



AMERICAN
COLLEGE of
CARDIOLOGY

ASE
American Society of
Echocardiography
Heart & Circulation
Ultrasound Specialists



AMERICAN SOCIETY OF
NUCLEAR CARDIOLOGY



Heart Rhythm Society



August 29, 2008

Mr. Kerry Weems
Acting Administrator,
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: **CMS-1403-P**; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule; **Physician Self-Referral and Anti-Markup Issues**

Dear Mr. Weems:

The American College of Cardiology (ACC), the American Society of Echocardiography (ASE), American Society of Nuclear Cardiology (ASNC), The Heart Rhythm Society (HRS), the Society for Cardiovascular Angiography and Interventions (SCAI), the Society for Cardiovascular Computed Tomography (SCCT), and the Society for Cardiovascular Magnetic Resonance (SCMR) are pleased to submit these comments addressing Section II.N. [*Physician Self-Referral and Anti-Markup Issues*] of the 2009 proposed Medicare Physician Fee Schedule, as published in the July 7, 2009 Federal Register, 73 Fed. Reg. 38502 (“the Proposed Rule”) regarding the anti-markup, IDTF, and gainsharing provisions.

Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. We believe that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments on Section II.N. in support of that goal. In addition, the societies remain eager to assist CMS

with any efforts to further review, revise, or otherwise clarify the anti-markup rule; produce guidance on compliance for affected providers; and develop alternative methods for promoting appropriate use of services to reduce the occurrence of fraud, waste, and abuse in the Medicare program.

Anti-Markup Provisions

The cardiovascular community appreciates CMS's decision to delay the extension of the anti-markup rule adopted last year pending further consideration of the many concerns raised by our organizations and others. However, we still have very serious concerns with the agency's current proposal, as set forth in the Proposed Rule. While we agree with CMS that the Medicare program should be protected from unreasonable markups on diagnostic tests purchased from outside suppliers, the agency's attempt to expand the scope of the anti-markup rule to encompass both physician services and diagnostic tests performed within the group is inconsistent with the Medicare law and misguided from a policy perspective. As explained in more detail below, we believe the adoption of this rule will have the effect of eliminating many legitimate, non-abusive arrangements that serve to expand access to care to Medicare beneficiaries while resulting in little or no countervailing benefit to the Medicare program.

A. The Proposal Exceeds CMS' Statutory Authority.

The anti-markup rule is based on Section 1842(n) of the Social Security Act, 42 U.S.C. § 1395u(n). That provision precludes physician practices from "marking up" diagnostic tests purchased from outside suppliers. The statute specifically excludes from the anti-markup prohibition diagnostic tests that are performed personally, or supervised, by the billing physician or another physician "with whom [the billing physician or entity] shares a practice." For many years, Section 1842(n) has been interpreted by CMS to prohibit the mark-up of the technical component of diagnostic tests that are purchased from outside suppliers. It was never, until recently, viewed as encompassing services performed by physicians such as the professional interpretation of diagnostic tests; nor was it ever considered to cover ancillary services performed within a physician practice.

Last year, CMS finalized (and subsequently delayed) a rule that would have extended the reach of Section 1842(n) to tests performed by physician groups that take place outside of a building in which the physician performs the full range of services s/he typically provides. In other words, the agency defined the statutory term "shares a practice" based on where the test was performed. This year, CMS is proposing two options. The first is essentially the same as last year's regulation with some elaboration on the site-of-service concept. The second option is to define "shares a practice" to exclude any physician in a group (regardless of whether they are an employee or contractor) if that physician also provides services and reassigns billing rights to more than one Medicare provider including, presumably, a hospital. The cardiovascular community believes that both options are severely flawed and should not be implemented.

The first option defines “shares a practice” based on whether a test is performed in the same building as where the billing physician (or ordering physician in the case of a group practice) provides “substantially the full range of patient care services that the physician organization provides generally.” We question how CMS can reasonably conclude that this definition is consistent with the statutory term “shares a practice.” According to this interpretation, physicians who are all employees of, and reassign all, of their billing rights to a single practice entity that meets the Stark law definition of group practice would not be deemed to “share a practice” because of the physical location where testing is performed.

The second option would define “shares a practice” to mean an exclusive relationship with a single provider entity. Thus, a physician who is a full-time employee of a practice but who occasionally or on a limited basis supervises or interprets tests at a hospital or other provider location would be considered not to “share a practice” with anyone including physicians in his or her group. Nothing in the statute would suggest Congress intended such a strained interpretation of “shares a practice.”

Finally, the anti-markup provisions in Section 1842(n) are limited to “diagnostic test[s] described in Section 1861(s) (3).” The physician interpretation of a diagnostic test is not a service described in 1861(s)(3). Physician services are described in Section 1861(s)(1).¹ Congress, in enacting Section 1842(n), specifically limited the applicability of the anti-markup provision to diagnostic tests. CMS cannot, through rulemaking, alter the clear intent of the Medicare statute by interpreting Section 1842(n) to include physician services. The proposal to do so is inconsistent with the plain meaning of the law and congressional intent.

B. The Proposal Effectively Overrides the Physician Self-Referral or Stark Law.

The anti-markup proposal essentially discards a nineteen-year process under the Stark law designed to determine when and under what conditions physician offices could furnish ancillary services consistent with the Stark law goals of eliminating abusive physician self-referrals. At the heart of the Stark law exception for “in-office ancillary services” is the definition of “group practice,” which turns on whether physicians are, in effect, “sharing a practice.” This concept has been the focus of a lengthy and complex rulemaking spanning almost two decades that has addressed in considerable detail the requirements that must be met in order for physicians who practice together to provide and bill Medicare for ancillary services, including diagnostic tests. The overriding focus of this rulemaking has been on ensuring that arrangements that create inappropriate incentives for ordering of diagnostic tests were prohibited. Now CMS is proposing an altogether different definition of what it means for physicians to share a practice such that physicians working in arrangements that meet the Stark law definition of “group practice” would not be considered to “share a practice” under the anti-markup rule. Since the Stark law and the

¹ CMS has specifically addressed this issue in a previous fee schedule notice in which the agency stated: [d]iagnostic services that have physician work RVUs are not “other diagnostic tests” covered under section 1861(s)(3) of the Act but physician services and services incident to a physician’s services covered under sections 1861(s)(1) and 1861(s)(2)(A) of the Act. *See* Final 1998 Physician Fee Schedule Rule, 62 Fed. Reg. 59048, 59059 (October 31, 1997).

anti-markup rule were both enacted to curb potential program abuse associated with ordering and billing for ancillary services, including diagnostic tests, we see no policy reason for interpreting the scope of these provisions differently.

Further, we question the policy basis for extending the anti-markup rule to diagnostic tests other than those described in the Stark law. Congress clearly identified in that law those ancillary services, including a number of diagnostic tests, that it believed were potentially abusive. CMS has provided no rationale or facts that would justify imposing restrictions on the ability of physician groups to provide diagnostic services that Congress consciously chose to exclude from the Stark law. *See* Section 152(b)(1) of the Social Security Act Amendments of 1994, P.L. 103-432 (removing “other diagnostic tests” from the definition of “designated health service”).

C. The Proposal Will Adversely Affect Access to Cardiology Services.

Under the site-of-service option, in order to qualify as “the same building,” the test would need to be performed at a location in which the ordering physician provides “substantially the full range of services” that s/he generally provides. This raises a number of complex issues. For example, a cardiology practice may have three main offices in one city, but only one with a CT scanner. If a cardiologist in office A orders a CT scan for a patient to be performed in office B, the anti-markup rule would apply unless that cardiologist provides “substantially the full range of services” at office B. If that cardiologist only provides services at offices A and C, then any CT scans ordered by that cardiologist would be subject to the anti-markup rule even though the cardiologist is a full-time employee of the group and the scan is supervised by another physician in the group. This would force practices to track each ordering physician and ensure that physician provides patient care services at any location in which tests are provided based on his or her referral.

Also in jeopardy are arrangements cardiologists have with hospitals for interpreting EKGs or other tests or for performing diagnostic cardiac catheterization. If the cardiologist, who is an employee of a group practice, reassigns billing rights to the hospital, he or she would fail the “exclusivity” test and thus be deemed not to “share a practice” with the physicians in his or her group. If the site of service test is adopted, cardiologists who perform the professional component of a diagnostic procedure in the hospital or other facility, as is often the case for complex or high risk procedures, would fail this test and the anti-markup rule would apply because the test is conducted outside the office of the billing physician. For example, the our organizations have heard from cardiology groups that provide outreach services in rural areas and are the only providers of certain cardiac subspecialty services in such areas. These groups have expressed concern that their provision of hospital-based cardiac diagnostic tests to rural patients could become financially impossible under the anti-markup rule thereby reducing access to this already underserved population.

In summary, if CMS finalizes either of the proposed alternatives, many legitimate arrangements under which physicians provide access to high quality interpretations of EKGs and other diagnostic services will be eliminated.

Equally problematic is the proposal to treat a test as purchased from an outside supplier if the technician who performs the technical component is not an employee of the billing physician. It should not matter whether the group has an employment or contract relationship with a technician, provided the technician is supervised by a physician in the group and the services is provided on the premises of the group using its equipment. Rather, practices should be able to engage the services of qualified clinical personnel through either an employment or contract arrangement. Smaller cardiology practices that may not need the services of a full-time employed technician should be able to enter into an independent contractor arrangement to obtain the services of a qualified technician without those services being treated as “purchased” from an outside supplier.

D. The Definition of “Net Charge” Must Be Withdrawn or Modified to Include Practice Expenses.

For the reasons stated above, the undersigned organizations argue that CMS should not proceed with either anti-markup proposal. We also believe that the concept of “net charge” is entirely unworkable when referring to tests done within the practice that are not purchased from another entity. However, to the extent that CMS decides to proceed with this approach, it is critical that the definition of “net charge” permit the inclusion of normal practice expense costs such as overhead and equipment. These are legitimate costs that are recognized in the Medicare physician fee schedule payment. It would be entirely inconsistent with well-established Medicare policy to take the position that Medicare should not pay for these costs.

In summary, both anti-markup options would impose substantial additional and potentially conflicting site-of-service or practice requirements on physician groups that are already subject to complex and burdensome regulations under the Stark law. These requirements offer no benefits to patient care and indeed may restrict access for Medicare beneficiaries in many locations.

If CMS believes that the anti-markup restrictions must be applied to diagnostic tests performed within physician practices (as opposed to tests performed by outside suppliers), the agency should delay implementation of any such requirements until it can publish actual regulatory language for each option under consideration and provide additional opportunity for public comment.

I. IDTF Proposal

CMS proposes to require that any physician office that provides diagnostic tests enroll in the Medicare program as an “Independent Diagnostic Testing Facility” or IDTF and be subject to the same performance standards that apply to IDTFs. Our organizations agree that physician practices that perform diagnostic tests should adhere to rigorous quality standards, including personnel qualifications and equipment standards. However, we strongly oppose CMS’s proposal to require physician offices to enroll as IDTFs and meet IDTF performance standards.

The IDTF standards were designed to address particular concerns about the quality of tests performed in those settings. They are not appropriate for physicians' offices, where care is provided by or under the supervision of a physician to his or her own patients and subject to specific Medicare supervision requirements.

Imposing the IDTF standards on physician practices would result in substantial and ongoing administrative costs, both on providers and on the Medicare program. These include preparation of a lengthy enrollment application (in addition to the enrollment application required of physicians and physician groups) and presumably use of a special IDTF supplier number when billing for diagnostic tests (which could be confusing for patients). Practices would be required to update their enrollment form every time there is a change in clinical personnel or supervising physician and to meet other administrative requirements, many of which do not seem relevant to physician offices.

For example, the IDTF rules state that an IDTF cannot share a practice location with another Medicare entity. If physician practices are required to enroll in Medicare as IDTFs, they will automatically be in violation of this requirement. Would this require that physician offices relocate diagnostic testing to some other location outside of the physician office suite? And if they were to do so, would those tests still pass the "same building" test under the anti-markup rule?

Even more significant, however is that this proposal is inconsistent with the direction recently taken by Congress in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). That Act requires accreditation of imaging services, regardless of location, and relies on private accreditation bodies that would develop national standards through a process that includes input from affected stakeholders. We believe this is a better approach than attempting to graft IDTF standards onto physician practices and relying on local Medicare contractors to develop and implement personnel standards. The Act also authorizes CMS to conduct a pilot study of appropriateness criteria. Our organizations have invested significant time and resources in developing appropriateness criteria for cardiovascular imaging services. We believe that implementation of such criteria will ultimately prove to be the most effective answer to concerns about inappropriate self-referral for diagnostic imaging services.

Because Congress has specifically addressed quality of diagnostic tests in MIPPA through accreditation, we believe CMS should withdraw its IDTF proposal and focus on implementation of that Act. This would be a more effective use of scarce government resources than requiring Medicare carriers, without any additional funding, to manage the enrollment and inspection of thousands of additional practices.

II. Exception to the Stark Law for Incentive Payment and Shared Savings Programs

The cardiovascular community strongly supports efforts to align incentives among providers for improvements in quality and efficiency and therefore commends CMS for proposing an exception to the Stark law in the Proposed Rule for incentive payments and shared savings

programs (sometimes collectively referred to here as “gainsharing”). Such programs are potentially of great interest and value to cardiologists who practice in hospitals and other facilities.

As a general principle, we believe that any exception to the Stark law for incentive payment and cost sharing programs should be consistent with the analyses of gainsharing arrangements by the HHS Office of Inspector General (OIG) under the Medicare-Medicaid anti-kickback rules and the Civil Monetary Penalty rules against payments from hospitals to physicians that create incentives for reducing services. The OIG has issued several favorable advisory opinions on gainsharing arrangements that include the following features:

- (i) Measures that promote accountability and transparency;
- (ii) Adequate quality controls (e.g. efforts to ensure no decline in quality of care or reduction in service occurs due to implementation of the arrangement); and
- (iii) Controls on payments related to self-referrals.

While the proposed Stark exception for incentive payment and cost sharing programs appears to follow these same principles and requires that such programs not violate the anti-kickback law, the we are concerned that requirements of the proposed Stark exception are much narrower and more detailed than the factors considered in the OIG advisory opinions addressing gainsharing arrangements. We fear that the exception is so narrowly drafted and contains so many potentially burdensome requirements that it may not be useful for most physicians and hospitals hoping to participate in an incentive payment or shared savings program. We therefore urge CMS to scale back the number of fixed requirements and to provide more flexibility for compliance so that the exception can meet the agency’s goals of encouraging the development of incentive payment and shared savings programs.

With these general comments in mind, we also have the following comments on specific aspects of the proposed exception:

A. The Proposed Exception Should Provide More Flexibility with Respect to the Number of Eligible Physicians and Types of Eligible Facilities.

The proposed gainsharing exception only allows payments to physician organizations where all members participate in the program (a “qualified physician organization”) and to physicians who are members of the hospital medical staff at the beginning of the program. While we understand that CMS wants to prevent improper referrals and minimize the risk that abusive programs will be used to attract physicians from competing hospitals, this condition likely will significantly limit the number of physicians who can participate. The proposed exception defines a qualified physician organization as one composed entirely of physicians participating in the same incentive payment or shared savings program. The exception would be more practical if CMS were to expand the definition of “qualified physician organization” to allow payments to physician practices even if not all the physicians participate in the program. We agree that only physicians participating in the program should be able to share in the incentive or shared savings

programs on a per capita basis and believe this will provide adequate protection against payments to physicians who do not participate in the program.

The exception should also allow physicians who join the medical staff after the commencement of a gainsharing program to participate. Otherwise, the exception will artificially limit the number of physician who can participate in such programs and thereby greatly hinder their effectiveness. Indeed, as written, the exception would not apply to *any* physician who joins the medical staff after the gainsharing program starts, including physicians who are new to an area or have recently graduated from residency or fellowship programs. Thus, the limitation would apply to more than just physicians practicing at competing hospitals. Most importantly, the restriction against physicians joining a program after it starts is not necessary. The proposed exception contains numerous other conditions that will prevent the exception from applying to hospitals that use their gainsharing programs to entice physicians from competing hospitals to join their medical staff.

The proposed exception applies only to payments made by hospitals. It does not include payments by other types of providers or suppliers. The preamble suggests that CMS is concerned that providers and suppliers reimbursed on a fee schedule or other fee-for-service basis might have an incentive to create programs that result in the provision of more items and services and thereby increase costs to the Medicare program and beneficiaries without any actual quality improvement. Assuming this is true, the cardiovascular specialties would support expanding the exception just to other providers that are paid under a prospective payment basis such as hospital outpatient departments, inpatient rehabilitation facilities, long-term care hospitals, and skilled nursing facilities.

B. The Proposed Exception May Limit the Participation of Small Providers.

The proposed exception requires physicians participating in a program or in a particular measure within a program to do so in “pools” of five or more participating physicians. Our organizations oppose this requirement because it may prevent smaller practices and hospitals from participating in incentive payment or cost sharing practices and may encourage abusive practices. Gainsharing arrangements are typically established for specific specialties within a hospital. Larger specialty practices will be able to form pools more easily than smaller groups, and smaller hospitals may not have five doctors on staff within a given specialty. Also, a hospital may chose a larger group to participate in a program over a smaller group because of the larger group’s importance as a referral source, but the hospital could point to the “five or more” requirement as justification for favoring large groups.

We recommend that CMS adopt a more flexible approach to this requirement by allowing for smaller pools of participating physicians. First of all, it is not clear that pools of fewer than five physicians will lead to program abuse. The proposed exception contains sufficient other checks on participant conduct to prevent such misconduct. Second, hospitals and other covered facilities should able to establish minimum pool sizes based on the specifics of their particular incentive payment or cost sharing programs. The only requirement should be that hospitals

establish pools of physicians of a size that is sufficient to yield meaningful cost savings and quality outcomes based on the particular facts and circumstances. In some cases that might require pools of at least five physicians, but in other cases, involving smaller hospitals, two or three physicians from a particular specialty might be sufficient.

C. Several Conditions of the Proposed Exception Appear Arbitrary.

Several of the requirements in the Proposed Rule also seem to be arbitrary or without a rational basis. For example, CMS proposes to limit the duration of a program to no shorter than one year and no longer than three years. The agency also proposes to impose a 50-percent limit on physician cost sharing along with other limits on physician remuneration. CMS states that these safeguards are necessary to ensure that incentive payment and shared savings programs do not reward physician referrals or result in altered referral patterns, but it does not explain how it arrived at these limits. Moreover, the proposed exception already has a number of other safeguards to protect against abuses, such as independent medical review requirement and the restriction on tying remuneration to the volume or value of referrals from the participating physician. Likewise, CMS has provided no reason for limiting incentive or cost sharing payments to cash or cash equivalents. The Stark law covers both monetary and non-monetary remuneration. It makes no sense for the gainsharing exception to have a different definition of remuneration.

D. Fraud and Abuse Issues Should Be Addressed in Separate Rulemaking.

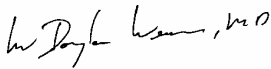
We recommend that CMS make changes to fraud and abuse laws through a separate rulemaking process. CMS should issue a separate rulemaking on this Stark exception so that all stakeholders will be aware of and can properly focus on it. This will also ensure that CMS has the benefit of the full range of comments and concerns about such changes.

In summary, while we applaud CMS for proposing an exception for incentive payment and cost sharing programs, we recommend CMS change or delete some of the requirements in order to ensure consistency with the OIG's analysis of gainsharing arrangements and to create an exception that both helps prevent fraud and abuse and gives physicians and hospitals the flexibility to create programs that are effective in increasing quality and achieving cost savings. We also urge the agency to issue a separate NPRM on this exception to ensure full participation by all stakeholders.

* * * * *

The ACC, ASE, ASNC, HRS, SCAI, SCCT, and SCMR thank CMS for this opportunity to comment on the 2008 proposed Medicare Physician Fee Schedule rule. We welcome any opportunity to assist CMS in general, and if we may be of any help on the anti-markup, IDTF, or gainsharing provisions in particular, please contact Rebecca Kelly, ACC Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org with any questions.

Sincerely,



W. Douglas Weaver, M.D., F.A.C.C.
President, American College of Cardiology



William A. Zoghbi, M.D.
President, American Society of
Echocardiography



William A. Van Decker, M.D.
President, American Society of Nuclear
Cardiology



N. A. Mark Estes III, MD, FHRS
President, Heart Rhythm Society



Ziyad A. Hijazi, M.D., M.P.H., F.S.C.A.I.
President
Society for Cardiovascular Angiography
and Interventions



Daniel S. Berman, M.D.
President, Society for Cardiovascular
Computed Tomography



Charles B. Higgins, M.D.
President, Society for Cardiovascular
Magnetic Resonance