June 24, 2004

VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Re: CMS-1810-IFC; Comments on Interim Final Rule regarding Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships

Dear Administrator McClellan:

The American Society for Therapeutic Radiology and Oncology ("ASTRO") welcomes the opportunity to comment — on behalf of its more than 7,500 members — on the Interim Final Rule governing physician referrals to health care entities with which they have financial relationships, published by the Centers for Medicare & Medicare Services ("CMS") on March 26, 2004. See 69 Fed. Reg. 16054. Founded in 1958, ASTRO's mission is to advance the practice of radiation oncology by promoting excellence in cancer care, providing opportunities for educational and professional development, encouraging and disseminating research, and representing ASTRO members regarding health policy issues that affect the quality, availability and delivery of cancer care.

I. The Interim Final Rule

The Interim Final Rule includes changes and revisions to the Final Rule published in the Phase I rulemaking under Section 1877 of the Social Security Act (the "Stark Law"), 66 Fed. Reg. 856 (January 4, 2001), as well as significant new provisions added through the Phase II rulemaking. We appreciate the thorough and diligent manner in which CMS has considered and responded to the thousands of comments submitted in connection with this regulatory rulemaking process. Moreover, we recognize the considerable resources and effort that the agency has devoted to trying to develop clear and comprehensive regulations, which fulfill both the letter and the spirit of the Stark Law, while minimizing any negative impact on the quality or availability of patient care. Finally, we applaud the additional guidance and clarification that CMS has provided through the recent Phase II rulemaking, particularly with respect to some of the

unique (and complicated) Stark Law issues confronting certain medical specialists and specialty groups, including radiation oncologists.

II. Specialty Practices Changes

With respect to radiation oncology, ASTRO specifically supports CMS' (1) stated intention to modify the “consultation” exception to the "referral" definition to include certain non-radiation therapy designated health services (“DHS”) (e.g., certain computerized axial tomography, magnetic resonance imaging and ultrasound procedures) that are performed as part of, and are integral to, radiation therapy treatment, 69 Fed. Reg. at 16065; (2) replacement of the requirement in the “same building” component of the in-office ancillary services exception (as defined in the Phase I rulemaking) that the referring physician or his or her group practice perform a “substantial” amount of services unrelated to DHS in the building at issue with the more relaxed standard that only “some” non-DHS services be so performed, id. at 16074-16075, 16135; (3) expansion of the “consultation” exception to the "referral" definition to encompass radiation therapy that is requested by a radiation oncologist and performed by the radiation oncologist, under his or her supervision, or under the supervision of another radiation oncologist in his or her group practice, id. at 16065, 16130-16131; (4) elimination of the requirement in the “same building” component of the in-office ancillary services exception (as defined in the Phase I rulemaking) that the receipt of DHS not be the “primary reason” for the patient's coming in contact with the referring physician or group practice, id at 16075; and (5) refinement of the definition of the term “set in advance” to permit percentage-based compensation arrangements, provided certain conditions are met, id. at 16066.

III. The Need for Three Further Changes

While we recognize and appreciate the five positive changes (outlined above) that CMS has made in order to accommodate the unique nature of the specialty of radiation therapy, we are concerned that without some further refinement, these changes will be insufficient to accomplish CMS' stated goal of “protect[ing] legitimate arrangements involving specialty groups that primarily furnish DHS, such as oncology and radiology.” Id. at 16124. Our comments are focused on the first three of the five changes set forth above.

A. The Consultation Exception: Covering Other Integrally Related DHS

As noted above, CMS agreed with commenters that the "consultation" exception "would fail its intended purpose" with respect to radiation oncology consultations, "if it did not also protect necessary and integral ancillary services requested, and appropriately supervised, by the radiation oncologists." Id. at 16065. CMS stated: "[w]e have modified the regulations accordingly." Id. While we agree with, and enthusiastically support, CMS' stated approach to this issue, we are unable to identify the modification in the Interim Final Rule implementing this change. Thus, the definition of "radiation therapy" fails to include computerized axial tomography, magnetic resonance imaging, ultrasound or other integral ancillary services since these CPT codes are not included in the list of codes defining "radiation therapy services and supplies." Nor have the definitions of "consultation" or "referral" been revised to reflect the changes that CMS endorses. We respectfully urge CMS to make the textual changes necessary in the Final Rule to effectuate this important modification. In particular, we recommend that the definition of the term "referral," as set forth at 42 C.F.R. § 411.351, be amended to exclude requests made by a radiation oncologist — who is operating pursuant to a request for a radiation oncology consultation — for radiation therapy and other non-radiation therapy DHS (such as computerized axial tomography, magnetic resonance imaging and ultrasound procedures) that are a part of, and integrally related to, the performance of the radiation therapy at issue.

B. Self-Referred Cancer Patients

As set forth above, in response to concerns that the Stark Law prevented certain cancer patients — particularly those suffering from prostate cancer — from self-referring to, and receiving radiation therapy from, a radiation oncologist of their choice, CMS changed (and indeed relaxed) the "same building" component of the in-office ancillary services exception. According to CMS, these "changes should enable most radiation oncologists to provide radiation therapy services to self-referred patients . . .." 69 Fed. Reg. at 16066.

Although we appreciate and applaud these changes, we believe that the changes are insufficient because they fail to address common situations where patient self-referral is desirable and should be accommodated. We offer examples of two such situations.

1. Radiation Oncologist Leases Facility on Part-Time Basis, But Does Not Perform Non-DHS Services at Facility

Assume that Radiation Oncologist A ("Dr. A") is on the faculty of a leading academic medical center, has written and spoken widely on the diagnosis and treatment of prostate cancer, and enjoys a reputation as one of the foremost brachytherapy clinicians in the relevant geographic area ("Area"). Dr. A practices through her professional corporation, which, among other things, employs a physicist. Although Dr. A evaluates patients at her office, she prefers to lease (through her corporation) the operating room at a nearby and recently built ambulatory surgical center ("ASC") to perform brachytherapy. As with many other radiation oncologists across the country, Dr. A finds that she is able to perform cases more efficiently — and that her patients are therefore typically able to go home quicker — when services are furnished at the ASC rather than in one of the Area hospitals. Dr. A has no financial relationship with the ASC.

Assume further that Patient X, a resident within the Area, is diagnosed with prostate cancer by his urologist. The urologist refers Patient X to Dr. B, a radiation oncologist, for a prostate brachytherapy consultation. After examining Patient X, and reviewing his medical file, Dr. B concurs that Patient X is a candidate for prostate brachytherapy. A volume study performed by Dr. B further indicates that Patient X's prostate is sufficiently small for the procedure.

Upon making additional inquiries, Patient X makes an appointment with Dr. A. Dr. A is prepared to treat Patient X, but fears that any radiation therapy that she requests will not be protected by the "consultation" exception to the term "referral," and, as such, will implicate the Stark Law. Although radiation therapy that is self performed by Dr. A would not give rise to a prohibited referral, Dr. A may not request — and her professional corporation may not bill for — the technical work typically performed by her practice's employees (such as the physicist) without violating the Stark Law.

If Patient X had been referred to Dr. A by the urologist, the consultation exception would apply and Dr. A would be permitted to proceed on Patient X's behalf and bill globally for the professional and technical services performed by her practice. The consultation exception is unavailable here, however, and, as CMS notes, cannot be forged out of a self-referral without engaging in prohibited circumvention. Id. at 16066. More important, even as amended, the in-office ancillary services exception provides no additional protection. For example, all of the services performed by the physicist during the procedure itself will be radiation therapy (i.e., DHS) furnished at the request of Dr. A, a physician that owns the furnishing entity — i.e., her professional corporation.

Even though the services would satisfy the first and third prongs of the in-office ancillary services exception (the services will be performed under the supervision of Dr. A and be billed by and in the name of Dr. A's practice), they cannot meet the second prong. The reason for this is straightforward: although Dr. A routinely furnishes medical services at the ASC, none (let alone "some") of these services are non-DHS.[1] Thus, Dr. A has to decline to treat Patient X.

2. Situations Where a Facility is Jointly Owned by More than One Radiation Oncologist

A second hypothetical (based on another common business arrangement) further illustrates why the in-office ancillary services exception often will not serve to protect radiation oncologists who wish to treat self-referred cancer patients. Assume that there are three radiation oncologists (Drs. C, D and E) who practice independently of one another in separate locations in Medium Town, a community of 70,000 people. Given that linear accelerators are expensive, Drs. C, D and E form a joint venture to (1) secure the necessary space and equipment to establish a freestanding radiation therapy center ("Center") and (2) hire necessary technical and other personnel to operate the Center. The three doctors, who contribute equally to the venture, each enter into written agreements with the Center pursuant to which they lease the space, equipment and personnel to treat their respective patients at the Center in return for a commercially reasonable fair market per procedure fee. Because there is vacant space in the basement of the medical office building ("Building") where Dr. C leases office space, the doctors agree to locate the Center in the Building. None of the doctors owns the Building.

Under this scenario, Dr. C is the only radiation oncologist who could treat self-referred patients at the Center, making it fortuitous for him that his landlord could accommodate the Center. Drs. D and E could not use the Center to treat self-referred patients as the "consultation" exception would not apply and neither physician could meet the "same building" requirement of the in-office ancillary services exception, even as amended, since none of the services provided by the doctors at the Center would constitute non-DHS. Thus, the only available option would be for each physician to invest in his or her own linear accelerator, a highly inefficient solution that has significant negative consequences from a public policy perspective.

From a patient care perspective, it is critical for cancer patients to be able to choose the radiation oncologists who will treat them. It is hard to imagine a more important or deeply personal choice for an individual to make. In most instances, such decision will be based on the professional recommendation of a trusted specialist or other physician. But, in a small subset of cases, the decision will be based on the

[1] For a host of reasons, the ASC does not constitute a "centralized" building used by a group practice.

individual's own assessment of factors critical to him or her, such as the physician's reputation in the medical community, familiarity with a particular subspecialty within the field of radiation oncology, or word-of-mouth patient referral. While self-referrals are clearly the exception, and represent only a small subset of cancer patients seen by radiation oncologists each year, we believe that it is important to ensure that the Final Rule does not interfere with patient freedom of choice.

3. Recommended Revisions

Specific improvements can be made to the Final Rule, which are consistent with the Stark Law's goals and directives yet minimize the negative impact on cancer patients and lessen the potential disruption to existing arrangements involving radiation oncologists. We offer two possible alternatives for accomplishing this goal.

As an initial matter, we urge CMS to extend the "consultation" exception to the "referral" definition to include the narrow subset of cases where an individual who has been diagnosed with cancer chooses a radiation oncologist other than the one selected by his or her primary physician. CMS could make this change under its statutory authority to create regulatory exceptions that pose no risk of fraud or abuse. This modification would be consistent with CMS' recognition of the limited ability of radiation oncologists to generate patient referrals of services they either perform or supervise. 66 Fed. Reg. at 896. There is no reason whatsoever to believe that a radiation oncologist who treats a self-referred patient is more likely than one operating pursuant to a consultation to over radiate. As CMS acknowledged in the context of the Phase I regulations to the Stark Law, radiation oncologists typically assume control of the patient's care even where they are technically operating pursuant to a "consultation." Id. at 874-875.

Alternatively, we urge CMS to relax the "same building" requirement in the in-office ancillary services exception as it applies to radiation oncologists so as to permit the exception to apply wherever radiation therapy is provided in a properly licensed and certified facility. This modification would recognize that as a practical matter radiation oncologists tend to provide only DHS services in certain facilities. The failure to include such a modification would mean that in many instances services could not be performed because of the manner in which the patient came to see the radiation oncologist. The Stark Law expressly permits HHS to modify the same building exception where it "determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(2)(A).

As previously stated, because radiation oncologists typically assume control and responsibility for a patient's care — with or without a consultation — it makes eminent sense to permit such specialists to honor the wishes of those patients who self-refer to them. We further posit that such self-referrals will always remain the exception rather

than the rule, and will likely occur where a specialist has proven his or her worth through optimal outcomes.

For the foregoing reasons, we strongly encourage CMS to either (a) modify the "referral" definition to exclude radiation therapy requested by a radiation oncologist who is treating a self-referred patient, or (b) modify the "same building" requirement in the in-office ancillary services exception such that the exception will be met whenever a radiation oncologist performs services in a properly licensed and certified facility.

C. The Consultation Exception: Who May Perform Therapy

The statutory "consultation" exception to the term "referral" allows a radiation oncologist who is operating pursuant to a request for a consultation made by another physician to request radiation therapy without triggering the Stark Law's referral prohibitions, provided the radiation therapy is performed by the radiation oncologist or by someone under the radiation oncologist's supervision. 42 U.S.C. § 1395nn(h)(5)(C). The Interim Final Rule expands the "consultation" exception to permit the radiation therapy to be performed "by or under the supervision of the . . . radiation oncologist, or under the supervision of a . . . radiation oncologist . . . in the same group practice . . .." 42 C.F.R. § 411.351 ("Referral") (69 Fed. Reg. at 16131). Read literally, the exception, as amended, would permit a radiation oncologist in the consulting radiation oncologist's group practice to supervise the radiation therapy, but not to perform it. To the extent that the radiation oncologist at issue would perform the radiation therapy, the Stark Law would not be implicated because self-performed DHS does not give rise to a "referral" under the Law. 42 C.F.R. § 411.351 ("Referral") (69 Fed. Reg. at 16130). Nevertheless, there is value to having the Law and its implementing regulations be articulated in as coherent, consistent and correct a manner as possible. For that reason, we respectfully request that CMS further amend the definition of the term "referral" to clarify that a radiation oncologist — who is operating pursuant to a request for a consultation made by another physician — may request radiation therapy without violating the Law, provided that the radiation therapy is performed by (1) the radiation oncologist who is the subject of the consultation request, (2) another radiation oncologist in the consulting radiation oncologist's group practice, or (3) another person who is under the supervision of the radiation oncologist in (1) or (2).

D. Proper Balance

As CMS has repeatedly stated, the objective of the Stark Law and its implementing regulations is to strike the proper balance between seeking to prohibit abusive self-referral practices and not unduly hampering access to quality patient care or the evolution and advancement of medical procedures. We would oppose any effort to reverse the practical course that has been set forth in the Interim Final Rule with respect to the "consultation" definition and the scope of the in-office ancillary services exception, among other things. Congress and CMS have wisely embraced a

sophisticated and nuanced approach to determining appropriate physician self-referrals. For the most part, we believe that CMS has struck the proper balance and that no major changes in the regulations are necessary, except as proposed herein.

In conclusion, we appreciate the opportunity to comment on these issues and to make recommendations concerning ways the Interim Final Rule can be further refined to minimize the adverse impact on cancer patients and members of the radiation oncology community while adhering to the goals and directives of the Stark Law. If you have any questions concerning these comments, or require additional information, please contact ASTRO at (703) 502-1550.

Respectfully submitted,

Laura Thevenot
Executive Director,
ASTRO