CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

September 4, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1590-P, Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013

Dear Ms. Tavenner:

The undersigned cancer patient, provider, and research organizations are writing to share their concerns about the changes in reimbursement for certain radiation oncology services proposed in the physician fee schedule update for calendar year 2013. We share the goal of the Centers for Medicare and Medicaid Services (CMS) that physician fee schedule payments be based on the most accurate and up-to-date data available, and we support CMS efforts to evaluate and adjust payments to achieve that goal. Such an approach is necessary to ensure a high-quality Medicare program that provides beneficiaries access to appropriate care and also protects the long-term viability of Medicare.

We understand that the proposed physician fee update for CY 2013 would significantly reduce payments for intensity modulated radiation therapy (IMRT) and stereotactic body radiation therapy (SBRT), services that are important care options for patients with certain cancers. The recommended levels of reimbursement are based on revised assumptions about the length of IMRT and SBRT sessions. CMS indicates that the agency relied on a patient fact sheet about radiation therapy for prostate cancer as well as a patient-directed website about radiation therapy for information about the length of IMRT and SBRT sessions and that it based reductions in reimbursement levels on that information.

Many of the undersigned organizations provide educational materials that assist patients in making treatment decisions and also educate them about what to expect as part of their

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treatment experience. In some cases, partnerships of patient organizations, professional societies, and research groups convene to create patient education materials. The patient education materials that we and others create are intended to serve patients. These materials are not designed to reflect or describe the time necessary to deliver professional services, including the technical requirements of the services that may be undertaken before and after the patient experience.

We urge that CMS reconsider its use of patient education materials to guide decisions about radiation oncology reimbursement decisions. This significant departure from the usual process for ascertaining the time required for a service and setting reimbursement rates is ill-advised. We are concerned that this reimbursement recommendation has the potential to adversely affect patient access to high-quality radiation oncology services. Moreover, the use of patient education materials as the basis for reimbursement decisions will have a negative impact on collaborative educational efforts that empower and equip patients to make decisions about and manage their cancer care.

We appreciate your careful consideration of this recommendation.

Sincerely,

Cancer Leadership Council

American Cancer Society Cancer Action Network
American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Cancer Support Community
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
College of American Pathologists
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance

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Congress of the United States
Washington, DC 20515

September 24, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Sebelius:

On behalf of the millions of cancer patients we represent, as well as the cancer centers providing high quality care to those patients, we are writing to express our serious concern with Medicare reimbursement cuts proposed for radiation oncology services in the Centers for Medicare and Medicaid Services' (CMS) CY 2013 Physician Fee Schedule (PFS) Proposed Rule.

Radiation oncology is an important tool in the fight against cancer. It is a safe treatment option with a long track record of safely and effectively treating cancer with minimal side effects. In the last 25 years, the survival rate for many cancer patients has increased steadily, particularly for diseases such as breast and prostate cancer, thanks in large part to advances in radiation oncology, such as Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT).

If finalized, the rule would result in an overall 15 percent reduction in reimbursement for radiation oncology and a 19 percent reduction in payments for radiation therapy center services effective January I , 2013. These cuts represent a $300 million reduction in reimbursement for the provision of cancer care services in just one year. The most significant portion of the cut is due to a change in the treatment times for IMRT and SBRT procedure codes. These changes would reduce delivery reimbursement by 40 percent for IMRT and 28 percent for SBRT in 2013. We believe that such drastic payment cuts may limit cancer patients' access to lifesaving radiation therapy in communities across America, particularly rural areas. In addition, cuts of this magnitude could force cancer clinics to close their doors, delay purchasing or not purchase new equipment, lay off staff, and delay treatments for Medicare patients.

The rule proposes to adjust the procedure time assumptions for IMRT and SBRT delivery. Rather than rely on auditable data, CMS relies on "patient fact sheets" and internet searches to make these assumptions. We believe the materials cited by CMS are inappropriate for serving as the only basis for such dramatic reimbursement changes because they do not have the necessary sophistication to value complex medical procedures. These materials are designed for patient education purposes only. The patient fact sheets do not fully account for the time spent positioning the patient for treatment, performing safety checks, or the work that occurs after each patient's treatment. In addition, we are surprised to see CMS change only one aspect of its

complex 28-step methodology used to derive practice expense relative value units under the PFS. There are multiple direct cost inputs (including the pricing of equipment, supplies, and clinical labor), and a proper revaluation of any CPT code in the PFS requires a review of inputs for that code.

Every year, more than I million cancer patients receive radiation therapy. New technology and improved techniques allow radiation oncologists to better target radiation in an attempt to eliminate cancer cells while at the same time protecting healthy tissue. We urge CMS to work with radiation therapy stakeholders to develop holistic payment reform policies, built on evidence-based clinical guidelines, to ensure fair and stable payments for radiation therapy services.

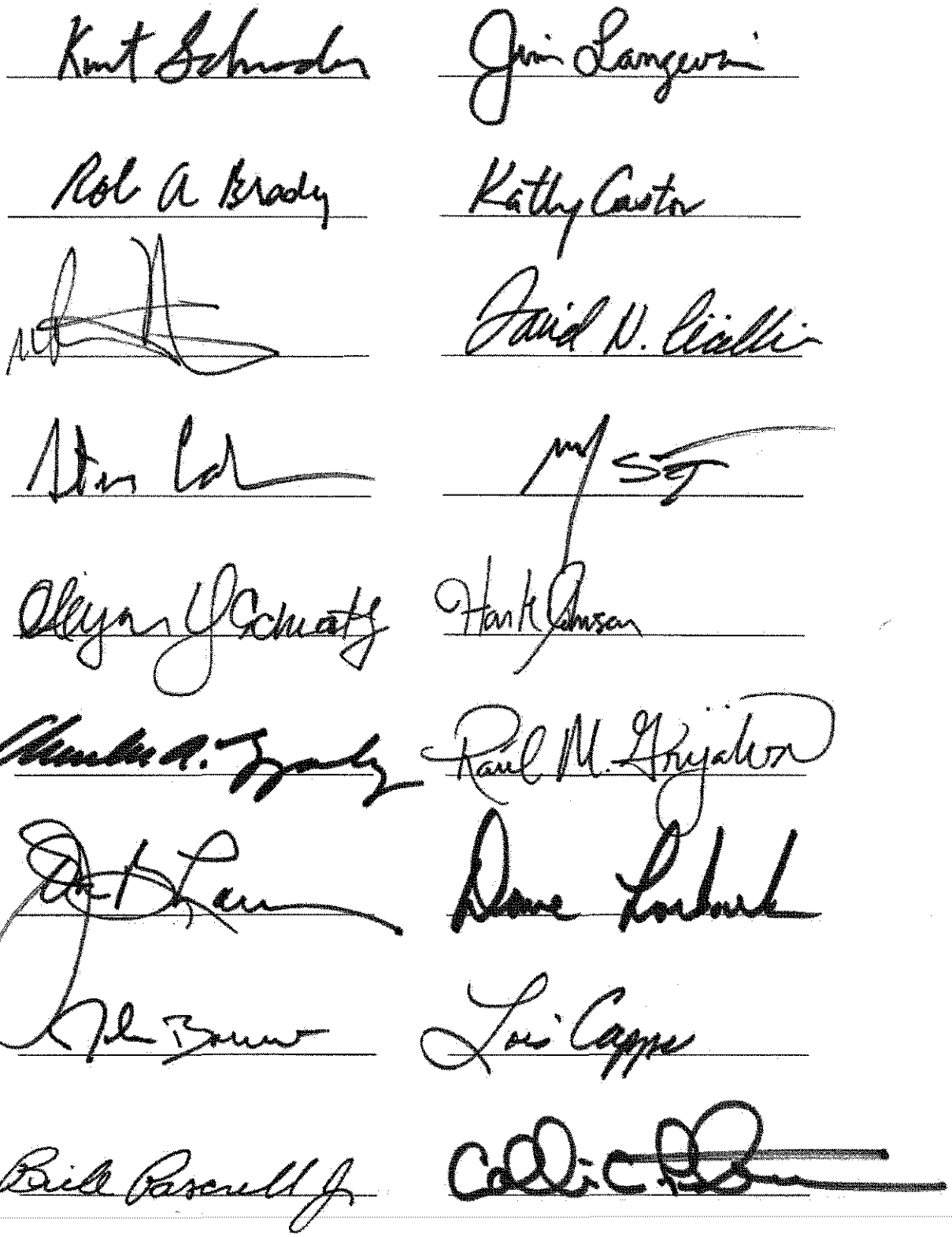
We urge CMS to reconsider its proposals to reduce payments for radiation therapy services in the CY 2013 PFS. Thank you for your attention to this important matter.

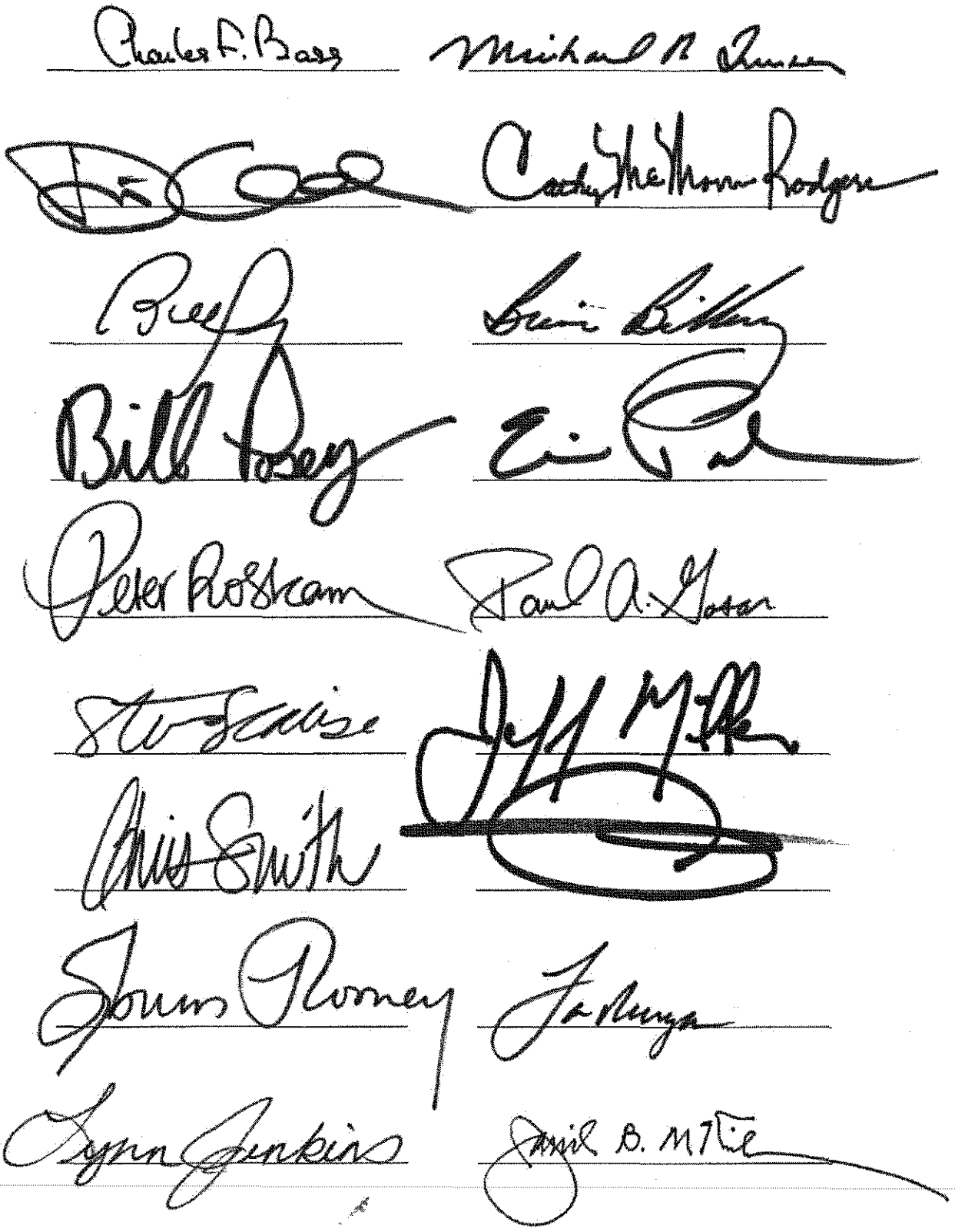
Sincerely,

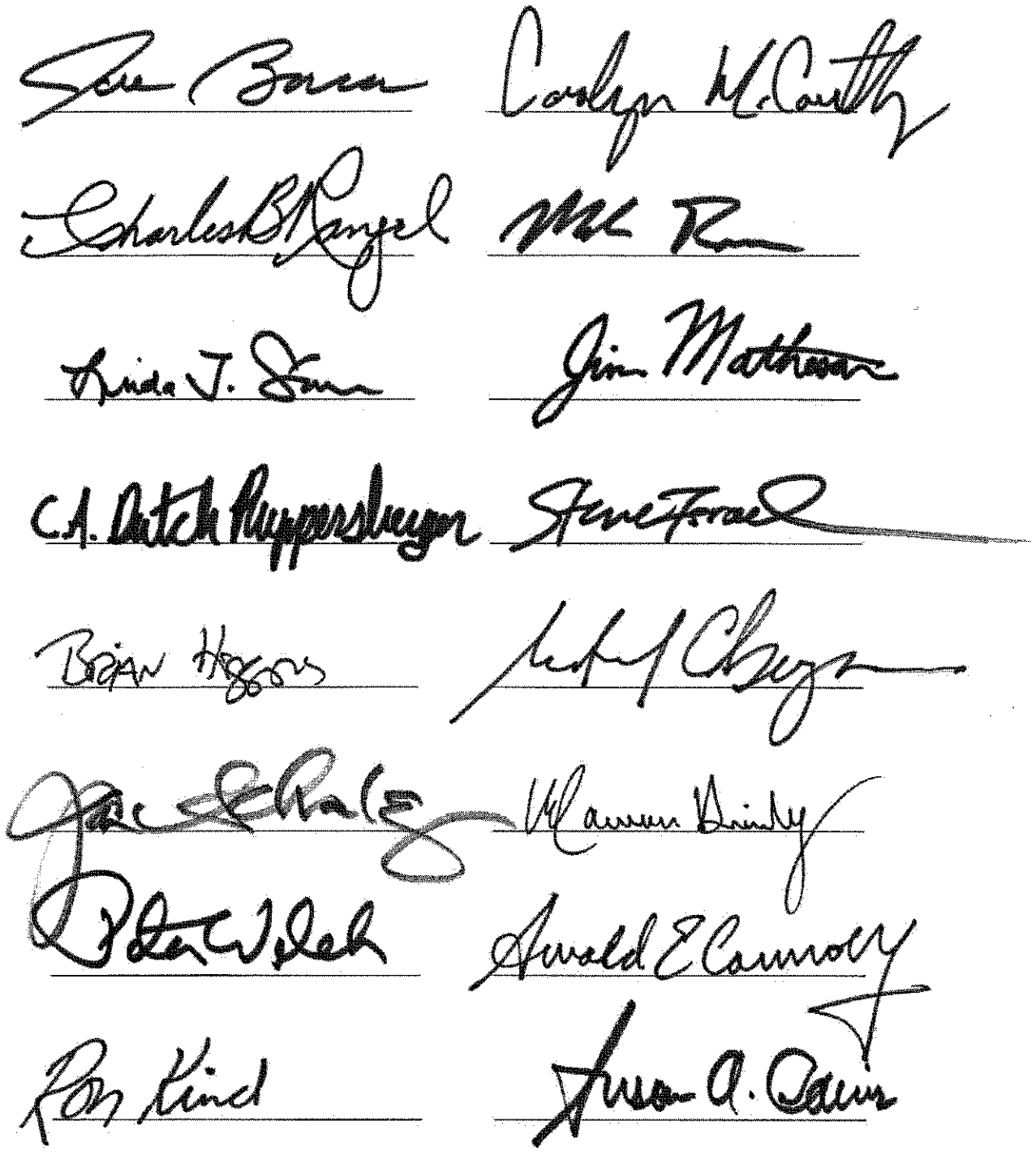
Joseph R. Pitts
Chair, Subcommittee on Health
Energy and Commerce Committee

Frank Pallone
Ranking Member, Subcommittee on Health
Energy and Commerce Committee


TN-04
Pete Olson
Marsha Blackburn
Michele Bachmann








Mike Coffman
Howard Coble
Walter B. Jones

Tim Murphy

Mark Walker

Jody Hice

Van Hollen NY-19

Austin Scott

D. Bucshon

Pitts/Pallone Letter to Sec. Sebelius (9/24/12)
Signatures

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Barney Frank
David Roe
Jason Altmire
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Hansen Clarke
John Dingell
Tom Price
Phil Gingrey

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Dennis Ross
Martha Roby
Aaron Schock
Vern Buchanan
Sue Myrick
Mike Rogers (MI)
Mary Bono Mack
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Brett Guthrie
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C.A. Dutch Ruppersberger	Steve Israel
Brian Higgins	Michael Burgess
Jan Schakowsky	Maurice Hinchey
Peter Welch	Gerry Connolly
Ron Kind	Susan Davis

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Alan Nunnelee	Rich Nugent
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Greg Walden	Tom Latham
Pete Sessions	Dan Burton
Elton Gallegly	Mike Simpson
Walter B. Jones	Lee Terry

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Tim Murphy	Mario Diaz-Balart
Mac Thornberry	Nan Hayworth
Austin Scott	Dave Reichert

United States Senate

WASHINGTON, DC 20510

September 18, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Sebelius:

We are writing to express our concern regarding the Medicare reimbursement cuts proposed for radiation oncology services in the Centers for Medicare and Medicaid Services' (CMS) CY 2013 Physician Fee Schedule (PFS) Proposed Rule. We are concerned these proposed cuts could force cancer centers to close their doors, and reduce access to cancer treatments in our communities, particularly those in rural areas. We ask that if CMS undertakes a reevaluation of the practice expense inputs for radiation oncology services, that it examine all the components of the expenses and their interactions in order to ensure appropriate reimbursement that more accurately reflects the full costs associated with the delivery of these services.

Radiation oncology is an important tool in the fight against cancer. Thankfully, in the last 25 years, the survival rate for many cancer patients has increased steadily. There has been particular progress for diseases such as breast and prostate cancer thanks, in part, to advances in radiation oncology such as Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT).

If finalized in its current form, the cuts proposed in the Physician Fee Schedule Rule would result in an overall 15 percent reduction in reimbursement for radiation oncology and a 19 percent reduction in payments for radiation therapy center services, effective January 1, 2013. The most significant portion of the proposed cut is due to a change in the treatment times for IMRT and SBRT procedure codes. We have heard from radiation oncologists in our states that such a cut could potentially limit cancer patients' access to radiation therapy as some cancer clinics could be forced to close, cut their staff, or put off purchasing equipment. The impact would be especially challenging in rural communities, where patients could be forced to travel further distances for care as a result of the reimbursement cuts in these settings.

Given the potential impact of the payment reduction, we are concerned that CMS only chose to reevaluate one component of the practice expense relative value units (PERVUs) used to establish payment rates for IMRT and SBRT. If CMS believes that the information used to establish the PERVUs for these codes is inaccurate, it is important to reevaluate the information for all components of the PERVUs and how they may interact with one another, not just one component. In this case, it is possible that changes in the time component of the PERVUs are the result of changes in other components such as equipment costs. We therefore urge CMS to

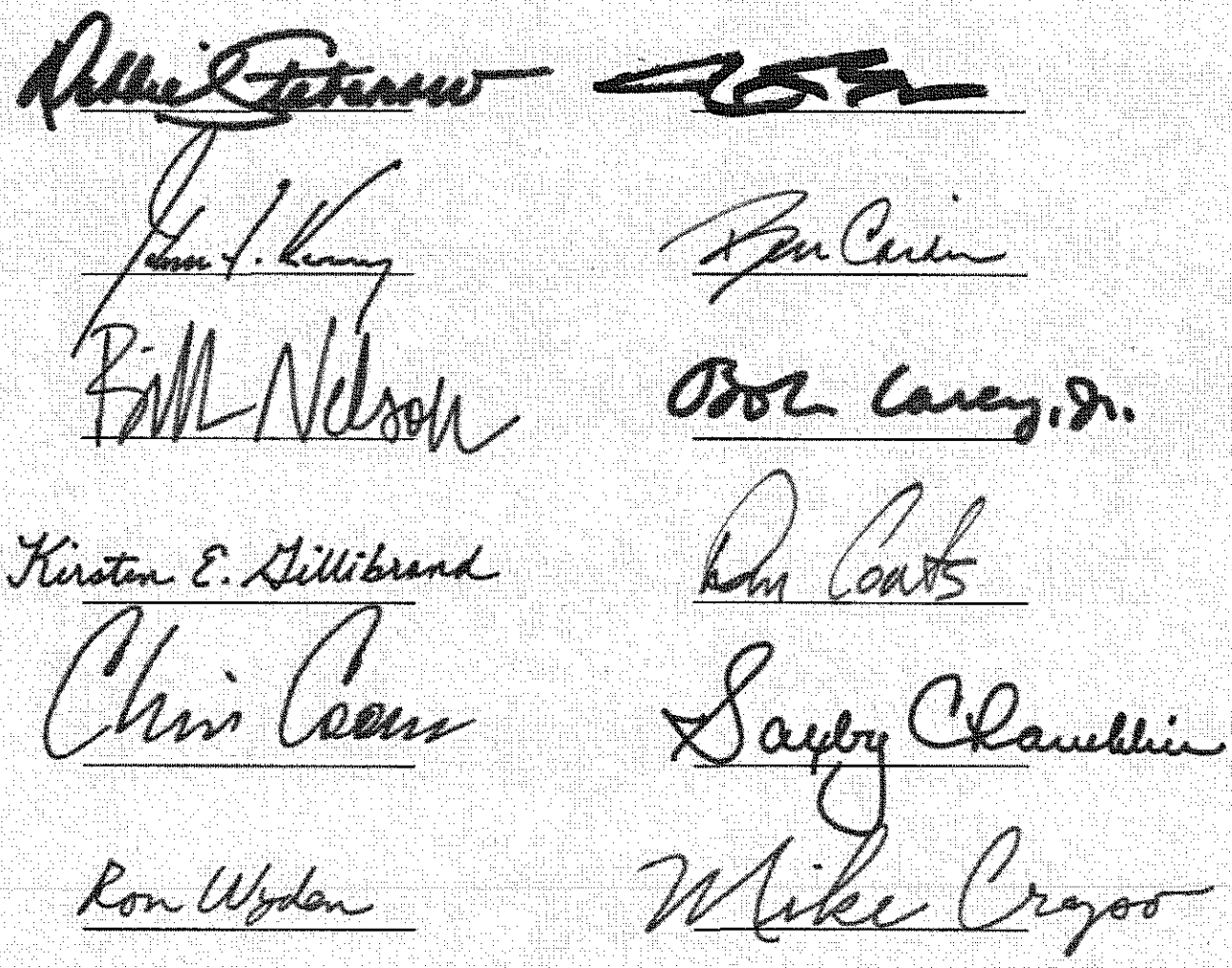
reevaluate the PERVUs for IMRT and SBRT codes by looking at all possible changes to inputs that could be affected in order to ensure a sound level of reimbursement for these services.

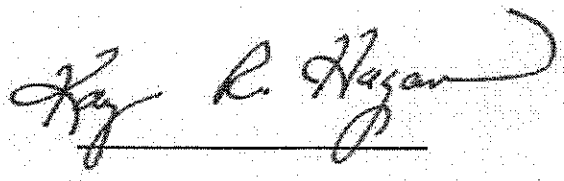
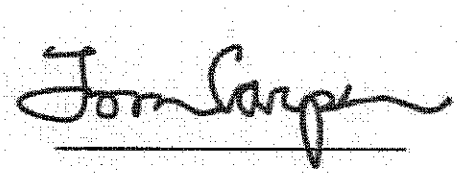
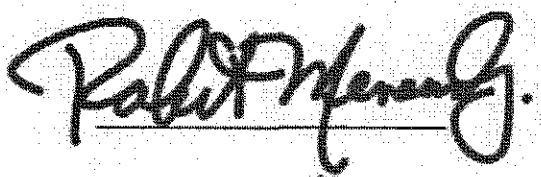
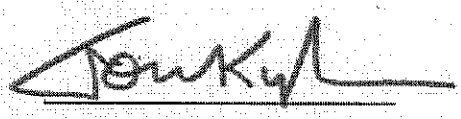
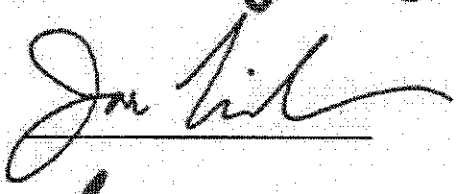
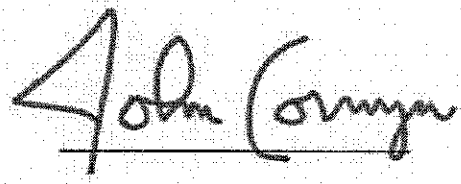
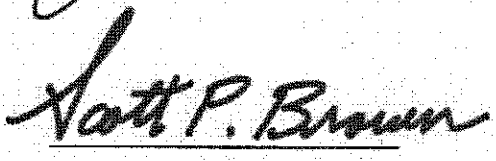
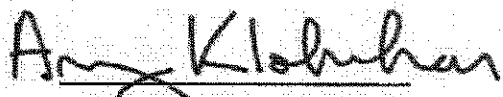
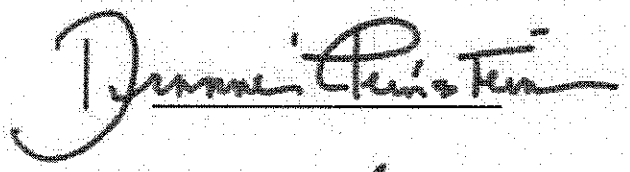
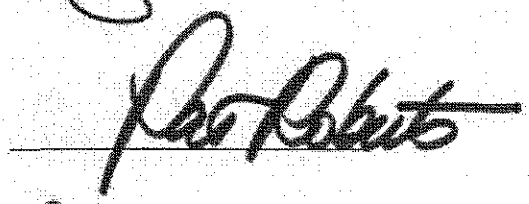
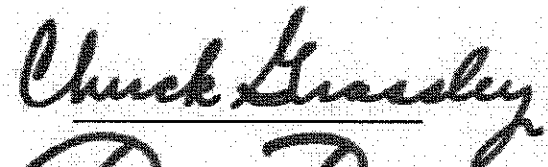
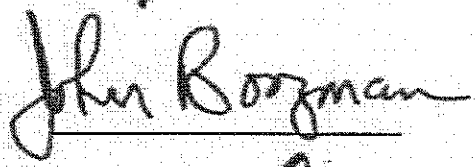
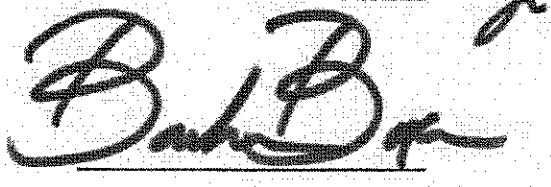
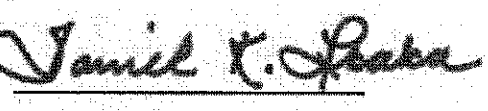
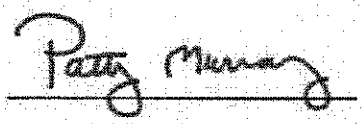
In addition, we were pleased to see that the proposed rule notes that "the Secretary may make appropriate coding revisions… which may include consolidation of individual services into bundled codes." We therefore encourage CMS to continue working with the radiation oncology community on alternative payment models such as bundled payments.

It is critical that we ensure physician payments are appropriate and accurate, and that they do not impede access to care for patients. That is why we ask that CMS reconsider the narrow reevaluation of only one component of radiation oncology practice expense inputs and the resulting payment reductions, and instead consider a holistic approach to the reevaluation of the practice expense inputs for these services.

We thank you for your attention to this important matter.

Sincerely,



ASTRO
TARGETING CANCER CARE

Significant Medicare Cuts to Radiation Oncology Would Devastate Cancer Care

On July 6, 2012, the Centers for Medicare and Medicaid Services released proposed changes in the Medicare physician fee schedule that will result in an average 15 percent cut for radiation oncology overall and a 19 percent cut to community-based radiation therapy centers. In the face of these $300 million in proposed cuts, the American Society for Radiation Oncology (ASTRO) launched a survey to determine how these proposed cuts would impact practices and patient care.[1]

Individual practices will face cuts of varying levels because of their particular patient mix. For instance, an analysis of 2012 Medicare claims for a community-based practice located in Arizona revealed that Medicare's proposal would result in a 20 percent reduction for that clinic. The impact of these cuts on cancer care will be devastating to communities across the country.

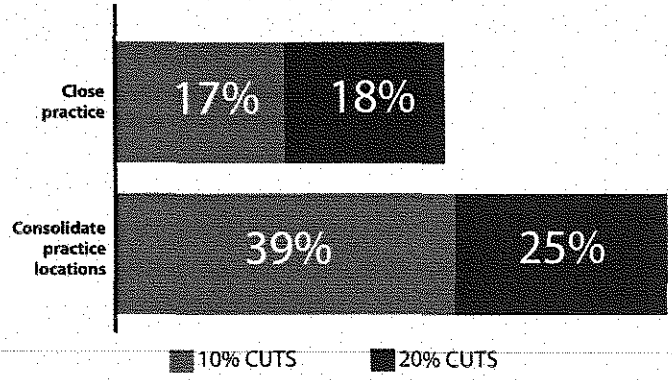
According to our survey, these proposed cuts will cause many community radiation oncology centers to close their doors or consolidate their practices, forcing patients to drive longer distances each day for weeks to receive treatments.

"It will ultimately undo the last 20 years of progress made in improving the efficacy and safety of radiation treatment (and the corresponding increase in patients' confidence in this form of cancer treatment). I would probably choose to retire early. . . ." – Lacey, Wash.

"It will have a **significant impact on our ability to cover our costs for the center.** A drop in Medicare reimbursements will reduce our ability to provide other non-reimbursable costs including dietitian, support groups, and nursing care."
– Gainesville, Va.

"Further reduction in reimbursement would **cripple our ability to provide lifesaving treatments** to individuals diagnosed with cancer, as well as prevent us from enabling those suffering the pain of cancer from receiving palliative care, which would make their last days with their family bearable."
– East Syracuse, N.Y.

IMPACT OF PROPOSED CUTS:
Percentage of community-based practices that anticipate closure and consolidation of radiation oncology practices.



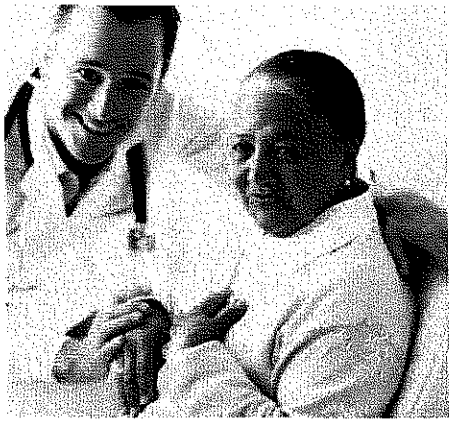
[1] This survey had 599 total respondents and 58 percent of those respondents are from community-based or combined community- and hospital-based practices. The results featured here reflect only the responses of the community-based or community- and hospital-based practices. Quotes are taken from descriptions of respondents regarding how the proposed cuts will affect their practice.

RADIATION ONCOLOGY IS AN IMPORTANT TOOL IN THE FIGHT AGAINST CANCER.

Radiation oncology is a safe treatment option with a long track record of **safely and effectively treating cancer with minimal side effects.** In the last 25 years, the survival rate for many cancer patients has increased steadily, particularly for diseases such as breast and prostate cancer, thanks in large part to advances in radiation oncology technologies, which are the target of these cuts.

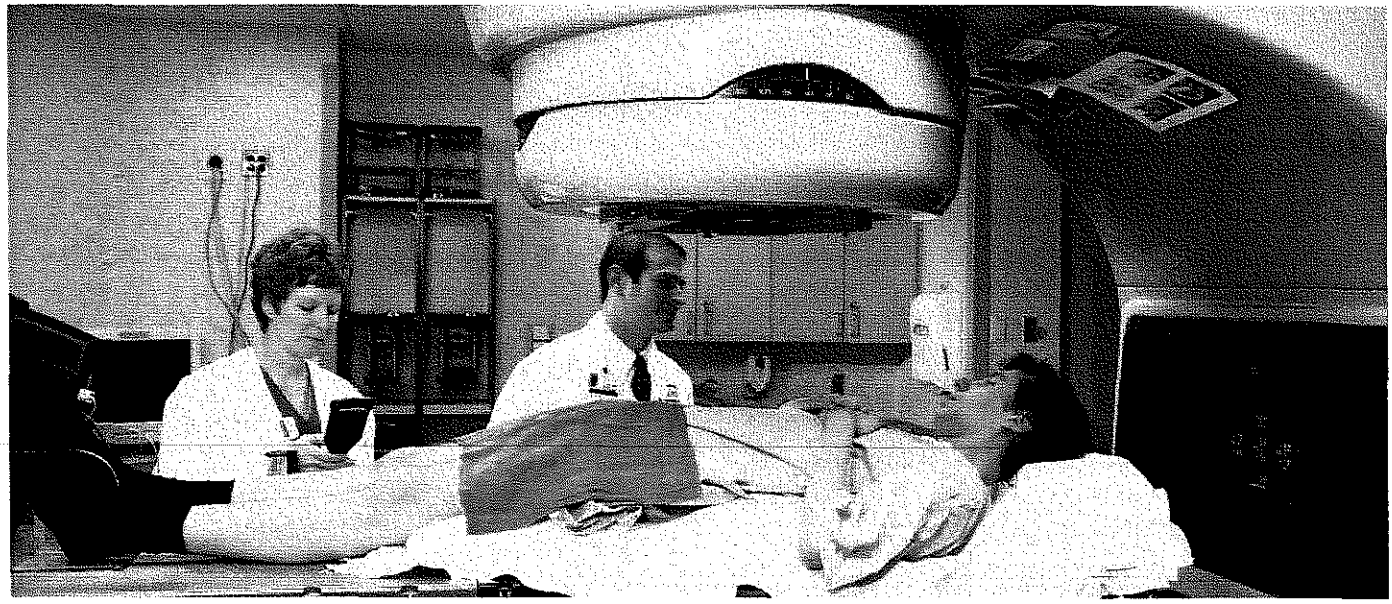
Patients usually receive radiation therapy treatments daily for six to eight weeks. If practices close or consolidate, 35 percent of respondents estimated that patients will have to drive more than 50 miles round trip, often about 1 ½ to 2 ½ hours, to reach the nearest radiation oncology provider. This increased expense and time is a significant barrier to care.

Studies have found that increased travel time to the nearest radiation facility is associated with declining odds of receiving radiation for elderly patients.[2] For example, studies have shown that the distance to a radiation therapy center significantly increases mastectomy rates, with many more breast cancer patients choosing mastectomy rather than driving long distances every day for treatment. For many of these patients, lumpectomy and radiation therapy is an equivalent, and often preferred, treatment.[3] Patients who do not receive radiation after lumpectomy are at significantly higher risk of additional complications, such as their cancer returning or spreading.



"Closing practices, and reducing staff will increase patient load on fewer centers, forcing more patients to drive further (or opt out of standard of care recommendations) and have **longer wait times for procedures and treatments."**
– Columbia, Mo.

"These cuts would negatively impact our ability to offer all patients, regardless of their ability to pay for services, the quality of care we are presently offering. Our overhead costs are such that we would have no choice but to close several locations if there are dramatic cuts in reimbursement. We serve both metro and rural locations. **In the rural areas, patients would have to drive 120-150 miles per day** if we were forced to reduce our services or close our rural locations." –Edina, Minn.

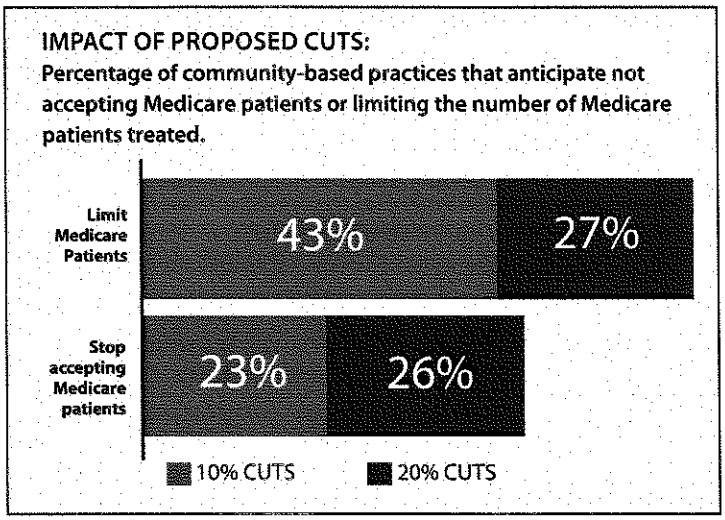


[2] Int. J. Radiation Oncology Biol. Phys., Vol. 66, No. 1, pp. 56–63, 2006.
[3] Journal of Clinical Oncology, Vol. 23, No. 28, pp 7074-7080, 2005.

Radiation Oncology Cuts Are Bad for Patients

Those practices that manage to stay open in the face of these cuts will be forced to make major practice changes. According to the survey, many foresee limiting the number of Medicare patients they will treat or stop accepting any new Medicare patients.

Numerous respondents noted that those remaining community cancer centers and hospital-based facilities will be unable to handle the surge in patients, particularly in light of the expected rising incidence of cancer. The impact will be particularly acute on community practices in rural areas, which already face greater financial challenges than other cancer centers. Patients will be left with fewer treatment options, longer waits to begin treatment and significantly longer travel times.



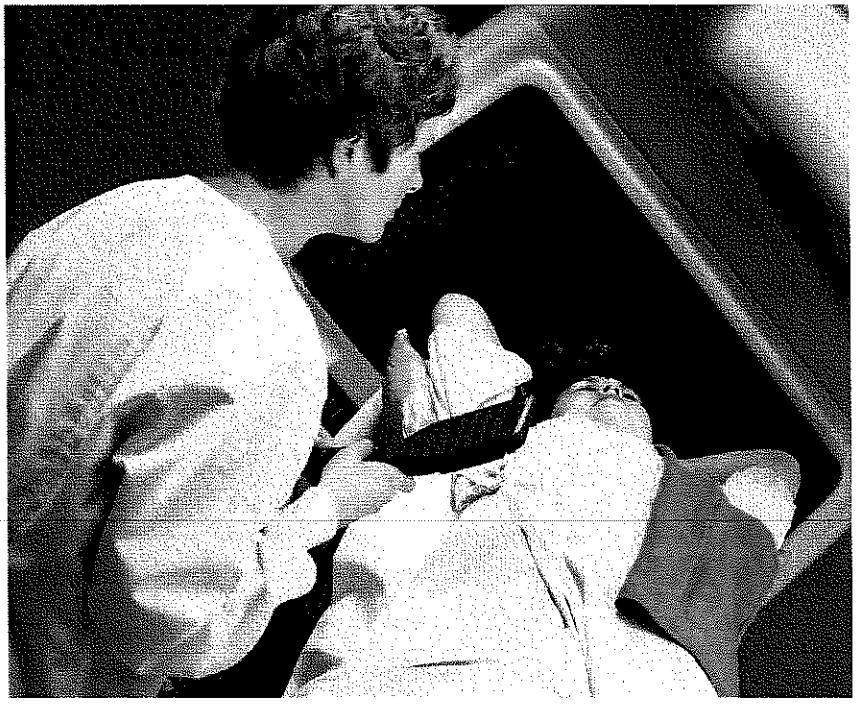
"I am a solo practitioner in rural Nebraska. The nearest other radiation oncology center is at least 50 miles away. The majority of my patients are Medicare, since our demographics are an older than average population. Our margin is so small that with continued Medicare cuts, **I will try to sell the practice (if someone would buy it) or close it.**" – Omaha, Neb.

"Given our percentage of Medicare patients we would not be able to continue to offer services and would be forced to close our practice. We have streamlined our operating expenses and cut certain services already. We are located in a state where 10-15 percent of our patients are treated on a charity basis. **Medicare is now a break-even proposition. We cannot absorb additional cuts."**

– Charleston, W.Va.

"We are making due in a very challenging health care environment. Cuts of over 10 percent will make it **difficult for us to maintain current staffing levels.**

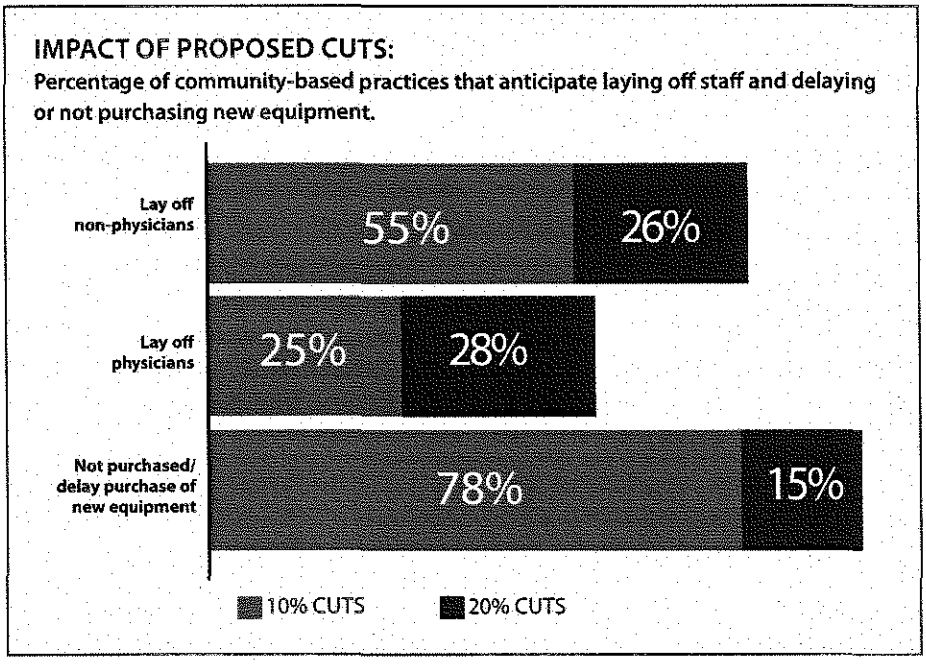
– San Francisco



Radiation Oncology Cuts Are Bad for the Economy

In many communities, radiation therapy centers not only provide excellent care, but also are a source of skilled, good-paying jobs for people dedicated to curing cancer. These proposed cuts will make it hard for many clinics to continue providing care. In addition, many expect to respond to cuts by laying off specially trained physicists, radiation therapists and dosimetry professionals, along with additional staff who are critical in the delivery of safe and accurate treatment. Those who do not lay off physicians and professional staff anticipate cutting salaries and benefits, such as health insurance benefits to their employees, to reduce overhead costs.

In addition to staff changes, many practices foresee delaying scheduled upgrades in equipment. As technology continues to advance, having access to current technology is vital to enabling physicians to better target the tumors to cure cancer. Today's technology helps avoid some of the side effects of cancer treatments that can lead to hospitalizations, additional surgeries and lost productivity for patients.



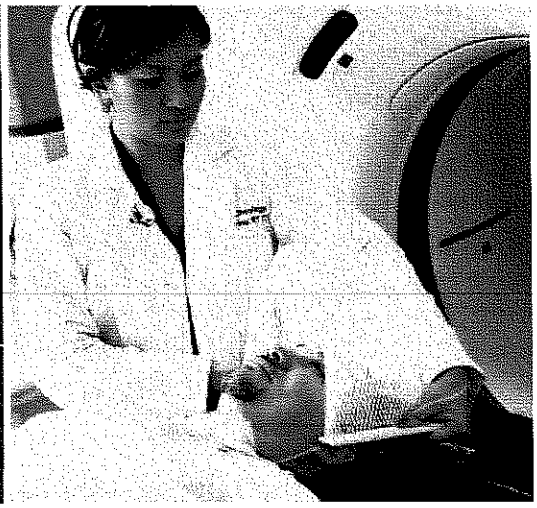
"The proposed cuts will **seriously impair our ability to hire additional staff needed**, pay for needed new equipment, expand services to provide cancer survivorship support, and efforts to comply with government regulations to achieve e-prescribing and electronic medical records."- Honolulu, Hawaii

"We will likely have staff reductions therefore having to limit Medicare patients on a weekly/monthly basis. Since the bulk of the cuts center on IMRT and SBRT, both highly technical treatments which require much greater staffing needs, **patient safety concerns with reduced staffing** would dictate limiting or potentially not using these modalities for Medicare patients." - Dallas

ACT NOW

Act now to protect patients and stop these cuts to community cancer care.
Tell your members of Congress to sign the radiation oncology letters to Medicare.
Visit, www.rtanswers.org/advocate.

For more information, please contact ASTRO's Director of Government Relations, Dave Adler, at 703-839-7362 or davea@astro.org.



ASTRO

TARGETING CANCER CARE

July 12, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
The U.S. Department of Health and Human Services
200 Independence Avenue, N.W.
Washington, D.C. 20201

Dear Madame Secretary:

I am writing on behalf of the millions of cancer patients treated, and in many cases saved, by treatment with radiation each year. Nearly sixty-five percent of all cancer patients are treated with radiation in the course of their illness.

In the last 25 years, the survival rate for cancer has increased steadily. For example, in the mid-1970's, the five-year survival rate for breast cancer was 75 percent; for prostate cancer it was 69 percent. Today, the five-year survival rate is 90 percent for breast cancer and 99 percent for prostate cancer. The Medicare Physician Fee Schedule Rule released on July 6 threatens that progress and will potentially compromise access to care for thousands of cancer patients.

The proposed rule would result in an overall 15 percent reduction in payment for radiation oncology services, with free standing centers being even harder hit with an overall 19 percent cut. The level of cuts aimed at radiation oncology is double that of any other specialty. New technology and improved techniques have led to improved outcomes and these inappropriate cuts will stymie that achievement. Cuts of this magnitude will harm cancer care, particularly in rural areas, and lead many treatment centers to close their doors.

In order to fully understand the impact of these cuts on our members and their patients, ASTRO launched a survey for our members to tell us how they would respond to even a 10 percent reimbursement cut. In three days we have received nearly 500 responses from across the country:

- 53% will stop providing charity care
- 52% will lay off staff
- 45% will limit hours of operation
- 75% will not purchase new equipment
- 45% will limit accepting Medicare patients
- 24% will stop accepting Medicare patients
- 48% will consolidate or close practice locations

The impact will be even greater for freestanding centers that, depending on their case mix, could see between 20 and 30 percent cuts.

Frankly, it is unfathomable that the same Administration that worked so hard to secure access to health care for millions of Americans would now act to deny needed access to this vulnerable population. With practices closing, particularly in rural areas, patients will face increased travel times for care, longer waits to begin treatment, and reductions in time their physicians can spend with them. Even if practices are able to remain open, many will be forced to lay off staff and delay purchasing needed equipment.

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To give you a better picture of the impact of these cuts, perhaps it is best to use the words of my members:

- *"I am a solo practitioner in rural Nebraska, the nearest other radiation oncology center is at least 50 miles away and the majority of my patients are Medicare. I will be forced to sell my practice (if anyone would buy it) or close it,"* Rural Nebraska;
- *"I have such a high Medicare, Medicaid and Veterans Administration case load, these cuts would force the center to completely close."* Tallahassee, FL;
- *"It would be devastating. Over the last few years, our practice income has already dropped significantly due to reimbursement cuts, higher overhead and increased numbers of unfunded patients."* Port Arthur, Texas;
- *"We are a rural practice heavily dominated by two broad demographic classes, retirees and rural poor. Many patients can't afford the gas to travel to their treatments. If we close, they won't be able to afford the gas to travel to the large city centers 150 miles away."* Northern Minnesota;
- *"We may have to close the practice and patients will have to travel for greater than an hour each direction for radiation therapy."* Poulsbo, WA
- *"Further reduction in reimbursement would cripple our ability to provide life saving treatments to individuals diagnosed with cancer, as well as prevent us from enabling those suffering the pain of cancer from receiving palliative care which would make their last days with their family bearable."* Syracuse, NY

The most significant portion of the cut is due to a change in the treatment times for Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT). The changes reduce delivery reimbursement by 40 percent for IMRT and 28 percent for SBRT. Instead of relying on analytical data to identify potentially misvalued codes, CMS cited patient education materials that refer to the time a patient is actually laying on the treatment table with the radiation beam on. These materials do not account for time spent positioning the patient, performing safety checks and other services to ensure the treatment is delivered accurately and safely. We recommend that if your staff believes a code is misvalued, it should be referred to the RUC for consideration per CMS' stated process.

These cuts will halt progress and, to again quote one of my members "will ultimately undo the last 20 years of progress made in improving the efficacy and safety of radiation treatment."

We urge you to protect cancer patients' access to care by stopping these devastating cuts.

Sincerely,

Laura Thevenot

Laura Thevenot
Chief Executive Officer

Cc: Marilyn Tavenner, Acting Administrator, CMS

ASTRO

TARGETING CANCER CARE

September 4, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1590-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (CMS-1590-P)

Dear Ms. Tavenner:

The American Society for Radiation Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (CMS-1590-P)" published in the *Federal Register* as a proposed rule on July 30, 2012.

ASTRO members are medical professionals, practicing at hospitals and cancer treatment centers in the United States and around the globe, and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

ASTRO has very significant concerns about the proposed cuts to radiation oncology in the 2013 proposed Medicare physician fee schedule. Nearly 65 percent of all cancer patients are treated

[1] ASTRO is the largest radiation oncology society in the world, with 10,000 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 evolving healthcare environment.

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with radiation during the course of their illness, and the proposed cuts will have a significant impact on cancer providers and Medicare beneficiaries with a cancer diagnosis. The proposed rule would result in an overall 15 percent reduction in payment for radiation oncology services, with free standing centers hit harder with an overall 19 percent cut. The level of cuts aimed at radiation oncology is double that of any other specialty. New technology and improved techniques have led to improved outcomes and these inappropriate cuts will stymie that achievement. Cuts of this magnitude will harm cancer care, particularly in rural areas, and could lead many treatment centers to close their practices.

In order to fully understand the impact of these cuts on our members and their patients, ASTRO launched a survey for our members to tell us how they would respond to even a 10 percent reimbursement cut. We received almost 600 responses. According to our survey, these proposed cuts could cause many community radiation oncology centers to close their doors or consolidate their practices, forcing patients to drive longer distances each day for several weeks to receive their treatment. Individual practices will face cuts of varying levels because of their particular patient mix. For instance, an analysis of 2012 Medicare claims for a community-based practice located in Arizona revealed that this proposal would result in a 20 percent reduction for that clinic's Medicare reimbursement.[2]

The most significant portion of the cut is due to a change in the treatment times for Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT), reducing reimbursement by 40 percent for IMRT delivery and 28 percent for SBRT delivery. In proposing this change CMS did not rely on analytical data to identify potentially misvalued codes as they have done in the past and as is directed in the Affordable Care Act (ACA). ASTRO vehemently opposes this proposal and in this letter we provide arguments against the validity of the methodology used by CMS to propose this change. ASTRO requests CMS to apply a rigorous analytical methodology to review these services.

In this letter, in addition to the reduction in procedure time for IMRT and SBRT treatment delivery, we address a number of topics that will impact our membership and the patients they serve including:

- Radiation oncology services identified for review – Table 9
- Updated interest rate assumption
- Public nomination of potentially misvalued code – CPT Code 77336, Medical physics consult
- Oncology measures group for PQRS 2013
- Proposed reporting criteria for satisfactory reporting of measures groups for PQRS 2013
- Proposed criteria for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments
- PQRS Group Reporting Option (GPRO)

[2] American Society for Radiation Oncology (ASTRO). "Significant Medicare Cuts to Radiation Oncology Would Devastate Cancer Care." 2012. https://www.astro.org/uploadedFiles/Content/Advocacy/2012factsheetCMS_final.pdf. Accessed August 30, 2012.

Reduction in procedure time for IMRT and SBRT treatment delivery

In the 2013 proposed rule, CMS is proposing to reduce the assumption for the procedure for IMRT delivery (CPT code 77418) from 60 minutes to 30 minutes. CMS is also proposing to adjust the procedure time for SBRT delivery (CPT code 77373) from 90 minutes to 60 minutes. The agency's stated rationale for this change is that they have identified wide discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these services and the procedure times made widely available to Medicare beneficiaries and the general public.

ASTRO strongly opposes this proposal, which will have a significant negative impact on the value of these two codes. We believe CMS has contravened its own policy by not relying on sound data or a rigorous methodology to implement this change. Instead, CMS is citing patient education materials. They are employing information targeted to patients to help them better understand the patient experience of radiation therapy and using this information to estimate the time related to a complex medical procedure that begins before a patient enters the treatment room and ends after the patient has left the treatment room. Importantly, the treatment times cited in the patient information materials do not fully account for the time spent positioning the patient for treatment, performing safety checks or the work that occurs before and after each patient's treatment. While CMS proposes adding seven minutes to account for before treatment and post treatment activities, we believe this amount of time is insufficient. What has resulted is a gross misunderstanding of the facts surrounding these two important and highly complex radiation therapy services.

The current procedure times associated with CPT codes 77418 and 77373 were developed through the AMA RUC process. We understand that CMS has raised concerns about the rigor of the AMA RUC process. We believe the process is sound and based on analytical data. ASTRO stands ready to assist CMS in implementing potential improvements to the RUC process so that CMS can feel confident in relying on their recommendations.

In this next section we have summarized our practice expense recommendations for CPT codes 77418 and 77373 that we will be submitting to the RUC for their October 2012 meeting. Complete recommendations are attached. Details on the rationale for our recommendations are also provided below.

Intensity Modulated Radiation Therapy (CPT code 77418)

The procedure time for CPT code 77418 was first assigned to the code for CY 2002 based on recommendations from the AMA RUC. The most recent RUC recommendation for CPT code 77418 that CMS received for CY 2012 rulemaking (October 2010 RUC meeting) support the current procedure time assumption.

Number of Therapists/Clinical Time

CMS continues to ignore our plea to include clinical time for two therapists in CPT code 77418. This issue was not appropriately addressed in CMS' 2013 proposed drastic reductions. We continue to maintain that there should be clinical time in this code for two therapists. We presented two therapists to the RUC when the code was originally created, which the RUC approved. CMS rejected that position arguing, "Only one technologist is required to actually

deliver the treatment." We discussed the issue with CMS, but they continued to publish in the Federal Register that only one therapist was needed. The use of two therapists is a safety and quality of care issue that is documented in two professional publications listed below.

A recent ASTRO quality and safety publication states,

> *"It is recommended that a minimum of two qualified individuals be present for any routine external beam patient treatment."*[3]

This document was developed and endorsed by twelve major professional organizations in the field of radiation oncology.

Additionally, the American Society of Radiologic Technologists (ASRT) position statement reads:

> *"It is the position of the American Society of Radiologic Technologists that two registered radiation therapists per patient per treatment unit is the minimum standard for safe and efficient delivery of radiation therapy"*[4]

Although both publications require the use of a minimum of two qualified individuals, we found that most practices use three. These therapists are assigned to the treatment room 100% of the time. We are recommending to CMS a total clinical time of 97 minutes While we strongly believe there should be clinical time for three therapists in CPT code 77418, our recommendations have clinical time for only two therapists, as we suspect CMS would reject our position for three. To better understand what the therapists are doing during treatment, please review the chart below.

Process of Care IMRT Delivery – Radiation Therapists
Key
□□ *Two therapists performing task with each other*
□ *Single therapist task*

Therapist #1		**Therapist #2**	
Description	*Time (min)*	*Description*	*Time (min)*
Greet patient, provide gowning, ensure appropriate medical records are available	3	Prepare room, equipment, supplies	2
Prepare and position	2	Prepare and position	2
Set up computer-controlled component of linear accelerator (linac) operation, working outside room at console *(Open electronic medical record and electronic prescription of patient to be treated,*	5	Set up mechanical component of linac operation, working inside room *(Operate manual control to verify functionality and move gantry, table and collimators to starting position)*	5

[3] American Society for Radiation Oncology. Safety is No Accident: A Framework for Quality Radiation Oncology and Care. (2012). *Table 2.3 Minimum Personnel Requirements for Clinical Radiation Therapy.* https://www.astro.org/Clinical-Practice/Patient-Safety/Safety-Book/Safety-Is-No-Accident.aspx Accessed September 3, 2012.

[4] American Society for Radiologic Technologists. Staffing for Radiation Therapy Treatment Delivery. *ASRT Position Statements*. (July 2012): 9. http://www.libs.uga.edu/ref/mla2009.pdf; Accessed August 30, 2012.

Therapist #1		Therapist #2	
Description	*Time (min)*	*Description*	*Time (min)*
review prescription parameters, Open Record and Verify)			
Perform Procedure (Therapist #1) ☐☐*Attach immobilization devices (2)* ☐☐*Verify vertical/horizontal patient position around site to be treated (2)* ☐☐*Use orthogonal 3-point laser light system to align patient w/external tattoos (2)* ☐☐*Verify Isocenter (2)* ☐ *Upload the patient's treatment plan into the software driving linac and MLC motion (3)* ☐*Maintain Visual surveillance of gantry motion to verify no collision with table or patient and continuous audio-visual surveillance to verify patient comfort and positional stability during therapy (3)* ☐*Repeat prior step for remaining 6 beams (18)* ☐☐*Set gantry to safe position allowing patient to arise from table and assist patient up from treatment table and out of immobilization device (3)*	35	**Perform Procedure (Therapist #2)** ☐☐*Attach immobilization devices (2)* ☐☐*Verify vertical/horizontal patient position around site to be treated (2)* ☐☐*Use orthogonal 3-point laser light system to align patient w/external tattoos (2)* ☐☐*Verify Isocenter (2)* ☐*Verify proper performance of two audio/video monitoring systems (3)* ☐*Set control to rotate the gantry angle of first beam for treatment, initiate treatment and continuous visual surveillance of computer monitor showing desired pattern of MLC motion during beam on time (3)* ☐*Repeat prior step for remaining 6 beams (18)* ☐☐ *Set gantry to safe position allowing patient to arise from table and assist patient up from treatment table and out of immobilization device (3)*	35
Clean Room	3	Other Clinical Activity (please specify) Document treatment administered in record and verify system	5
Total Therapist Time	48		49

Equipment Times for IMRT
We are recommending that CMS update the equipment times for the accelerator, MLC, intercom, laser diode and video camera from 37 minutes to 49 minutes to appropriately account for the time the IMRT room is used during a typical IMRT treatment.

Validity of Recommendations
ASTRO convened an expert panel to develop these practice expense recommendations. The consensus panel had 10 key participants - eight radiation oncologists and two medical physicists. The panel outlined steps in the process of care, working with their practice clinical staff to develop consensus language outlining the steps. Then the clinical staff personnel were asked to record their times for each step for their IMRT patients over the course of an entire day. There were over 30 clinical personnel staff in 10 practices involved with these informal time in motion studies. The recommendations in this letter are based on the findings from the consensus panel and the clinical staff analysis, with adjustments down to the PEAC standards for activities with pre determined standards (i.e. clean room, position patient, etc) and deletion of quality assurance

related time (since CMS does not allow specialties to account for QA in the PEAC recommendations).

Equipment Pricing for IMRT
ASTRO urges CMS to update the pricing information currently used to calculate the equipment rates. The cost of the linear accelerator has increased since the code was originally valued, which has not been taken into account in CMS' 2013 proposed drastic reductions. For CMS to update the procedure time assumption independent of updating the equipment pricing information is inappropriate.

Stereotactic Body Radiation Therapy (CPT Code 77373)
The direct PE inputs for SBRT treatment delivery (CPT code 77373) reflect a procedure time assumption of 90 minutes. These procedure times were first assigned to the code for CY 2007 also based on a recommendation from the AMA RUC. The most recent RUC recommendation that CMS received for CY 2012 rulemaking (Feb 2011 RUC meeting) supported continuing the procedure time assumption.

ASTRO reviewed time and motion SBRT data submitted to us by a high volume center utilizing a consistent treatment delivery methodology performed by an experienced team. In that data, over 700 SBRT cases were tracked to examine the length of treatment time for SBRT cases. The findings revealed that for the over 700 cases, over a three-year period, the average length of treatment time was 1 hour and 31 minutes. When just the lung cases are examined, which remain the majority of the cases for CPT code 77373 (and the typical vignette), that number increases to 1 hour and 37 minutes. The findings from that time and motion study support the current procedure time assumption of 90 minutes for SBRT treatment delivery (actual treatment time not total room time).

It is important to note that the time and motion data for SBRT cases is consistent from year to year. Clinical papers in the field, technical articles and users all confirm that SBRT treatment times have not 'gotten quicker' over the years.[5,6] CMS and other regulators often cite the passage of time as a conclusive correlate to a procedure being performed in less time. That is not the case with SBRT. Much of the time spent in SBRT treatment is consumed with issues relating to movement of the tumor (as with respiration) or movement of the patient (due to discomfort, respiratory distress, etc) and the imaging and repositioning required to account for motion. Technology has not changed the cancer patients we treat nor has it impacted the time required for our typical SBRT treatment.

ASTRO strongly urges CMS to maintain the clinical time of 210 minutes for CPT code 77373, the existing supplies and the current equipment time of 114 minutes for the SBRT treatment system and the pulse oximeter. The treatment time of 90 minutes along with the other clinical

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[5] van der Voort van Zyp NC, Prevost J-B, Hoogeman MS, et al. (2009). Stereotactic radiotherapy with real-time tumor tracking for non-small cell lung cancer: Clinical outcome. *Radiother Oncol.* 91(3):296–300.
[6] I.C. Gibbs and B.W. Loo, Jr. (2010). CyberKnife stereotactic ablative radiotherapy for lung tumors. *Technology in Cancer Research and Treatment*, 9, 589-596.

activities that take place in the room (i.e. room set up, entering treatment plan, building a correlation model, documentation and room clean up) support the 114 minutes of room time.

The Role of Self Referral

In the proposed rule, CMS explains how media sources like the *Wall Street Journal* and the *Washington Post* have encouraged CMS to consider the possibility that potential overuse of IMRT services may be partially attributable to financial incentives resulting from inappropriate payment rates. These articles have shed valuable light on potential overuse of IMRT. However, by not mentioning the articles' emphasis on the role of self-referral in the growth of IMRT services in the proposed rule, we believe the agency has missed a key aspect of these articles and failed to acknowledge an important driver of inappropriate IMRT utilization. We believe the agency's policy justification and resulting recommendations fail to address the misaligned incentives at play.

Reducing reimbursement rates to control utilization is a blunt and ineffective instrument that fails to address the root problem of self-referral arrangements that consistently have been shown to overutilize expensive diagnostics and procedures, most recently in the area of anatomic pathology[7]. Additionally, these articles specifically examined the role of physician self-referral in leading to overuse of IMRT services for prostate cancer only, yet the proposed payment changes would affect IMRT treatment for all cancers, including head and neck, lung and the myriad of other cancers treated by radiation oncologists.

ASTRO strongly supports efforts to rein in inappropriate spending in the Medicare program to sustain the program for current and future beneficiaries. As we have commented to CMS previously, we are confident that removing radiation therapy services from the physician self-referral law's in-office ancillary services (IOAS) exception, while preserving the ability for truly integrated multi-specialty practices to continue providing services through the exception, will remove the incentive to over utilize IMRT services.

ASTRO was encouraged by a recent article in the *New England Journal of Medicine* written by premier health policy experts and former high ranking administration officials, including former CMS Administrator Donald Berwick, MD, MPP. The article explicitly recommends that the physician self-referral loophole for radiation therapy services "should be closed," and the law expanded to prohibit physician self-referrals for services that are paid for by private insurers.[8] The article also rejects the notion of government agencies imposing deep payment cuts unrelated to value and quality care, which "are not in the long-term interests of patients, employers, states, insurers, or providers." ASTRO agrees that closing the self-referral loophole for radiation therapy services, in lieu of deep payment cuts, would effectively root out abuse while preserving access to those that utilize expensive health care services judiciously. Congress has asked the Government Accountability Office to investigate self-referral in radiation therapy and other services, and we urge CMS to work closely with Congress to close the self-referral loophole.

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[7] Mitchell, J. "Urologists' Self-Referral For Pathology Of Biopsy Specimens Linked To Increased Use And Lower Prostate Cancer Detection" *Health Affairs* April 2012 31:4741-749.

[8] Emanuel E., Tanden N., Altman S., et al. "A Systemic Approach to Containing Health Care Spending" New England Journal of Medicine August 2012 http://www.nejm.org/doi/full/10.1056/NEJMsb1205901

ASTRO does not support the CMS proposed revisions to the clinical time assumptions for CPT codes 77418 nor 77373. The AMA RUC has agreed to place CPT codes 77418 and 77373 on the agenda for their October 2012 meeting. Enclosed with this letter are updated PE inputs for CPT codes 77418 and 77373 ASTRO will submit to the RUC for their review at the October 2012 RUC meeting. ASTRO requests that CMS implement the practice expense recommendations outlined in this letter. If CMS is not satisfied with our recommendations, ASTRO requests CMS use an alternative that has similarly rigorous analytical methods and that is consistent with the value driven healthcare system the ACA directed the Secretary to develop.

Missing Equipment

Subsequent to the publication of the 2012 final rule, ASTRO and other stakeholders informed CMS that the direct PE inputs forwarded to CMS for CPT code 77418 inadvertently omitted seven pieces of equipment typically used in furnishing the service. The omitted equipment items are listed below.

- computer system, record and verify
- IMRT physics tools
- laser, diode, for patient positioning (Probe)
- video printer, color (Sony medical grade)
- intercom (incl. master, pt substation, power, wiring)
- video camera
- isocentric beam alignment device

These items had been used as direct PE inputs for the code prior to CY 2012. There was broad agreement among stakeholders that these seven equipment items are typically used in furnishing the services described by CPT code 77418 and that they should be added back. While CMS did not incorporate these items for CY 2012, CMS is proposing to include them for CPT code 77418 in CY 2013. These proposed adjustments are also reflected in the CY 2013 proposed direct PE input database.

ASTRO was very pleased to see that CMS is proposing to incorporate the missing equipment back into CPT code 77418. We appreciate the agency's consideration of comments from ASTRO and other stakeholders. The omitted items are critical in the provision of IMRT services. ASTRO urges CMS to finalize this proposal in the CY 2013 final rule.

Radiation oncology services identified for review – Table 9

In addition to the proposed actions for CPT code 77373 and 77418, CMS proposes to review and make adjustments to several other codes described in the proposed rule as having stand-alone procedure time assumptions used in developing their nonfacility PE RVUs. These codes are listed in Table 9 of the proposed rule and include various radiation oncology services. The radiation oncology related services included in Table 9 are listed in the table below.

CPT Code	Short Descriptor	CPT Code	Short Descriptor
77280	Set radiation therapy field	77408	Radiation treatment delivery
77285	Set radiation therapy field	77409	Radiation treatment delivery
77290	Set radiation therapy field	77412	Radiation treatment delivery
77301	Radiotherapy dose plan IMRT	77413	Radiation treatment delivery
77338	Design mlc device for IMRT	77414	Radiation treatment delivery
77372	SRS linear based	77416	Radiation treatment delivery
77373	SBRT delivery	77418	Radiation tx delivery IMRT
77402	Radiation treatment delivery	77600	Hyperthermia treatment
77403	Radiation treatment delivery	77785	HDR brachytx 1 channel
77404	Radiation treatment delivery	77786	HDR brachytx 2-12 channel
77406	Radiation treatment delivery	77787	HDR brachytx over 12 channel
77407	Radiation treatment delivery		

As outlined above, CMS proposes to adjust the times associated with two radiation oncology CPT codes in the 2013 Proposed Rule, 77418 and 77373. CMS argues *"these two treatment delivery codes are PE only codes and are fairly unique in that the resulting RVUs are largely comprised of resources for staff and equipment based on the minutes associated with clinical labor."* CMS went on to state that there were several other codes on the PFS established through the same methodology and that they believed the procedure time assumptions for these kinds of services have not been subject to all of the same mechanisms recently used by CMS in the valuation of the physician work component of PFS payment. As such, CMS is proposing to review and make adjustments to CPT codes with standalone procedure time assumptions used in developing nonfacility PE RVUs.

CMS should remove CPT codes 77301, 77338, 77785-87 and 77600 from this screen as they are not standalone PE only codes, they are PC/TC codes. In addition, the RUC recently reviewed CPT Codes 77301, 77338 and 77785-7. As part of this process all the activities associated with these procedures were carefully reviewed and ASTRO provided significant details on the numerous tasks performed by clinical labor staff. The tasks performed during the intra service period were broken into sub categories and then details were included for each sub category.

ASTRO believes that this review provided ample details on the clinical labor time associated with these services. There were detailed discussions about the intra service activities (work and PE) and how they related to one another. The clinical times are directly linked to physician work and have been subject to all the same mechanisms used by the RUC and CMS for review.

ASTRO spent considerable resources preparing and presenting these recommendations, including bringing medical physicists and additional physician presenters to the meetings to present and answer questions. If these codes were presented again, we do not anticipate any changes or new issues. We recommend the direct practice expense inputs be maintained for these codes.

CPT Code 77600 had four TC claims in CY2011. ASTRO recommends maintaining the value for this code due to the very low frequency of the service.

We support the agency's efforts in ensuring the accurate pricing of physician services in the Medicare physician fee schedule. ASTRO will work with the AMA RUC and CMS in reviewing the radiation oncology services included in Table 9 of the CY 2013 proposed rule. The AMA RUC has placed these codes on the agenda for their October 2012 meeting and requested submission of action plans. By the time this letter has been received by CMS, ASTRO will have responded to the RUC's call for action plans for all of the codes listed in Table 9. As stated above, we will be recommending CPT codes 77301, 77338, 77785-7 and 77600 be removed from CMS' screen. We will agree to address the remaining radiation oncology codes in Table 9.

Updated interest rate assumption

A section of the proposed rule that will have a significant impact on radiation oncology is the proposal to update the interest rate assumption used by CMS to calculate equipment cost per minute. This rate is then used as an input in calculating nonfacility practice expense RVUs. The current interest rate assumption of 11 percent was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). CMS is proposing to replace the current 11 percent interest rate with a "sliding scale" approach based on the current Small Business Administration (SBA) maximum interest rates. Table 84 in the proposed rule estimates this policy will have a negative 3 percent impact on radiation oncology and a negative 4 percent impact on radiation therapy centers.

The SBA has maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment).

- Fixed rate loans of $50,000 or more must not exceed Prime plus 2.25 percent if the maturity is less than 7 years, and Prime plus 2.75 percent if the maturity is 7 years or more.
- For loans between $25,000 and $50,000, maximum rates must not exceed Prime plus 3.25 percent if the maturity is less than 7 years, and Prime plus 3.75 percent if the maturity is 7 years or more.
- For loans of $25,000 or less, the maximum interest rate must not exceed Prime plus 4.25 percent if the maturity is less than 7 years, and Prime plus 4.75 percent, if the maturity is 7 years or more.

ASTRO supports the agency's efforts to ensure that the most current and accurate data are used in the development of RVUs. These efforts are consistent with the agency's commitment to be an active payer of high quality healthcare. Collecting accurate data can be a complex, time consuming, and sometimes costly process, yet it is a necessary component of maintaining the fee schedule. For example, malpractice RVUs are based on malpractice premium data. By collecting actual premium data, CMS ensures that the true costs borne by physicians for obtaining malpractice insurance are captured in malpractice RVUs. In contrast, ASTRO does not believe the proposal to use maximum interest rates from the SBA will capture the true costs physicians face to borrow money to finance the purchase of equipment. ASTRO has found that

recent published data indicates most physicians do not get government funded SBA loans to finance the purchase of equipment.

According to data released in early 2012, from 2000 to 2011, SBA loans to physician offices, including private practice doctors and mental health specialists increased from less than $60 million to $650 million per year. The $650 million represents 1,516 approved loans.[9] According to recent Bureau of Labor Statistics (BLS) there are 691,000 physicians in the US.[10] Assuming that half of these physicians are in private practice, the 1,516 SBA loans obtained by physicians in 2011 are only a fraction of the loans obtained by Medicare physicians. The increase in the number of physicians receiving SBA loans is likely more notable for what it may be indicating about the financial state of US physicians than being a benchmark for interest rate assumptions for medical equipment financing by physicians. When the data on physicians and SBA loans was released in early 2012 many financial experts concluded that the growth in SBA loans for physicians was a reflection of the financial struggles of physicians. They were described as cash-strapped solo or small private practices taking out loans to make payroll and pay business and medical expenses.

Preliminary results from a recent ASTRO membership survey also provides further evidence that most physicians are not getting SBA loans to purchase equipment. The question on the survey was: "Where do you get financing to purchase capitol equipment?" The chart below summarizes preliminary results. We received almost 300 responses from members practicing in freestanding centers.

Type of Loan	Percent
Small Business Administration	2.4%
Bank	45.7%
Loans from Individuals	6.2%
Equipment Manufacturer	8.6%
Capital Investment in Practice	20.6%
Other Financial Company	16.5%
Total	100.0%

Source: 2012 ASTRO Membership Survey, preliminary results

Additionally, SBA loans have lower payments, longer terms and relaxed criteria to allow some businesses to borrow more money than they would otherwise be able to obtain. ASTRO believes that these factors also make SBA loans an inappropriate proxy.

Another factor that makes SBA loans an inappropriate proxy is that in general they are too small for large equipment purchases. According to the SBA website the 7(a) loans are the most common SBA loan. They are also the most flexible, since financing can be guaranteed for a variety of general business purposes, including working capital, machinery and equipment,

[9] Berry, Emily, "5 Mistakes Doctors Make When Borrowing Money." Amednews.com; Posted April 9, 2012; Accessed August 15, 2012; http://www.ama-assn.org/amednews/2012/04/09/bisa0409.htm.
[10] Bureau of Labor Statistics (BLS), "Occupational Handbook: Physicians and Surgeons." Posted March 29, 2012; Accessed August 15, 2012; http://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm.

furniture and fixtures, land and building (including purchase, renovation and new construction), leasehold improvements, and debt refinancing (under special conditions). Yet even with the loan size increase for 7(a) loans in October 2010 to $5 million under the Jobs Act, the average loan size is $624,000.[11] While this is not an insignificant amount, it is far less than what a radiation oncologist would need to borrow when purchasing new equipment.

The interest rates that a provider can obtain are a function of the individual's credit, the size of the loan, and the assets of the practice. It is unreasonable to use SBA loan maximum interest rate guidelines as a benchmark since these loans have lower interest rates, and there is no evidence that this is where physicians typically obtain financing to purchase equipment. ASTRO believes it is more likely that physicians are obtaining loans from private banks to finance equipment purchases. In other areas of the fee schedule that require data (i.e. malpractice RVUs, supplemental practice expense survey), CMS collects information directly from physicians or from relevant data sources. In this instance, CMS has failed to follow that methodology. ASTRO believes CMS must use interest rates that truly reflect the cost of financing equipment. We do not believe the SBA maximum interest rate assumptions provide a reliable benchmark for this purpose.

ASTRO is also concerned that CMS proposes to update the interest rate on an annual basis. The recent volatility of the PE RVUs has been very difficult for physicians. ASTRO recommends that the interest rate assumption be updated less often than once a year. We recommend reviewing the timelines for updating other data in the fee schedule as guidance.

While ASTRO supports the agency's efforts to ensure the most accurate data are used to develop PE RVUs, we do not believe that the SBA maximum interest rates are an accurate or appropriate data source. ASTRO believes most physicians are obtaining private bank loans to finance equipment. ASTRO urges CMS to explore data sources within this market to use as a benchmark for interest rates.

Public nomination of potentially misvalued code – CPT Code 77336, Medical physics consult

In the 2013 proposed rule, CMS proposed CPT code 77336 Radiation physics consult to be reviewed as a potentially misvalued code since there may have been changes in technology and other practice expense inputs. ASTRO supports this proposal and urges CMS to finalize it.

In the CY 2012 PFS final rule, CMS finalized a public nomination process for potentially misvalued codes. This newly established annual call for potentially misvalued codes consolidated the statutorily mandated Five Year Review of Work and Practice Expense. CMS believes combining the review of both physician work and practice expense for each code will better align the review of these codes and lead to a more accurate and appropriate payment. To allow for public input and to preserve the public's ability to identify and nominate potentially

[11] Mandelbaum, Robb. "SBA Backed Loans Set Record in 2011." New York Times; Posted October 6, 2011; Accessed August 28, 2012; http://boss.blogs.nytimes.com/2011/10/06/s-b-a-backed-lending-set-a-record-in-2011/.

misvalued codes, CMS also established a process by which on an annual basis the public could nominate codes. As indicated in previous comment letters, ASTRO supports this new process.

In the 2012 final rule, ASTRO nominated CPT code 77336 Radiation physics consult as misvalued code and provided compelling evidence for this recommendation. This evidence demonstrated that this service has changed substantially since the original valuation by the RUC in 1998. ASTRO provided evidence that:

- technology has changed, and
- prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.

The Society also provided national surveys of physician time and intensity from professional and management societies and organizations. ASTRO believes all of this evidence provides a very strong argument for review of CPT code 77336.

ASTRO supports the CMS proposal to review CPT code 77336 and urges the agency to finalize this proposal.

Oncology measures group for PQRS 2013

The Physician Quality Reporting System (PQRS) as set forth in section 1848(a), (k), and (m) of the Social Security Act, is a quality reporting program that provides incentive payments to eligible professionals who satisfactorily report data on quality measures (and payment adjustments for those who fail to do so). The regulation governing PQRS is located at 42 CFR 414.90.

Physicians and other eligible professionals have the option of participating in PQRS by either reporting individual measures or a measures group. Participating via a measures group versus individual measures significantly reduces the burden of participating in PQRS and increases the chances of success for an eligible professional. ASTRO is pleased to learn that CMS is proposing an oncology measures group for PQRS 2013 and beyond. The following measures are included in the proposed oncology measures group:

- 71 Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
- 72 Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients
- 110 Preventive Care and Screening: Influenza Immunization
- 130 Documentation of Current Medications in the Medical Record
- 143 Oncology: Medical and Radiation – Pain Intensity Quantified
- 144 Oncology: Medical and Radiation – Plan of Care for Pain
- 194 Oncology: Cancer Stage Documented
- 226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

This measures group was submitted by ASTRO and the American Society for Clinical Oncology (ASCO). Currently, there is no measures group available for radiation oncologists or one that applies specifically to Medicare beneficiaries with a cancer diagnosis. ASTRO believes that the introduction of this measures group in 2013 and the reduced administrative burden that it

provides will encourage increased participation by radiation oncologists and thereby will also provide CMS increased measure reporting by providers caring for patients with cancer. On a related front, ASTRO recently launched a PQRS registry for our members. We believe a PQRS measures group will greatly facilitate registry-based reporting among cancer care providers. ASTRO is especially excited about this measures group because we believe the measures are particularly meaningful to patients with a cancer diagnosis. In general, these are broadly applicable to all cancer patients and address the domains identified by CMS to be important (i.e., clinical appropriateness/efficiency, population and public health, patient and family engagement, care coordination and patient safety). Additionally, all measures in the proposed oncology measures group are currently in the PQRS program and NQF approved. As re-specification of these existing PQRS measures to include ICD-10 is already required, the creation of an oncology measure group will not create additional work for CMS.

We would only note that, within the proposed oncology measures group, ASTRO supports replacing the current specifications for 194. Oncology: Cancer Stage Documented measure with the updated specifications submitted by the AMA PCPI, which expands the denominator to include cancer diagnoses beyond breast, colon and rectal cancers, making the measure more broadly applicable across the group. We believe this modification will further strengthen the measures group.

ASTRO is extremely pleased with the proposal for the inclusion of an oncology measures group in the CY 2013 PQRS program. The anticipated increased participation by radiation oncologists will benefit providers, Medicare beneficiaries, and CMS. ASTRO urges CMS to finalize the proposal to include an oncology measures group in the CY 2013 PQRS program.

Proposed reporting criteria for satisfactory reporting of measures groups for PQRS 2013

In CY 2012, eligible providers are required to report one measures group for at least 30 Medicare Part B FFS patients for both claims and registry reporting in order to meet the criteria for satisfactory reporting. CMS says it received feedback that it is difficult for some specialties to meet that patient threshold. In response to this feedback, for CY 2013, CMS is proposing to change the criteria to "at least 20 patients, a majority of which must be Medicare Part B FFS patients." ASTRO appreciates CMS considering comments from stakeholders when proposing this change. ASTRO believes that, depending on the patient mix, it may be difficult for some specialties to meet the current threshold of 30 patients and supports this proposal.

ASTRO is pleased with the proposal of changing the criteria for measures groups to "at least 20 patients, a majority of which must be Medicare Part B FFS patients." ASTRO urges CMS to finalize this proposal.

Proposed criteria for satisfactory reporting for the 2015 and 2016 PQRS payment adjustments

The Affordable Care Act established that eligible professionals that do not satisfactorily report data on quality measures through the Medicare PQRS program will be subject to a payment adjustment. The payment adjustment for CY 2015 is 1.5 percent. The payment adjustment for CY 2016 is 2.0 percent. In the CY 2012 final rule CMS established 2013 as the reporting period for the 2015 payment adjustment and CY 2014 as the reporting period for the 2016 payment

adjustment. In the CY 2013 proposed rule, CMS articulates the proposed criteria for satisfactorily reporting for the 2015 and 2016 payment adjustments.

In the CY 2013 proposed rule, CMS proposes satisfactory criteria for the 2013 and 2014 incentives. In addition, CMS proposes that these same criteria ***also*** satisfy the satisfactory reporting requirements for the 2015 and 2016 payment adjustments, respectively. In other words, if an eligible provider meets the criteria for receiving an incentive in 2013 and 2014, he or she will also have satisfied the requirements to avoid a payment adjustment in 2015 and 2016.

For those eligible providers who fail to meet the criteria for an incentive in 2013 and/or 2014, CMS is also proposing an alternative criterion for satisfactory reporting for the 2015 and 2016 payment adjustments: report one measure or measures group using the claims, registry, or EHR based reporting mechanisms. CMS acknowledges that this proposed criterion is significantly less stringent than what has been proposed for the 2013 and 2014 incentives. CMS states that they are proposing less stringent criteria to ease eligible professionals and group practices who have not previously participated into the PQRS program. CMS anticipates eliminating these alternative proposed criteria in future years and establishing criteria that more closely resembles the proposed satisfactory reporting criteria for the 2013 and 2014 incentives.

ASTRO is very supportive of the alternative criterion for satisfactory reporting for the 2015 and 2016 payment adjustments. We commend CMS for trying to align the PQRS incentive payment criteria with the payment adjustment criteria for those years when the incentive and payment adjustment reporting periods of PQRS overlap. We also are pleased that CMS is considering the challenges facing the many providers who have not yet participated in PQRS. ASTRO urges CMS to finalize this proposal.

ASTRO has been a strong supporter of PQRS since the beginning. The Society has been actively involved in measure development and engaged in numerous educational activities related to PQRS, including a CMS-ASTRO-ASCO conference call on PQRS in 2010. More recently, ASTRO submitted a request for an oncology measures group that we are very pleased to see CMS has proposed for the 2013 PQRS program. As mentioned previously, ASTRO launched a PQRS registry for members. Despite our best efforts, participation rates for radiation oncologists have remained low. While the PQRS program as a voluntary incentive program began back in July 2007 and many changes and improvements have been made these past few years, physicians continue to face challenges participating in the program. The alternative criterion for the 2015 and 2016 payment adjustments gives the extra time needed to boost participation in this important program.

The next few years will be very challenging for physicians. Numerous Medicare value based purchasing programs are converging, ICD-10 is being implemented, and physicians are transitioning to electronic health records. ASTRO believes the more gradual transition into PQRS payment adjustments is necessary. ASTRO fully supports the proposed criteria for the 2015 and 2016 PQRS payment adjustments and requests CMS to finalize the proposal.

PQRS Group Reporting

In terms of PQRS group reporting, CMS proposes to define a group practice as a single TIN with two or more eligible professionals, as identified by their individual NPI, who have reassigned their Medicare billing rights to the TIN. CMS is also proposing to change the number of eligible professionals comprising a PQRS group practice from 25 or more to two or more to allow all groups of smaller sizes to participate in the Group Practice Reporting Option (GPRO).

ASTRO supports the proposal to reduce the size of an eligible PQRS group practice from 25 to two. This proposal takes into account the heterogeneous practice environments and business relationships that exist among physicians. ASTRO believes the increased flexibility of allowing smaller group practices to take advantage of GPRO will encourage increased PQRS participation.

ASTRO urges CMS to finalize the proposal to reduce the size of a PQRS group practice from 25 to two.

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 Sheila Madhani, Assistant Director, ASTRO Health Policy Department at (703) 839-7372 or sheilam@astro.org.

Respectfully,

Laura Thevenot

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