Community Oncology Alliance
Dedicated to high quality, affordable, and accessible cancer care

1101 Pennsylvania Ave., NW
Suite 700
Washington, DC 20004
(202) 756-2258
communityoncology.org

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Georgia
Vice President:
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New York
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September 2, 2014

Ms. Marilyn Tavenner
Administrator & Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P. O. Box 8013
Baltimore, MD 21244-8013

Re: *CMS-1612-P, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015*

Dear Administrator Tavenner:

I am the new President of the Community Oncology Alliance (COA), a non-profit organization representing the interests and wellbeing of community oncology practices and the patients they serve. On behalf of the COA Board of Directors, I am submitting comments on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS), *CMS-1612-P*: *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015* (MPFS). I begin with general comments on the MFPS proposed rule, then provide specific comments and recommendations by referenced sections.

For the past three years, COA has been working with Congress and the committees of Medicare jurisdiction, private payers, self-insured employers, and other cancer organizations on oncology payment reform tied to COA's Oncology Medical Home (OMH) model of care. A steering committee comprised of payer, oncology provider, patient advocacy, and industry representatives have developed and endorsed specific measures of cancer care quality and value, including a patient satisfaction measurement system. In conjunction with that effort, a COA task force of community oncologists and practice administrators developed, and thoroughly tested, a 4-phase oncology payment reform model, which ties to the endorsed quality and value measures. Those measures, as well as the payment model, are being used by providers and private payers in pilot programs across the country. Community oncology is leading the way with oncology payment reform.

Additionally, COA spent considerable time, resources, and funds to apply for a grant from the Centers for Medicare & Medicaid Innovation (CMMI) to implement this model in a national demonstration project. I and several of my oncologist colleagues on the COA Board have participated in the Brookings discussions on payment reform that have resulted in a model proposed by CMS to be implemented by CMMI. We believe aspects of the model have merit; however, we are concerned that other aspects are too complex and prescriptive. We will be providing comments back to CMS on the model after submitting this comment letter.

On October 22, 2014, COA will hold an Oncology Payer-Exchange Summit on oncology payment reform in Washington, DC, bringing together teams of oncology providers and private payers who have been working together on oncology payment reform pilot programs. Private payers such as Aetna, UnitedHealthcare, PriorityHealth, and others will discuss their

pilots along with participating providers. Other payers not yet implementing oncology payment reform will hear about what is working, what is not, and how oncology payment reform should be shaped going forward. This landmark event is not a one-off meeting but is meant to be the start of a national information exchange to advance oncology payment reform.

If you look at what is happening in community oncology with payment reform there is much hope going forward, as community oncology is collectively well ahead of academic and institutional-based oncology, as well as other areas of medicine, in implementing payment reform. However, the advances being made are threatened by the continued ratcheting down of Medicare reimbursement for cancer care by CMS, as well as by Congress' inability to fix the broken SGR (sustainable growth rate) basis of Medicare payment. It is incomprehensible how CMS can continue to cut reimbursement to independent community cancer clinics while actually increasing reimbursement to outpatient hospital systems for identical services. Rather than create payment parity for the same services delivered in independent community cancer clinics and hospital outpatient facilities as recommended by MedPAC[1], CMS continues to substantially widen the gap for delivery of the same cancer care services between the two settings, without any data on differences in quality of care, types of cancers treated, or other potential site differences justifying this payment gap. *If you analyze just payments for the administration of chemotherapy and related infusion services, CMS will be reimbursing hospital outpatient facilities almost double of what it pays community oncology clinics for the identical services provided in 2015.*

CMS' reimbursement policies are forcing cancer care into the more expensive hospital setting, with higher costs for both Medicare and seniors. In preparing this comment letter, I just received a letter from a patient (of our practice) relating an experience where the patient needed a supportive care drug (Neulasta) administered on a weekend day and had to go to the hospital because we have to restrict our hours on weekends precisely because of lowered Medicare reimbursement. *The patient was upset in having out-of-pocket costs from the hospital of $1,458 for a single shot versus $31 when the drug is administered in our clinic. In the process, the patient's insurer paid over three times the amount for the hospital to administer the drug.*

Community oncology practices for years have provided quality, accessible, and affordable cancer care in an increasingly hostile reimbursement environment. The broken SGR-based system, with looming severe payment cuts, have kept community cancer clinics on a financial cliff. Although fixing that falls within Congress' jurisdiction, the continued ratcheting down of infusion, imaging, radiation, and laboratory services reimbursement by CMS has been the nail in the coffin for many cancer clinics. Additionally, CMS' ill-advised decision to apply the Medicare sequester cut to the underlying cost of cancer drugs has further pushed cancer clinics to merge with large hospital systems, especially those with favorable 340B pricing that are aggressively pursuing buying community cancer clinics. I note that the Administration exempted portions of the Affordable Care Act from the sequester cuts but said it had no choice but to apply the sequester cut to the underlying cost of cancer drugs.

COA is in the process of updating its *Community Oncology Practice Impact Report*, which has clearly documented the consolidation of cancer care into large hospital systems and the closing of clinics, especially in rural areas. The 2013 report[2] showed that over the previous 6 years 1,338 clinics have been impacted, most notably with *288 treatment facilities closing and*

[1] *Report to the Congress: Health Care and the Health Care Delivery System,* MedPAC, June 2013. MedPAC states in part, "If the same service can be safely provided in different settings, a prudent purchaser should not pay more for that service in one setting than in another. Payment variations across settings may encourage arrangements among providers that result in care being provided in higher paid settings, thereby increasing total Medicare spending and beneficiary cost sharing. In general, the Commission maintains that Medicare should base payment rates on the resources needed to treat patients in the most efficient setting, adjusting for differences in patient severity to the extent that severity differences affect costs more for that service in one setting than in another."

[2] *Community Oncology Practice Impact Report*; Community Oncology Alliance, June 2013.

469 practices (typically having multiple treatment facilities) merging into or affiliating with hospitals. A study of Medicare data by The Moran Company found that in 2005 87% of chemotherapy was administered in independent community cancer clinics but by the end of 2011 it had declined to 67%.[3]

The 2015 MPFS proposed by CMS will only further drive community cancer clinics into hospital systems. The proposed cuts to imaging and radiation are inappropriate and we urge CMS to reconsider any reimbursement cuts affecting community cancer clinics. We are especially concerned about the cut to advanced imaging services provided by community oncology clinics, which is an essential component of cancer diagnosis and treatment management. CMS' cuts to radiology of 2% mask the 7% cut to imaging services provided by community cancer clinics. We arrived at this by inputting the relevant proposed MPFS codes into a model and having community cancer clinics run the model based on actual practice use of imaging services. CMS-reported cuts are lower because they are based on global estimates of the "radiology" specialty that are not specific to community cancer clinics.

What follows are specific comments on the MPFS proposed rule with specific section references.

II. Provisions of the Proposed Rule for PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
3. Changes to Direct PE Inputs for Specific Services
e. *Radiation Treatment Vault*

COA strongly opposes any further cuts to reimbursement for radiation treatment services. Over the past five years, CMS has lowered reimbursement for radiation treatment by close to 20%, which is just another factor pushing cancer care into the hospital setting. Some of the identical services delivered in outpatient hospital facilities are close to 25% higher than those offered in independent community cancer clinics. The proposed payment cut in the MPFS proposed rule based on reclassifying the radiation treatment vault from a *direct* practice expense (PE) to an *indirect* PE is both arbitrary and inappropriate. First, it is arbitrary to suddenly make a reclassification out of the blue that undermines the established cost structure of community cancer clinics and results in reduced reimbursement in an already pressured environment. Second, it is inappropriate for several reasons based on the very specialized nature of the radiation treatment vault. The vault space serves a very specific purpose that cannot be used for other clinical or operational purposes. It is required to comply with Nuclear Regulatory Commission licensing regulations and the Internal Revenue Service classifies radiation treatment vaults as medical equipment that is depreciated separately from the clinic building.

Recommendation: We strongly urge CMS to not make any change to the classification of the radiation treatment vault, or in any way continue to lower reimbursement for radiation treatment services to community cancer clinics. We further ask CMS to comply with its own direction to provide for enhanced transparency and input for new codes starting in 2016 by not making any changes to radiation treatment codes in the final 2015 fee schedule.

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
4. Using OPPOS and ASC Rates in Developing PE RVUs

We are very concerned about *"the possible uses of the Medicare hospital outpatient cost data (not the APC payment amount) in potential revisions of the PFS PE methodology"* per the

[3] *Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries*, The Moran Company, May 2013.

request for comment by CMS in the MPFS proposed rule. We are especially concerned with CMS using hospital outpatient data, when convenient, to *"set upper payment limits for office-based procedures"* while at the same time actually increasing the gap between reimbursement for the identical services delivered in community cancer clinics and outpatient hospital facilities. It is problematic when old costs/rates in the outpatient hospital setting are used to update current rates for physicians. CMS' intention in the 2014 proposed rule fee schedule to do exactly that would have resulted in significant reimbursement cuts to radiation treatment services.

We do take note of the following from the MPFS proposed rule:

"In addition to soliciting comments as noted above, we continue to seek a better understanding regarding the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments affects payments under PFS and beneficiary cost-sharing. MedPAC continues to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physician offices become hospital outpatient departments, and to recommend that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 Report to Congress)."

CMS should be very concerned about the continued significant consolidation of cancer care into hospitals and the higher payments made by both Medicare and beneficiaries (out-of-pocket) for outpatient hospital-based cancer care. A study by Milliman in 2011 found that Medicare pays $6,500 more on an annualized basis and seniors $650 more for just chemotherapy administration in outpatient hospital facilities versus the identical service provided in community cancer clinics.[4]

Recommendation: We urge CMS to instead identify identical cancer care services delivered in the outpatient hospital and community clinic settings and to pay the same amount for those identical services. We support CMS' intention to collect data on services delivered in provider-based departments of hospitals using a code modifier for these hospital-centric facilities only. However, we would not limit this to "off campus" facilities as many acquired physician practices were originally located on the hospital "campus."

B. Potentially Misvalued Services Under the Physician Fee Schedule

3. CY 2015 Identification and Review of Potentially Misvalued Services

COA understands the mandate that CMS has to review codes that are perceived to be "misvalued" due to time and/or process changes and improvements. While we recognize that a review and resetting of codes is often warranted, we are very concerned about the potential negative impact to cancer care, especially reviews targeted at codes simply with high overall payments, such as certain chemotherapy administration and radiation treatment services listed in TABLE 10 of the MPFS proposed rule. It is disconcerting that misvalued codes for consideration are always viewed as overpayments, as opposed to underpayments based on old data, etc.

Recommendation: We urge that CMS not make any downward revisions to payment codes without thorough, representative, accurate, and current data to justify changes, and that CMS undertake an objective, market-based analysis of the impact of any changes on both beneficiary access, beneficiary costs, and Medicare spending. We further recommend that CMS make a complete analysis of the identical cancer care services provided in outpatient hospital facilities and community cancer clinics in terms of payment rates for identical services. This is per the CMS mandate to identify and correct misvalued *"codes for which*

[4] *Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy*, Milliman, October 2011.

there is a significant difference in payment for the same service between different sites of service."

F. Valuing New, Revised, and Potentially Misvalued Codes

4. Proposal to Modify the Process for Establishing Values for New, Revised, and Potentially Misvalued Codes

CMS states that, *"After considering the current process, including its strengths and weaknesses, and the alternatives to the current process described previously, we are proposing to modify our process to make all changes in the work and MP RVUs and the direct PE inputs for new, revised and potentially misvalued services under the PFS by proposing the changes in the proposed rule, beginning with the PFS proposed rule for CY 2016. We propose to include proposed values for all new, revised and potentially misvalued codes for which we have complete RUC recommendations by January 15th of the preceding year. For the CY 2016 rulemaking process, we would include in the proposed rule proposed values for all services for which we have RUC recommendations by January 15, 2015."* CMS asks for specific comments on this process and timetable.

Recommendation: We highly recommend that CMS push back implementation of this process by one year. There is insufficient time for input to CMS by January 15, 2015. Additionally, the proposed use of G-codes would be administratively burdensome for practices.

G. Chronic Care Management (CCM)

1. Valuation of CCM Services

Allowing payment for non-face-to-face chronic care management (CCM) services and applying a per-beneficiary, per-month payment for CCM services provided to patients with two or more significant chronic conditions is a positive change proposed by CMS. However, the proposed payment of $43.67 per patient per month is simply too low and does not realistically account for the staff and associated overhead costs on a per-patient, monthly basis.

Recommendation: CMS must increase payment of this code substantially to justify the time realistically involved in patient care coordination, especially by an oncologist, the likely practitioner for Medicare beneficiaries in active cancer treatment.

G. Chronic Care Management (CCM)

3. Scope of Services and Standards for CCM Services

Previously, one of the standards to be met to qualify for billing CCM services was certification as a patient-centered medical home, which COA supported. CMS now proposes that the provider have immediate access to patient information via an electronic health record, with no other credentialing necessary. We question how health technology, on its own accord, confirms that a patient is being managed efficiently for multiple chronic conditions. When a patient is being treated for cancer, their primary health care provider is the oncologist, as he or she has to consider the cancer patient's comorbidities. Recognizing an Oncology Medical Home as a qualified integrated care provider is more important than employing health record technology. CMS should be more concerned about the outcome of care coordination, and ensuring practices have the resolve/interest in coordinating care, rather than being too prescriptive in requiring use of health record technology that is certified to particular standards.

Recommendation: We highly recommend that CMS not implement a scope of service that requires the use of specifically certified health record technology. Instead, we recommend that CMS allow medical practices accredited as a patient-centered medical home by NCQA,

the Commission on Cancer, or other accreditation entities have met the criteria of *"sufficient scope of service"* to receive the CCM payment.

H. Definition of Colorectal Cancer Screening Tests

The suggested change to the colorectal cancer pre-screen or colonoscopy, wherein anesthesia services associated with this procedure will have "no cost," removes yet another barrier allowing beneficiaries to avail themselves of this potentially life-saving service. Unfortunately, additional significant costs are incurred when the simple colonoscopy involves removal of a polyp or other growth, converting that free screening into a significant out-of-pocket surgical procedure.

Recommendation: If CMS wants to encourage more Medicare beneficiaries to avail themselves of this screening procedure, we suggest a flat rate or bundled service to providers of these services for both screening and simple removal of suspicious growths, along with associated anesthesia and other services associated with the colonoscopy procedure.

III. Other Provisions of the Proposed Regulations

F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

An expeditious process for local coverage determinations (LCDs) can be a positive in quickly clarifying reimbursement policy. However, we are concerned that any streamlined process not limit stakeholder input and relevant scientific/clinical information/documentation, as well as not restrict access to important new tests that are the standard of care.

Recommendation: A better improvement would be the conversion of that LCD to a national coverage determination (NCD) when it has been determined that such decision can be applied nationally for the benefit of all Medicare beneficiaries. Collaboration among all Medicare Administrative Contractors (MACs) will only enhance that benefit. It is critical that any process allow meaningful physician and other stakeholder input, and not be used as a means of restricting access to important new diagnostic tests. We have found that reimbursement for radiopharmaceuticals varies across the nation by MAC, which harms beneficiaries in certain states where the MAC is reimbursing community cancer clinics at invoice minus 2% (for the Medicare sequester) rather than 95% of average wholesale price (AWP) less 2%. COA has been working towards consistent payment at the AWP-based rate to ensure that all Medicare beneficiaries have access to these important treatment agents.

H. Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

A reconsideration of the 60-day maximum for substitute physician billing arrangements is encouraged. It often becomes necessary for a longer than 60-day reciprocal or substitute arrangement due to illness, injury, travel, or sabbatical. With the current physician shortage in oncology, it is challenging at best to find a "locum tenens" physician. To force the automatic termination of that contract after 60 days could result in an access issue for patients, something that can be disastrous for Medicare beneficiaries in active cancer treatment.

A real-life example of such an access issue occurred when a radiation oncologist was called out of the country because a parent had become gravely ill. That physician had to care for her elderly mother for 6 months, forcing the practice to find a substitute radiation oncologist for an extended period. The search was exhaustive but an appropriate candidate was identified; however, the physician's contract had to be terminated at 60 days to comply with the Medicare requirement. That forced treatment delays.

Recommendation: An alternative for consideration would be supplying Medicare with appropriate credentialing of "locum tenens" physicians for a one-year period, with an explanation of the expected function of the physician, reason for the substitute situation, and anticipated time required. That could possibly be a function of the MAC director.

I. Reports of Payments or Other Transfers of Value to Covered Recipients
2. Continuing Education Exclusion (§403.904(g)(1))

In general, we are very concerned about implementation of the Open Payments Program. We say that without any concern for transparency of payments made to physicians. Our concern has to deal with the readiness of CMS to provide validated, accurate data, especially in light of the fact that it is reported that over one-third of the data supplied by drug and device manufacturers is inaccurate, as reported by CMS although contested by PhRMA. Additionally, the malfunctions on the CMS end with the physician validation website leaves little time for physicians to protest and report inaccurate data. Additionally, we are concerned about what CMS will provide to consumers relating to the context and meaning of the data.

Specifically relating to the program and reporting of continuing medical education (CME) programs, we are uncertain as to the reasoning behind the reporting of payments associated with continuing education events. First, we note that physicians are mandated to obtain a specific number of hours of continuing medical education in order to maintain their licensing. It is education, pure and simple. If we have interpreted the CMS suggested reporting changes correctly, if a manufacturer conveys full discretion to the continuing education provider, reported payments are outside the scope of the rule (78FR 9292). On the other hand, if the manufacturer provides sponsorship to an entity other than a continuing education provider, such funds are subject to disclosure. Further, if the payment is not related to a specific covered or non-covered drug, device, biological, or medical supply, the education benefit is not reportable. As a not-for-profit entity that holds educational conferences for physicians, it is important that COA offer CME credits to conference attendees.

Recommendation: First, we urge CMS to delay implementation of this program until data is validated and accurate. Second, we urge CMS to clarify the CME reporting exclusion by not restricting funding to a "continuing education provider" but include that to any non-profit organization providing accredited continuing education programs. Meaning, that when the manufacturer or applicable GPO provides funding to a continuing education provider or non-profit organization providing accredited CME programs, and such manufacturer does not either select or pay the covered recipient speaker directly, or provide the continuing education provider or non-profit organization providing accredited continuing education with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, that CMS will consider those payments to be excluded from reporting under §403.904(g)(1).

J. Physician Compare Website
3. Proposals for Public Data Disclosure on Physician Compare in 2015 and 2016

We support reporting of quality and value measures in cancer care, and benchmarking those measures by oncologist and practice. However, we are very concerned about the state of the Physician Compare Website and reported inaccuracies related to simple demographic information. Providing more in-depth information derived from the Physician Quality Reporting System (PQRS) on the Physician Compare Website presents several problems. Specifically in oncology, relevant information to consumers is scarce and we are concerned of the context of how this information is presented. We are encouraged that CMS intends to study how consumers contextualize and understand this information before making it available on the website. This is critical with cancer patients, who are already under duress with their

diagnosis. Information can be very positive; however, inaccurate information, or information out of context, can be potentially damaging to patients.

Recommendation: We encourage CMS to thoroughly study and analyze the potential consequences of providing oncology-based information before it is actually posted to the website. Additionally, it is important that group practices have longer than a 30-day period to check the information to be provided. Regarding specialty quality information, we are not opposed to this as long as practices or individual providers do not have to pay for having this information collected or the information itself is proprietary. *Information must be open sourced, at no cost, and available to all.*

N. Value-Based Payment Modifier and Physician Feedback Program

We are very concerned about the aggressive timeline established by CMS in implementing the Value-Based Payment Modifier (VBM). Group practices of 100 or more physicians will be eligible for the VBM in 2015 based on 2013 data. Yet, these practices have no idea on what or how they were measured in 2013. Rather than the VBM be a tool to increase the quality and value of cancer care based on meaningful feedback, practices will have no idea of what they did right or wrong. This holds true in 2016 when groups of 25 providers or more will become eligible for the VBM. Quite simply, this makes no sense.

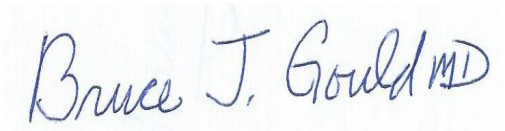
Additionally, the MPFS proposed rule suggests that Medicare costs for only Parts A and B will be included in the VBM total per capita cost measures along with the Medicare Spending Per Beneficiary (MSPB) Measure. With approximately one-third of the oncology drug pipeline dedicated to oral formulations, we believe it is critically important that Medicare Part D costs also be included in the VBM. We note that a recent concept draft released by CMS on oncology payment reform proposes including Part D costs in spending measures. Therefore, it appears that CMS already has a method for aggregating Medicare Parts A, B, and D.

Recommendation: CMS must slow VBM implementation and provide context of the measurements for practices. CMS cannot expect the VBM to be a real tool to enhance quality and value of medical care delivered if providers do not understand what is being measured and how it is being measured. Additionally, Part D costs must be included in the VBM in order to present a complete picture of cancer care spending.

In summary, as I previously related, community oncology is leading the way in implementing true payment reform that is tied to quality and value improvements. Just recently, our practice completed the pilot phase of the UnitedHealthcare program that demonstrated a 34% savings in cancer care delivery. We are involved in several other private payer programs as well as the major oncology pilot being tested by the CMMI.

On behalf of our patients, I implore CMS to create payment equity between the sites of cancer care delivery and to carefully study new sources of information being provided to cancer patients. I stand ready, with the COA Board and staff, in working with CMS to strengthen, not consolidate, the nation's cancer care delivery system.

Sincerely,



Bruce J. Gould, MD
President