COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

1225 New York Avenue, NW, Suite 600
Washington, DC 20005
(202) 729-8147 | communityoncology.org

President
Michael Diaz, MD
Florida

Vice President
Kashyap Patel, MD
South Carolina

Secretary
Miriam J. Atkins, MD, FACP
Georgia

Treasurer
Ricky Newton, CPA
Virginia

Executive Director
Ted Okon
Washington, DC

Directors
Lakshmi Aggarwal, MD
Indiana
Robert Baird, Jr., RN
Ohio
Harry (Mac) Barnes, MD
Alabama
Edward (Randy) Broun, MD
Ohio
Steve D'Amato, R. Ph., BSPharm
Maine
Marsha DeVita, NP, AOCN
New York
Stephen (Fred) Divers, MD
Arkansas
Chancellor Donald, MD
Louisiana
David Eagle, MD
North Carolina
Stuart Genschaw
Michigan
Lucio Gordan, MD
Florida
Bruce Gould, MD
Georgia
Edwin Graham
New York
Robert Green, MD
New York
Anshu Jain, MD
Kentucky
Terrill Jordan
New Jersey
Dinesh Kapur, MD
Connecticut
Edward Licitra, MD
New Jersey
Joseph Lynch, MD
Pennsylvania
Barbara L. McAneny, MD
New Mexico
Mark Nelson, PharmD
Washington
Todd O'Connell
New York
Kathy Oubre, MS
Louisiana
Debra Patt, MD
Texas
Jeff Patton, MD
Tennessee
William (Bud) Pierce, MD
Oregon
Marissa Rivera, MBA
Oregon
Barry Russo
Texas
Jeff Vacirca, MD
New York
Seaborn (Donny) Wade, MD
Virginia

September 27, 2019

Submitted electronically to: http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: *Medicare Program: CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc. (CMS-1715-P)*

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter regarding the CY2020 Medicare Physician Fee Schedule (MPFS) Proposed Rule, *Medicare Program: CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc. (CMS-1715-P)* (Proposed Rule).

COA is a non-profit organization that is dedicated to advocating for the complex care and access needs of cancer patients and the community oncology practices that serve them. COA is the only organization in the US dedicated solely to independent community oncology practices, which serve the vast majority of Americans receiving treatment for cancer. COA's mission is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities. For over 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support cancer patients.

As such, COA appreciates the work of the Centers for Medicare & Medicaid Services (CMS) in developing the Proposed Rule. There are provisions in the Proposed Rule that COA can support, such as **the reversal of CMS' previous decision to collapse Evaluation & Management (E&M) codes to a flat rate for CY2021, as finalized in previous rulemaking, and reducing the administrative burden of physicians participating in CMS' Merit-based Incentive Payment System (MIPS)**. These are important problem areas in our health care system that we are encouraged to see CMS addressing.

However, COA is deeply concerned about several provisions in the Proposed Rule, especially **the limitation of selecting the E&M level based solely on the time spent the day of the patient's visit, the restructuring of the MIPS Value Pathway Framework that treats oncology as a one-size-fits-all disease state, and the increase in weighting of the MIPS "Cost" category.** Furthermore, COA seeks clarification from CMS on several parts of the proposed rule that have the potential to significantly affect community oncologists, including **the impact of E&M billing time limits on Chronic Care Management (CCM) reimbursement and the specific Relative Value Unit (RVU) code adjustments for CY2021.**

COA is focused on providing solutions to the challenges that community oncologists face, including oncology payment reform and the delivery of quality cancer care. In this comment letter, while we strongly object to aspects of the Proposed Rule, *we also advance recommendations and potential solutions.*

It is of utmost importance that CMS understands the pressures that independent community oncology faces and the impact that a variety of misguided public policies, notably including the CMS decision to continue to apply the sequester cut to Medicare Part B (Part B) drugs and the reduced payment for new Part B drugs from WAC plus 6% to WAC plus 3%, have had and will have on community oncology practices. These decisions have caused increasing financial stress to cancer treatment sites, especially those in rural areas, resulting in the closing of locations and consolidation of independent practices into hospitals that limit access to care and raise costs for seniors, Medicare, and taxpayers.

We encourage CMS' leadership and staff to proactively engage with independent community oncology practices by visiting at least one of our member practices to experience first-hand the complexity of providing high-quality cancer care in the context of the overall shifting cancer delivery landscape. It is absolutely impossible to craft reasonable, real-world Medicare policy in the "bubble" of Washington, DC.

Comments on the Proposed Rule

COA will be providing specific comments and recommendations on the following topic areas in the Proposed Rule:

- E&M Payment Changes
- E&M Billing Changes
- RVU Proposals
- Changes to MIPS
    - Reducing Administrative Burden in MIPS
    - Restructuring of MIPS Value Pathway Framework
    - Increase in Weighting of "Cost" Category

E&M Payment Changes

COA is staunchly opposed to any proposals that would jeopardize value-based, patient-centered cancer care. In the CY2019 MPFS Final Rule, CMS finalized a proposed decision to collapse payment for E&M visits and establishing a blended rate for complexity levels 2-4 for both new and established patients in CY2021. Under this decision, physicians providing care to patients who require a thorough and critical evaluation and management of life-threatening complex cases, such as seniors with cancer, would be provided the same level of reimbursement as if they were evaluating a far simpler illness, such as the common cold. In response to this proposal, and later finalized change, COA expressed deep concern that a flat rate would inadequately reimburse physicians' time spent caring for patients with disease states requiring consistent management through level 4 and 5 visits, and thus devalue and disincentivize quality patient care. The implementation of this drastic change to physician reimbursement would not only counteract CMS' interest in rewarding high-value patient care by instead rewarding quantity of care over quality of care, but it also would have the potential to completely devalue the complexity of care offered at community cancer programs across the country.

However, in the CY2020 Proposed Rule, CMS is reversing its previous decision and instead proposing to use the new E&M codes created by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel for CY2021. Rather than the flat rate of payment for E&M code levels 2-4 that CMS finalized in last year's rule, the agency is proposing to adopt the AMA Relative Value Scale Update Committee (RUC)-recommended values for office and outpatient E&M codes for the various levels. These new codes would retain 5 levels of E&M coding for established patient visits, while codes for new patient visits would be reduced to 4 levels. CMS proposes to adopt the new coding and guidance framework as the agency believes it would accomplish greater burden reduction than the policies finalized for CY2021, as well as more broadly aligning with the current practice of medicine. COA appreciates CMS' decision to roll back it's prior proposal to avoid devaluing the complex, specialized medical care provided by community oncologists.

The goal of patient-centered care is better served when physicians are adequately incentivized to spend more time with their patients coordinating care. Moreover, most cancer patients are seen at a level 4 or 5 E&M visit, and many cancer patients also experience multiple co-morbidities in addition to their cancer diagnosis. Paying physicians based on patient complexity accurately reflects the concept of value-based healthcare; this proposal compensates the time and expertise of oncologists seeing complex cases.

Under the Proposed Rule, the E&M code level would be chosen based on time or medical decision-making and would only require performance of history and exam as medically appropriate. COA appreciates the proposal to exclude patient history and/or physical exam in choosing the coding level, as this helps address the administrative burden that sometimes occurs when repeating the history or physical exam components of an office visit. CMS' interest in reducing administrative burdens on providers is one shared by COA. We agree that physicians should be able to prioritize patient care over additional, unnecessary paperwork.

While these changes will ultimately benefit both patients and physicians, COA notes that they will necessitate several adjustments to existing internal policies and procedures at physician offices and seeks assistance from CMS to alert and inform providers of these adjustments. This includes potential changes to patient office visit schedule templates based on the CY2021 CPT changes regarding time and documentation requirements as well as the timing, frequency, and expectation to document non-decision-making criteria for each patient. These changes will require revisions to documentation templates to address the changes to history, physical exam, and decision making. There is also a need to include new tools or resources to existing electronic health record and practice management software to assist with the gathering and recording of start and stop times of assisting specific patients on the day of their service. COA seeks assistance from CMS in informing electronic health record and practice management vendors of these needs.

Recommendation: COA supports CMS' decision to compensate physicians for providing quality care to their patients by stepping down from the previously-finalized decision to collapse E&M payments to a flat rate. We also applaud CMS for engaging with the physician community on this issue and for pursuing a policy resulting from cooperation with the AMA. We recommend that CMS continue to avoid the implementation of policies that incentivize more frequent, shorter patient visits in lieu of comprehensive E&M visits, which would result in avoidable inconvenience for Medicare beneficiaries, higher out-of-pocket costs, and an alarming shift back to paying for volume instead of value.

Changes to Billing Times for E&M Codes

Another change CMS is proposing for E&M codes is troubling to COA. CMS proposes to adopt the finalization by the AMA CPT Editorial Panel for CY2021 E&M codes levels 2 through 5 office/outpatient E&M visits, the level would be decided based upon either the level of medical decision making or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). Notably, this decision strictly limits the window of time to include only the minutes spent on **the same day** for a visit. Under this system, physicians and members of the community oncology multi-disciplinary cancer care team *would not be reimbursed for the time spent the day before and after the patient is seen*. This is counterintuitive to the work done by community oncologists, who often use the evening prior to a patient's appointment to review their history in order to prepare for the patient's visit. It is a detriment to the entire cancer care team if physicians, nurses, and anyone else working with a patient is unable to adequately document and be reimbursed for the time all complex cases require. **COA strongly believes that community oncologists should be reimbursed for the total amount of work they put into preparing to provide high-quality treatment to their patients.**

Furthermore, it is unclear to COA how the total time spent with patients should be documented if CMS does not require this information to be included in claim submissions but Recovery Audit Contractors (RACs) may require it as supporting documentation. **COA seeks further clarification from CMS on whether cumulative time spent on the patient each day should be required in the patient record, and if this time should be documented by a physician or can be documented by another qualified healthcare professional.**

Additionally, in previous years, reimbursement for Chronic Care Management (CCM) was limited to 20 minutes per month and any time spent on an E&M could not be counted towards the CCM code. Thus, miscellaneous prolonged service codes and care management codes may be affected by these proposed changes to E&M billing times, and **COA requests more clarity from CMS in how physicians should be expected to accurately count and bill their time and how prolonged service codes and care management codes may be affected by billing time limits**. With the proposed rule, what would be the split between CCM and E&M, and could time be counted towards CCM on an E&M day?

Recommendation: While COA understands that the decision to limit billing by time for E&M visits was finalized by CPT and not CMS, we urge CMS to engage with AMA to modify this decision so that providers are accurately reimbursed for the total time they provide to their patients per visit. We recommend the expansion of the window for what time may be counted in choosing the level of E&M code billing as to accurately account for community oncologists' time in furnishing the comprehensive, quality care they provide to their patients. This time typically includes time outside of the date of the patient visit.

Adjustments to RVU Codes for 2021

COA recognizes that the process of developing appropriate adjustments to RVUs each year is very complex and takes into account recommendations provided by the AMA/Specialty Society Relative Value Scale Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and others. We also understand that Section 1848(c)(2)(H)(i) of the Social Security Act requires CMS to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services and that, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

As E&M codes are the most highly utilized codes within MPFS, COA seeks more information on the potential impact of the code changes for CY2021. Specifically, we seek to understand the specific inputs and RVUs of the revised E&M codes in order to accurately model the impact of these adjustments for CY2021. Additionally, COA understands that these changes are intended to be budget neutral and seeks information from CMS on the overall net impact of these changes to all specialties. We expect E&M rates to significantly increase overall spending in CY2021 and are concerned as to how budget neutrality will be achieved if the payment for E&Ms increases as proposed while maintaining a high level of utilization.

Recommendation: COA urges the agency to avoid changing the E&M valuations in such a way that modifies PE RVUs for other unrelated codes and compounds potential negative effects of other coding and payment changes. CMS must carve out medical oncology in such a manner that the indirect practice cost index (IPCI) change reflects reality and is not hostage to a methodology flaw. COA considers this last point to be very important. As we have previously mentioned to you in person and documented this with your staff, it is a big problem, and very disconcerting, that as practice costs increase methodological flaws associated with the IPCI are not fixed by CMS.

Reduction of Administrative Burden

COA supports the inclusion of interoperability on the Qualified Clinical Data Registries (QCDRs) to move closer to a single, common QCDR for all stakeholders as this helps reduce physician administrative reporting burden and allows clinicians to provide high-value care for patients. While QCDRs were created to provide additional measures for specialties that lack measures, their use has led to increased administrative burden due to lack of interoperability between these registries. This increased administrative burden is counterintuitive to the agency's focus of Patients Over Paperwork, and COA looks forward to further initiatives that decrease the overall administrative burden. In the CY2019 Proposed Rule, CMS is proposing to align the list of Electronic Clinical Quality Measures (eCQMs) available for CY2020 with measures available to MIPS-eligible providers and offer greater flexibility to the eCQMs reporting period for Medicaid Eligible Professionals. These proposed changes would allow physicians to reduce the time spent on redundant administrative reporting and instead focus their time on providing quality patient care. A continued focus on decreasing administrative burden seeks to aid physicians and other members in working at the top of their licensure to provide the best care for cancer patients in the community oncology setting.

In general, the movement toward value-based care has resulted in increased reporting requirements for physicians that, when not streamlined, can create unnecessary administrative burdens that take time away from patient care. COA has reflected the importance of streamlining quality reporting in its own OCM 2.0 effort, which would simplify implementation and operations for oncology practices participating in the OCM program.

COA is a leader of national efforts to advance meaningful, patient-centered oncology payment reform, including the establishment of a network of over 80% of the participants in the Oncology Care Model who collaborate to share best practices and innovative ideas to further improve cancer care. The unique ability of COA's OCM network allows for the collection of data-driven and anecdotal evidence of small and large methodology changes to this model. This network goes even further beyond the sharing of best practices to better help inform CMMI's OCM team of how changes to MIPS methodology and reporting directly impact one of the only national value-based care incubators of community oncology professionals. COA is actively engaged with the Center for Medicare and Medicaid Innovation (CMMI) OCM team to provide suggestions to address the pitfalls and challenges within the OCM as highlighted by COA's membership. We are dedicated to the success of the OCM, and as such are deeply involved with the development of the OCM 2.0 that is designed to improve upon the successes of the OCM 1.0 while further advancing COA and CMS' shared goal of improving cancer care, including streamlining the model and directly incorporating value-based drug performance into the model. The OCM 2.0 would expand beyond Medicare to create a universal and innovative oncology payment system. We are very engaged with both insurers and employers to pressure-test these new models of oncology payment reform in practice.

Restructuring of MIPS Value Pathway Framework

As mentioned above, COA supports CMS' efforts in reducing administrative burden by identifying and harmonizing quality measures that are meaningful in assessing clinicians' performances. Beginning in the 2021 performance year, CMS is considering restructuring MIPS under a new MIPS Value Pathway (MVP) framework, which would aim to align and connect measures and activities across the Quality, Cost, Promoting Interoperability, and Improvement Activities performance categories of MIPS for different specialties or conditions. A clinician or group would be in the MVP associated with their specialty or with a condition, reporting on the same measures and activities as other clinicians and groups in that MVP. MVPs would utilize measure sets and activities that integrate the existing MIPS requirements and create a more streamlined experience for participating clinicians.

COA recognizes that this new concept of the MIPS Value Pathway (MVP) introduces a potential avenue for connecting and streamlining measures and activities across the MIPS program for different specialties and conditions. **However, we are concerned by CMS' proposal to introduce the MVP for vulnerable cancer patients before the concept has been fully tested.** While the intent of the CMS MVP framework is to connect existing measures across the four MIPS performance categories, as well as provide greater data and information to providers and their patients, there are a few risks to this new framework. The creation of more uniformity in reporting across the performance categories reduces flexibility too much and penalizes clinicians through no fault of their own. Furthermore, **the proposed MVP is too much of a one-size-fits-all approach given different clinical areas**, presents an uneven level of difficulty between measures across clinical disease states, and is problematic in that all measures outside of quality may not be developed enough for robust implementation, specifically cost measures.

Currently, there are 260+ measures and 25 specialty sets in the MIPS program. Implementation of the MVP would require CMS to identify impactful measures for all 25+ specialties and align quality improvement activities. COA understands that CMS is seeking feedback on 1) the criteria used to select measures; 2) whether there should be a choice of measures and activities within the MVP; and 3) the methodology for structuring the MVPs. Given these outstanding questions, **COA urges CMS to convene relevant stakeholders in each specialty set to develop a methodology and criteria for how measures and activities are selected for each MVP.** COA would be more than pleased to participate in the development of a methodology and criteria for measure selection in a potential oncology MVP.

The MIPS Oncology measure set includes over 20 measures that assess care for different cancer types. Cancer is not just one disease; it is a categorization of a large variety of highly complex and very different cancer types. Developing an MVP with meaningful measures for patients and oncologists requires identifying the right measures for each cancer type. Given the complexity of oncology care, **COA urges CMS to seek input from oncology stakeholders such as CancerCare, American Society of Clinical Oncology, National Cancer Center Network, and of course COA before the implementation of oncology-related MVPs.** Secondly, **COA recommends that CMS should not start the implementation of MVPs with oncologists.**

Rather, CMS should pilot MVP implementation with select, less complex, specialties to gain information regarding barriers and facilitation to success.

Increase in Weighting of "Cost Category"

While COA understands that by statute (the Balanced Budget Act of 2018) CMS is required to slowly increase the weight of the cost component from 20% in CY2020 to 30% in CY2022 and decrease the weight of quality score from 40% in CY2020 to 30% in CY2022, we remain very concerned about the methodology of how cost is attributed to individual eligible clinicians based on our extensive experience with the OCM 1.0. Unlike the other MIPS categories, clinicians do not fully understand the complex attribution methodology for the cost measures and struggle with identifying the data to help them monitor their costs.

Given this mandated increase, CMS must provide clinicians with more education on how cost measures might be applicable to them and the attribution methodologies for each measure. This continuous increase in the cost category should ensure that oncologists are not precluded from providing clinically appropriate or innovative care due to a lack of understanding of how cost measures apply to them. **We urge CMS to develop clear educational materials that outline the attribution methodologies in a way that is easily understood by clinicians, given the current confusion over the cost measures. We underscore that accurate cost attribution is a huge problem we have identified with the OCM 1.0.**

COA appreciates the opportunity to comment on the CY2020 Physician Fee Schedule Proposed Rule. We look forward to working with CMS to further patient-centered policies and improve both the quality and cost of oncology care.

We are available to discuss any of our concerns or recommendations regarding the comments provided in this letter and thank you for your consideration.

Sincerely,

Michael Diaz, MD
President

Ted Okon
Executive Director