COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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

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September 8, 2015

Mr. Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P. O. Box 8013
Baltimore, MD 21244-8013

Re: ***CMS-1631-P**, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and other Revisions to Part B for CY 2016*

Dear Acting Administrator Slavitt:

I am the President of the Community Oncology Alliance (COA), a non-profit organization representing the interests and wellbeing of community oncology practices and, most importantly, the patients they treat. 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-1631-P**, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and other Revisions to Part B for CY 2016* (MPFS). Please allow me to begin with some general comments in relation to the MPFS proposed rule, to be followed by specific comments, referenced by sections.

COA is committed to enhancing the quality of cancer care and to making cancer care more cost-effective and affordable, especially for patients. Over the past four to five 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 payers, oncology providers, patient advocates, and industry representatives have developed and endorsed specific measures of cancer care quality and value, including a patient satisfaction measurement system that includes almost 60,000 completed patient surveys. We have worked with the Commission on Cancer on an OMH accreditation program that was just piloted in 10 community oncology practices, resulting in eight of the practices receiving full accreditation.

In conjunction with COA efforts related to the OMH, 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. Recently, Representatives Cathy McMorris Rodgers (R-WA_ and Steve Israel (D-NY) introduced the Cancer Care Payment Reform act of 2015 (H.R. 1934), which incorporates many OMH concepts and associated payment reform.

On October 27 in the DC area, COA will host a third summit on oncology payment reform, which will feature community oncology providers and payers coming together to discuss what is working and what is not in oncology payment reform. Clearly, community oncology is leading the way with oncology payment reform and COA's actions and accomplishments in this area speak for themselves.

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 and the disparity between identical services delivered by physician-run community oncology practices and hospital outpatient departments. 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 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.

In addition, we are very concerned about proposed Medicare payment cuts to aspects of cancer care, especially those to radiation therapy and certain payment codes deemed "misvalued" by CMS. All of these payment cuts are only putting more unneeded pressure on community oncology clinics. The COA *Community Oncology Practice Impact Report*, the latest version issued in October 2014, has clearly documented the consolidation of cancer care into large hospital systems and the closing of clinics, especially in rural areas. The 2014 report[2] shows that over the previous 8 years 1,447 clinics have been impacted, most notably with *313 treatment facilities closing and 544 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] Studies by Moran, Milliman, and Avalere, among others, have documented the higher cost of cancer care in the hospital setting.

We implore CMS to reconsider any additional payment cuts to cancer care in the physician-office setting, and to equalize payment rates between office and hospital settings. Failure to do this will result in a meaningless Medicare physician fee schedule in oncology because all cancer care will be developed in the more expensive hospital setting.

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

II. Provisions of the Proposed Rule for PFS

C. Potentially Misvalued Services Under the Physician Fee Schedule

Table. 8: Proposed Potentially Misvalued Codes Identified Through High Expenditures by Specialty Screen

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 those excerpted here:

- 36215 Place catheter in artery
- 36569 Insert picc cath
- 38221 Bone Marrow biopsy

[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, October 2014.

[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.

- 88184 Flow Cytometry/first marker
- 88185 Flow Cytometry/each additional marker
- 88189 Flow Cytometry/read
- 88360 Morphometric Analysis/manual
- 88361 Morphometric Analysis/computer-assisted
- 96401 Chemo anti-neopl sq/im
- 96402 Chemo hormone antineopl sq/im
- 96409 Chemo IV Push sngl drug
- 96411 Chemo IV push addl drug

For example, CMS proposes cutting payment rates for flow cytometry by approximately 67% (depending on the number of markers). Additionally, CMS has identified CPT codes 88185 and 88189 as "potentially misvalued" and these codes will be reviewed in 2016 for possible additional payment cuts in 2017. Additional supporting documentation against the revaluing of these and other codes listed above has been articulated in comment letters from both the American Clinical Laboratory Association (ACLA) and The College of American Pathologists. These payment cuts are simply not realistic and will result in flow cytometry and other related pathology services not being financially feasible in the less expensive physician-office setting. It is disconcerting that misvalued codes for consideration are always viewed as overpayments, as opposed to underpayments based on old data, et cetera. We strongly recommend that you take into consideration the commentary from both the ACLA and The College of American Pathologists which detail, in a most thorough and concise manner, the processes that must be followed to produce an accurate and credible laboratory result. Degrading the value of services performed by reducing compensation for same could potentially result in less than optimal laboratory findings leading to both poor decision making and patient outcomes.

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

We especially urge CMS to reconsider any further cuts to flow cytometry and to further reevaluate the logic/rationale for those payment cuts. COA welcomes the opportunity to discuss, in greater detail, our concerns over the direct Professional Expense reimbursement, RVU reductions and rulemaking to implement Sec. 216 of the Protecting Access to Medicare Act.

II. Provisions of the Proposed Rule for PFS

K. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

There appears to be a notable change relating to Section 410.26(b)(5), which, if implemented in rule making by CMS, would have a profound negative effect on the delivery of cancer care by community oncology practices.

To elaborate, CMS is proposing to amend Section 410.26(b)(5) by removing the last sentence, which specifies that a physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the "incident to" service is based. This would lead one to conclude that the physician who prescribed the treatment/professional service **must also be the supervising physician at the time the treatment/professional service is given**. Should this be the actual intention of CMS in omitting

this sentence, there would be very serious negative consequences for both oncology providers and their patients. After-hour emergencies, patient access to timely cancer care, especially in rural areas, and weekend treatments are just some of the situations impacted if indeed CMS is requiring that the treating physician always be the supervising physician. Additionally, a practicing oncologist would never be able to attend CME courses, provide on-call services, or take time off, for fear of being absent during critical cancer treatment times for his/her patients, with the requirement that the treating physician be the supervising physician.

It is ironic that community oncology practices that are transforming themselves into OMHs are expanding patient access to 24/7. If CMS is intending to significantly change the "incident to" rule by requiring that the treating and supervising be the same, this will make 24/7 cancer care infeasible. It would also force cancer care into the more expensive hospital setting, a setting where there is no such requirement simply because it is infeasible.

There have always been questions relating to proper billing of "incident to" services. If the intention of CMS is to clarify that when billing "incident to" providers are being reminded that the individual who actually supervises the "incident to" service must then bill using his or her NPI, without a modifier required, then we suggest CMS make that clarification. If, in fact, the prescriber provider of that supervised treatment must also be in the clinic at the time that treatment occurs, then COA requests reconsideration of the inclusion of this amendment to Section 410.29(b)(5).

A recent inquiry by COA (Mary Kruczynski, COA Director of Policy Analysis) to Regina Walker-Wren at CMS dated August 3, 2015 regarding this proposed change to "incident to" billing resulted in the following response by Ms. Walker-Wren:

> *"Ms. Kruczynski, Thank you for your comment concerning the "incident to" proposal under the FY 2016 Physician Fee Schedule proposed rule. The proposal is intended to clarify that the ordering physician or other practitioner and the supervising physician or other practitioner DO NOT need to be one in the same. Rather, the proposal is intended to clarify that the physician or other practitioner who bills for the "incident to" services must always be the supervising physician or other practitioner." I hope that my response is helpful to you.*
>
> *Regina Walker-Wren*
> *CMS/CM*
> *HAPG/Division of Practitioner Services*
> *(410) 786-9160; Regina.WalkerWren@cms.hhs.gov*

Recommendation: Notwithstanding the expressed intent of CMS, COA requests that CMS clarify that either the proposed change is intended merely as a clarification of the supervising physician's status as the billing physician, or if, in fact, more substantive changes in billing or supervision are intended, such as the treating physician must be the supervising physician. We cannot emphasize enough the serious, negative ramifications for community oncology practices and the patients they treat if CMS is intending to make a major change in the "incident to" rule.

III. Other Provisions of the Proposed Regulation

E.5. Part B Drugs — Payment for Biosimilar Biological Products under Section 1847A

First, we note that biosimilars are not simple chemical copies (generics) of an established brand drug. Rather, they are "similar" to the reference brand biological. As such, the simplicity of the generic market cannot necessarily be translated to the new biosimilar market being developed in the United States. Second, we believe that the development of a healthy biosimilar market will be a positive in cancer care, by encouraging both the introduction of cost-effective biosimilars and the discovery and introduction of new, patented cancer treatments. Key to this will be a controlled

versus over-regulated environment which will allow for the establishment of healthy and effective markets for new branded drugs and biosimilars.

CMS is proposing to "lump" all biosimilars of a reference product into one single billing code. We are concerned about this proposal.

First, we note that biosimilars are a hybrid between distinct originator drugs and generics, although somewhat closer to a distinct product given that they are biologics. Because biologics are new to the United States, we believe that erring on the side of caution in terms of giving these drugs separate J-codes may be warranted in terms of facilitating tracking related to both outcomes and adverse events. We are especially concerned about creating undo confusion and logistics regarding product choice, covered indications, dosing and billing, with multiple biosimilars bearing the same billing code. Additionally, as supported by legislation passed in more than 30 states to date relating to the prescribing of biosimilars, it is critical that the prescriber be notified of any allowable substitution made of one biosimilar for another, or for a biosimilar for the reference product. As importantly, the patient should be notified when a substitution is made. We believe that having separate J-codes would facilitate tracking to compare outcomes, adverse events, etc., especially in those situations where a substitution is made.

Second, we are concerned about creating a healthy market for biosimilars in terms of controlling one of the important cost drivers of cancer care. We note that the generic market, especially relating to generic injectables, has been adversely impacted since full implementation of the Medicare Modernization Act of 2003, which both created Medicare Part D and significantly changed reimbursement for Part B. Since then, we have experienced drug shortages and a general consolidation and shrinkage of the generic market. In fact, the lessening of generics available has resulted in substantial price escalation for many generics. Although we note certain differences in the new biosimilars market as compared to the generics market, especially in terms of the investment required for market entry, we are nonetheless concerned about the "race to the bottom" of pricing experienced in the numerous generic injectable markets we have analyzed. While COA advocates for lower prices through price competition, for the benefit of patients, providers, and Medicare, we are concerned about the development of a healthy, and competitive, biosimilars market.

III. Other Provisions of the Proposed Regulation

H. Physician Compare Website

The primary intent of Physician Compare is to help consumers make informed health care decisions relating to physician selection. In our opinion, Physician Compare is not ready for "primetime" as a meaningful tool for making any type of informed decisions. The information, unlike Hospital Compare, is sparse and we are very concerned that CMS is incorporating quality and cost-related data that will be taken out of context and not relevant to informed decisions regarding provider choice.

Recommendation: We highly recommend that CMS revisit the Physician Compare website as it exists currently and reassess its value to consumers. We also highly recommend that CMS consider the potentially adverse consequences of adding quality and Medicare cost data that is not clearly explained to consumers of health care in the proper context. As it is, we believe that the quality and cost data CMS is incorporating into Physician Compare is especially meaningless, in many cases to community oncologists, due to skewed attribution of quality and cost. What would perhaps be more meaningful to consumers would be number of years in practice, volume of patients, participation in clinical trials, board certification, participating in Medicare, areas of expertise within the subspecialty, and other demographic-type information. We also highly recommend that CMS conduct extensive consumer interviews and focus groups relating to the utility and comprehension of Physician Compare and make summaries of findings available to Medicare providers.

III. Other Provisions of the Proposed Regulation

H. Physician Compare Website

3. Proposed Policies for Public Data Disclosure on Physician Compare

a. Value Modifier

CMS proposes to expand the section on each individual eligible provider and group practice profile page that indicates Medicare quality program participation, noting those who received an upward adjustment for the Value Modifier (VM). In that currently only large physician groups of 100 or more providers are included in the VM, the information furnished in calendar year 2016 would not include those groups of less than 100, even though CMS will open up participation in 2016 to groups of 10 or more providers.

Recommendation: COA recommends that CMS hold off incorporating the VM into Physician Compare until CMS explores the perceptions of consumers and how CMS should contextualize the VM to consumers. We also recommend holding off incorporating the VM until it is available for all practice size groups (after 2017).

We would like to note that we agree with the CMS proposal to waive the VM in 2017 if at least one eligible professional participated in any of the following Centers for Medicare & Medicaid Innovation (CMMI) initiatives: Comprehensive ESRD Care Initiative, Oncology Care Model, or Next Generation ACO Model. COA would like to recommend that CMS consider inclusion of participation in any alternative payment model, public or private, including COA's Oncology Medical Home model.

III. Other Provisions of the Proposed Regulation

H. Physician Compare Website

3. Proposed Policies for Public Data Disclosure on Physician Compare

g. Patient Experience of Care Measures

CMS proposes to report patient experience data for all group practices of two or more eligible providers.

Recommendation: COA recommends that CMS include in its summary patient survey, measures developed as a result of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) guided survey querying Clinical Groups 2 and 3. Those statistics have been CAHPS approved and are included in COA's Oncology Medical Home model and survey tool. That Patient Satisfaction Survey which has almost 60,000 patient responses to date. COA's Patient Satisfaction Survey is a requirement of the OMH model and has been incorporated into the CMMI COME Home pilot and the Commission on Cancer accreditation program. Summary and benchmarking detail is available comparing physicians within a practice, the practice to similar practices on a regional basis, and the practice to national benchmarks.

III. Other Provisions of the Proposed Regulation

N. Physician Self-Referral Updates

CMS inquires if there is a need for new exceptions to the physical self-referral law to support alternative payment models. If so, CMS asks what types of financial relationships should be exempted. We applaud CMS for examining this issue in light of the many new care models both in pilot or demonstration mode, as well as for those early adopters of payment reform.

In order for any new integrated care model to not only survive, but also thrive, it must be able to have readily available any and all patient information that is pertinent to treatment. Further, as we move toward models that must be *at the ready* for patients, primary providers often depend on their

ancillary providers to alert them about medical conditions or factors on an emergency or timely basis. CMS has expressed concerns about fraud and abuse, as well as accountability, transparency, and quality. Considering the high degree of care coordination required in oncology among providers, and relying on experience with the highly integrated OMH model, we believe that any alternative payment model must have the freedom necessary to allow providers to effectively communicate. This translates into, if anything, relieving some of the self-referral restrictions. We note that the restrictions on self-referrals were put in place in a very different era, when the goal was generally to restrict rather than promote care integration and coordination.

Recommendation: Rather than make more complicated rules to prevent such, COA recommends that if an alternative payment model has been recognized and approved, such entity should have license to secure whatever services its patients require from relationships previously established within the existing model of care. We believe that provider-led organizations that use processes meeting certain requirements can be recognized as qualified provider-led entities. Perhaps this same methodology should be applied to alternative payment models.

VI. Regulatory Impact Analysis

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

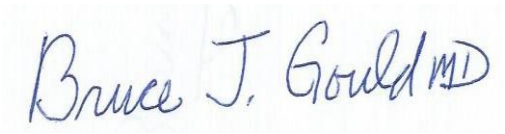
Once again, we express our deep concern and disappointment with CMS' decision based on insufficient and faulty information to further ratchet down reimbursement to community oncology practices providing therapeutic radiation and also to freestanding radiation clinics. If CMS continues to cut payments in this manner there simply will be no radiation facilities outside of the hospital setting. This will both decrease patient access as well as increase costs for both cancer patients and Medicare, as numerous studies have documented.

We commend CMS for increasing payments to pathology and specific testing services, given the inordinately large reimbursement cuts enacted in this area for the current year.

Recommendation: We highly recommend that CMS reconsider the continued cuts to radiation treatment facilities. We ask CMS to reconsider changing the equipment utilization rate from 50% for linear accelerators to 75%. Most practices are at or below the 50% and we remain puzzled by CMS decision to increase the utilization rate without clear, documented evidence.

I am available, as well as the COA team, to discuss any of our concerns and recommendations regarding the comments provided in this letter. We thank you for your consideration of our recommendations.

Sincerely,



Bruce J. Gould, MD
President