Katten
Katten Muchin Rosenman LLP

2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
202.625.3500 tel
202.298.7570 fax

June 18, 2013

HOWARD R. RUBIN
howard.rubin@kattenlaw.com
202.625.3534 direct
202.339.6057 fax

VIA FEDERAL EXPRESS & ELECTRONIC MAIL

James Cosgrove, PhD
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW, Room 5021
Washington, DC 20548

Re: GAO Draft Report on the Impact of Self-Referral of Radiation Oncology Services

Dear Dr. Cosgrove:

On behalf of the Large Urology Group Practice Association (LUGPA), I am writing as a follow-up to our meeting on June 5, 2013, at which GAO invited LUGPA to review and comment on GAO's draft report regarding the impact of self-referral arrangements on utilization of radiation oncology services, and in response to the email I received from GAO Health Care Analyst Brian O'Donnell on June 12, to which Mr. O'Donnell attached a summary of the comments that LUGPA had presented orally to you and your staff during the June 5 meeting. In his email, Mr. O'Donnell asked that LUGPA confirm that GAO's summary accurately reflects the comments LUGPA made at the June 5 meeting. He explained that the document would be used to summarize LUGPA's position in the final report.

GAO emphasizes as part of its "mission, responsibilities, strategies and means" that its ability to achieve its strategic goals and objectives rests on "providing professional, objective, fact-based, nonpartisan, non-ideological, fair, and balanced information to the Congress and other stakeholders." Since our initial meeting three years ago, my clients have been engaged in a dialogue with you and your staff regarding GAO's study of self-referral of radiation oncology services, seeking to be a resource in evaluating a complex issue with multiple overlapping variables. We have spent hundreds of hours collecting and analyzing Medicare data pertaining to the issues GAO was called upon to study by the Congressional requestors, identifying the most relevant peer-reviewed literature on the topic, preparing written submissions addressing the many questions that your staff had on clinical and cost considerations in the management of prostate cancer, and meeting on three separate occasions with your staff to present data and answer questions.

Against that backdrop, it was deeply disappointing to find none of the data, academic literature, or analysis we had presented to you and your staff over the last three years reflected in the 30-plus page Draft Report. With that said, the written summary Mr. O'Donnell sent to me on June 12 misstates or omits critical points LUGPA made at the June 5 meeting. I am enclosing with this letter a revised version of the summary Mr. O'Donnell sent to me on June 12 and ask that this corrected document be used as the summary of LUGPA's comments in the final report.

As the enclosed comments reflect, there are serious flaws in both methodology and data presentation in the Draft Report. Respectfully, we submit that in order for GAO to present the Congressional requestors with a fair, balanced and accurate report, it is necessary for these flaws to be rectified in the final document.

Sincerely,

Howard R. Rubin

Enclosure

cc: Deepak A. Kapoor, M.D., LUGPA President *(via electronic mail only)*
John McManus, The McManus Group LLC *(via electronic mail only)*
Tracy Spicer, Avenue Solutions LLC *(via electronic mail only)*
Thomas A. Walke, Ph.D., GAO Health Care Assistant Director *(via electronic mail only)*
Brian E. O'Donnell, GAO Health Care Analyst *(via electronic mail only)*

Large Urology Group Practice Association's Comments on GAO's Draft Report on the Impact of Self-Referral on Radiation Oncology Services

LUGPA strongly disagrees with the GAO's conclusion that financial incentives for self-referring providers—specifically those in limited specialty groups—are likely a major factor driving the utilization of IMRT to treat prostate cancer. GAO provided no evidence that patients were being provided radiation therapy inappropriately by integrated urology practices that had acquired IMRT technology. LUGPA believes that the increase in IMRT line items for treatment of prostate cancer in limited specialty groups, particularly in the integrated urology group setting, has been driven by two other factors: (1) an increase in the absolute number of urologists who participate in group practices that have elected to incorporate radiation services as part of a comprehensive, integrated strategy to treat prostate cancer, resulting in an increase in the number of Medicare beneficiaries treated at urology group practices; and (2) patient preference in choosing equally efficacious, less invasive therapy that occurs as a natural consequence of shared decision making in the setting of comprehensive cancer care. LUGPA has six specific concerns including these two overarching points:

1) ***GAO's failure to index absolute utilization and cost data to the increase in the number of physicians treating Medicare beneficiaries in integrated urology groups is both methodologically invalid and misleading.*** GAO repeatedly presents data on absolute numbers of line items and dollars spent, but never reports the number of physicians within integrated group practices offering radiation services. As this number has increased, the number of patients receiving care in this setting has increased dramatically—with a concomitant decline in prostate cancer patients treated at either free standing radiation centers or hospitals.

2) ***LUGPA firmly believes that cancer care is most optimally delivered in a comprehensive, integrated fashion, in which shared decision making is enhanced by patient exposure to providers of differing disciplines who can provide viewpoints based on their clinical expertise and experience.*** Peer-reviewed literature strongly supports this notion in general, and data specific to Medicare beneficiaries with prostate cancer indicates that the utilization of radiation therapy is substantially higher when patients consult a radiation oncologist in addition to a urologist prior to making a decision regarding their cancer treatment—of particular note is that this data pre-dates the integration of radiation services into urology groups. GAO acknowledged that it did not even consider that modifications in practice structure could have impacted utilization of different prostate cancer treatments. As a multi-disciplinary approach to cancer decision making is the hallmark of integrated urology group practices, GAO's failure to examine the proportion of patients who received consultations from radiation oncologists before and after the integration of radiation services into group practices, as well as to compare multi-disciplinary decision making between integrated urology groups and physicians in other settings, is inexplicable.

3) ***GAO's assertion that IMRT, brachytherapy, and radical prostatectomy are clinically equivalent treatments for prostate cancer is inappropriate, as it does not consider differing morbidities or age-appropriateness associated with these interventions in the Medicare population nor does it reflect changing clinical standards that occurred during the study period.*** GAO failed to properly emphasize

the changing clinical standard in external beam radiation from an older, more dangerous and less effective form of radiation therapy (3D-CRT) to a newer, safer and more effective technology (IMRT), and further failed to acknowledge that this trend started prior to the integration of radiation services into urology groups. Research published in the peer-reviewed literature suggests older men, who often are diagnosed with intermediate or high risk cancer, are under-treated—in fact, literature cited by the GAO itself acknowledges that a majority of these men undergo external beam radiation as a component of their cancer therapy. Indeed, the National Comprehensive Cancer Network (NCCN) no longer recommends brachytherapy as a monotherapy for patients with intermediate or high risk prostate cancer. GAO failed to consider that Medicare beneficiaries, many of whom are older patients who may have higher risks for anesthesia and surgery, would benefit from access to IMRT, a non-invasive technology that could produce identical or improved outcomes at substantially lower risk.

4) ***GAO fails to acknowledge that all sites of service have essentially identical financial incentives to perform services for which they receive compensation.*** These incentives are accentuated when providers offer only a single form of treatment—such as radiation services at free standing radiation centers. That newly diagnosed patients treated at integrated urology groups received a nearly equal proportion of active surveillance and a lower use of androgen deprivation therapy as patients treated at other sites of service is evidence that patient choice and sound clinical decision making are the principle driving forces at such groups.

5) ***GAO should not have limited its study to the use of IMRT for treatment of prostate cancer.*** An analysis of the Medicare 5 percent files indicates that, since 2009, more patients receive IMRT for diseases other than prostate cancer and that from 2007 through 2011 IMRT utilization to treat prostate cancer increased by only 2.2%, while IMRT utilization to treat other cancers during that same five-year period increased by 51.2%. GAO also completely ignored that financial incentives for hospital systems are likely a major factor driving the proliferation of non-standard prostate cancer treatments that result from millions of dollars in direct-to-consumer marketing. Focusing on one form of therapy in one disease state in one practice setting provides a skewed and incomplete picture of radiation utilization and expenditures and cannot be relied upon by legislators.

6) ***GAO's estimation of the use of 3D-CRT to treat prostate cancer is substantially understated.***

Recommendation and Matter for Congressional Consideration

In regard to GAO's matter for Congressional consideration that Congress should consider directing the Secretary of Health and Human Services to require providers to disclose their financial interests in IMRT to their patients, LUGPA supports transparency in disclosing financial interests in all practice settings and would not be opposed to disclosure requirements applicable to all therapeutic modalities at all sites of service—indeed, many LUGPA member practices already have such policies in place. That said, as LUGPA is committed to the rights of all patients stricken with cancer, LUGPA opposes any discriminatory disclosure obligation that does not apply equally to providers with ownership interests in single-specialty or multi-specialty practices, free-standing radiation centers and hospital-owned facilities.