April 06, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted Electronically at www.regulations.gov

Re: CMS-4190-P; Medicare and Medicaid Programs; Contract Year 2021 and 2022
Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association of Clinical Oncology (the Association) in response to the Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 (CMS-4190-P) proposed rule, which was published in the Federal Register on February 18, 2020 (85 FR 9002).

The Association is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

The Association recognizes the Centers for Medicare and Medicaid Services (CMS) for streamlining and clarifying certain patient protections and codifying important sub-regulatory guidance in the Code of Federal Regulations in an effort to strengthen Medicare Parts C and D. The Association appreciates the opportunity to comment on the following provisions in the proposed rule:

1. Network Adequacy
2. Out-of-Network Telehealth
3. Opioid Support Efforts
4. A Second “Preferred Specialty” Tier
5. Real Time Beneficiary Tool
6. Pharmacy Performance Measures

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1) The Association encourages CMS to add Oncologists to the list of telehealth providers; however, we are concerned about the proposal to credit a Medicare Advantage (MA) plan 10% toward the percentage of beneficiaries residing within published time and distance standards when the plan contracts with specified specialty telehealth providers. The Association does not support a reduction in network adequacy.

MA plans are required to maintain a network of appropriate providers sufficient to meet the needs of the covered population to ensure that 90% of beneficiaries have access to at least one provider/facility of each specialty type within published maximum time and distance standards.

Under the proposed rule, CMS would codify a practice it refers to as “customization,” which allows plans to expand the time and distance standards if provider shortage makes the base standards impossible to meet. CMS also proposes to modify its network adequacy policy to further account for access needs in counties, including rural counties, and to take into account the impact of telehealth providers in contracted networks. To encourage MA in rural areas, CMS proposes to reduce the percentage from 90% to 85% in micro counties, rural counties and counties with extreme access conditions where there is evidence of lower supply of physicians compared to urban areas.

CMS proposes to give an MA plan a 10 percentage point credit toward the percentage of beneficiaries residing within published time and distance standards for certain provider specialty types when the plan contracts with telehealth providers, ultimately reducing the proportion of the population that must be within time and distance standards to 75%. CMS is accepting comments on the physician specialties to be included: dermatology, psychiatry, neurology, otolaryngology and cardiology.

CMS further proposes that MA organizations would receive a 10 percentage point credit toward the percentage of beneficiaries residing within the time and distance standards for affected provider and facility types in states with certificate of need laws or other state-imposed restrictions that limit providers or facilities in the county or state.

The Association is extremely concerned about these three proposals and the resulting reduction in network adequacy, and we strongly urge CMS not to finalize these proposals as outlined above. CMS states the intent of these proposals is to encourage MA in rural areas; however, these proposals could have the opposite effect and reduce potential access to care in areas where beneficiaries need it most. If CMS finalizes each of these proposals only 65% of beneficiaries must fall within the required time and distance standards.

Cancer patients and survivors are a particularly vulnerable subset of the population. They require timely access to cancer specialists, facilities, and supportive care. It is imperative that federal standards create a regulatory floor that is robust enough to support the medical needs of all beneficiaries independent of their residence. As written, the proposed changes would significantly alter the minimum network adequacy requirements potentially eroding and jeopardizing access to the full continuum of cancer care in a timely and efficient manner. CMS must always consider the
impact these changes could have on patient access to specialists, and carefully monitor network adequacy.

While we support the agency’s efforts to increase the use of telehealth services and agree that these services should not replace face-to-face care, we do not believe that this is justification for reducing network adequacy. The Association supports network adequacy standards that promote access based on specific patient needs, availability of care and providers, and appropriate utilization of services. We believe these proposals have the potential to dissolve cancer patients’ and survivor’s meaningful access to medically necessary cancer care services in a timely fashion.

Our membership includes medical oncology practices in every state and across a wide range of settings, including urban, rural and underserved areas. The Association supports network adequacy standards that promote access based on specific patient needs, availability of care and providers, and appropriate utilization of services. We believe the proposed framework can be strengthened to better assure cancer patients and survivors have meaningful access to medically necessary cancer care services in a timely fashion.

One specific area in need of refinement relates to time and distance for certain provider types and specialties. The CMS approach that predicates network adequacy standards for specialists and facilities on time and distance is susceptible to manipulation. A general time and distance standard ensures that there are providers within a locality but fails to account for several important factors like subspecialty expertise, and more importantly the capacity of network providers to accept new patients. These concerns are important to patients with cancer because the treatment of cancer is often time sensitive, complex, labor intensive and costly. These characteristics result in greater susceptibility of vulnerable patients to discriminatory practices in provider network construction.

CMS previously recognized that cancer patients face challenges in accessing oncology providers in the Federally Facilitated Marketplace for the purchase of qualified health plans. In its 2016 Call Letter for the Federally Facilitated Marketplace, CMS stated that it would apply special scrutiny to the availability of oncology services given the historical challenges in ensuring adequate oncology access.\(^1\) We commend CMS for taking these actions in the context of the exchanges, and we urge CMS to create similar protections in Medicare Advantage by mandating oncology-specific protections given the vulnerability of this patient population.

2) The Association supports CMS’ proposal to allow all MA plan types to allow additional telehealth benefits through non-contracted providers and to treat those benefits as basic benefits.

In 2019, CMS finalized requirements for MA plans offering additional telehealth benefits. The Bipartisan Budget Act of 2018 authorized MA plans to offer additional telehealth benefits beginning with the 2020 plan year, and to treat these additional benefits as basic rather than supplemental. In its implementing regulations, CMS finalized a requirement that MA plans only furnish these benefits

using contracted providers. The regulations provided that benefits furnished by non-contracted providers could only be covered as supplemental benefits. For example, a PPO plan could cover telehealth services provided out-of-network only as a supplemental benefit.

CMS is seeking comment on whether to allow all MA plan types, including PPOs, to offer additional telehealth benefits through non-contracted providers and treat them as basic benefits under MA. We support this proposal as it has the potential to result in greater beneficiary access to telehealth services; however, we encourage CMS to consider how this may affect beneficiary cost-sharing.

The telehealth policy environment is rapidly shifting, and in this proposed rule, CMS has acknowledged the increasingly important role telehealth plays in the healthcare system for Medicare beneficiaries by making it a basic benefit under Medicare Advantage. Telehealth services are a crucial part of medical service delivery, especially for beneficiaries in underserved and rural areas of our country. While the Association supports this effort to increase access to telehealth services by considering telehealth as a basic benefit when supplied by a non-contracted provider, we urge CMS to clarify that cost sharing should not be greater than when provided from an in-network provider in an effort to preserve access for all cancer patients.

3) The Association supports CMS’ efforts to combat the opioid epidemic and we urge CMS to consider the special needs of cancer patients and survivors as they implement drug management program (DMP) requirements.

In 2018, President Trump signed into law the Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. The proposed rule would implement a SUPPORT Act provision requiring Part D plans to establish DMPs to identify and manage beneficiaries at risk for prescription drug misuse or abuse for plan years beginning on or after January 1, 2022. CMS proposes to modify the definition of “potential at-risk beneficiary” to include a Part D eligible individual who is identified as having a history of opioid related overdose. Plans currently have the option of establishing DMPs but are not required to do so.

The proposed rule would also implement the SUPPORT Act’s modified medication therapy management program requirements for Part D plans beginning January 1, 2021. These modified requirements aim to better assist enrollees who are at risk for prescription drug abuse. For plan years 2021 and beyond, Part D sponsors would be required to provide information to certain enrollees about pain treatment, including coverage of non-pharmacological therapies, devices and non-opioid medications.

Once potential at-risk beneficiaries are identified, plan sponsors engage in case management of these beneficiaries through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a sponsor determines through case management that a beneficiary is potentially at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit. Exempted beneficiaries currently include those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care.
Cancer patients represent a special population that should be largely exempt from regulations intended to restrict access or limit doses, in recognition of the unique nature of the disease, its treatment, and potentially life-long sequelae. It is widely acknowledged that too much pain goes untreated, and while not all patients with untreated pain require opioids, these agents remain an essential part of many pain treatment plans, especially among patients with cancer. While we fully support efforts to address the issues surrounding opioid misuse and abuse, we urge CMS not to limit access to treatment of pain for all cancer patients, not just those in active treatment.

While we are encouraged that CMS acknowledges the unique situation cancer patients are in by excluding those in "active cancer treatment" from the definition of a potentially at risk beneficiary, it is important to note that the definition of active cancer treatment may not be clear and some patients may not be under active treatment but have active disease or are at high risk of recurrence; some patients have pain as a consequence of specific, highly effective cancer treatments; palliative care is an evolving set of service delivery models that may be started at the time of diagnosis and there is no standard definition of end-of-life care.

In addition to those in active treatment, cancer survivors often suffer recognized post-cancer or treatment syndromes, and others present with less common, potentially unique, but nevertheless very real post-treatment pain syndromes. More commonly recognized post-cancer pain syndromes may include chemotherapy induced peripheral neuropathy, lymphedema, post-surgical pain syndromes such as phantom limb pain, graft versus host disease after transplant, or post-radiation therapy syndromes. The approximately 12 million cancer survivors in the United States (US) represent a heterogeneous population that may suffer pain related or unrelated to previous cancer diagnoses and may be considered similar to other populations with chronic pain. Opioid therapy may be appropriate for a carefully selected subgroup, as long as benefits clearly outweigh the risks over time and treatment can be monitored.

For additional information, we would refer you to the guidelines on pain management in cancer survivors developed by our affiliate organization, the American Society of Clinical Oncology.²

We support the agency’s efforts to continue to stress the importance of patient education through DMPs and Medication Therapy Management programs, and the Society has published a statement addressing best practices in this effort.³

4) The Association has concerns regarding the establishment of a second preferred specialty tier as currently proposed and asks CMS for additional information regarding the types of drugs that will appear on each tier. We are concerned that the addition of another tier may increase the cost of the drugs that move on to this tier.

CMS allows Part D sponsors to offer plans that are either a defined standard benefit or an alternative benefit design equal in value to the defined standard benefit (actuarially equivalent), and to provide enhanced benefits. Plans with alternative benefit designs often use tiered formularies. The top tier—known as the “specialty tier”—is reserved for the most expensive drugs that are brand name, specialty and not-preferred. Cost-sharing on this tier is typically based on a coinsurance rather than a copayment amount. Part D sponsors are currently permitted to include in their plan design only one specialty tier, which is intended to allow them to manage high-cost drugs separately from tiers with less expensive drugs.

The proposed rule would allow Part D sponsors to establish two specialty tiers, provided that one is a preferred tier offering lower cost sharing than the proposed maximum allowable specialty tier cost sharing. Stakeholders have argued that creating an additional specialty tier could improve Part D sponsors’ ability to negotiate with pharmaceutical manufacturers to help lower the prices of high-cost Part D drugs and could encourage the use of lower-cost biosimilar products and boost competition among existing specialty Part D drugs.

While we share the overall goal of supporting value-based care, certain cost containment approaches used by a growing number of payers threaten to undermine patient access to medically necessary oncology care. In particular, we strongly oppose the trend toward tiered formularies. This approach places specialty drugs in the highest tiers, which carry higher percentages of coinsurance and places vulnerable patients in the cross hairs of a problem they did not create. If their disease requires the use of an effective and high value therapy, they should not be asked to bear the financial burden of the higher price tag associated with this necessary—and sometimes life-saving—treatment.

Before CMS establishes an additional tier, we believe that more details should be made available along with additional periods for public comment and stakeholder feedback. CMS has not currently proposed any requirements around tier composition and in fact the agency requests comments on whether the preferred specialty tier should be limited to certain types of drugs (e.g., biosimilars and generics). While it is possible, if utilized appropriately, that a second, preferred specialty tier could lower costs to Medicare beneficiaries, the converse is true: inappropriate use could drive up costs by incentivizing the placement of additional drugs onto the preferred specialty tier, where co-pays (generally, co-insurance) is higher than on other tiers. Finally, we are concerned that cost sharing on other tiers may increase as plan sponsors are required to maintain actuarial equivalence, which will not help the administration’s efforts to lower out-of-pocket drug costs for all seniors.

We support CMS in its efforts to identify innovative mechanisms to lower drug costs for Medicare beneficiaries but given the concerns detailed above we believe that more information from CMS is necessary to provide input on this proposal. ASCO remains particularly concerned about the impact of any proposal affecting specialty drug costs, and many patients with cancer bear the brunt of the financial burdens associated with specialty drug tiers.

5) The Association supports CMS’ proposal to establish a Real Time Beneficiary Tool (RTBT) to advance the Administration’s goals of improving transparency for consumers and reducing prescription drug costs.
The proposed rule would require Part D sponsors to implement a real time benefit tool that would allow enrollees to view accurate, clinically appropriate, real-time formulary and benefit information, effective January 1, 2022. This proposal aims to support the Administration's goals of improving transparency for consumers and reducing prescription drug costs.

The goal of the proposed tool is to allow prescribers and patients to consider the potential cost differences of medications. The tools would be required to provide real-time values for cost-sharing information and formulary alternatives, where appropriate, and would include the formulary status of clinically appropriate alternatives and utilization management requirements. CMS also proposes to allow plans to offer certain rewards and incentives to enrollees who use the tool.

Transparency is frequently called out as an important component of any reforms to the US health care system. It is seen by policymakers both as a way to drive cost conscious consumer choices and as a necessary tool to decode the largely opaque health care marketplace. A lack of transparency frequently leaves patients and their providers with very little ability to determine the true cost of care, either preemptively or after billing. Prices for health care services and goods vary widely by location, choice of provider, or health insurance plan benefit design.

Cancer patients bear an enormous amount of out-of-pocket expenditures, in the form of cost sharing for drugs or full liability for non-covered drugs. As a result, cancer patients are often at risk of financial toxicity related to the cost of their care. This can have a critical impact on health care decision-making, and overall quality of care. Patients with cancer are more likely than people without a cancer history to modify their behaviors as a result of these hardships and are more likely to report delayed prescription filling, use of less medication, or skipped medication doses. Patients and physicians would benefit from access to real-time information about the cost of treatment at the point of care to avoid the unintended consequences associated with high out-of-pocket costs.

The Association commends CMS for pursuing policies that facilitate the development of and incentivize use of RTB Ts to provide meaningful information on the value of drug therapies at the point of care. Such tools will support the most appropriate therapeutic choices for patients and physicians. To be effective, however, providers must be willing to adopt a solution, which means factoring another technology into their workflow. For this reason, it is important that physicians do not encounter additional burden in implementing such systems. Many practices currently struggle with integration of data into current electronic prescribing and EMR systems and adding additional requirements across various payers will prove burdensome to physicians. Moreover, RTB Ts will need to provide the elements that are important to oncologists and their patients, such as cash price, patient assistance programs, prior authorization requirements and medication alternatives.

6) The Association supports CMS’ proposal to require Part D sponsors to disclose to CMS the measures they use to evaluate pharmacy performance.

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Under the Part D program, plans currently do not have to disclose to CMS the measures they use to evaluate pharmacy performance in their network agreements. The measures used by plans potentially impact pharmacy reimbursements. Therefore, CMS proposes to require Part D sponsors to disclose to CMS the measures they use to evaluate pharmacy performance. CMS seeks to better understand the use of pharmacy performance measures in network pharmacy agreements and to determine financial rewards and penalties incurred at the point of the sale. CMS plans to publish the measures it collects allowing them to report this information publicly to increase transparency on the process and to inform industry in their recent efforts to develop a standard set of pharmacy performance measures.

If this CMS proposal is finalized, the actual reporting requirements, data elements, timelines and method of submission would be proposed through the Office of Management and Budget Paperwork Reduction Act process. CMS seeks comments on the principles that should govern pharmacy performance measures and the data elements, timeline and method of submission for reporting measures.

We applaud CMS for proposing to make pharmacy measures transparent and for reflecting recommendations in the Society’s position statement on pharmacy benefit managers (PBMs) in this proposed rule. We offer the following recommendations and guiding principles as CMS works to establish pharmacy measures. The following paragraphs outline principles to consider when developing pharmacy performance measures as published in the Society’s policy statement.

Measures should address quality of care concerns related to the cancer patients PBMs and payers serve, including assessing whether changes to prescribed therapy for patients with cancer are made only in the context of prior consultation and approval of their physician. Our members have reported that some patients have had their medication or dosage changed by PBMs without prior approval by—or consultation with—the treating physician. As these practices have the potential to erode access and quality of care, we urge CMS to develop measures to assess, and eventually prevent, such practices from occurring.

We also encourage CMS to consider PBM imposed network restrictions as the agency works to develop pharmacy measures and reporting requirements. Timely access to therapies may be harmed by PBM-imposed network restrictions. Some PBMs require that patients use only their proprietary specialty pharmacy for certain drugs, despite the possibility that the patient could access the drug more cheaply and quickly from a different pharmacy. It is not uncommon that PBMs allow the first fill of an oral oncology drug to be carried out at the local or practice pharmacy. Thereafter, all other prescription refills are often required to go through the PBM-associated specialty pharmacy.

We urge CMS to assess whether pharmacies share with patients the most cost-effective option for purchasing needed medications (i.e., gag clauses). CMS should assess and measure contractual requirements that prevent pharmacists from sharing with patients their most cost-effective option for purchasing required medications. CMS recently issued a letter to Part D plan administrators,

reminding them that such clauses are considered "unacceptable," and we now urge CMS to act and establish reporting requirements regarding gag clauses.

CMS should require PBMs to provide detailed accounting of direct and indirect remuneration (DIR) fees and instruct contractors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies. Recently, PBMs have created a separate—and additional—DIR fee structure, known among pharmacists and physicians with in-office dispensing and pharmacies as “claw backs.” This involves retroactive collection of fees by PBMs, the amounts of which are based on physicians’ and pharmacists’ performance according to certain metrics. PBMs justify imposition of these performance-based DIR fees by referencing CMS' Star Rating System. The Star Rating System is used by CMS in Medicare Advantage and Medicare Part D to measure performance on plans covering drug services. The Star Rating System measures relate largely to medication adherence for conditions such as diabetes, hypertension, and cholesterol; and was designed to apply to Part D plan sponsors, not pharmacies. No such measures exist for medication management in oncology. We urge CMS to instead rely on measures and standards that are more appropriate to the specialty.

Given the enormous leverage that PBMs have over the delivery of cancer care, we thank CMS for the provisions in its proposal to improve PBM transparency. We also appreciate CMS for working with us to improve cancer care for all Americans, and we look forward to continuing to work with the agency as the U.S. cancer care delivery system continues to evolve.

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We appreciate the opportunity to comment on the Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 proposed rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology

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