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August 4, 2008

Carol G. Potter
Medical Facilities Planning Section
701 Barbour Drive
Raleigh N.C., 27603

Dear Ms. Potter,

We write to register our firm opposition to a proposed CON application for a urology specific linear accelerator under consideration for Linac Service Area 20 and endorse the opinions put forward by Dr. Robert Fraser and Dr. Robert Anderson. Please find enclosed 3 attachments which have bearing on the issue at hand:

1. Letter from ASTRO (American Society for Therapeutic Radiology and Oncology) to Herb B. Kuhn, Acting Administrator for the Centers for Medicare and Medicaid Services (CMS), August 20, 2007. Section IV lays out in great detail the real motivations for these types of ventures and the associated pitfalls.
2. Saul, Stephanie. "Profits and Questions on Prostate Cancer Therapy" New York Times, December 1, 2006.
3. Saul, Stephanie. "Sales Pitch for a Treatment" New York Times, December 1, 2006.

The Department of Facility Services in North Carolina currently serves a valuable purpose by evaluating the need for major medical equipment including linear accelerators. It is our belief that allowing any disease-specific or specialty-specific radiation centers to operate would be the antithesis of why CON statutes were designed. It is our hope and belief that CMS will listen to the American College of Radiology, American College of Radiation Oncology, and the American Society for Therapeutic Radiology and Oncology about the powerful financial incentive for self-referral by referring urologists with ownership in linear accelerators. These organizations are actively working with the CMS to exclude radiation oncology as an in-office ancillary service (IOAS) under the Stark physician self-referral regulations. If this exclusion occurs, which we believe it will, the proposed prostate cancer center would not only be a bad idea and horrible precedent, but also illegal.

We would also appreciate any notification regarding any public hearings or meeting on this topic so that we may send a representative. Thank you for your consideration and allowing us the opportunity to comment.

Sincerely,

Michael A. Papagikos, M.D.

Patrick D. Maguire, M.D.

Charles R. Neal, M.D.

Martin B. Meyerson, M.D.

Michael A. Nichols, M.D., Ph.D.

ASTRO
American Society for Therapeutic Radiology and Oncology

August 20, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1385-P
PO Box 8018
Baltimore, MD 21244–8018

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (CMS–1385–P)

Dear Mr. Kuhn:

The American Society for Therapeutic Radiation and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the *Federal Register* as a proposed rule on July 12, 2007. Our comments focus on issues related to: (1) resource-based practice expense (PE) relative value units (RVUs); (2) malpractice RVUs; (3) Independent Diagnostic Testing Facilities (IDTFs); (4) physician self-referral; (5) the Physician Quality Reporting Initiative (PQRI); and (6) the Sustainable Growth Rate (SGR) and (7) Impact.

I. RESOURCE-BASED PE RVUs

The proposed rule includes a variety of discussions and proposals related to resource-based practice expense (PE) relative value units (RVUs). We will address four of these in this section of our comments.

1. Equipment Usage Percentage (72 Fed. Reg., 38132)

As part of the calculation of the PE equipment costs, CMS assumes equipment is in use 50 percent of the time a physician's office is open. Several interested parties have requested that CMS increase this usage percentage. We support the conclusion reached by CMS that there is insufficient empirical evidence to justify an alternative proposal at this time, and we are willing to work with CMS to collect the necessary data.

[1] ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing healthcare environment.

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2. Equipment Interest Rate (72 Fed. Reg., 38132)

As part of the calculation of the PE equipment costs, CMS assumes an interest rate of 11 percent is incurred in the purchase of the equipment. The majority of comments on the CY 2007 PFS final rule requested an interest rate of prime plus 2 percent. In the proposed rule, CMS provides an analysis of 2007 Small Business Administration (SBA) data on loans and applicable interest rates. Based on this analysis, CMS believes 11 percent continues to be an appropriate assumption and no proposal is made to adjust this rate at this time. We believe the analysis provided by CMS is sound and we support the decision to maintain the current interest rate of 11 percent.

3. Radiology Practice Expense per Hour (PE/HR) (72 Fed. Reg., 38132)

CMS proposes to revise the PE/HR for the specialty of radiology using American College of Radiology (ACR) survey data weighted by practice size. The result is an increase from $174.18/HR to $204.86/HR. We support this change. In addition, we support the 2008 SMS and supplemental survey PE/HR data listed in Table 2 in the proposed rule for all specialties, including radiation oncology.

4. Supply and Equipment Items Needing Specialty Input (72 Fed. Reg., 38136 and 38137)

In tables 5 and 6 of the proposed rule, CMS lists supply and equipment items for which additional pricing documentation is needed. Two of the items are related to radiation oncology. The first is Sealant spray (supply code SL119) and the second is Portal imaging system (w/PC work station and software) (equipment code ER070). We are happy to supply the pricing information for the requested items. We will forward the required documentation to the appropriate staff person under separate cover. Please let us know if you need additional information.

II. MALPRACTICE (72 Fed. Reg., 38142)

The RUC's Professional Liability Insurance (PLI) Workgroup brought to the attention of CMS the fact that there are approximately 600 services which have a technical component malpractice (MP) RVU greater than the professional component MP RVU. The RUC asked CMS to change the technical component MP RVU values, stating that, because physicians have to pay the larger PLI premiums, there should be higher RVUs associated with the professional portions of these services. CMS cites an absence of data as the basis for rejecting the recommendations of the RUC.

We acknowledge the lack of data for technical component services. In fact CMS notes in the proposed rule there are some technical services which have assigned MP RVU values that have never been part of the review process. We do not believe the necessary data can be easily obtained without incurring significant cost and taking years to complete. Given that many of the current MP RVUs assigned to technical component services are not based on actual resource-based data, we question CMS' reluctance to make the requested change. We note that making such a change is clearly within the agency's statutory authority granted in section 18489(c)(2)(A)(ii) of the Social Security Act which reads:

> "The Secretary may use extrapolation and other techniques to determine the number of relative value units for physicians' services for which specific data are not available and shall take into account recommendations of the Physician Payment Review Commission and the results of consultations with organizations representing physicians who provide such services."

We urge CMS to redistribute the MP RVUs so that the technical MP RVUs do not exceed the corresponding professional component service. This change would maintain that total pool of available PLI RVUs while redistributing them more appropriately. The recommended change could be made on an interim basis, pending the collection of additional data.

III. IDTF ISSUES (72 Fed. Reg., 38169)

As part of the physician fee schedule final rule for CY 2007, CMS adopted 14 performance standards for independent diagnostic testing facilities (IDTFs) in response to an HHS Office of the Inspector General (OIG) finding of potential improper payments to IDTFs during 2001, as well as CMS's determination that a number of IDTFs were defrauding Medicare. In the CY 2008 PFS proposed rule, CMS proposes to clarify certain of these performance standards as well as proposes several new standards. We support the CMS proposals.

IV. PHYSICIAN SELF-REFERRAL PROVISIONS
In-office Ancillary Services Exception (72 Fed. Reg., 38181)

ASTRO is particularly pleased with CMS' recognition of the extent to which the in-office ancillary services exception ("IOAE") has come to be misapplied in practice well beyond Congress' original intent. ASTRO's membership has for some time raised concerns specifically with respect to the relationship of the IOAE to radiation therapy services.

While, as CMS notes, previous commenters have warned CMS that the exception has always been "susceptible to abuse," the recent liberalization of the "centralized building" and other IOAE qualifying criteria have encouraged physicians and physician groups to use the exception to cover services in no way "ancillary" to the physician service which initially brought the patient in for care. Based on the IOAE, physician business models have evolved – often with the involvement of for-profit operators/owners – that have permitted certain physicians to benefit not only from the in-group "ancillary" revenues from the specialized services they are able to capture, but also to seek to capture profits from all services they can bring into their group practice with the force of their referral power. Some are also drawn into the use of highly specialized equipment these physicians are able to "lease" to themselves. The result is that these arrangements can and do lead to distortions in the healthcare marketplace that result in over-utilization and over-referral, higher costs, the potential for lower quality and inappropriate care, a reduction in patient choice, and a pernicious and unhealthy narrowing of the healthcare marketplace. Radiation therapy services present perhaps the most disturbing example of how the IOAE has truly become "the exception that has swallowed the rule" and in so doing eviscerated the Stark Law's original intent.

ASTRO is therefore grateful at this time for CMS' recent recognition of the potential problems that have arisen in this area. We were especially pleased to see that CMS appears to share at least some of ASTRO's concerns in this regard. While these concerns already appear well-placed and warrant immediate corrective action, ASTRO understands that at this juncture CMS does not propose changes in the IOAE itself. Instead, CMS has asked for input on whether *inter alia* a) certain designated health services ("DHS") ought not to qualify for coverage under the IOAE, and b) certain non-specialists should be able to use the exception to refer patients for specialized services provided by specialists and involving the use of equipment owned by the non-specialists. As providers of the specialized service of radiation oncology, ASTRO's members are pleased to respond to these inquiries.

In response to CMS' inquiries, ASTRO's position is as follows:

1. "Radiation therapy services" are not "ancillary services" (i.e., services that are subordinate or auxiliary), and therefore should not be included in the group of DHS which qualify for coverage under the "in-office ancillary services" exception. The inclusion of radiation therapy services on the list of DHS qualifying for IOAE protection is inconsistent with the original intent of the law and with the policy goals intended to be furthered thereby.

2. Permitting physicians without significant training in radiation oncology to refer patients for radiation therapy services, from which the non-radiation specialists will benefit financially, has and will result in abusive arrangements. ASTRO has mounting concerns that these arrangements will lead to increased utilization, questionable quality and inappropriate care, increased costs, reduction in patient choice and access, and will also impact negatively on the healthcare marketplace.

3. "Radiation therapy services" should therefore be excepted from, or carved out of, those DHS which qualify for coverage under the IOAE.

The In-Office Ancillary Services Exception Should Apply Only to Those Services That Are Subsidiary to the Primary Physician Service the Patient is Seeking. Radiation Therapy is Not Such an "Ancillary" Service.

The legislative history leading up to the establishment of the statutory IOAE is very clear. Only two types of services were originally intended by Congress to be covered by the exception, that is, services that *supplement* or are *subsidiary* to the service that brought the patient to the physician's door originally. As Congressman Stark himself testified in 1989:

> *The exception would most commonly apply* ***to in-office lab tests or x-rays.*** *The exception reflects a judgment that there is often a clear need for* ***quick turn-around time on crucial tests.***[2] (Emphasis added.)

Years later, in drafting its own Stark I regulations, CMS itself commented upon and endorsed Congress' purpose in establishing the in-office ancillary exception:

> *First, Congress clearly was concerned with regulating physicians' ordering of DHS, even in the context of their own practices; otherwise, a detailed exception would not have been necessary. Second, the Congress intended to protect* ***some*** *in-office ancillary* ***services provided they were truly ancillary to the medical services being provided by the physician or group.***[3] (Emphasis added.)

Thus, not only the literal language of the exception itself, but the statute's underlying Congressional intent, as well as CMS' own commentary, reflect a clear understanding and expectation that only a limited scope of services would qualify for IOAE coverage. Services intended to be covered were only those *integral* to the *medical service* for which the patient was *then seeking* treatment, and those that

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[2] 135 Cong. Rec. H240-01 at 6 (Feb. 9, 1989).
[3] 66 Fed. Reg. 856, 881 (Jan. 4, 2001).

needed to be performed in a timely manner to ensure a "quick turnaround" so that the physician can properly and thoroughly perform his or her core medical service on that patient.

"Radiation therapy services" do not qualify on any of these grounds. These services should never have been included as an "ancillary service" for which the exception applied. Instead, radiation therapy services occupy a distinct, clearly distinguishable "next step" from any other physician's treatment and care of cancer patients. These services are neither "ancillary" to the diagnostic and/or general medical services performed by any other physician, nor is their provision essential to the comprehensiveness or quality of the patient care provided by any other physician during a patient visit. As such, radiation therapy services stand in sharp distinction to diagnostic imaging services such as x-ray, MRI, CAT scan or laboratory test, which all may inform and guide the physician's clinical care at the time a patient is being treated.

In contrast, the decision for a patient to receive radiation therapy treatments is usually made after a series of physician consultations. For example, a patient who has symptoms associated with prostate cancer is referred to a urologist by a primary care physician. The prostate cancer diagnosis is confirmed by the urologist and the pathology report. The patient is then referred by the urologist to consult with other specialists such as a radiation oncologist (who is expert with radiation therapy) and a medical oncologist (who is expert with chemotherapy agents). Depending on the stage and histology of the cancer and the patient's general medical condition, each specialist examines the patient, reviews the patient's diagnostic studies, discusses the case with the patient and his family and finally makes recommendations as to the treatment he/she believes to be the most appropriate for that specific patient. Potential treatment options include prostatectomy, brachytherapy, external beam radiation, chemotherapy, some combination of the aforementioned treatments, or watchful waiting. Radiation therapy, surgery and chemotherapy are all primary cancer therapies and none of them are "ancillary."

Thus, in "referring" a patient for radiation therapy services, the treating physician is concluding simply that the patient's condition requires the clinical expertise and input of another physician before another altogether distinct treatment modality is next applied. The "referring" physician is specifically acknowledging that the patient's clinical needs require the evaluation, care and treatment of a radiation oncologist. The "referral" is thus from one physician to another – not to an "ancillary service." Once referred, based entirely on the knowledge and experience of the radiation oncologist – the only specialist who has completed a four-year residency in the specialty and who can truly determine whether radiation therapy is appropriate, and if so, its nature and extent – the patient then may embark upon a wholly unique course of sophisticated treatments, planned and supervised by specialists expert in the sophisticated techniques of radiation therapy.

In short, radiation therapy services occupy a distinct service level on the cancer treatment continuum. The provision of these services result from the "referral" from one physician to another physician – not to an "ancillary service." Sweeping "radiation therapy services" into the IOAE's "ancillary" coverage is wholly inconsistent with Congress', CMS' and Rep. Stark's intentions in the original crafting of this exception.

The IOAE Protection of Radiation Therapy Services Has Led to Abuses and Hampered the Achievement of Laudable Health Policy Goals.

Had the IOAE remained appropriately focused on truly "ancillary" services, physician group practices would be able to utilize the exception only to assure the availability of those services essential to treating

patients in a high quality, comprehensive fashion within the context of a primary care setting. However, the evolving elasticity of the IOAE has enhanced the ability of some physicians to gather under their group practices services (and revenues) from a wholly separate and distinct treatment setting, thereby creating the establishment of financially integrated, but service distinct practice environments.

More specifically, the attractiveness of folding radiation therapy services into a group practice's core business through use of the IOAE has not gone unnoticed by financially aggressive physicians or certain for-profit companies. These companies have established lucrative business models – and attracted physician participants to these models – based on dropping turnkey radiation therapy services into these groups, permitting the sharing of the revenues from the "captured" radiation therapy revenues and the equipment leases related thereto. The following example of how ASTRO has seen this model work in practice – time and time again – will serve as a basis for setting forth ASTRO's legal and policy concerns with this method of exploitation of the IOAE:

- A for-profit company will target the premier urology group since they are the gatekeepers to referral and treatment for patients with prostate cancer in a community and offer to provide a "turnkey radiation oncology service." The proposal will focus on using their market power as the gatekeeper to bring into the urology group practice radiation therapy services for patients with prostate cancer.

- The for-profit "pitch" will emphasize the increase in revenues the urology group will attain by capturing these referrals within the group's business structure. The pitch may also include an opportunity for the physicians to joint venture in an equipment leasing company which will lease the radiation therapy equipment "to" the group.

- The company will recruit a radiation oncologist – usually from an existing radiation oncology center – to provide the radiation therapy services for the urology group. The radiation oncologist will not be offered ownership in the business, but will be paid via a services contract only.

- The radiation therapy services will typically be set up in a location separate from the urology practice (a "centralized building"). The radiation oncologist and his/her technical staff will function separate and apart from the group on a day-to-day basis. There is little or no integration of the physicians, staff, locations or services.

- The urology group benefits from the revenue flowing from its referrals and, if available, the equipment lease. The for-profit company may share in those revenues directly and/or through its share of the equipment leasing fees, as well as through a management fee.

This business model – increasing in prevalence at a rapid rate – presents the sort of potentially abusive relationships CMS is rightfully concerned about, and which the IOAE has spawned. The model poses the following hindrances to achieving laudable health policy goals:

Patient Choice

By setting up a business model that holds the radiation oncologist captive to the referral, cancer patients are denied the independent judgment and choice they need and deserve in making life and death decisions. Further, the patient does not understand how the referring physician's deriving a financial benefit from the referral potentially impacts the involved physician's judgment and recommendations.

Quality of Care

The quality of care may suffer because the model focuses on only a single cancer specialty and a single treatment modality. The only radiation therapy services of interest to a urology group practice will be those focused on the treatment of prostate cancer. In the model described, only one type of radiation therapy service – Intensity Modulated Radiation Therapy ("IMRT") – is typically offered for prostate cancer patients because of its reimbursement. Thus, while a typical comprehensive radiation treatment center may offer its prostate patients alternative radiation therapy treatment options, i.e. low or high dose brachytherapy, radionuclide therapy, etc., this business model results in the urologist overwhelmingly recommending IMRT for his or her patients.

Not only does this business model pose the risk of restricting the type of radiation therapy a patient might be offered, there is the added risk that alternative prostate cancer treatment options aside from radiation might not be fully explored with these patients. For example, it is often the case with prostate cancer that "watchful waiting" prior to any proactive treatment might be the most prudent course of treatment. With the substantial financial return that a urology group can realize on IMRT treatments, however, the risk is not insignificant that a urologist's clinical judgment would be skewed by financial considerations toward recommending IMRT – the most costly form of radiation therapy – over other potentially appropriate alternatives.

Quality of care may also suffer as radiation therapy service components are pulled piecemeal from more comprehensive settings into smaller, one dimensional treatment settings. Providing radiation therapy on a group-by-group basis can create a number of smaller, less utilized, therapy services, and threaten the ongoing existence of more comprehensive, highly utilized centers with the capacity to offer additional supportive services such as social work, nutritional services, etc.

Access to Services

Access to care issues are also exacerbated by this model when its overall effect on the healthcare marketplace is considered. In a recent situation illustrating this point, a well-regarded radiation oncology group in the state of New York has fallen victim to sophisticated efforts to take advantage of the IOAE to capture radiation therapy revenues. A radiation oncology group operates a radiation oncology center a half a block from a community hospital which has no radiation therapy capabilities and that has depended on this center for those services. The radiation oncology center offered state-of-the-art and capital intensive equipment. The group offers a full range of curative and palliative radiation therapy treatments for patients with a variety of cancer types (i.e., breast, prostate, colon, etc.).

The practice is the sole provider of radiation oncology services for referrals from the local hospital. This practice historically received approximately 35% of its referrals – prostate cancer referrals – from the urologists in town. These prostate cancer referrals were critical to the ongoing viability of the radiation oncology practice and to its ability to continue to provide the full spectrum of therapy services described above with state-of-the-art technology.

A urology group recently approached the radiation oncologists to advise that they would cease referring prostate patients and instead the oncologists should "sell the practice" to the urologists. Given the high percentage of the oncologists' patient base that came from the urologists' referrals, the radiation oncologists recognized that failure to acquiesce in the sale would likely result in the collapse of their practice, to their detriment and that of the community.

Such was the market power of the urology group that the radiation oncologists were compelled to sell. The radiation oncology services will become those of the urology practice, for whom one of the group's

oncologists will now work. The New York community in question now faces the conversion of this radiation oncology center and the loss of readily accessible radiation therapy services for all the non-prostate cancer patients normally served at the center. Moreover, the prostate cancer patient population in this community is now left with one single resource for cancer treatment services – the urology group – and with an overwhelming preference for a single therapy treatment approach – IMRT.

ASTRO has received a growing number of reports of similar tactics undertaken by large urology practices around the country. In each case non-radiation oncologists seek to control specialized clinicians and specialized equipment so they can capture the revenues from the specialized services they had previously referred to independent groups. In each case, if successful, reductions in quality, patient choice and access are likely to occur, and costs will rise.

Continuity of Care Issues

ASTRO anticipates that those who have benefited financially from the ability of urology groups and other physician groups to control radiation therapy services and their revenues within their groups, through use of the IOAE, will assert that "continuity of care" or "comprehensiveness of care" is furthered in such a model. These assertions are belied in practice by the lack of integration which occurs when turnkey radiation oncology services are "dropped in" to the existing group practice. The radiation therapy service is typically provided in a separate "centralized" building separate from the group's core practice; the radiation oncologist(s) is typically on contract with the group, but is not a partner or owner of the group; technical staff report to the radiation oncologist, not the group's other physicians.

The notion that "continuity of care" is the driving force in the creation of the financially lucrative business models created when radiation therapy services are dropped into a urology group practice is also belied by the marketing material produced by one national for-profit purveyor of this approach. Quoting from that company's own website, the following "Frequently Asked Questions" and their responses are telling:

> ***Why should we integrate radiation oncology into our practice?***
>
> In light of decreasing LHRH and rising overhead, urologists need to seriously begin considering new revenue sources, and there is no better revenue source available to urologists than IMRT. In fact, the opportunity cost associated with IMRT is very high. Every month that a group with the necessary critical mass delays in developing a center is potentially a loss of over $500,000 of gross revenues PER month.
>
> ***What is the breakeven point for an IMRT center?***
>
> The breakeven point would be 4 new patients per month. This would approximately yield each of the 14 physicians an annual return of $8,600. However, the more typical rate of new patients per physician is between 1 and 2 new patients per month. With a new patient rate of 1 per physician, the projected annual return per physician is approximately $255,000 per physician. At an average rate of 1.5 new patients per month, the projected annual return per physician is over $425,000. These projections are based on current prevailing Medicare reimbursement.

Continuity of care has taken the proverbial backseat to the real driving force behind this model. Instead, economic gain is the answer to the question "why integrate," *not* quality or continuity of care.

It is indeed ironic, given the Stark Law's core purpose that the IOAE now actually serves as a catalyst for revenue-producing schemes heretofore unheard of. Today, under the current regulatory framework, there are truly no serious barriers to physicians and physician groups enjoying fully the benefits of their DHS referral revenues. Clever physicians and their business and legal advisors no longer see the Stark Law as a serious regulatory problem to overcome, but as a simple IOAE-based puzzle to solve, the solution of which can lead to precisely the "referral based on financial incentive" behavior the Stark Law was intended to eliminate.

ASTRO appreciates the opportunity to comment on the current state of the IOAE and how it should be changed. Simply put, the exception has grown far beyond the original intent of Congress and CMS itself, that is, as a safe harbor to protect those services closely and directly related to the underlying purpose of the patient visit – lab tests, x-rays, etc. Radiation therapy neither was nor is that sort of "ancillary" service. ASTRO strongly believes that the law should no longer allow for the establishment of business models which are based upon rewarding physicians solely for the referral of a patient.

Based on our analysis of the exception's original intent, ASTRO is convinced that "radiation therapy services" should be explicitly excluded from the list of designated health services for which the in-office ancillary services exception may apply.

V. Physician Quality Reporting Initiative (PQRI)

1. "TRHCA—SECTION 101(b): PQRI" (72 Fed. Reg., 38196)

ASTRO's members are committed to achieving excellence in cancer care for our patients. ASTRO is engaged in internal efforts to develop evidence-based guidelines for treatment decisions and will use these guidelines as the foundation for future performance measures. In the interim, we are working with external stakeholders to develop measures that will help us provide even better care for our patients.

ASTRO is concerned that the process for developing the 2008 Physicians Quality Reporting Initiative (PQRI) is advancing despite the 2007 PQRI having only just started July 1. Furthermore, we are concerned that the program is being developed without any attempt to evaluate the most basic elements of the 2007 PQRI program, such as impact on patient care, physician participation rates, and implementation costs. While we understand that CMS is required by TRHCA to implement the 2008 program, we urge the agency to use its discretion to closely review the 2007 program before moving ahead.

ASTRO also is concerned that the requirement that measures for the 2008 program be developed "through the use of a consensus-based process" is too broad. For any reporting system to improve quality, the measures must be meaningful to clinical care and relevant to the specific specialty physicians. Therefore, direct physician involvement in the development, testing and implementation of quality measures is the only way to ensure measures are appropriate and clinically-relevant. While we appreciate that the proposed rule recognizes the American Medical Association's Physician Consortium for Performance Improvement (AMA-PCPI) as a source for the development of quality measures eligible for inclusion in PQRI 2008, we urge CMS to go further and consider the AMA-PCPI as the ***only*** entity appropriate for the development of physician-level quality measures. The AMA-PCPI process is consensus-based and is physician-led. This characteristic will ensure physician buy-in on measures, which is essential for an effective quality reporting program. Further, tasking the AMA-PCPI as the only

group for developing physician measures significantly reduces the risk of duplicative or contradictory measures and ensures measure harmonization.

ASTRO is co-sponsoring the AMA-PCPI's Oncology Workgroup in partnership with the American Society for Clinical Oncology. We fully expect that this workgroup will produce a strong set of cancer measures. This measure set is currently out for public comment and is expected to be approved by the AMA-PCPI in September with AQA approval before the November 15 deadline. However, we are concerned that these draft measures are not listed in Table 17 of the proposed rule. Once approved and endorsed according to the requirements outlined in the proposed rule, we urge CMS to consider these important oncology measures for inclusion in the PQRI 2008.

The proposed rule indicates that the 2008 PQRI program will be largely structured and implemented in a manner similar to the 2007 program and that the standards for eligibility and satisfactory reporting will apply across the seven categories of proposed measures. Before the final rule is released, we believe CMS should clarify the reporting requirements for the seven measure categories, specifically regarding the standards for satisfactorily reporting on the non-physician and structural measures developed by the Pennsylvania QIO. It is unclear how to report on the structural measures in a manner that would satisfy the "80% of eligible claims" requirement. For instance, would a physician who has implemented health information technology report on this measure once or on all claims? We hope CMS will provide additional guidance in the final rule on these issues.

2. "TRHCA—Section 101(d): PAQI (72 Fed. Reg., 38205)

ASTRO urges CMS to reverse its decision not to apply the $1.35 billion available in the Physician Assistance and Quality Improvement Fund to buy down the deleterious effects of the 9.9% payment cuts scheduled to take effect Jan. 1, 2008. We believe this decision is counter to the intent of Congress and the recommendation of the Medicare Payment Advisory Commission. CMS should overcome the "legal and operational" problems associated with applying the funds to the negative update, as the dire situation posed by the harmful cuts surely prevails over the potential obstacles. For example, CMS could explore applying the $1.35 billion to past years' SGR debt. This would reduce the slated cuts to the 2008 conversion factor. Radiation oncologists and our physician colleagues are committed to providing the highest level of quality care regardless of financial incentive. Therefore it is important that CMS use the funds to buy down the cut, which will have a positive impact on all physicians, rather than a future quality reporting program whose value has not been studied, let alone demonstrated.

VI. BACKGROUND

The Sustainable Growth Rate (SGR)

In many previous comments, we have described the flaws in the SGR formula that led to a 5.4% payment cut in 2002. Additional cuts in 2003 through 2007 were averted only after Congress intervened. Consistent with the position of the American Medical Association (AMA), we identified several steps that should be taken that would significantly reduce the costs associated with a permanent legislative fix to the Sustainable Growth Rate (SGR) formula. Most importantly, we recommended that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

We are extremely disappointed that CMS continues to believe it does not have the authority to make necessary changes. In the proposed rule, CMS announced its most recent estimate of a 9.9 percent reduction in the 2007 conversion factor from $37.8975 in to $ 34.1456 in 2008. If these cuts begin on

January 1, 2008, average physician payment rates will be less in 2008 than they were in 1995, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. Physicians simply cannot absorb these severe payment cuts and, unless CMS or Congress acts, physicians will be forced to reevaluate their relationship with Medicare and will be forced to avoid, discontinue or limit the provision of services to Medicare patients.

We recommend that CMS remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

VII. IMPACT (Fed. Reg., 38211)

Medical physicists are a very important part of radiation therapy as far as safety and effective delivery of radiation are concerned. Their primary responsibility is to establish protocols to guarantee accurate patient dosimetry, determine treatment doses and aid radiation oncologists in optimizing the balance between the beneficial and deleterious effects of radiation. Insofar as radiation therapy is an ever evolving and intricate modality of cancer therapy it clearly warrants the ongoing assistance of these highly trained individuals. We are therefore extremely concerned that the proposed PE RVUs for medical physics services may be too low to cover the costs of these services. They have been decreasing steadily over the last few years and as a result of this continued decrease could possibly result in an approximately 70% decrease by the year 2010.

We recommend that CMS review the proposed PE methodology to include accurate salary and time data for medical physicists (and all other direct inputs).

Conclusion

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Trisha Crishock, MSW, Director, Health Policy and Economics Department at (703) 502-1550.

Respectfully,

Laura Thevenot

Laura Thevenot
ASTRO, Executive Director

cc: Trisha Crishock
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