Medicare Part B revisions final rule for calendar year (CY) 2009. Significant portions of the rule are of interest to hospitals including a proposed exception to the physician self-referral rules, payments to end-stage renal disease (ESRD) facilities for renal dialysis services, physician enrollment rules, mobile diagnostic testing facility requirements, a new electronic prescribing measure, new rules for documented non-emergency ambulance transport and other matters. In addition, the rule covers issues arising from enactment of the *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) after the physician fee schedule proposed rule was released that pre-empted or revised certain provisions of the proposed rule, including the physician payment update, electronic prescribing (eRx) policy and other issues.

The rule, available at http://www.cms.hhs.gov/center/physician.asp, was published in the November 19, 2008 *Federal Register* and took effect January 1.

AT ISSUE

PHYSICIAN SELF-REFERRAL PROVISIONS

In the final rule, CMS announced that it needed more information before finalizing its proposed new exception under the physician self-referral law for "incentive payment and shared savings programs." The proposed exception would cover hospital payments to physicians for "various types of hospital-sponsored pay-for-performance (P4P), shared savings (for example, gainsharing), and similarly-styled programs that offer financial incentives to physicians intended to foster high quality, cost-effective care." The deadline for submitting comments is February 17. In reopening the comment period, CMS requested input on 55 specific questions. The agency is particularly interested in receiving detailed and practical examples of how it might modify the initial proposal while meeting the overall goals to achieve transparency and accountability, ensure quality of care and prevent disguised payments for referrals.

We welcome CMS' decision not to move forward with the earlier version of its proposal. In our comment letter on CMS' prior proposal, the AHA expressed support for creating a new exception, but cautioned that the proposal was "so complex, costly and limiting that it will not realistically advance the goals for health care delivery." The AHA called for an exception that was "simple, straightforward and not so costly as to negate its value or become prohibitive to implement." CMS has acknowledged that its starting proposal was narrowly

drafted and has expressed interest in expanding it in a "meaningful way" if sufficient safeguards to protect against abuse can be developed.

The AHA is developing a comment letter that will offer recommendations for the specifics of a new exception. To assist us, we welcome hospital input on the issues or questions listed below or any other comments by February 4. Go to http://www.aha.org/aha/advocacy/compliance/self-referral-stark.html to access the AHA's prior comment letter, the text of CMS' proposed exception and CMS' 55 questions. Please send your comments, examples or illustrations to mmudron@aha.org.

REQUIREMENTS RELATED TO THE DESIGN OF THE PROGRAM

Purpose. The remuneration must be provided as part of a documented program to achieve quality improvement through changes in physicians' clinical or administrative practices, or actual cost savings for the hospital from the reduction of waste or changes in physicians' clinical or administrative practices.

Remuneration. The exception only applies to payments in the form of cash or cash equivalents. Nonmonetary remuneration, e.g., additional staff members or new equipment, is not covered.

> QUESTION***:*** *Is limiting the exception to only cash or cash equivalents too narrow? If yes, what are examples of the use of nonmonetary remuneration that should be permitted?*

Performance Measures. The measures for achieving quality improvement or cost savings must be based on an objective methodology, be verifiable, supported by credible medical evidence, and individually tracked, as well as be reasonably related to the hospital's practices and patient population. For quality incentives, the proposal only permits use of measures included in CMS' Specification Manual for National Hospital Quality Measures.

In prior comments, we objected to the exclusive use of CMS' Specification Manual as too narrow. The AHA urged that patient safety and quality improvement practices that have been shown by credible, scientific evidence to improve the quality of care also should be covered by the exception. CMS is reconsidering its position.

> QUESTION: *If quality practices other than those in the CMS' Specifications Manual are permitted, what are specific examples of other lists or sources to draw from?*

> QUESTION: *Under what circumstances should the parties be permitted to establish their own quality practices?*

Physician Participation. A minimum of five physician participants is required for each performance measure. Only physicians on the medical staff of the hospital at the commencement of a program may participate. A program may involve a particular department or specialty, provided that all physicians in the department or specialty have the opportunity to participate under the same terms and conditions.

In earlier comments, we urged that hospitals should have the latitude to determine which or how many physicians may participate. We pointed out that in some instances hospitals may not have five practicing physicians in a particular area of focus, and that in other instances some physicians will have financial interests that conflict with the interests of the hospital or will vary in their commitment to achieving the hospital's goals. CMS is asking for input on alternative approaches.

> QUESTION: *If the requirement for membership on the medical staff at the time a program begins is omitted, are there other conditions that should apply to protect against the programs being used to recruit physicians from hospitals that do not have such programs?*
>
> QUESTION: *If the "five-physician pool" requirement is omitted, should there be a minimum and should all participating physicians be of the same specialty?*

Independent Medical Review. The program must include independent medical review of the impact on the quality of patient care services and corrective action must be taken if the independent review indicates a diminution in care. "Independent medical review" means review by an organization that is not affiliated with the hospital or any participating physician, and at the time of the review, no reviewer is participating in a program at the hospital.

Previously, the AHA objected that the CMS' definition of "independent" would unnecessarily require a new infrastructure and generate a cottage industry to perform these review functions. We pointed out the extensive quality review processes currently in use at hospitals and the important role their independent governing boards serve in quality and patient safety activities.

> QUESTION: *If an outside review entity is not required, what are the alternative means to assure the appropriate choice of performance objectives and that the incentive or shared savings programs improve or maintain appropriate care?*

REQUIREMENTS RELATED TO PAYMENT

Per Capita. Payments must be distributed to the pool of physicians on a *per capita* basis.

In prior comments, we urged that payment methods should reflect the performance of individual physicians and that per capita payment could simply reward participation.

> QUESTION: *If the requirement for a per capita payment is omitted, what alternatives would protect against unreasonable payments, e.g., an absolute cap on individual payments, limitation on the duration of payment?*
>
> QUESTION: *If payment to a physician based on his or her personal efforts and achievement were permitted, what requirements or conditions should apply?*
>
> QUESTION*: Should payments be permitted based on global improvement in quality (rather than individually indentified measures)? If yes, what requirements should apply; how is improvement measured?*

Prior Payments. Current payments must take into account payments previously made for quality improvements or cost savings that were achieved during a prior period of the arrangement. No payment may be made for cost savings that result in a diminution in patient care quality.

Cost Savings. Cost savings are measured by comparing the hospital's actual acquisition costs or the costs of providing the specified services to the hospital's baseline costs for the same items, supplies or services during the one-year period immediately preceding the commencement of the program. CMS is considering placing a cap of 50 percent on the amount of savings that may be shared.

In prior comments, the AHA argued that these types of limitations are too prescriptive and burdensome. We urged that instead of focusing on the amount that is paid, it is most important to have a clear and fixed means for determining how much may be paid.

> QUESTION: *If a flat cap on the amount of cost savings that may be shared is omitted, what alternative safeguards are appropriate?*
>
> QUESTION: *If payment for continued achievement (or maintenance) of quality, savings or efficiencies is permitted, what safeguards should be in place?*

OTHER REQUIREMENTS

Term. An arrangement must be for a period of time that is no less than one year and no more than three years.

Notice. The hospital must provide prior written notice to patients who are affected by the incentive payment or shared-savings program that identifies the physicians participating in the program; discloses that participating physicians receive payments for meeting targets for performance measures; and describes the performance measures in a manner reasonably designed to inform patients about the program.

In earlier comments we argued that disclosures related to treatment decisions should not be treated any differently when they are part of a quality improvement protocol. Requiring prior notice in these circumstances would create the wrong impression that use of quality protocols would mean lesser care.

PHYSICIAN PAYMENT UPDATE

The rule announces that the fee schedule update factor for 2009 is 1.1 percent, as required under MIPPA, which produces a 2009 conversion factor of $36.0666 (compared to $38.0870 in 2008). The lower conversion factor in 2009 is due to another MIPPA requirement to apply the budget neutrality adjustment related to the most recent CMS five-year review of work values (0.8806) to the conversion factor rather than the physician work values themselves. The initial estimate for the sustainable growth rate for CY 2009 is 7.4 percent. MIPPA also provides that in 2009, physicians who successfully report quality measure data under the Physician Quality Reporting Initiative (PQRI) will receive incentive payments of 2 percent of their estimated total allowed charges for all covered professional services furnished during the reporting period. Further, physicians who successfully report under the eRx initiative, in 2009 also will receive incentive payments of 2 percent.

ELECTRONIC PRESCRIBING INCENTIVE PROGRAM

As part of MIPAA, new eRx incentives took effect January 1. The final rule also extends the exemption for prescriptions for Medicare Part D covered drugs by means of computer-generated fax. While these programs do not apply to hospital facility services, outpatient physician services provided in the outpatient hospital department can qualify. Further, in situations where eligible physicians or nonphysician practitioners (NPPs) are employees or contractors and have assigned their payment to their employers or facilities (e.g., hospitals), the statute specifies that any bonus payment earned will be paid to the employers or facilities.

More information about the CMS eRx initiative can be found in the AHA's December 9, 2008 *Regulatory Advisory* available at http://www.aha.org/aha/advisory/2008/081209-regulatory-adv.pdf. CMS provides

information and specifications at www.cms.hhs.gov/eprescribing and at http://www.cms.hhs.gov/partnerships/downloads/11399.pdf.

PHYSICIAN ENROLLMENT ISSUES

The final rule addresses several enrollment issues related to physicians and NPPs.

EFFECTIVE DATE OF MEDICARE BILLING PRIVILEGES

Currently, physicians and NPPs may bill Medicare prior to their enrollment date. In addition, once enrolled, physicians and NPPs, depending on their effective date of enrollment, may retroactively bill the Medicare program for services that were rendered up to 27 months prior to being enrolled as providers in the Medicare program.

Due to concern that some physicians and NPPs may bill Medicare for services when they are not meeting other program requirements, in the final rule CMS sets a new effective date for Medicare billing privileges for physicians and NPPs. CMS establishes the initial enrollment date as the *later* of: (1) the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor (i.e., carrier, fiscal intermediary or Medicare administrative contractor; or (2) the date an enrolled supplier first started furnishing services at its new practice location.

CMS also will permit physicians and NPPs to retrospectively bill for services furnished up to 30 days prior to their effective date of billing "when the physician or NPP organization met all program requirements, including State licensure requirements, where the services were provided at the enrolled practice location prior to the date of filing, and circumstances precluded enrollment in advance of providing services to Medicare beneficiaries." In addition, CMS will allow retrospective billing for services furnished up to 90 days prior to the effective date of billing when the provider meets all program requirements, services were furnished at the enrolled practice location prior to the date of filing and a presidentially-declared disaster precluded enrollment in advance of providing services.

The final rule also notes that CMS will be implementing a new Internet-based Provider Enrollment, Chain and Ownership System (PECOS), which is intended to be more efficient than the traditional paper-application enrollment method. CMS expects 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. This system is being implemented in phases, starting late last year with *individual* physicians and NPPs. The Internet-based PECOS will be available for enrolling *organizational* providers, such as hospitals, beginning this spring. CMS

emphasizes that all providers and suppliers will continue to have the option of submitting an enrollment application by paper. CMS also notes that the Internet-based PECOS will not be available to hospitals, billing agents or clearinghouses who wish to enroll physicians or NPPs. Instead, only the paper enrollment will be available. Additional information regarding PECOS is available at www.cms.hhs.gov/MedicareProviderSupEnroll.

MEDICARE BILLING PRIVILEGES AND EXISTING TAX DELINQUENCY

The Federal Payment Levy Program (FPLP), run through the Department of Treasury, recovers delinquent federal income tax debts by levying non-tax payments, including Medicare payments.

In fiscal year (FY) 2009, CMS will implement the FPLP process for payments made to providers and suppliers reimbursed under Medicare Part A and B.

CMS is concerned that the FPLP does not allow it to offset a payment when an individual reassigns his or her benefits to a third-party, such as to a hospital or to a group practice where an existing federal tax delinquency exists. In the final rule, CMS notes that it is considering revoking the billing privileges for those individuals for whom a tax delinquency exists and the agency is unable to directly levy future payments through the FPLP. The agency may propose this type of change in future rulemaking.

DENIAL OF ENROLLMENT IN THE MEDICARE PROGRAM

CMS will deny enrollment applications for additional Medicare billing privileges if the physician or NPP has an active payment suspension or has an existing overpayment that has not been repaid. CMS also will deny enrollment to any current owner, physician or NPP, who is participating in the Medicare program and is under a current Medicare payment suspension.

REPORTING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS

Current regulations require providers and suppliers (except durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers and independent diagnostic testing facilities (IDTFs) to report to CMS most changes to the information that was furnished on the Medicare enrollment application and to furnish supporting documentation within 90 calendar days of the change (changes in ownership must be reported within 30 days). DMEPOS suppliers and IDTFs have only 30 calendar days to submit changes of information to CMS.

In the final rule, CMS adopts a reporting requirement under which physicians and NPPs will be required to report a change in ownership, a change in practice location and a final adverse action *within 30 days*. Failure to comply may result

in revocation of billing privileges and a Medicare overpayment from the date of the reportable event.

An adverse action is defined as:

- a Medicare-imposed revocation of any Medicare billing privileges;
- suspension or revocation of a license to provide health care by any state licensing authority;
- revocation or suspension by an accreditation organization;
- a conviction of a federal or state felony offense as defined in §424.535(a)(3)(i) within the last 10 years preceding enrollment, revalidation or re-enrollment; or
- an exclusion or debarment from participation in a federal or state health care program. CMS emphasizes that it considers a final adverse action to have occurred when the sanction is imposed, not when a supplier has exhausted all of the appeal rights associated with the action itself.

MAINTAINING ORDERING AND REFERRING DOCUMENTATION

Current manual instructions require providers and suppliers to maintain ordering and referring documentation for seven years from the date of payment. Since there may be a delay in claims payment for up to 27 months from the date of service, CMS is putting this requirement into regulation with a slight change. CMS believes that it would be administratively less burdensome for providers and suppliers to maintain ordering and referring documentation from the date of service, rather than the date of payment; as a result, the agency will require documentation to be maintained for seven years from the date of service. This requirement is effective with services furnished on or after January 1. Failure to comply with the documentation requirements could result in revocation of billing privileges.

REVOCATION OF ENROLLMENT AND BILLING PRIVILEGES

Historically, CMS has allowed providers and suppliers whose Medicare billing numbers have been revoked to continue billing for services furnished prior to revocation for up to 27 months after the effective date of the revocation. However, CMS believes this extensive billing period poses significant risk to the Medicare program, and will require physicians and NPPs whose billing numbers have been revoked to submit all outstanding claims not previously submitted within 60 calendar days of the revocation effective date.

OTHER PROVISIONS OF INTEREST TO HOSPITALS

IDTF MOBILE ENTITY BILLING REQUIREMENTS

CMS finalized its proposed performance standard that will require entities furnishing mobile diagnostic services to enroll in Medicare as independent diagnostic testing facilities (IDTFs) regardless of where the services are furnished. IDTFs must meet Medicare performance standards found at 42 CFR 41-33(g). Further, CMS will require that mobile testing entities bill directly for the services they furnish. However, consistent with the AHA's recommendations, mobile diagnostic services that are part of a hospital service and furnished under arrangement with that hospital are exempted from the direct billing requirement. In this case, the mobile diagnostic testing entity will be required to provide documentation of the arrangement with its initial or revalidation enrollment application, or change in enrollment application.

BENEFICIARY SIGNATURE FOR NONEMERGENCY AMBULANCE TRANSPORT

In the 2008 physician fee schedule final rule, CMS adopted policies allowing ambulance providers and suppliers to sign ambulance claims on behalf of the beneficiary in the case of emergency ambulance transports if the beneficiary is physically or mentally incapable of signing and certain conditions are met. In the final rule for 2009, CMS extends the same policy to nonemergency ambulance transports (such as when a resident in a long-term care facility is transported for nonemergency medical treatment). Further, given that most claims are submitted electronically, CMS amended the regulation to define a "claim" for purposes of the beneficiary signature requirements as the claim form itself or a form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary.

PAYMENT FOR RENAL DIALYSIS SERVICES IN ESRD FACILITIES

Consistent with MIPPA requirements, CMS increases the composite rate payment for most services furnished to beneficiaries with ESRD by 1 percent for services in 2009. MIPPA also requires that the base composite rate for hospital-based renal dialysis facilities be the same as the base composite rate for independent dialysis facilities and, when applying the geographic index, reflect the labor share based on the labor share otherwise applied for renal dialysis facilities. The base composite rate for 2009 will be $133.81. Further, although total drug expenditures for 2009 are projected to decline 1.8 percent, CMS finalizes a zero percent update to the drug add-on payment. This results in a drug add-on payment, unchanged from 2008, at $20.33 per treatment.

CMS also updates the wage data to complete the four-year transition to a wage index based on core-based statistical areas and reduces the wage index floor from 0.75 to 0.70 for 2009**.**

CMS estimates that the combined impact of the changes to payment for renal dialysis services included in this final rule will have a 0.4 percent increase in overall payments relative to current overall payments. However, as a result of the MIPPA provision mandating a site-neutral composite rate, hospital-based ESRD facilities are projected to see a 2.1 percent decrease in payments, while payments to independent ESRD facilities are projected to increase by 0.7 percent. Table 51 of the final rule shows the impact of the 2009 changes on payments to ESRD facilities by facility size, type of ownership, geographic location and region.

TECHNICAL COMPONENT OF PATHOLOGY SERVICES FOR HOSPITAL PATIENTS

CMS implements the MIPPA requirement that allows independent laboratories to continue to bill Medicare directly for the technical component of physician pathology services furnished to hospital inpatients and outpatients until December 31, rather than requiring that it be bundled into the payment to the hospital.

CLINICAL LABORATORY FEE SCHEDULE UPDATE

CMS implements the MIPPA provision that sets the clinical laboratory fee schedule update at the Consumer Price Index for all Urban Consumers minus 0.5 percentage points for each calendar year 2009 through 2013, but repeals a competitive bidding demonstration program for clinical laboratory services that had been required under the *Medicare Modernization Act*.

CONDITIONS OF PARTICIPATION FOR CAHS

The final rule withdraws the provision finalized in the 2008 physician fee schedule, that required critical access hospitals (CAHs) to directly employ physical therapists, occupational therapists and speech-language pathologists, rather than being allowed to use contract therapists as other provider settings do. CMS failed to include this item in the proposed 2008 physician fee schedule and provided no rationale for this unique treatment of CAHs. The AHA raised concerns to CMS about the lack of opportunity for public comment and the absence of a policy justification, and is pleased that this item has been rescinded.

NEXT STEPS

Comments on the proposed physician self-referral exception are due to CMS by February 17. As noted in this advisory, the AHA is developing comments to CMS on the proposed new exception for incentive payment and shared-savings programs. We have included selected questions for which it would be particularly helpful to have your input, including examples or illustrations. Please send your comments to Maureen Mudron at mmudron@aha.org by February 4.

Comments to CMS may be submitted electronically at http://www.regulations.gov. Follow the instructions for "Comment or Submission." Attachments can be in Microsoft Word, WordPerfect or Excel; however, CMS prefers Microsoft Word. CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

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