RBMA
Building the Business of Radiology

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December 26, 2008

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

Subject: CMS-1403-FC Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Final Rule

Dear Mr. Weems:

The Radiology Business Management Association (RBMA) appreciates the opportunity to comment on the final rule for the 2009 Medicare physician fee schedule as published in the November 19, 2008 *Federal Register*.

Founded in 1968, the RBMA represents over 2,300 radiology practice managers and other radiology business professionals. In the aggregate, RBMA's influence extends to over 24,000 radiologic technologists and 26,000 administrative staff. RBMA is the leading professional organization for radiology business management, offering quality education, resources and solutions for its members and the healthcare community, and helping shape the profession's future.

RBMA's comments are divided into three sections and are presented in the following order:

- General Comments: These are broad, over-arching observations regarding issues in the 2009 final rule as a whole, but that are not directed at any one particular topic.
- Response to CMS' Decision on Specific Issues in the Final Rule: These are in response to the agency's decisions in the final rule.
- Issues for the 2010 Medicare Fee Schedule Proposed Rule: These are important topics that relate to issues that are discussed in the 2009 proposed rule that RBMA recommends CMS consider in its 2010 rulemaking.

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General Comments

The proposed rule contained policies that, if adopted, would have: a) improved the quality of imaging services received by Medicare beneficiaries through the application of the independent diagnostic testing facility standards to physicians and non-physician practitioners and b) helped to reduce the unnecessary utilization of imaging services through the expansion of the IDTF standards and more rigorous anti-markup language. Unfortunately, CMS elected to defer or significantly modify these provisions. RBMA encourages CMS to include the original proposals for IDTFs and anti-markup as they pertain to the delivery of imaging services in an office-based environment in the rulemaking for

2010, subject to and incorporating the prior recommendations that the RBMA has submitted with respect to these issues.

We appreciate CMS acting in accordance with RBMA's recommendations pertaining to the IDTF standards for mobile providers, ordering/referral documentation retention, and revocation of billing privileges for tax delinquencies. RBMA is grateful for the opportunity to contribute to the discussion now and in the future.

Responses to Decisions in the Final Rule

Malpractice RVUs

RBMA eagerly awaits the results of CMS' research into malpractice RVUs and stands ready to assist the agency as appropriate. However, RBMA reiterates its position that there should be resource-based malpractice values for the technical component (TC).

Imaging centers typically purchase umbrella liability policies (such as an employment liability policy) to cover both the center and its non-physician clinical personnel (e.g., radiologic technologists, nurses, physician assistants). This malpractice coverage is separate and distinct from a radiologist's professional liability insurance which is represented by the professional component (PC) malpractice RVUs. Such providers also carry other (non-malpractice) forms of insurance including e.g. errors & omissions policies, general liability policies (specifically written for underwriting the risks associated with diagnostic imaging facilities), property liability policies, etc. RBMA agrees with CMS that the TC's malpractice values should be resource-based and stands ready to assist the agency and its contractors with this issue.

Independent Diagnostic Testing Facilities (IDTF)

We are disappointed by CMS' decision not to implement the IDTF standards for physicians and non-physician providers (NPPs) who provide imaging services to their patients in an office-based environment. By expanding these standards to include physicians and NPPs, CMS had the opportunity to improve the quality of imaging care received by Medicare beneficiaries by "weeding out" physicians who are not in compliance, i.e. substandard providers. RBMA believes this proposal would have had the additional beneficial effect of curbing the inappropriate use of imaging. RBMA supports CMS' decision to require timely filing of claims from IDTFs that have had their billing privileges revoked.

RBMA encourages CMS to reintroduce the application of the IDTF standards to diagnostic testing services that are provided in an office-based environment at its earliest opportunity. In anticipation of the standards' eventual inclusion in future rulemaking, RBMA offers the following recommendations:

- Imaging personnel who perform services in non-hospital-based imaging centers should be registered/certified as defined by the American Registry of Radiologic Technologists (ARRT), the American Society of Radiologic Technologists (ASRT), the American Registry for Diagnostic Medical Sonography (ARDMS), and other appropriate certifying entities. Imaging center personnel should be state licensed, where applicable. CMS is also advised to consult specialty societies' practice standards or guidelines for additional personnel requirements. RBMA does however recommend that CMS exempt rural providers and, further, that subspecialty certification not be a requirement for imaging personnel.

- Certain IDTF standards (under §410.33(g)) should not apply to physician practices, namely:
  - 410.33(g)(6) – Maintaining additional comprehensive liability insurance policy of at least $300,000 per location
  - 410.33(g)(8) – Maintaining a formal clinical complaint process
  - 410.33(g)(9) – Posting [IDTF] standards for review by patients and the public
  - 410.33(g)(14)(ii) – Maintaining a visible sign posting business hours
  - 410.33(g)(15)(i) – Separately enrolling each practice location
  - 410.33(g)(7) – RBMA understands the intent is to prohibit the <u>direct</u> solicitation of patients (e.g., telephone, computer, or in-person), <u>not</u> mass media advertisements (print, radio, television).

- The IDTF standards should apply to CT, MR, Nuclear Medicine, and PET initially and thereafter be phased in for other imaging modalities (plain film, ultrasound, fluoroscopy, etc.) over time.

- The delivery of and payment for non-testing services should remain unrestricted, primarily to ensure uninterrupted access to these services by Medicare beneficiaries.

- Physicians and NPPs should be given ample lead-time before implementation and contractors should continue to pay their claims while these entities are in the application and enrollment process.

<u>Physician and Nonphysician Practitioner Enrollment Issues</u>

Electronic Enrollment

In RBMA's comments on the proposed rule, we urged CMS to expedite implementation of an electronic enrollment process. We are pleased by CMS' recent announcements that electronic enrollment is going "live" across the country.

However, we are concerned by the requirement that physicians and NPPs not share their NPPES UserID/password. The agency's Internet-based Provider Enrollment, Chain and Ownership System (PECOS) has the requirement that, ". . . physicians and NPPs not share their NPPES UserID/password with billing agents, clearinghouses, academic medical institutions, or staff within their practice. Physicians and NPPs choosing to use billing agents, clearinghouses, academic medical institutions, etc. will be required to submit a paper enrollment application to enroll or make a change in their Medicare enrollment record. In order to use Internet-based PECOS to enroll or make a change in an organizational enrollment record, we will verify that the authorized official associated with the Medicare enrollment record is employed by the organization and is authorized by the organization to submit or make changes to the organization enrollment record." To RBMA, this seems unreasonably restrictive and likely to inhibit what could be a very beneficial on-line enrollment process. Sharing this information in a controlled and documented environment would reduce the chance for any inappropriate use of the NPPES UserID/Password. **RBMA recommends that CMS permit physicians and NPPs to share their NPPES UserIDs and Passwords for electronic enrollment purposes and corresponding updates and to require that written documentation of who has access to this information be maintained in a secured (locked) location.**

Effective Date

RBMA sees CMS' decision on the effective date for Medicare billing privileges as a step in the right direction, albeit an incomplete one, towards the timeliness of contractor claims processing. RBMA reiterates its original recommendation that the effective date be the date an enrolled provider/supplier first started rendering services at a practice location. Moreover, CMS' decision to allow retroactive billing for services up to 30 days prior to a provider/supplier effective date (when all requirements have been met) is unlikely to compensate practices completely for services rendered during the enrollment process since delays of up to 180 days have been encountered. RBMA, however, is encouraged by CMS' roll-out of Internet-based provider enrollment.

Tax Delinquency

RBMA agrees with CMS' decision to withdraw its proposal to revoke a group practice's Medicare billing privileges based on an individual's tax delinquency.

Ordering and Referring Documentation Retention Requirements

RBMA appreciates CMS' decision to require practices to maintain ordering and referring documentation for seven years from the date of service instead of 10 years from date of payment as proposed. We also welcome CMS' clarification permitting electronic storage and retrieval of such documentation.

Physician Self-Referral and Anti-Markup Issues

Incentive payment and shared savings program

RBMA supports an exception from the physician self-referral statutes for "incentive payment and shared savings programs" involving physicians and hospitals.

RBMA believes that such an exception would encourage physicians and hospitals to seek out such opportunities to the benefit of both their patients, and the Medicare program. The agency's approach as described in the proposed rule serves as a reasonable starting point.

Anti-Markup

RBMA appreciates CMS' refinements of the anti-markup rule. The language in the 2009 final rule is clearer and more straight-forward than what had been proposed previously. However, the final language still falls substantially short of eliminating the ordering physician's ability to profit from purchasing diagnostic tests, particularly for the technical component (TC). RBMA strongly recommends that CMS continue pursuing stronger anti-markup language in future rulemaking.

Other Issues – Revisions to Appeals

Expedited reconsideration

RBMA disagrees with CMS' decision not to create an expedited reconsideration process in cases where revocation is based on CMS/contractor error. We believe that such a process would help to avoid unintentional revocation of billing privileges due to notification delays (e.g., change in practice location), and would be consistent with a common sense standard of fairness. We ask that CMS reconsider this decision in future rulemaking.

Issues for the 2010 Medicare Fee Schedule Proposed Rule

RBMA strongly supports CMS in applying the IDTF performance standards to physician practices and encourages the agency to reintroduce this proposal in rulemaking for the 2010 Medicare fee schedule. In addition to earlier comments regarding specific issues in the 2009 proposed rule, RBMA recommends that the following IDTF-related issues also be considered in that rulemaking.

General Supervision

RBMA recommends CMS revisit its definition of the physician providing general supervision in an IDTF. RBMA recommends that a radiologist provide general supervision.

Medicare requires that IDTFs contract with or employ a physician who is responsible for the overall direction and quality control of services provided in the IDTF. Medicare has the additional requirement (in 42 CFR 410.33) that the supervising physician be proficient in the performance and interpretation of the tests performed in the IDTF. General supervision is an important responsibility, one dealing with the technical and clinical aspects that contribute to high-quality imaging studies. Some carriers have interpreted this to mean that a radiologist must provide general supervision of IDTFs. RBMA agrees that the physician providing general supervision in an IDTF should be a radiologist. Furthermore, RBMA recommends the agency develop performance standards for radiologists who are providing general supervision. (See RBMA's comments below under *Number of IDTFs Supervised*.) Medicare rules, under 410.33(b)(2) regarding general and personal supervision, will need to be amended to be consistent with these recommendations.

Direct Supervision

RBMA requests for CMS to clarify that the physician providing direct supervision in an IDTF setting need not be a radiologist.

In an IDTF setting, certain procedures, typically those requiring the use of contrast agents, require direct (on-site) supervision by a physician. Though allergic reactions from contrast agents are extremely rare and non-physician imaging personnel are trained to identify at-risk patients prior to service delivery, RBMA agrees that a physician should be on-site in the event of a severe allergic contrast reaction. Many physicians are trained in how to treat severe allergic reactions and RBMA therefore recommends that the physician providing direct supervision need not be a radiologist.

Number of IDTFs Supervised

RBMA recommends that CMS propose eliminating the "Number of IDTFs Supervised" requirement in favor of developing performance guidelines for general supervision.

Under Medicare's current IDTF regulations, a physician may provide general supervision for no more than three sites. Rather than focus on quantity of sites, RBMA suggests that CMS develop quality performance guidelines (with stakeholder input) for radiologists who provide general supervision. Examples of performance guidelines include: (1) regular visits to the IDTF, (2) meeting with IDTF personnel on a regular basis, (3) appropriate quality control and assurance monitoring, and (4) documentation. RBMA recommends that fulfillment of any performance guidelines be supported with written documentation. RBMA believes that written performance guidelines will serve to improve technical quality, thus making a

"number of sites" requirement unnecessary. Radiologists who supervise IDTFs via teleradiology should be expected to adhere to these guidelines as well. If CMS retains a "number of sites" supervision requirement, RBMA believes the number should be evidence-based with supporting documentation.

Physician-Owned Imaging Facility

RBMA recommends CMS consider creating a Physician-Owned Imaging Facility (POIF) entity or classification with regulations modeled after those for IDTFs but that are more specific to imaging facilities.

The range of tests under Medicare's IDTF rules spans diagnostic imaging (including vascular ultrasound), gastroenterology, ophthalmology, otorhinolaryngology, audiology, cardiography, allergy, pulmonology, sleep testing, and central nervous system assessment. With such a diverse mix of tests and specialties (many of which are unrelated), we can appreciate CMS' difficulties in maintaining §410.33. Rather than a "one size fits all" approach to IDTFs, RBMA recommends CMS define a new entity called a "Physician-Owned Imaging Facility" (POIF) with rules and regulations more appropriate to the practice of imaging. With the passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS will be developing and implementing (with stakeholder input) accreditation programs for many of the imaging services currently provided in the proposed POIF. RBMA also recommends CMS take a fresh look at its Requirements for Ordering and Following Orders for Diagnostic Tests as they apply to a POIF.

A POIF would have the following criteria:

- Be non-hospital and either solely physician/radiologist-owned or physician/radiologist/hospital-owned
- Provide diagnostic imaging, image-guided therapies, and E/M services
- Employ registered/certified and state-licensed (where applicable) non-physician clinical personnel
- Be subject to the IDTF's quality standards and be accredited
- Abide by specialty societies' applicable guidelines or standards

In-Office Ancillary Exception

RBMA recommends CMS address changes to the in-office ancillary exception that are designed to curb the unnecessary utilization of imaging services.

RBMA believes CMS missed an opportunity with the 2009 Medicare fee schedule proposed rule to make changes to the in-office ancillary exception designed to reduce the unnecessary utilization of imaging due to self-referral. In its report entitled, "MEDICARE PART B IMAGING SERVICES -- Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices," the GAO reports a near doubling of Medicare spending on imaging from 2000 to 2006, particularly for CT, MR, and nuclear medicine. During the same time period, the proportion of Medicare's expenditures on in-office imaging grew from 58 percent to 64 percent with non-radiology physicians accounting for a significant percentage of in-office imaging.

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The RBMA appreciates the opportunity to comment on CMS' final rule regarding Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009. If questions arise or additional information is needed, please feel free to contact RBMA's Executive Director, Michael R. Mabry at 703.621.3363 or mike.mabry@rbma.org.

Sincerely,

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