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To: John F. Morrall III/OMB/EOP@EOP

cc:
Subject: Comments

Mr. Morrall--attached are comments of the Society of Nuclear Medicine submitted in response to the March 28 Federal Register notice concerning the costs and benefits of federal regulation. I have also Faxed them to you and FedExed the original.

Thank you for your consideration.

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May 28,2002

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB Room 10235
725 17th Street, NW
Washington, DC 20503

Dear Mr. Morrall:

The Society of Nuclear Medicine ("Society") is pleased to present these comments in response to the Federal Register notice of March 28,2002, requesting comments on the costs and benefits of federal regulation and suggesting regulatory reform improvement. The Society is an international scientific and professional organization founded in 1954 to promote the science, technology and practical application of nuclear medicine. Its 13,000 members are physicians, technologists and scientists specializing in the research and practice of nuclear medicine. In this comment, we wish to address an issue that is important to patients in need of nuclear diagnostic scans and the physicians who provide that service.

CMS Rules Prevent the Efficient Delivery of Safe and Effective Nuclear Diagnostic Services to Medicare Beneficiaries

Current CMS rules governing the office performance of nuclear diagnostic scans prevent an arrangement that allows for efficient, cost effective delivery of nuclear diagnostic scans to patients, discriminating against nuclear medicine specialists and encouraging non-expert physicians to interpret nuclear diagnostic scans, to the detriment of Medicare patients.

Ideally, physicians, such as a cardiology group practice, could contract with nuclear medicine specialists to provide teleradiology interpretations of nuclear diagnostic scans off the site of the cardiology practice. As independent contractors, the nuclear medicine specialists would reassign their right to bill and receive payment to the physician practice, which would bill globally for the technical and professional components of the nuclear diagnostic scan services and pay the nuclear medicine specialist an independent contractor fee that would otherwise meet all applicable CMS regulations. The economics of this arrangement would improve the quality of care delivered to patients, because interpretations would be performed by expert nuclear medicine specialists, rather than less experienced physicians.

But the CMS rules create economic disincentives for this arrangement, with the result that patients may receive a reduced quality of care in that nuclear medicine specialists are prevented from providing their expertise and non-nuclear medicine physicians are encouraged into the unwanted position of attempting to interpret nuclear diagnostic scans when they have limited expertise.

The problem arises primarily in Medicare Carriers Manual Section 3060.3.C, which governs an exception to the general prohibition on the reassignment of claims. The exception is called "Payment to Health Care Delivery System." This exception allows a physician group that uses nuclear diagnostic scans to bill globally for the technical and professional component, even when the professional component, or interpretation, is provided by an independent contractor nuclear medicine physician. That much of the exception makes good economic sense for physicians and nuclear medicine specialists and, consequently, for patients who receive expert diagnostic services.

However, the potential common sense benefit of this exception is prevented by the additional requirement that, in order for the physician group to bill globally for the professional component/interpretation of the nuclear diagnostic scan provided by the independent contractor nuclear medicine physician, the nuclear medicine physician must perform the interpretation *physically located at the physician group practice location*. The additional costs of being physically present rather than providing the interpretations remotely makes the long term engagement of nuclear medicine specialists as independent contractors not economically feasible for the physician group, with the result that the physicians choose the less medically beneficial option of interpreting the nuclear diagnostic scans themselves.

Justifications for Changing the Rules that Prevent Efficient Interpretations of Nuclear Diagnostic Scans

The most salient objection to the physical presence requirement in Medicare Carriers Manual section 3060.3.C is that it makes the provision of expert nuclear diagnostic scan interpretations by independent contractor nuclear medicine specialists not economically feasible for the physician groups, whose only alternative is to perform the interpretations themselves with a lesser degree of expertise. **As** a result, patients are deprived of a superior level of service. It is difficult to find a convincing policy justification for this result.

Objections to this physical presence requirement in the "Payment to Health Care Delivery System" exception to the general prohibition on reassignment also arise from comparison to related CMS policy. CMS has recognized the value of teleradiology as an outgrowth of advances in electronic information exchange. Medicare currently pays for the interpretation of diagnostic procedures using images or other data transmitted via teleradiology.[1] The physical presence requirement in this exception frustrates the primary basis for teleradiology, namely, the efficient provision of expert diagnostic imaging interpretations that would otherwise not be available to patients.

There is another aspect of CMS policy that gives rise to an objection to the physical presence requirement. Under Medicare payment and coverage rules for nuclear diagnostic scans, physical presence of the interpreting physician is *not* required. In effect, CMS has determined that nuclear diagnostic scans are safe and effective without direct, on site supervision. The supervision level for

[1] See Medicare Carriers Manual section **2020.A.**

nuclear diagnostic scans is set forth in Program Memorandum No. B-01-28 (April 19,2001) as "general supervision."[2] General supervision is defined in Program Memorandum No. B-01-28 as follows:

> "General supervision" means the procedure is furnished under the physician's overall direction and control, *but the physician's presence is not required during the performance of the procedure*. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician. (emphasis added).

Originally, in the final rule for the physician fee schedule, nuclear diagnostic scans were assigned a supervision level of "direct supervision," which requires physician presence in the office suite where the procedure is being provided.[3] However, the final rule designating this level of supervision was delayed, and ultimately changed by the aforementioned Program Memorandum No. B-01-28. This change in the supervision requirements indicates that, in CMS's judgment, nuclear diagnostic scans are safe and effective and appropriately supervised without requiring the presence of the nuclear medicine specialist who interprets them. Furthermore, nuclear diagnostic scans are "reasonable and necessary for the diagnosis and treatment of illness or injury'' for the purposes of Medicare reimbursement without requiring physician presence at the site where the services are provided.

Because the nuclear diagnostic scans are appropriately performed without the physical presence of the nuclear medicine specialist under Medicare payment rules, it is unnecessary to require an independent contractor nuclear medicine specialist to perform interpretations of nuclear diagnostic scans at the site where the services were provided.

The in-office ancillary services exception to the Stark self-referral prohibition reflects and supports the policy that nuclear diagnostic scans do not require that the supervising physician be physically present where the services are provided.[4] Under the proposed Stark self-referral regulation, it was required that

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[2] The HCPCS codes for the relevant nuclear diagnostic procedures subject to the general supervision requirement as detailed in Program Memorandum No. B-01-28 are 78000,78001,78003,78006,78007,78010,7801 1,78015,78016,78018,78070, 78075,78102,78103,78104,78110,78111,78120,78121,78122,78130,78135,78140,78160,78162,78170,78172, 78185,78190,78191,78195,78201,78202,78205,78206,78215,78216,78220,78223,78230,78231,78232,78258, 78261,78262,78264,78270,78271,78272,78278,78282,78290,78291,78300,78305,78306,78315,78320,78350, 78414,78428,78445,78455,78457,78458,78460,78461,78464,78465,78466,78468,78469,78472,78473,78478, 78480,78481,78483,78494,78496,78580,78584,78585,78586,78587,78588,78591,78593,78594,78596,78600, 78601, 78605, 78606, 78607, 78610, 78615, 78630, 78635, 78645, 78647, 78650, 78660, 78700, 78701, 78704, 78707, 78708,78709,78710,78715,78725,78730,78740,78760,78761,78800,78801,78802,78803,78805,78806,78807, 78990; PET scans also subject to the general supervision requirement as detailed in the Memorandum are as follows: G0030, G0031, G0032, G0033, G0034, G0035, G0036, G0037, G0038, G0039, G0040, G0041, G0042, G0043, G0044, G0045, G0046, G0047, G0125, G0126, G0163, G0164, G0165.

[3] See 62 FR 59048,59069 (October 31, 1997).

[4] It should be noted that nuclear diagnostic scans are not designated health services ("DHS") covered by the Stark self-referral prohibition, but are analogous to DHS with respect to the issue of physician supervision. The fact that nuclear diagnostic scans are not considered DHS indicates that CMS found them to be pose little risk of inappropriate billing to Medicare.

designated health services ("DHS") be supervised by a physician who was present in the office suite in which the services were being furnished.[5] In response to criticisms that such a requirement would be "overly burdensome, result in enigmatic technical rules, and require wasteful and inefficient practices,"[6] CMS revised that supervision requirement. CMS acknowledged that "Congress did not intend to require physicians to be present at all times that ancillary services were being performed."[7] CMS changed the supervision requirement in the final rule, adopting the "sensible approach"[8] that supervision requirements should be the same as those under applicable Medicare payment or coverage rules for the specific services at issue.' As indicated by Program Memorandum No. B-01-28, the appropriate level of supervision for nuclear medicine (including PET) scans does not require the physical presence of the interpreting physician.

Recommended Changes to CMS Rules

Given the aforementioned justifications, the Society takes the position that any regulations or policies that contradict CMS's policy allowing off site supervision of nuclear diagnostic scans should be changed.

Therefore, the Society recommends two changes to the Medicare Carriers Manual. First, section 3060.3.C should be reworded to eliminate the phrase "on the premises of the clinic" from the sentence that reads "Payment may be made to the clinic for services provided on the premises of the clinic by an independent contractor physician as long as the clinic enters into a contractual arrangement with the physician allowing the clinic to bill and receive payment for the physician's services." This change would allow an independent contractor nuclear medicine specialist to provide interpretations to another physician group without the "wasteful and inefficient practice" of physically going to the site where the technical component of the nuclear diagnostic scan is provided to perform the interpretation.

The Society also recommends a second change to the provisions of the Medicare Carriers Manual governing reassignment. Section 3060.5-Payment to Supplier of Diagnostic Tests for Purchased Interpretations prevents the independent contractor arrangement by which a nuclear medicine specialist could provide nuclear diagnostic scan interpretations off site from the physician practice that bills globally for the service. The language in section 3060.5 that causes the obstacle reads as follows:

> A person or entity that provides diagnostic tests may submit the claim, and (if assignment is accepted) receive the Part B payment, for diagnostic test interpretations which that person or entity purchases from an independent physician or medical group if…[t]he tests are initiated by a

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[5] 66 FR 856,885 (January 4,2001).

[6] Id.

[7] Id.

[8] Id.

[9] *See* Id.

physician or medical group which is independent of the person or entity providing the tests and of the physician or medical group providing the interpretations.

As a result of this language, there must be a tri-partite arrangement of treating physician who initiates the test, diagnostic testing facility that provides the technical component of the test, and a physician or group that provides the professional component/interpretation of the test. This discriminates against treating physicians who are able to provide the technical component of nuclear diagnostic scans themselves, but would like to tap the interpretive expertise of nuclear medicine specialists for the benefit of their patients.

The Society recommends a simple change to the language of section 3060.5 that would eliminate the obstacle to the desired arrangement; addition of the words "either" and "or" to the aforementioned sentence, to read as follows:

> **A** person or entity that provides diagnostic tests may submit the claim, and (if assignment is accepted) receive the Part B payment, for diagnostic test interpretations which that person or entity purchases from an independent physician or medical group if…[t]he tests are initiated by a physician or medical group which is independent of **either** the person or entity providing the tests **or** ~~and of~~ the physician or medical group providing the interpretations. (recommended changes in **bold underline,** deletions in ~~strikethrough~~).

If both of these changes are made, instead of one or the other, the Society recommends a further technical alteration to section 3060.3.C. The language in that section makes the 3060.3.C exception unavailable for an arrangement that would otherwise qualify for the "Payment to Supplier of Diagnostic Tests for Purchased Interpretations" exception at 3060.5. If the Society's recommended changes to 3060.3.C and 3060.5 are both made, 3060.3.C would still be unavailable unless the aforementioned limitation is eliminated. Therefore, the Society recommends changing the language of 3060.3.C from its current form as follows;

> The health care delivery system exception (3060.3.C) does not apply…where payment may be made to the clinic under 3060.4-3060.7 (purchased tests, purchased interpretations, reciprocal billing and locum tenens arrangements).

to;

> The health care delivery system exception (3060.3.C) does not apply…where payment may be made to the clinic under 3060.4, 3060.6, and 3060.7 (purchased tests, reciprocal billing and locum tenens arrangements).

In this way, if both 3060.3.C and 3060.5 are changed as recommended by the Society, both exceptions would still be available, to be chosen according to the suitability of the situation and with the best interests of patients in mind.

The Society acknowledges that the recommended changes would have broad ramifications for supervision in the furnishing of other types of diagnostic tests. However, the physician fee schedule adequately addresses the issue of supervision, and will require personal or on site supervision where

CMS has determined that such a level of supervision is necessary or appropriate. These changes would merely conform the reassignment rules to the broader policies on physician supervision.

The Society thanks OMB for the opportunity to present these comments. CMS's objective of providing quality health care to Medicare beneficiaries in a way that provides efficiencies to Medicare as payor would be well served by these proposed changes. The Society is committed to working with OMB and CMS to ensure that the recommended changes comport with sound policy in favor of Medicare and its beneficiaries.

Sincerely,

Alan H. Maurer, MD
President