October 2, 2020

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-1734-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (the “CY 2021 Medicare Physician Fee Schedule Proposed Rule” CMS-1734-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 CY 2021 Medicare Physician Fee Schedule Proposed Rule (Proposed Rule).

As you know, COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. Over the past 17 plus years, COA has built a strong national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

COA appreciates the work of the Centers for Medicare & Medicaid Services (CMS) in developing the Proposed Rule. There are provisions in the package that COA can support, such as the expansion of the Medicare Telehealth List and the creation of a new category of services eligible for telehealth during the Public Health Emergency (PHE). As health care providers continue to adjust their practices to adapt to the challenges to care delivery presented by the COVID-19 (novel coronavirus) pandemic, COA appreciates CMS’ continued efforts to accommodate providers and ensure that they have the tools needed to continue to provide high-quality care in the midst of the PHE.

However, COA is concerned about several provisions in the Proposed Rule, especially the educational and administrative burden that will accompany the implementation of the new
methodology for determining the level of complexity of Evaluation and Management (E&M) visits, and the limiting nature of the requirements for Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient surveys to receive full credit within the Medicare Shared Savings Program (MSSP). Additionally, COA seeks clarification from CMS on the calculation used to estimate the impact of the Proposed Rule on independent community oncology practices. It is unclear how the impact of the changes outlined in the Proposed Rule would reach the magnitude of a 14 percent payment increase estimated by CMS for community oncology practices.

COA is dedicated to 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 express concerns about aspects of the Proposed Rule, we also advance recommendations and potential solutions.

It is of utmost importance that you, your leadership, and staff at CMS understand the impact that the COVID-19 pandemic has had on community oncology practices, and the extraordinary efforts made by these practices during the COVID-19 PHE to adapt and overcome tremendous challenges to ensure that patients with cancer continue to receive the highest-quality, most affordable and accessible cancer care that Medicare seniors and other Americans with cancer require and deserve. COA is dedicated to providing critical cancer care to patients, including high-risk patients who are elderly and/or immunocompromised, all while following state COVID-19 regulations and stay-at-home orders. By rapidly adopting changes to the standard workflow of their practices, such as widespread adoption of telehealth services and team staffing models, community oncology practices have continued to offer continuity of care in spite of the challenges posed by the PHE to hospital-based practices inundated with treating COVID-19.

We encourage CMS leadership and staff to proactively engage with independent community oncology practices to fully understand the complexity of providing high-quality cancer care in the context of the PHE, as well as an overall shifting cancer delivery landscape.

It is vitally important that the Administration and all members of Congress understand just what has happened to cancer care in this country, and what will continue to happen as the COVID-19 pandemic continues to rage and we approach the uncertainties of the flu season. Simply put, cancer does not stop for COVID-19. There is no pause button, or no shelter-in-place option, for cancer. And patients with cancer, who are immunocompromised and typically older, are prime targets for COVID-19. As hospitals have been overrun treating COVID-19, it has been independent community cancer practices – the backbone of the nation’s cancer care delivery system – that have stayed open and continued safely treating patients with cancer. This has required extraordinary lengths to keeping both their facilities and clinical personnel COVID-19 free in order to treat their patients and keep them COVID-19 free. These have been extremely challenging times, and mentally, physically, emotionally, and financially exhausting.

Compounding all the challenges community oncology practices have faced are the uncertainties of the flu season and the impact that decreased cancer screenings will have on the demand for cancer care and on patient outcomes, as many patients will be diagnosed at a later stage of cancer. Limitations on the delivery of medical care due to COVID-19 have resulted in significant reductions in cancer screenings, with the greatest dips occurring in April, including for mammograms (-84%), colon screenings (-74%), lung screenings (-80%), and prostate screenings (-58%), according to an analysis COA is currently conducting with Avalere Health. Reduced cancer screenings due to COVID-19 will have uncertain intermediate and longer-term impacts on patient outcomes, as delays in diagnosis and care delivery could negatively influence disease progression and overall survival. Altogether, the burdens and challenges to the oncology “ecosystem” due to the impact of COVID-19 could likely exacerbate an increase in cancer mortality.

- With COVID-19 still raging – last week, there were close to a third of a million new cases of COVID-19 – and the uncertainties of the flu season, community oncology practices are faced with continually
mounting pressures. Added to these pressures is the ill-advised and unthinkable implementation of the Radiation Oncology Model (commencing January 1, 2021; see COA’s letter submitted to Secretary Azar and you on October 2, 2020 attached) and the threatened implementation of the Most Favored Nation’ Executive Order on Drug Pricing. As the Administration and Congress did with provider relief funds and the expansion of telehealth, everything should be squarely focused on supporting community oncology practices, not to burden them further. It is disconcerting that while the Administration has taken important steps to move towards site-neutral payments, where independent practices and hospitals are paid the same amounts for identical services, it is putting additional and unnecessary pressures on practices. Given that independent oncology practices are less costly than hospitals, why would the Administration pressure practices and jeopardize forcing them into joining hospitals and increasing costs to Medicare and taxpayers?

Comments on the Proposed Rule

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

- Telehealth Changes
- E&M Billing Changes
- Scope of Practice Changes
- Cuts to Radiation Services
- Estimated Impact
- Changes to MSSP
  - CAHPS Survey Credit

Telehealth Changes

In the Proposed Rule, CMS proposes to add eight services (nine HCPCS codes) to the Medicare telehealth list on a Category 1 basis that align with services currently eligible for payment under Medicare when provided via telehealth. Additionally, CMS proposes to add five services (13 HCPCS codes) to the Medicare telehealth list on a Category 3 basis; these services will remain on the list through the calendar year in which the PHE ends. In the March 31st COVID-19 Interim Final Rule (IFR), CMS established separate payment for audio-only telephone evaluation and management services during the PHE. CMS is not proposing to continue to recognize payment under the MPFS after the conclusion of the PHE because, outside of the PHE, CMS would not be able to waive the requirement that telehealth services be furnished using two-way audio/video communication technology. CMS is seeking comment on whether it should develop coding and payment for similar virtual check-in services after the PHE ends.

The COVID-19 pandemic brought significant changes in the opportunities and incentives to use telehealth services. In response to the novel coronavirus outbreak, CMS has implemented a range of new flexibilities concerning the use of telehealth services that allow Medicare and Medicaid beneficiaries to access remote care, regardless of where they live for a significantly expanded set of services, as well as providing parity reimbursement for telehealth services. Widespread adoption by community oncology practices of telehealth occurred rapidly within a three to four-week period in March and early April 2020. According to our current study on the impact of COVID-19 on cancer diagnosis and treatment, 95 percent of the increase of telehealth care has been driven by physician offices, not hospitals, as reflective of COA’s commitment to continue to manage the care of homebound, frail, immunocompromised patients with cancer. There are multiple reasons for the rapid adoption of telehealth. As “stay at home” orders were issued by all but five state governments (AR, IA, NE, ND, SD), many patients experienced challenges in or expressed fear of going to oncology practices. There were significant initial concerns about whether practices could be made safe from the risk of COVID-19 exposure for
high-risk patients, especially the elderly and those receiving active chemotherapy and/or immunotherapy treatments. Oncologists began to understand how telehealth allowed practices to offer continuity of care that was of high quality compared to an in-person visit but was safer, easier, and often the modality preferred by patients during the PHE.

However, as with most rapidly adopted and implemented technologies and care strategies, the use of telehealth has not been without issues. For instance, technology and broadband access have been significant burdens for many patients. Not all patients have access to smart devices, such as smartphones, tablets, or computers, and/or broadband internet services needed to deliver care most effectively or even to meet the reimbursement and coverage requirements of certain commercial payers. This is especially true in rural areas of the United States. Most practices have been obligated to devote considerable technology and human resources to educate patients on telehealth tools, get them signed up and connected, and support them during the initial and follow-up visits. This support has been essential to make telehealth visits a reality for many patients and to determine the best format for each patient based on their technology and internet access availabilities.

The experience of clinicians and community oncology practices during the COVID-19 PHE has been that providing telehealth services is demanding for practices. These visits are both resource and time-consuming. There is a learning curve to the use of telehealth services, though practices are seeing improvement in the value of providing these services over time. Reimbursement parity has made developing and implementing this new value-driven service reasonable. In the future, sustained reimbursement parity for appropriate services will need to continue taking into consideration the investment in technologies and the total resource utilization for such visits.

**Recommendation:** COA appreciates the flexibility that CMS has provided during the COVID-19 PHE as a way to ensure patients with cancer are able to continue to receive care while sheltering at home in order to limit exposure risk. COA fully supports continuing these Category 3 conditions through 2021 and preferably through 2022 and that close scrutiny of the benefits of telehealth be thoroughly explored and adjustments made before returning to the rules in place prior to the COVID-19 PHE.

The COVID-19 crisis has revealed telehealth to be an underutilized method of improving the quality of care by adding convenience and value to the patient experience. Patient satisfaction with telehealth is high. Oncologists are overwhelmingly in favor of maintaining the expanded rules and regulations, enabling them to continue to provide telehealth services when appropriate. As such, COA encourages CMS to develop coding and payment for virtual check-in services after the PHE ends. Additionally, COA would like to highlight that access to technology has been a significant burden for patients, as many patients do not have access to smart devices or broadband internet services, especially in rural areas. As such, COA urges CMS to consider how to best address this access gap, either through continued reimbursement of audio-only services or by supporting other efforts to expand patient access to smart devices and sufficient broadband. Additionally, broadband limitations, which are also being encountered in implementing distance learning at all levels of education during the COVID-19 PHE, need to be addressed as a top priority of Congress on a bipartisan basis.

Attached is the COA position statement on telehealth just recently published. It provides additional information on the extensive work that COA and its Telehealth Task Force and Government Affairs & Policy Committee have done in documenting COA’s position on telehealth in cancer care.

**Changes to Billing Times for E&M Codes**

One change that CMS proposes for E&M codes is concerning to COA in the context of the ongoing PHE. In the CY 2021 Proposed Rule, CMS restates its CY 2020 acceptance of the new E&M code definitions where providers choose the level of visit either by time or medical decision-making (MDM). History and physician exam may still be performed as part of the visit but will no longer be required elements. Previously, the level of E&M was
chosen by a combination of history, physician exam, or MDM. Although time was allowed to be used as a determinate of level in CY 2020, relatively few oncologists or providers use time as a variable when choosing a level. As such, the proposed changes to E&M code determination will necessitate adaptation from providers from current standards of practice.

COA acknowledges that CMS’ decision to implement changes to how the complexity of level 2-5 E&M visits is determined aligns with the description of these services by the American Medical Association (AMA) that will go into effect in 2021. However, we are concerned with the significance of these changes to providers, who are simultaneously continuing to adapt to the additional burden of the COVID-19 pandemic. There is a significant educational lift needed to inform providers and coders of these changes, which would fall on top of the burden of reviewing and adopting new codes proposed by CMS in the Proposed Rule, as well as those finalized in the CY 2020 Final Rule, in addition to the additional burden of the COVID-19 PHE. While an extensive educational effort has been made by COA to prepare oncologists, practice administrators, coders, and ancillary staff for these changes, COA urges CMS to take action to advance provider education and ease the burden of this transition.

COA would also like to request that CMS take further action to recognize and allow use of Modifier 25 (significant, separately identifiable evaluation and management E&M service by the same physician on the same day of the procedure or other service) for injections and infusions on the same day of E&M visits. This has long frustrated oncology practices seeking to provide high-quality and efficient care to patients with cancer that not only respects their time but also reduces multiple clinic visits, especially during the public health emergency, when practices are rightly attempting to discourage unnecessary visits for patient and staff safety.

**Recommendation:** COA understands that the decision to change the methodology to determine the complexity of E&M visits was finalized by the AMA and not CMS, and that this change in methodology will inevitably ensure that providers are appropriately reimbursed for the level of care that they provide to their patients. However, given the additional burden represented by these changes in the context of the ongoing PHE, COA requests that CMS work closely with providers to make this transition easier and smoother, including providing education sessions and materials, an ombudsman to hear concerns and solve issues, and Q&A documents, for providers across the country. We also request expanded recognition and acceptance of Modifier 25 for same-day infusions and injections during E&M visits.

**Scope of Practice Changes**

Another change proposed by CMS in the Proposed Rule would expand the ability for non-physician providers (NPPs), including pharmacists, to provide and receive payment for services provided incident to physicians’ services. CMS clarified in the May 1st COVID-19 IFR that pharmacists are included within regulation of auxiliary personnel as written under § 410.26, which allows for services incident to the billing of a physician or NPP. In the Proposed Rule, CMS seeks comments on whether this clarification that pharmacists fall within the definition of auxiliary personnel under “incident to” regulations and may provide services incident to the billing physician or NPP should be continued once the PHE ends.

Pharmacists are extremely vital members of the care coordination team responsible for managing the continuum of care that cancer patients require, especially with more cancer drugs produced in oral formulations. The cancer drug products handled and distributed by pharmacists are complex agents that require a nuanced understanding of both the broad oncology therapeutic area as well as the specialized needs of individual patients. Pharmacists spend a lot of time working with patients helping find financial assistance due to Part D costs being so great for patients receiving oral therapies. They educate patients on multiple fronts about each medication and follow up regularly with patients dealing with the side effects of these complex agents and assuring they stay compliant with taking the medications. As such, COA strongly recommends that CMS continue to allow pharmacists to
receive payment for providing services incident to billing physicians, as this captures many of the additional services that these critical NPP deliver to their patients on a daily basis.

**Recommendation:** COA appreciates CMS’ efforts to expand the scope of practice for NPP, as this allows patients to benefit from a wider continuum of care and alleviates physician burden. Further, expanding the scope of practice to pharmacists is beneficial for cancer care management, especially in practices with in-office dispensing capabilities or affiliated retail pharmacies, as pharmacists are able to provide additional patient medication management and education. COA also recommends that CMS consider further expanding the scope of the practice of pharmacists beyond ‘incident to’ services, as these NPP are critical members of the cancer care coordination team and should be properly reimbursed as such.

**Cuts to Radiation Therapy Services Payment**

COA has concerns about cuts to professional management services provided to patients with cancer receiving radiation therapy. In the Proposed Rule, CMS puts forth a nearly 10 percent cut to CPT code 77427 for “Physician Treatment Management,” a professional service provided by radiation oncologists to ensure that patients under treatment are monitored carefully. This code is inclusive of all professional services that a patient receives during a week of radiation therapy, and the services provided are an important part of ensuring that cancer patients receive high-quality care and monitoring. It is also important to recognize that this work encompasses all professional services provided to a patient during radiation therapy, including ongoing face-to-face evaluations, as well as all video and telephonic communication, which has certainly increased during the COVID-19 pandemic. The proposed cut of nearly 10 percent is a large driver of the overall six percent proposed cut for radiation therapy services. It is one of the largest sources of professional charge for radiation oncologists, allowing them to provide high-quality patient care. Cuts to this vitally important professional service will serve no purpose other than to increase the financial burden on physicians at a time when administrative and systemic burdens of care are at an all-time high. As such, COA requests that this cut be abandoned, particularly with the scheduled implementation of the Radiation Oncology Model to one-third of the radiation centers in the country.

**Recommendation:** COA requests that CMS abandon the proposal to cut CPT code 77427 for “Physician Treatment Management” as it is critical to patient care and practices’ ability to provide high-quality radiation oncology services to patients.

**Estimated Impact**

As a part of the Proposed Rule, CMS provides an estimated impact of total allowed charges by specialty, including the impact of changes to the Work Relative Value Unit (RVU), Physician Expense (PE) RVU, Malpractice (MP) RVU, and the combined impact of these changes. For CY 2021, CMS calculates that the combined impact of these changes will result in an increase of 14 percent within the hematology/oncology specialties. Additionally, and important to community oncology practices, CMS calculates that the impact of the changes to radiology (including imaging procedures used to detect and monitor cancer) will result in an 11 percent decrease, and the changes to radiation treatment will be a six percent decrease. However, the exact methodology used by CMS to determine these impacts is unclear. Based on our own modeling informed by real-world provider data on code utilization, COA does not anticipate that the proposed changes in the CY 2021 Proposed Rule will reach the magnitude of a 14 percent increase estimated by CMS. For example, COA has noted limited utilization of codes used to capture the Acute Care Management (ACM), Chronic Care Management (CCM), and Transitional Care Management (TCM) services that oncologists provide, resulting in these providers not receiving payment for providing these services due to a lack of education about properly using these codes. As such, COA seeks additional clarity from CMS as to how the impacts on oncology, radiology, and radiation are calculated.
Recommendation: Given the number of changes proposed in the CY 2021 Proposed Rule, COA understands that there will likely be a significant impact on oncology providers as a result. However, given the limited to-date utilization of new codes introduced in 2020/2021, such as ACM, TCM, and CCM, COA seeks further clarity on the assumptions underlying the methodology used by CMS to estimate the combined impact of the proposed changes in the CY 2021 Proposed Rule on oncology providers. Additionally, given the adverse impacts on certain imaging and radiation services provided by community oncology practices, we question the rationale for introducing these changes during a once-in-a-century pandemic. To reiterate, community oncology practices are under enormous pressures, and all the changes and models to be implemented just add to the pressures. CMS truly needs to step back and understand what it is doing during this challenging time.

Proposals for the Medicare Shared Savings Program (MSSP)

CAHPS Patient Survey

CMS proposes to provide full credit for the CAHPS patient experience of care surveys and seeks comments on an alternative scoring methodology under extreme and uncontrollable circumstances. COA appreciates CMS’ proposal to provide full credit for CAHPS patient surveys within MSSP, as this aligns with the electronic patient experience of care survey that has been implemented by community oncology practices. However, CMS’ requirements for CAHPS survey recognition are outdated and inefficient. By requiring these surveys to be completed via mail and up to six follow-up phone calls, CMS is missing a critical opportunity to make delivery of quality care more efficient by digital means, as patient response rates are significantly lowered via mail-in forms. COA urges CMS to consider adapting its requirements to better align with standard practices and enable the greatest success of the program.

Recommendation: COA urges CMS to consider revising its outdated requirements for CAHPS patient surveys as outlined in the Proposed Rule and instead consider innovative and successful patient experience surveys, such as the one currently employed by many community oncology practices. This survey is state-of-the-art and provides almost real-time input to practices on patient experience.

Conclusion

COA appreciates the opportunity to comment on the Proposed Rule. We look forward to working with CMS to further patient-centered policies and improve both the quality and cost of oncology care while continuing to provide the highest-quality, most affordable and accessible cancer care in the midst of challenging times caused by the COVID-19 PHE.

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