September 20, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1715-P
200 Independence Avenue, SW
Washington, DC 20201

Via electronic submission at www.regulations.gov

Re: Medicare Program; CY 2020 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations [CMS-1715-P]

Dear Administrator Verma:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recent proposed rule for the Medicare Physician Fee Schedule (MPFS) published in the Federal Register on August 14, 2019.

ASCO is the national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members 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, including Medicare beneficiaries.

ASCO recognizes the significant changes CMS is continuing to make to improve payment policies for Medicare services and appreciates CMS’ willingness to engage stakeholders in discussions of proposed changes to both the Physician Fee Schedule and Quality Payment Program policies. However, ASCO has concerns regarding some of the policies proposed by CMS for calendar years (CYs) 2020 and 2021, which we describe in greater detail in the balance of this letter. We offer our perspective and comments on the following areas:
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Specific comments follow below.

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IV. Provisions of the Proposed Rule for the Physician Fee Schedule

A) Coding and Payment for Evaluation and Management (E/M) Visits

In the 2019 PFS Final Rule, CMS finalized changes to the coding and payment structure for E/M services to be effective in CY 2021. In this rule, CMS is proposing to reverse some of the finalized policies and align E/M coding and payment with changes adopted by the CPT Editorial Panel for E/M services (i.e., eliminating code 99201 and revising code definitions). CMS also proposes to accept several payment recommendations made by the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) for the office/outpatient E/M visit codes for CY 2021 and the new add-on CPT code for prolonged service time. The AMA RUC-recommended values would increase payment for office/outpatient E/M visits. In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services. As such, this is a significant proposal impacting all specialties and the fee schedule across the board.
Effective CY 2021 CMS proposes the following changes:

- Adopt the changes to E/M services finalized by the CPT Editorial Panel; CMS notes that the CPT coding changes will also necessitate some changes to CMS’ policies for CY 2021, due to forthcoming changes in code descriptors;
- Establish new values for the codes as revised by CPT;
- Assign separate payment rather than a blended rate as finalized in the CY 2019 PFS Final Rule, to each of the office/outpatient E/M visit codes (except CPT code 99201, which CPT is deleting) and the new prolonged visit add-on CPT code (CPT code 99XXX);
- Delete the HCPCS add-on code CMS finalized last year for CY 2021 for extended visits (GPRO1); and
- Revise, consolidate and revalue the HCPCS add-on codes CMS finalized last year for CY 2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow the new code to be reported with all office/outpatient E/M visit levels (not just levels 2 through 4).

ASCO appreciates CMS’ willingness to consider stakeholders’ input prior to finalizing changes to E/M codes and services. We support the adoption of the AMA CPT Editorial Panel’s new code definitions; the AMA RUC’s recommendations for work RVUs and practice expense inputs; and the Medicare-specific add-on G code. However, ASCO does not recommend that CMS make systematic adjustments to other services to maintain relativity within the system. A thorough review of the coding structure for services should be conducted first before any changes are made.

**ASCO recommends that CMS finalize its proposal to adopt the AMA CPT Editorial Panel new code definitions and RUC recommendations for work RVUs and practice expense inputs. We urge CMS to work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the deserved increases to office visits.**

On a related issues, ASCO has some concerns with the agency’s clarification of their interpretation of reporting CPT prolonged service codes 99358 (prolonged evaluation and management service before and/or after direct patient care; first hour) and 99359 (prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (list separately in addition to code for prolonged service). CMS has indicated that codes 99358-99359 would no longer be reportable in association or “conjunction” with office/outpatient E/M visits. These codes are not commonly used for reporting prolonged evaluation and management service before and/or after direct patient care. Instead, ASCO recommends use of CPT guidance when interpreting CPT codes 99358 and 99359 which states “this service is to be reported in relation to other physician or other qualified health care professional services, including evaluation and management services at any level. This prolonged service may be reported on a different date than the primary service to which it is related.” Disregarding the CPT guidelines will cause a disconnect in appropriate reporting of these services. The new add on code represents a smaller increment (99XXX) of time than the current “Prolonged Service With Direct Patient Contact” (15 minutes vs. 1 hour) and would not be reported in addition to or instead of 99358 and 99359.

**ASCO recommends CMS use CPT guidelines in their interpretation of CPT codes 99358 and 99359 and allow these codes to be billed in conjunction with office/outpatient E/M visits as they were intended.**
B) Care Management Services

In recent years, CMS has updated PFS payment policies to improve payment for care management and care coordination services. CMS estimates that 9 percent of the Medicare fee-for-service (FFS) population receive these services annually, yet they believe that gaps remain in coding and payment for such services. CMS is proposing code set refinements related to transitional care management services (revised billing restrictions) and chronic care management services (addition of new G codes and refinement of the description of a typical care plan). CMS is also proposing separate coding and payment for principal care management (PCM) services through the establishment of two new G-codes. These new codes describe care management services for patients with a single serious chronic condition.

ASCO is encouraged that CMS is interested in expanding support for care management; as we have commented previously, oncologists and their team members frequently provide a significant proportion of care management and coordination services while their patients are under active anti-cancer treatment and palliation. We are pleased that CMS has proposed recognizing a new principal care management code that is appropriate for use with patients with one serious chronic condition, but we are concerned that implementation of the remaining care management codes may cause some confusion for practices attempting to utilize them. First, the AMA and CMS code descriptions are not universally in alignment (for example, CMS’ proposed changes to the transitional care management services almost directly contradict the CPT® language and instructions); second, CMS is essentially creating its own set of codes that are not reportable to private payers. Practices that attempt to report these services in this scenario will be working with two sets of codes which will add to administrative burden and may cause confusion at the practice level.

i. Transitional Care Management (TCM) Services

Utilization of these services has been low compared to the number of Medicare beneficiaries, likely due to the administrative burden of providing the services and the payment amount. There are also many codes that cannot be reported during the 30-day TCM timeframe. For 2020, CMS is proposing to remove the restrictions on 14 codes¹ that are currently disallowed for reporting during the same timeframe as TCM services. These services include Prolonged Services without Direct Patient Contact, Complex Chronic Care Management Services, and Care Plan Oversight Services.

ASCO appreciates CMS’ efforts to provide increased flexibility in code reporting and its recognition of the work associated with providing Transitional Care Management Services by increasing the work RVUs, and we note that removing restrictions on the 14 codes that are able to be reported with TCM services may increase utilization. However, this proposal directly contradicts AMA CPT language currently in the 2019 AMA CPT Professional Edition² and this change therefore will leave

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¹ Table 17 of the proposed rule.
² “A physician or other qualified health care professional who reports codes 99495, 99496 may not report care plan oversight services (99339, 99340, 99374-99380), prolonged services without direct patient contact (99358, 99359), home and outpatient INR monitoring (93792, 93793), medical team conferences (99366-99368), education and training (98960-98962, 99071, 99078), telephone services (98966-98968, 99441-99443), end stage renal disease services (90951-90970), online medical evaluation services (98969, 99444), preparation of special reports (99080), analysis of data (99091), complex chronic care coordination services (99487-99489), medication therapy management services (99605-99607), during the time period covered by the transitional care management services codes.”
providers with two different sets of instructions for the same codes. **ASCO suggests CMS delay the implementation of these changes to provide the CPT Editorial Panel time to review and possibly revise the language for Transitional Care Management service CPT codes.**

**ii. Chronic Care and Complex Chronic Care Management (CCMS) Services**

Like the transitional care management codes, CCM services are underutilized. To increase utilization, CMS is proposing to replace CPT code 99490 (CCM services, at least 20 minutes) with two HCPCS codes (GCCC1 and GCCC2). For complex CCM services, CMS is proposing two new G codes (GCCC3 and GCCC4) that would be used for billing under the PFS instead of CPT codes 99487 and 99489.

While ASCO appreciates CMS’ efforts to increase utilization for CCM and complex CCM services, the introduction of a set of G codes to replace CPT codes will only add to the confusion surrounding the reporting of these services. Since G codes are reportable only to CMS, providers are unable to report them to private payers. This may cause confusion in determining which codes are appropriate to report for each patient and therefore result in a delay in reimbursement. Having both CPT and G-codes for the same service also increases the administrative burden on clinicians who must determine which code to report depending on the payor. **ASCO recommends that CMS delay implementation of the G codes to allow the CPT Editorial Panel time to review and possibly revise the language for CCM and complex CCM services.**

**Finally, to avoid misreporting G code GPC1X, CMS should provide additional detail as to the definition of “visit complexity inherent to evaluation and management.”** For example, is it the work associated with providing care to a patient with multiple comorbidities, a difficult to treat condition, or a patient experiencing severe side effects due to medication/treatment? Further clarification on complexity would help providers identify when it is appropriate to report this code.

**iii. Principal Care Management Services**

CMs identified a gap in addressing services for patients with one chronic condition (the other care management services address multiple conditions). CMS is proposing separate codes and payments for principal care management services (PCM), which describe care management services for one serious chronic condition. There are no restrictions on the specialties that can report the services. It is anticipated that in most cases, PCM services would be reported when a single condition is so complex it cannot be managed in the primary care setting and requires management by a specialized practitioner. The goal is for the patient to be managed effectively so they can be returned to the primary care physician (PCP). PCM services includes coordinated of medical and or psychosocial care related to a single complex condition.

While the proposed G codes could be helpful to capture the work performed for a patient with a single chronic condition, ASCO believes that the codes and code descriptions should be reviewed by the CPT Editorial Panel. This will allow for input from multiple specialty societies in a formalized process. The codes can then be valued by the RUC to determine appropriate work RVUs and resource costs.

**C) Physician Supervision Requirements for Physician Assistant (PA) Services**

In this proposed rule CMS is responding to the evolving and expanding role of the non-physician provider in various healthcare environments. CMS is proposing modified regulations on physician
supervision in order to allow broader practice by PAs. The statutory physician supervision requirement for PA services would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA’s approach to working with physicians in furnishing their services.

This proposed change would substantially align the regulation on physician supervision for PA services with CMS’ current regulations on physician collaboration for NP and CNS services. In general, CMS’ proposal to align these supervision requirements highlights the evolving and valuable roles of mid-level providers; ASCO supports changes to regulations that allow for more flexibility in patients’ care teams while maintaining high quality care for patients with cancer.

D)  Review and Verification of Medical Record Documentation

CMS proposes to establish a general principle to allow the physician, the PA, or the advanced practice registered nurse (APRN) who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. This principle would apply across the spectrum of all Medicare-covered services paid under the PFS. Because this proposal is intended to apply broadly, CMS proposes to amend regulations for teaching physicians, physicians, PAs, and APRNs to add this new flexibility for medical record documentation requirements for professional services furnished by physicians, PAs and APRNs in all settings (teaching and non-teaching settings).

ASCO continues to recognize the work CMS is doing to reduce reporting burden and continuing to implement significant change as a part of the Patients Over Paperwork initiative. ASCO strongly supports this proposal and urges CMS to finalize it. It will decrease unnecessary re-documentation requirements, thus allowing clinicians to spend more time with their patients and less time completing unnecessary and burdensome paperwork. It will also lead to electronic health records (EHRs) being less cluttered with repetitive notes of little additional use, making more meaningful information easier for clinicians to identify. We appreciate CMS’ efforts via this proposal to decrease administrative burden on physicians and practices while posing no harm to patient safety or quality of care.

E)  Solicitation of Comments for Bundled Payments Under the PFS

While historically CMS has made separate payment for each service provided under the PFS, in recent years CMS has developed bundled payment approaches for the PFS and other Medicare payment systems through targeted processes. Many of these models have been implemented under the authority of the CMS Center for Medicare and Medicaid Innovation (Innovation Center). CMS is soliciting comments on opportunities to expand the concept of bundling to improve payment for services under the PFS. While by statute CMS is required to pay for services based on the resources required, they indicate in the proposed rule that they believe there is flexibility within the PFS to expand the definition of “bundled services.”

ASCO supports efforts to improve efficiency of the program in a way that benefits both providers and patients. However, we are concerned about the intent of this solicitation for comments. As stated in the proposed rule, CMS believes that bundling payments for services may achieve better care for patients, better health for communities, and lower costs in the health care system.

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However, we do not believe that CMS has the authority to create bundled payments under the Medicare PFS. The PFS requires payment for each individual service furnished to a beneficiary (Section 1848 of the SSA), based on the relative resources involved in providing the service.

We note that in recent years we have seen multiple services bundled into a single CPT code but believe this is a very different scenario than the one CMS is proposing. CPT codes that describe bundled services (e.g. imaging bundled with an existing procedure/service) go through a rigorous process for both development of code nomenclature as well for the valuation process. And, as an important distinction, services bundled into a single CPT code continue to reimburse physicians based on the relative resources involved in providing the services.

Finally, CMS already possesses authority through an existing mechanism to test new payment methodologies, including varieties of bundling. The Innovation Center was established by Section 1115A of the Social Security Act, in which Congress explicitly enumerated authority for the Secretary of Health and Human Services (HHS) to test “innovative payment and service delivery models to reduce program expenditures...while preserving or enhancing the quality of care.”

ASCO agrees on the need for testing multiple strategies to improve efficiency and value, but broad implementation of significant changes in physician payment should be pursued in the context of strategies that have been tested—and have demonstrated success in achieving efficiency while preserving quality and access. Since Congress hasn’t explicitly granted the authority under the PFS for bundled services, ASCO would request that CMS provide greater detail on their intent for seeking public comment on expanding bundled services under the Medicare PFS.

F) Coinsurance for Colorectal Cancer Screening Tests

The Affordable Care Act eliminated beneficiary responsibility for coinsurance for recommended colorectal cancer screening tests. In these instances, Medicare pays 100 percent of the allowable amount. When colonoscopies and sigmoidoscopies begin as a screening service, but a polyp or other growth is found and removed as part of the procedure (i.e. the procedure is now considered non-screening), the beneficiary then is responsible for the co-insurance. Often beneficiaries are surprised when co-insurance applies when they expected to receive a colorectal screening procedure without a coinsurance obligation. CMS believes that they do not have the authority to exclude the co-insurance in these cases, and they have released educational materials explaining to beneficiaries when co-insurance applies.

In the proposed rule, CMS is soliciting comments on whether they should require physicians to provide beneficiaries with a verbal notice with a notation in the medical record, or whether they should consider a different approach to informing patients of the copay implications, such as a written notice with standard language that they would require the physician, or their staff, to provide to patients prior to a colorectal cancer screening. ASCO recommends that CMS use its existing authority to waive the surprise co-insurance and not put the burden on physicians to communicate CMS’ payment policies to their patients.
V. Updates to the Quality Payment Program (QPP)

A) Increased Weight of the Cost Performance Category

Under the Merit-based Incentive Payment System (MIPS), the performance of eligible clinicians is based on their performance in four categories (Quality, Cost, Improvement Activities and Promoting Interoperability), each with a separate weight that contributes to the total MIPS score. Since MIPS was first implemented in 2017, the weight of the Quality Performance Category has comprised the greatest proportion of the score and Cost the smallest portion of the score (cost was not scored in the first year). By statute the weight of the Cost Performance Category must increase to 30 percent by CY 2022 and the agency has laid out its plan in this rule, with the Cost Performance Category increasing to 20% in 2020, 25% in 2021 and 30% in 2022.

Since the inception of the QPP in 2017, ASCO has shared its concerns with CMS that none of the existing cost measures adequately capture or reflect the cost of care provided by oncologists and their care teams. CMS continues to include the cost of drugs in the general cost measures (the Medicare Spending Per Beneficiary (MSPB) and the Total Per Capita Cost (TPCC)), despite the fact oncologists have no control over the price of drugs, including the launch price of ever-more-expensive innovator drugs and biologics used in cancer care. This methodological flaw is simply one of many inherent flaws to the MSPB and TPCC measures (see section below for more details), and over time the growing weight of the Cost Performance Category will more and more unfairly penalize oncologists under the MIPS program for factors beyond their control.

In addition, the unique characteristics of cancer care make even more apparent the inadequacies of the current cost measurement methodologies for measuring cost performance by oncology-focused providers and practices. Treatment decisions are highly dependent upon a patient’s unique medical characteristics, including their cancer morphology, cancer stage, genetic characteristics, mutation status, comorbidities and patient preferences. Individual physicians often specialize in treating specific types of cancer that may be especially complex or expensive to treat. Protecting the most vulnerable Medicare beneficiaries will require CMS to account for these considerations without threatening the viability of subspecialties that focus on treating certain cancers.

i. High-Quality Value-Based Pathways

Fortunately, there are very promising alternatives to the use of crude cost measures that penalize physicians in specialties that use expensive drugs over whose prices they have no control. One alternative ASCO strongly supports is the utilization of high-quality value-based oncology clinical pathways. As health care payment models continue to advance, private insurers have already embraced the use of oncology clinical pathways that incorporate both evolving scientific evidence and considerations of cost and value. We have encouraged the Medicare program to adopt high-quality value-based pathways as a mechanism to assure the highest quality and most appropriate care for Medicare patients facing a cancer diagnosis.

Clinical pathways are regularly updated treatment protocols that map care based on current scientific evidence. When used appropriately, high-quality pathways can reduce unwarranted variations in care and focus resources on the most appropriate and valuable therapies, while still allowing for justifiable individualized decision-making. Placing adherence to clinical pathways at the center of an oncology-based care model can improve both quality and efficiency of medical oncology services for Medicare beneficiaries, and would align Medicare policy with ongoing
pathway initiatives in use by commercial payers. Value-based pathways align with the goals of CMS to align payment with high quality care.

ASCO has done extensive work examining pathways in oncology and has developed robust criteria for the development and implementation of pathway programs. ASCO has used these criteria to assess several of the major clinical pathway vendors in the U.S. For more information on clinical pathways please visit: https://www.asco.org/practice-guidelines/cancer-care-initiatives/clinical-pathways.

**ASCO urges CMS to explore the integration of value-based pathways as an alternative tool to measure cost under MIPS for clinicians that use expensive drugs over whose price they have no control.**

**ii. Innovative Payment Models Including ASCO’s Patient-Centered Oncology Payment Model (PCOP)**

A second alternative supported by ASCO is the testing of innovative payment models developed by expert stakeholders for use in areas where innovative models are sorely lacking. Medicare coding and payment for outpatient cancer treatment could be transformed by adopting proposals such as ASCO’s “Patient-Centered Oncology Payment Model” (PCOP) and by implementing policies that are consistent with that model. Originally published in 2015, ASCO has recently convened a diverse team of clinicians, payer and employer representatives to update the PCOP model and incorporate learnings from the Oncology Care Model (OCM) and multiple commercial payer models.

The updated PCOP incorporates a community-centric oncology medical home structure that encourages a true multi-payer approach. The use of evidence-based clinical treatment pathways is a cornerstone of the PCOP model, along with measurement and rewards for high-quality, high-value care.

A draft of the updated PCOP model has already been provided to the Innovation Center and will be submitted to the Physician-Focused Payment Model Technical Advisory Committee later this year. We encourage CMS to adopt the PCOP as an additional Advanced Alternative Payment Model (APM) for oncology providers.

**B) Revisions to the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) Measures**

CMS is proposing to revise the total per capita cost (TPCC) and the Medicare Spending Per Beneficiary (MSPB) cost measures used in MIPS. CMS has proposed a revised attribution methodology and conducted field testing for both measures and continues to include the cost of drugs in overall resource use. As noted above, we have consistently objected to the inclusion of drugs costs in these measures, as they unfairly penalize physicians who have no control over the price of drugs set by the manufacturer.

In general, the proposed attribution method for the TPCC measure will likely cause confusion, as it relies on a complex combination of “candidate” events and services linked to the care provided by all individual physicians across multiple TINs. Further confusion will be caused by the timing of episodes: the episode itself consists of a four-week month, after an initial candidate event establishing a primary care relationship, yet the attribution period continues for a full year; it is therefore possible for a clinician to have more than one “episode” existing concurrently for the
same beneficiary. ASCO has two concerns: 1) this could magnify the impact on cost measures of any individual beneficiary and 2) it could complicate understanding any true differences in cost and value.

Earlier in the development of the TPCC measure, ASCO expressed support for attempts to remove certain specialty physicians such as oncologists from the measure, as its intent is to capture overall costs of care and encourage coordination of care by primary care providers. As currently proposed, however, the hematology/oncology and radiation oncology specialties are currently not included on the list of 56 provider types exempted from the TPCC measure. While the methodology does exclude providers when their services can be shown to be linked to chemotherapy and radiation therapy, there is the potential for providers such as physician assistants, nurse practitioners, and other advanced practice professionals who work with oncologists or radiation oncologists to have beneficiaries attributed to them, which would seem to defeat the purpose of the revised measure.

In addition, if the exclusion relies on the provider billing for chemotherapy administration or radiation therapy under the Medicare Physician Fee Schedule, it would fail to consider clinicians who order therapy to be delivered in the hospital outpatient department under the Hospital Outpatient Prospective Payment System. Given the existing scope of the list of 56 specialties proposed for exemption from attribution to the TPCC measure, into which the oncology specialties would seem to fit well, we are confused as to why CMS has proposed a more complex, unreliable method for potentially exempting oncologists from TPCC measure attribution. **ASCO strongly urges CMS to simply add the oncology specialties to the existing proposed list of 56 non-attributed specialties.**

### C) Proposed Revisions to Quality Measures

**Measure 449: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.

CMS proposes the removal of this measure as a quality measure from the MIPS program because the agency believes this to be standard of care clinically and that the performance data do not suggest a meaningful gap (the average performance for this measure is 97.4 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data). Alternatively, if CMS does not finalize removal of this measure, the measure would be maintained with the following substantive change(s) based on the measure steward’s input: update the denominator definition to align with current guidelines.³

*This measure has had substantive changes due to updates in recent guidelines; thus, the existing performance data on this measure is no longer valid. Given that it is not possible to know whether the measure is topped out in these circumstances, ASCO recommends keeping Measure 449 in the MIPS program.*

**Measure 454: Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.

³ Table D68 in proposed rule.
CMS proposed the removal of this as a quality measure from the MIPS program because this may be outside of the eligible clinician's control. The agency believes that the previously finalized measure Q455: Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better) is a related concept that can be a better indicator of compassionate outcomes to the end of life care for oncology patients.

The evidence supports existence of a significant gap and variation in care related to the measure. For patients with cancer at the end of life, the use of unnecessary services such as the ED can negatively impact a patient and family’s quality of life and satisfaction with end of life care. In general, unnecessary ED visits should be avoided for those concerns that can be addressed at the practice or clinic. Studies suggest that cancer treatments and care continue to be more aggressive than desired for patients at the end of life. ED visits in the last 30 days of life are one indicator that supportive care may not be provided effectively to these patients. More than one half of patients experienced hospitalization or an ED visit in the last month of life, which may represent potentially avoidable health care encounters. Care models that emphasize care coordination and symptom management may help reduce the incidence of such visits. **ASCO recommends keeping this Measure 454 in the MIPS program.**

**Measure 456: Percentage of Patients who Died from Cancer Not Admitted to Hospice (lower score – better): Percentage of patients who died from cancer not admitted to hospice.**

CMS proposes the removal of this measure as a quality measure from the MIPS program because the concept would be captured in measure Q457: percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better) and is the more robust measure as it requires at least 3 days of hospice prior to death.

Although the use of hospice and other palliative care services at the end of life has increased, many patients are enrolled in hospice less than 3 weeks before their death, which limits the benefit they may gain from these services. By potentially improving quality of life (QOL), cost of care, and even survival in patients with metastatic cancer, palliative care has increasing relevance for the care of patients with cancer.\(^4\) The rate of patients who do not have a hospice referral prior to death continues to be higher than desired, with one study reporting that more than 30% of patients were not referred and of those patients, only 7% had a documented discussion on the option of palliative care.\(^5\) Patients who were enrolled in hospice experienced increased survival times along with a reduction in resource use such as aggressive end of life care and hospital admissions; benefits that increased the longer patients were enrollment in hospice.\(^6\,7\) In addition, Medicare patients were less likely to enroll in hospice in the last 30 days of life than Medicare patients with only 51% of Medicaid patients enrolled versus 64% of Medicare patients.\(^8\) There remains significant value and


demonstration of quality care in ensuring a low percentage of patients dying from cancer who are not receiving hospice care through this measure. **ASCO recommends keeping Measure 456 in the MIPS program.**

*Measure 144: Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain*

CMS proposes to revert this measure to the 2018 performance period measure specifications. The 2019 measure narrows the patient population to those who report moderate to severe pain and requires the plan of care before or on the data of the second visit with the clinician. The measure steward has submitted this version to NQF for re-endorsement where the measure steward received feedback to further test the updated analytics. **As such, ASCO fully supports reverting to the NQF-endorsed, 2018 performance period measure specification for Measure 144. We further recommend that the measure title be changed to “Oncology: Medical and Radiation - Plan of Care for Pain,” in order to align with the proposed reversion to 2018 specifications.**

*Measure 069: Hematology: Multiple Myeloma: Treatment with Bisphosphonates.*

The two bisphosphonate drugs listed in the specifications are pamidronate and zoledronate. However, patients being treated with the drug denosumab and should not be counted as non-concordant for this measure. Not only is denosumab FDA-approved for this indication, it is also considered an alternative to pamidronate and zoledronic acid in the NCCN and ASCO guidelines. It should be noted that denosumab is not a bisphosphonate; it is a “RANK-ligand” inhibitor with a different mechanism of action compared to bisphosphonates. It works in the setting of patients with renal insufficiency and it is not inferior to the listed bisphosphonates. **ASCO recommends that before inclusion of Measure 069 in the Oncology/Hematology measure set, the measure steward review current guidelines and consider editing the numerator criteria so that a patient receiving pamidronate, zoledronic acid, or denosumab be considered concordant with the measure.**

D) Third Party Intermediaries (QCDRs)

i. **QCDR Approval Criteria – Requirement for QCDRs to Engage in Activities that will Foster Improvement in the Quality of Care**

CMS is proposing policies for QCDRs with regards to “fostering improvement in the quality of care.” Specifically, CMS is proposing that beginning with the 2023 MIPS payment year (CY 2021), QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives. CMS is proposing to require QCDRs to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval and states their intent to include the QCDR’s approved quality improvement services in the qualified posting for each approved QCDR.

**ASCO requests clarification and additional detail for this proposal.** It is not at all clear from CMS’ description what the agency’s expectations for this requirement would be. For example, CMS states that, “[q]uality improvement services may be broad, and do not necessarily have to be specific towards an individual clinical process. An example of a broad quality improvement service would be for the QCDR to provide reports and educating [sic] clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria.” This description is vague enough that we would need additional detail from CMS before we could comment meaningfully on this proposal.
CMS does attempt to give an example of an “individual clinical process specific quality improvement service.” Here, CMS states that, “if the QCDR supports a metric that measures blood pressure management, the QCDR could use that data to identify best practices used by high performers and broadly educate other clinicians and groups on how they can improve the quality of care they provide.” Although this example does provide a little more clarity on the intent of this proposal, we believe more concrete detail around this proposal is very much needed.

**ii. QCDR Approval Criteria – Enhanced Performance Feedback Requirement**

CMS is proposing, beginning with the 2023 MIPS payment year (CY 2021), to require that QCDRs provide performance feedback to their clinicians and groups at least 4 times a year (ASCO is among those specialty QCDRs already providing this level of performance feedback), and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period.

The current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st. CMS notes that clinicians may wait until the end of the performance period to submit data to the third party intermediary, which is then unable to provide meaningful feedback to clinicians 4 times a year. Therefore, CMS is seeking comment for future notice-and-comment rulemaking on whether the agency should require MIPS eligible clinicians, groups, and virtual groups who utilize a QCDR to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st), and is also seeking comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback and the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

ASCO believes that flexibility in the MIPS program can be helpful for clinicians but believes that clinicians should be afforded the option of when they choose to report to the MIPS program. Changing the reporting requirements abruptly could disrupt practice processes and lead to the perception of the MIPS program as even more onerous. Given a choice, some practices may opt to report throughout the performance period, while others may opt to maintain their current reporting processes. **If CMS plans to eventually require reporting during the performance period, ASCO recommends that the agency should a) phase in this requirement over time while maintaining practice choice, and b) work closely with QCDR and registry providers to ensure that the needed capabilities exist and can be implemented smoothly and without imposing yet more unreimbursed cost on QCDRs and registries.**

**iii. QCDR Measure Considerations and Requirements for Approval or Rejection - New QCDR Measure Considerations for Approval - QCDR Measure Availability**

In the CY 2018 Quality Payment Program final rule CMS finalized a policy, beginning with the 2018 performance period, that allowed QCDRs to seek permission from another QCDR to use an existing and approved QCDR measure. If a QCDR wants to report on an existing QCDR measure that is owned by another QCDR, they must have permission from the QCDR that owns the measure before they can use it in the performance period. Proof of permission must be included with self-nomination.
CMS states in the proposed rule that, to the extent that QCDR measure owners limit the availability of their measures, such limitations may adversely affect a QCDR’s ability to benchmark the measure, the robustness of the benchmark, or the comparability of MIPS eligible clinicians’ performance results on the measure. CMS therefore proposes they may consider the extent to which QCDRs make their measures available to MIPS eligible clinicians reporting through other QCDRs for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

While we recognize CMS’ authority in approving QCDR measure and CMS’ interest in ensuring wider availability of individual QCDR measures, we do not support a proposal that may decrease the availability of high quality QCDR measures. A society or other entity that owns or stewards a QCDR measure may have legitimate reasons for not providing that measure for use by another QCDR, such as concerns regarding inappropriate implementation or incorrect understanding of measure specifications, among others. Absent an understanding of all relevant circumstances, CMS through this proposal would essentially block QCDR measures that might otherwise be robust and valuable for use in MIPS simply due to this one criterion. ASCO does not support this proposal. We recommend that CMS revert to the policy finalized in 2018, which allows for collaboration amongst QCDRs without the risk of a measure being lost as could happen with this new proposal.

iv. QCDR Measures Meeting Benchmarking Thresholds

CMS is proposing to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive CY performance periods. CMS’ reasoning for proposing removal of these measures is that clinicians reporting these measures are unable to receive more than 3 points for each un-benchmarked measure, instead of the potential for 10 points with a benchmarked measure.

We agree that CMS has an interest in ensuring that benchmarks can be established wherever possible, but we would also argue that clinicians have an interest in a wider array of reportable measures, especially clinicians in specialized fields that may be lacking a large set of measures. We would urge CMS to work with measure stewards in order to understand the importance of measures identified for potential removal, as measure stewards may be able to provide CMS with data supporting continued inclusion of the measure, even in cases where benchmarks do not yet exist. It is critical that CMS has a full understanding of the value of a measure absent a benchmark.

We also request clarity on the removal of un-benchmarked measures across reporting mechanisms, i.e. would a measure be removed or kept if it fails to meet reporting criteria via one reporting mechanism (e.g. claims) but meets criteria via another (e.g. registry)? Would the measure have to remain un-benchmarked across all reporting mechanisms to be considered for removal?

We also seek clarity on earlier statements from CMS9 that “if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal [from the MIPS program].” Does “no longer able to maintain” refer to a loss of NQF endorsement? Or to a steward’s lack of participation in the CMS Quality Measures Management and Support (QMMS) Measure Owners Meeting and associated activities? Or that the steward went out of business or other business decisions? We would appreciate more detail on this point.

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9 Page 782 of the proposed rule; also see CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137)
Finally, we note some inconsistency within the rule regarding CMS’ criteria for removal of measures and the agency’s plan to “revisit and remove many of our scoring policies such as the 3-point floor, bonus points, and assigning points for measures that cannot be scored against a benchmark through future rulemaking.” If the agency does in fact plan to revisit its policies, it seems confusing to use the criteria from the current scoring methodology to remove measures.

*ASCO urges CMS, prior to finalizing any proposals in this area, to provide further clarity on the issues raised above.*

**v. Linking QCDR Measures to Cost Measures, Improvement Activities, and MIPS Value Pathways (MVP)**

In response to feedback from participating clinicians, a recommendation from the Medicare Payment Advisory Commission and CMS’s own analysis of the data from the initial launch of MIPS, CMS proposes to revamp MIPS with the establishment of the MIPS Value Pathway framework. CMS proposes by 2021 to transition away from the current MIPS structure, which involves reporting on activities and measures from the four performance categories (Quality, Cost, Improvement Activities and Promoting Interoperability). Instead, the Agency proposes an MVP framework with a unified set of measures and activities centered around a specific condition or specialty, along with a set of population health measures.

To prepare QCDR measures for self-nomination, CMS believes there should be consideration of how these QCDR measures relate to similar topics covered through the other performance categories. CMS notes that transformation of the MIPS program to a value-based system requires that MIPS and QCDR measures have an associated cost measure, improvement activity, and eventually a corresponding MVP. This would strengthen the QCDR measure’s relevance in the program. According to CMS, evaluating the strength of these linkages may decrease the frequency of receiving extraneous QCDR measures that are not relevant or meaningful within the framework of the MIPS program.

Therefore, beginning with the 2021 performance period and future years, CMS proposes that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) cost measure; (b) Improvement Activity; or (c) CMS developed MVPs.

As we describe in more detail below, we believe this paradigm shift in Medicare’s Quality Payment Program merits much more extensive discussion by the broad community of stakeholders than this comment period allows. We are therefore deferring our detailed comments to a later date. Given the compressed window for consideration of the rule by stakeholders and the importance of this major change to the MIPS program to all stakeholders, we urge CMS not to implement any changes related to the MVP—including the linking of QCDR measures—until the Agency has received and considered all comments related to the proposal and conducted outreach and meetings prior to the publication of next year’s proposed rule (or alternatively a separate request for information (RFI) soliciting feedback).

**vi. Completion of QCDR Measure Testing**

Beginning with the 2021 performance period and future years, CMS is proposing that, for a QCDR measure to be considered for use in the program, all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, and as used in the testing of MIPS
quality measures prior to the submission of those measures to the Call for Measures.

CMS states its belief that full development and testing with completed testing results at the clinician level helps to demonstrate whether the QCDR measure is ready for implementation at the time of self-nomination, and its intention to include only measures that are valid, reliable, and feasible for use by clinicians and will be consistent with the criteria that is expected of MIPS quality measures.

CMS acknowledges that there are costs associated with testing and that these costs associated with testing vary based on the complexity of the measure and the developing organization, and expresses its understanding that the proposed policy will result in additional costs for QCDRs to develop measures. However, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, CMS is unable to determine the financial impact of this proposal on QCDRs beyond the “likelihood of it being more than trivial.”

**ASCO strongly urges that CMS not implement this proposal.** First, Congress explicitly encouraged the creation of QCDRs with the expectation that these registries would be more nimble and able to respond to the needs of various specialty groups and providers and would serve as testbeds for more robust and creative measures. CMS’ attempts to essentially recreate MIPS measures through the QCDR mechanism is contrary to the intent of Congress and would completely undermine the unique nature and utilization of QCDRs.

Second, CMS’ finding of likely “more than trivial” costs vastly understates the real costs to QCDRs of the additional burden CMS is proposing. Many QCDRs already expend a significant amount of resources to develop and maintain their measures, and the addition of burdensome processes meant to bring QCDR measures in line with the development of MIPS measures may lead some QCDRs to question the continuing viability of their participation in the MIPS program. Ultimately, with proposals such as these, CMS’ aim seems to be a complete lack of differentiation between MIPS and QCDR measures, which negates the original intent behind the creation of QCDRs and restricts the ability of clinicians to report measures that are more meaningful to their practice and pursuit of quality improvement.

### vii. Multi-Year QCDR Measure Approval

Currently, QCDR measure approvals are on a year-to-year basis from September to December once self-nomination occurs. In order to help reduce yearly self-nomination burden and address stakeholder feedback, CMS proposes, beginning with the 2021 performance period, 2-year QCDR measure approvals (at CMS’ discretion) for QCDR measures that attain approval status by meeting established QCDR measure considerations and requirements. CMS also lays out a variety of criteria for revoking the second-year approval of a measure, including if the measure is topped out, duplicative of a more robust measure, or reflects an outdated clinical guideline.

ASCO has commented previously that a multi-year approval for QCDR measures would contribute to the stability of measures and the efficiency of new measure development. **We strongly support this proposal for multi-year approval and urge CMS to finalize the proposal in the final rule.**
viii. Participation Plan for Existing QCDR Measures that have Failed to Reach Benchmarking Thresholds

CMS states that there are instances where measures that experience low reporting rates may still be considered important to a respective specialty. Therefore, beginning with the 2020 performance period, CMS proposes that in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist’s practice, that the QCDR may develop and submit a QCDR measure participation plan for consideration. The QCDR measure participation plan must include the QCDR’s detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program. As examples, a QCDR measure participation plan could include one or more of the following:

- Development of an education and communication plan.
- Update the QCDR measure’s specification with changes to encourage broader participation, which would require review and approval by CMS.
- Require reporting on the measure as a condition of reporting through the QCDR.

Implementation of a participation plan would not guarantee that a QCDR measure would be approved for a future performance period. At the following annual review of QCDR measures, CMS would analyze the measure’s data submissions to determine whether the QCDR measure participation plan was effective (meaning, reporting volume increased, thereby increasing the likelihood of the QCDR measure being benchmarked). If the data do not show an increase in reporting volume, CMS may not approve the QCDR measure for the subsequent year.

ASCO appreciates CMS’ attempt to provide a mechanism for stewards to potentially maintain un-benchmarked measures when necessary. As stated earlier, we understand CMS’ legitimate interest in measures possessing a benchmark for purposes of comparison, but again would urge CMS to leave open a mechanism for the retention of measures that are important to small segments of reporting clinicians, even if those measures fail to reach a benchmark.

E) Promoting Interoperability (PI) Performance Category

i. E-Prescribing Objective Measures (Bonus Measures Related to Opioid Prescribing)

ASCO supports CMS’ proposal to remove the “Verify Opioid Treatment Agreement” measure as a bonus measure in the PI category in 2020 and urges CMS to finalize this proposal. As we stated in our comments on the QPP proposed rule for 2019, this measure—even though optional and eligible for bonus points—is not feasible for providers to perform. As we get closer to true interoperability with nationwide interconnectivity, this measure may become more realistic, but even then—as also stated in our previous comments—it would seem to lend itself more appropriately for use as a measure in the Improvement Activities performance category.

ASCO also strongly supports CMS’ proposal to change the optional, bonus-eligible “Query of PDMP” measure from numerator/denominator reporting to yes/no attestation. ASCO also supports CMS’ proposal to implement this change beginning in performance year 2019 and urges CMS to finalize this proposal. CMS recognizes that workflow needs and lack of EHR integration made this measure overly burdensome to report as a numerator/denominator measure. Further, not only are there technological issues with implementing this measure in a seamless way, but policies governing PMDP data access and sharing may not align with HIPAA rules.
or other policies even if successful integration of PDMP queries with EHR workflow is attained. These conflicts must be resolved before CMS can require providers to report this measure.

**ii. Request for Information on the Provider to Patient Exchange Objective**

Currently, the Promoting Interoperability program for hospitals and MIPS eligible clinicians requires health care providers to share patient health data (including laboratory and pathology data) through an API (application programming interface) within four business days of its availability to the MIPS eligible clinician. In an earlier rule, (“CMS Interoperability and Patient Access proposed rule”), CMS proposed that certain health plans and payers be required to make patient health information available through an open, standards-based API no later than one business day after it is received by the health plan or payer. In this current rule, CMS now seeks comment on whether MIPS eligible clinicians should make patient health information available immediately through an open, standards-based API, no later than one business day after it is available to the MIPS eligible clinicians in their CEHRT. Specifically, CMS seeks comment on the barriers to more immediate access to patient information; whether there are specific data elements that could be shared no later than one business day; and when implementation of such a requirement is feasible.

In general terms, feasibility of information exchange is driven by improvements in technology and interoperability. It relies on the availability of APIs and patient apps that physicians and patients trust to keep patient data safe and secure. These improvements in the health information technology (HIT) infrastructure are led by vendors and HIT developers, so we limit our comments here to the timing of patient access to certain elements of their medical record.

HIPAA regulations give health care providers (including laboratories and pathologists) 30 days to provide patients with access to protected health information (PHI) maintained in a designated record. CMS’ previous and ongoing efforts to enhance patient access to their data has led to decrease in this 30-day window via CMS regulations governing programs such as MIPS and hospital payment programs (e.g. the existing 4-day requirement for availability of data to the patient). ASCO supports patient access to their PHI, but we do have concerns related to providing almost-immediate availability of certain laboratory and pathology test results.

Under either the existing four-day requirement or the potential one-day requirement, patients facing a possible diagnosis of cancer—whether newly identified or a recurrence—may find themselves in a situation where they are able to access their pathology reports prior to review of these reports by their physician and thus prior to a consultation with their physician to aid in their understanding of results in the full context of the patient’s clinical situation. ASCO believes that significant patient (and caregiver/ family) distress could occur if a patient accesses their pathology results prior to physician interpretation and self-interprets their possible diagnosis of a new or recurrent cancer. This is a situation that all would agree is not the purposeful intent of any of the regulations referenced above and thus should lead to these data elements being considered “less feasible” for immediate release than other parts of the medical record. **We urge CMS to create guardrails around the “immediate” availability of laboratory, pathology, and radiology results, factoring in an allowance for physician judgement and discretion regarding the timing of release of certain laboratory, pathology, or radiology results.** We need to ensure that patients are equipped with the necessary contextual information and clinical expertise provided by their physician when reviewing test results that are difficult for non-medical professionals to interpret and can have life-altering consequences.
F) Improvement Activities

CMS proposes a new improvement activity for CY 2020 and future years, “Drug Cost Transparency.” To receive credit for this improvement activity, MIPS eligible clinicians must:

[A]ttest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients’ out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients’ eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary.

**ASCO supports the addition of this high-weighted activity to the menu of existing improvement activities and we urge CMS to finalize this proposal.** Many oncology practices routinely provide this type of financial counseling to their patients and absorb the costs of doing so, with many retaining dedicated, full-time financial counselors on their staff. While the addition of this activity to MIPS does not address the underlying reimbursement challenges faced by these practices for the provision of these services, it at least provides a pathway for providers to be recognized under the program for the services they provide.

G) MIPS Value Pathways (MVPs)

As noted above, in response to feedback from participating clinicians, a recommendation from the Medicare Payment Advisory Commission and CMS’s own analysis of the data from the initial launch of MIPS, CMS proposes to revamp MIPS with the establishment of the MIPS Value Pathway framework. CMS proposes by 2021 to move away from the current MIPS structure with reporting on activities and measures from the four performance categories (Quality, Cost, Improvement Activities and Promoting Interoperability) and transition to the MVP framework with a unified set of measures and activities centered around a specific condition or specialty along with a set of population health measures.

ASCO has previously engaged with CMS on similar concepts. We are eager to work with CMS as this proposal takes shape, as we believe it provides an opportunity to relieve physician and practice burden while still upholding the intent of the QPP. If, however, the many details that require addressing are not widely discussed in the stakeholder community, the move to MVPs could result in a more restrictive, burdensome program than that which currently exists. Given the time constraints with this year’s proposed rule, we believe that we cannot respond with the level of detail and thought required to do justice to this proposal at this time. Therefore, ASCO will follow these comments with more detailed input at a later date.
III. Other Provisions of the Proposed Regulations

A) Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy: Solicitation of Public Comments

Section 5012 of the 21st Century Cures Act (Cures Act, enacted December 13, 2016) created a separate Medicare Part B benefit to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment in the beneficiary's home, effective for January 1, 2021.

Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan for the individual is required to provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician’s office, hospital outpatient department) for the furnishing of infusion therapy. CMS is soliciting comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B.

CMS provides the following examples: a physician may verbally discuss the treatment options with the patient during the visit and annotate the treatment decision in the medical records before establishing the infusion plan. Some physicians may also provide options in writing to the patient in the hospital discharge papers or office visit summaries, as well as retain a written patient attestation that all options were provided and considered. The frequency of discussing these options could vary based on a routine scheduled visit or according to the individual’s clinical needs.

*ASCO supports the examples listed above and encourages CMS to retain the flexibility of allowing multiple mechanisms for providing patient notification, including alternative mechanisms suggested by stakeholders.*

Although not specifically called out in the RFI, ASCO notes that a small number of the drugs proposed for home infusion include certain chemotherapy drugs. We appreciate the availability of home infusion therapy for Medicare beneficiaries, which may work especially well for rural, homebound, or frail patients. We would, however, caution CMS to involve stakeholders with the necessary clinical expertise prior to adding new drugs to the list of those that may be infused at home. It is critical to ensure that the drugs proposed for home infusion are safe for patients to receive at home, including consideration of potential infusion reactions and the needed availability of supportive care drugs. The decision of which infusion drugs to provide to patients at home should always be driven by patient safety and not by cost savings. *ASCO recommends CMS seek input from clinical experts prior to approving drugs for home infusion therapy.*

B) Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm; Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535

*ASCO opposes the Agency’s proposal to revoke or deny provider enrollment for reasons related to patient harm.* While we support efforts to protect the Medicare program and beneficiaries through enforcement action targeting providers/practitioners who do not adhere to program parameters, we believe that the proposal lacks deference to state medical boards and other
oversight entities and is an overreach in CMS’ authority.

The Agency is correct in its assessment that CMS lacks the authority to take administrative action against a Medicare provider based solely on the action of medical licensing boards and other medical oversight entities. Enforcement action, up to and including disenrollment (exclusion) is sometimes warranted for providers who do not comply with Medicare rules, or found to have program integrity issues. However, we do not agree with the Agency’s proposal to revoke or deny a physician’s enrollment if they have been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO), or other governmental oversight bodies as a result of actions by the physician that led to patient harm.

State medical boards, IROs and other oversight entities serve a critical role in protecting the health and safety of patients and routinely review professional conduct, patient care issues, including instances of purported harm. Disciplinary action appropriately reflects rules, regulations and guidelines governing health care professionals and considers various factors related to a professional’s ability to continue providing patient care and any risk of harm associated with continued care. Disciplinary action often offers practitioners an opportunity to remedy issues and circumstances which they have reviewed. If the determination of these entities upholds the right for a provider to practice, absent other factors explicitly within CMS’ authority, practitioners should be allowed to continue participating in the Medicare program if they meet all other program requirements. **ASCO urges CMS to withdraw the proposal regarding revocation or denial of provider enrollment based on conduct leading to patient harm.**

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Thank you for the opportunity to provide comment on the CY 2020 Medicare Physician Fee Schedule and other payment policies related to Part B proposed rule. Please contact Karen Hagerty (karen.hagerty@asco.org) with any questions.

Sincerely,

Howard A. “Skip” Burris III, MD, FACP, FASCO
President, American Society of Clinical Oncology