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Via Electronic Submission

September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1695-P. Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model.

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 Hospital Outpatient Prospective Payment System for calendar year 2019 and the accompanying Requests for Information (RFIs) published in the Federal Register on July 31, 2018.

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 has significant concerns that the policies proposed by CMS for 2019 will undermine patient access to cancer care for Medicare beneficiaries due to proposed reductions in payment based on site-of-service that fail to address systemic deficiencies in Medicare payment for cancer services.

In summary:

- CMS should not finalize its proposals to reduce payment based on site-of-service. ASCO opposes arbitrary and indiscriminate reductions in resources devoted to cancer care that are determined by picking the lowest cost among care settings.

- CMS should not finalize changes that have the effect of diminishing patient access to cancer services in any setting of care.

- ASCO continues to oppose significant reductions in payment for Part B drugs purchased through the 340B program.

- ASCO supports billing and coding changes proposed by the Advisory Committee for CAR-T services.

- Consideration of a competitive acquisition program (CAP) should proceed with caution. CAP should only be tested in the context of a voluntary demonstration program and be designed in collaboration with key stakeholders.

Specific comments are below.

I. Hospital Outpatient Prospective Payment System

CMS should not finalize its proposals to reduce payment based on site-of-service. ASCO opposes arbitrary and indiscriminate reductions in resources devoted to cancer care that are determined by picking the lowest cost among care settings. We urge CMS to enhance patient access to cancer care across all ambulatory settings by avoiding implementation of additional utilization management strategies and facilitating participation in Advanced Alternative Payment Models (APMs) that use value-based clinical pathways to promote high-quality cancer care.

The proposed rule contains several policies that are focused on creating payment parity between the physician office and hospital outpatient sites-of-service. As detailed in our "Policy Statement on Site-Neutral Payments in Oncology" there are several deficiencies in Medicare's current payment for cancer services that render the proposed site-neutral payment policies counterproductive with respect to protecting patient access to medically necessary oncology care.

Medicare's current payment system for cancer services is outdated and is overly reliant on face-to-face drug administration and evaluation and management visits to support the financial viability of both independent and hospital-based oncology practices. The current fee-for-service reimbursement system does not provide separate payment for medically necessary services to manage and coordinate care or support ancillary services needed to optimize outcomes.

Before CMS implements additional policies that would impose across-the-board reductions in payments for cancer services, the Agency should implement additional Advanced Alternative Payment Models (Advanced APMs) that focus on promoting high-quality and high-value oncology care across all ambulatory settings. Arbitrary and overly-simplistic cuts based on finding and applying the lowest payment rate across all ambulatory settings undermine access in predictable and unpredictable ways and remove resources from cancer care without any consideration of the value or sufficiency of current payment levels. The flaws of this approach may manifest themselves in the form of inferior care and higher costs due to unexpected emergency department visits and hospitalizations of cancer patients.

CMS also seeks comments on whether the Agency should use prior authorization to control increases in utilization of hospital outpatient department services. Traditional utilization management approaches, such as prior authorization, create patient access barriers and treatment delays that lead to suboptimal cancer treatment outcomes. Although ASCO appreciates the Agency's overall goals to improve quality and value while decreasing the cost of care, imposing burdensome prior authorization requirements on oncologists will not serve the Medicare program's best interest. In cancer care, CMS can promote the appropriate use of health care resources by implementing Advanced APMs that measure adherence to high-value clinical pathways as a mechanism to promote appropriate access to the right drug at the right time for cancer patients.

Additional oncology-focused Advanced APMs are needed to strengthen patient access across all ambulatory settings of care and support the full scope of oncology services that are required to deliver high-value cancer care—but that currently are unreimbursed and under-reimbursed by Medicare. We urge CMS to implement ASCO's Patient Centered Oncology Payment (PCOP) Model as an Advanced APM. PCOP improves the quality and value of cancer care by providing enhanced resources that are dependent on achieving adherence to clinical pathways and other quality measures.

ASCO opposes the proposal to apply the physician fee schedule equivalent payment rate for all evaluation and management (E&M) visits provided in off-campus hospital outpatient departments because it would reduce the resources devoted to cancer care without addressing the underlying deficiencies in payment for cancer care.

CMS proposes to use its authority under section 1833(t)(2)(F) of the Social Security Act to apply site-neutral payments for E&M visits to all off-campus hospital outpatient department visits. If finalized, all E&M services (described by HCPCS code G0463) provided in excepted and non-excepted off-campus hospital outpatient departments would be paid at 40 percent of the OPPS payment rate. If finalized, the proposal would significantly diminish the aggregate resources Medicare provides at off-campus hospital outpatient departments without any improvement in the quality or value of cancer care.

The proposal would apply reduced payment levels to excepted off-campus provider-based hospital outpatient departments that were operational before the enactment of the Bipartisan Budget Act of 2015. These departments continue to be paid at 100 percent of the OPPS rate for

their services. Because they are not subject to the site-neutral requirements of section 603, excepted off-campus hospital outpatient departments operate on a different set of economic assumptions than non-excepted departments. Applying an immediate 60 percent cut for the highest volume service in the OPPS is reckless and will impose significant financial strain on these departments as they would struggle to continue to provide the same level of patient access to cancer services or would reduce the services provided.

CMS should not finalize changes that have the effect of diminishing patient access to cancer services in any setting of care.

The Agency proposes prohibiting excepted off-campus provider-based outpatient departments from receiving full OPPS payment for new clinical service lines provided in an excepted department. Under the proposal, CMS will analyze claims data from November 1, 2014 through November 1, 2015 to determine if the excepted department currently provides services in new clinical families that were not provided in the year before the Bipartisan Budget Act of 2015 was enacted. As a practical matter, this means an excepted outpatient department would be precluded from receiving 100% of the OPPS payment for cancer care services if it was not providing cancer care services before Congress passed the Bipartisan Budget Act of 2015.

As the Agency states in the preamble to the proposed rule, much of the rationale informing this proposal is based on a concern that hospitals will continue to purchase independent physician practices and integrate their operations into excepted off-campus provider-based outpatient departments. However, a large portion of the financial incentive to acquire independent oncology practices was removed through significant cuts to the payment rate for Part B drugs purchased through the 340B program. If implemented, this proposal could continue to diminish resources that would be otherwise devoted to cancer care and impede patient access in settings of care that may be the most appropriate for their needs, goals and preferences.

ASCO continues to oppose changes to the payment rate for separately payable Part B drugs acquired by hospital outpatient departments through the 340B program. Additional reforms to the 340B Drug Pricing Program are needed to ensure the program meets its original intent to support high-quality care for the uninsured, underinsured, and low-income patients.

The 340B Drug Pricing Program has a significant effect on the delivery of oncology services in the United States, especially given the critical role of drug therapies in the treatment of cancer. In 2014, ASCO prepared a detailed policy statement to provide guidance to policymakers on how to modify the 340B Drug Pricing Program to protect the interests of cancer patients and these recommendations remain relevant today.

ASCO opposed the reduction in 340B payment to ASP minus 22.5 percent for hospital outpatient departments in its response to the 2018 OPPS proposed rule. We continue to oppose these reductions and any additional reductions in 340B payment levels. Instead of expanding potentially destabilizing reductions in payment, CMS should collaborate with the Health Resources and Services Administration (HRSA) to address widely recognized concerns

with the program's growth, administration, and oversight in a manner that is consistent with ASCO's prior recommendations.

ASCO supports reforms to the 340B Drug Pricing Program to ensure it carries out its original intent of expanding patient access and ensuring high-quality care for underserved and vulnerable individuals. We recently provided comment on potential reforms to the 340B program in response to the *Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* and advocated for changes in the eligibility criteria for hospitals and for reforms that permit access to 340B pricing for standalone community oncology practices that care for low-income communities.

CMS should not finalize the proposed reduction in the add-on rate for separately payable drugs subject to payment through the Wholesale Acquisition Cost (WAC) methodology. Instead, CMS should focus on pursuing comprehensive solutions that drive adoption and access to models that facilitate value-based oncology care.

ASCO shares the Administration's concerns regarding the rising cost of prescription drugs, but we urge the Agency to forgo finalizing the proposal to reduce the add-on percentage for separately payable drugs paid according to WAC methodology from 6 to 3 percent. The reduction in payment will not meaningfully reduce drug costs since most drugs are paid through the WAC-based methodology on a temporary basis, while initial average sales price data is generated. The adverse impact of the proposed reduction is further exacerbated by the application of sequestration.

Instead of focusing its efforts on additional incremental cuts that are unlikely to produce significant savings, Medicare should pursue a comprehensive solution that addresses shortcomings in the current medical oncology reimbursement system and drives value-based cancer care.

ASCO supports the Advisory Committee on Hospital Outpatient Payment's recommendation to reassign the status indicator for new Category III Chimeric Antigen Receptor T-Cell (CAR-T) CPT "B" to "S" and to assign the codes to the Blood Product Exchange and Related Services APCs.

Chimeric Antigen Receptor T-Cell (CAR-T) Therapy is an exciting new development in cancer treatment. The FDA's approval of the first two CAR-T therapies in 2017 was a meaningful breakthrough and achievement in the field of immunotherapy. Given the promise of CAR-T and other cellular therapies under development, it is essential that CMS engages in policymaking that will ensure appropriate levels of patient access and prevent unintended consequences. ASCO urges the Agency to create policy that is consistent with the needs of Medicare beneficiaries with cancer and to preserve coverage for new therapies consistent with current statutory and regulatory safeguards.

ASCO supports the Advisory Committee on Hospital Outpatient Payment's recommendation to reassign four CAR-T Level III CPT[1] codes to separately payable status indicator "S" and to assign the codes to the Blood Product Exchange and Related Services APCs. These changes support the collection, preparation, and administration of CAR-T therapies and promote patient access by creating an environment that allows hospitals to receive fair and adequate reimbursement for the CAR-T services they provide on an outpatient basis.

II. Request for Information on Leveraging Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Demonstration

ASCO shares the Agency's concern regarding the rising cost of drug prices, and we are eager to work with CMS on solutions that promote patient access to oncology care and that are economically viable for oncology practices. There are a significant number of independent oncology practices that would be interested in participating in a Competitive Acquisition Program (CAP) Demonstration Model—but only if participation is fully voluntary, is designed to avoid reductions in the resources devoted to cancer care, assures timely patient access to oncology treatments, promotes efficiency, and prohibits the use of draconian utilization management policies. We urge CMS to be cautious in its development and implementation of any CAP Demonstration Model and to restrict its initial scope to the Medicare fee-for-service program.

ASCO anticipates that there are also members of the oncology community will oppose re-introducing a CAP model in any form because of concerns that it would not remain entirely voluntary or would be paired with changes that undermine access to care or otherwise complicate the delivery of cancer care. The flaws from the initial implementation of the CAP program from a decade ago must be avoided to increase the likelihood for CMS to achieve any measure of success if a CAP Demonstration Model is implemented. The Agency extensively discusses the Medicare Payment Advisory Commission's (MedPAC) Drug Value Program (DVP) proposal in the RFI; however, there are several elements that make the DVP unsuitable for implementation as a CAP Demonstration Model as applied to cancer care. The DVP would enable vendors to use utilization management strategies, including formulary placement, prior authorization and step-therapy as negotiating tools between vendors and manufacturers. These strategies will significantly limit patient access to medically necessary cancer therapies. ASCO opposes implementation of the DVP and encourages the Agency to explore other designs for a CAP Demonstration Model that are consistent with our recommendations below.

Provider participation in any CAP Demonstration Model must remain entirely voluntary, and CMS should not coerce participation in a CAP Demonstration Model Program by making the traditional buy-and-bill program less effective or less desirable for oncology practices.

[1] CPT codes: 05X1T (CAR-T therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day), 05X2T (CAR-T therapy; preparation of blood-derived lymphocytes for transportation (e.g., cryopreservation, storage), 05X3T (CAR-T therapy; receipt and preparation of CAR-T cells for administration) & 05X4T (CAR-T therapy; CAR-T cell administration, autologous).

CMS should not, under any circumstance, require any physician practice or other entity to participate in a CAP Demonstration Model. Voluntary participation means that an independent oncology practice retains its own discretion to choose whether participation in a CAP Demonstration Model is appropriate for their practice. Shifting from participation in traditional buy-and-bill for the acquisition of Part B drugs to a CAP Demonstration Model is a significant undertaking for an oncology practice that requires operational investments, including administrative staff and other resources needed to track and manage patient care. Voluntary participation also means a practice must retain its autonomy to choose the appropriate scope of their participation in any CAP Demonstration Model. This includes having a choice in whether to acquire some or all of the drugs used in their practice through a CAP Model or the buy-and-bill system. This flexibility is necessary, in part because switching to a CAP arrangement may implicate existing contractual relationships already in place between the physician practice and other third parties. The decision to participate in CAP is a complex one and should reside solely with the practice.

Additionally, there is fear among members of the cancer community that policymakers may coerce participation in the CAP Demonstration Model by taking actions to make buy-and-bill less effective or less desirable for oncology practices. As CMS considers implementing a CAP Demonstration Model, there must be assurances that policymakers will create a CAP Demonstration Model that is more desirable for patients, providers, and the Medicare program solely on the basis of its own merits.

A CAP Demonstration Model must avoid any aggregate reduction in payment to independent oncology practices. A practice management fee is necessary to provide fair and adequate payment to reimburse practices for the costs incurred in handling, preparing and storing hazardous drugs and to replace the drug margin in place under the buy-and-bill program.

Policymakers should avoid embedding payment cuts to medical oncologists within a broader CAP policy initiative. The average sales price formula serves as the dominant basis for the Medicare Part B buy-and-bill system in place today. Under section 1847A of the Social Security Act, oncologists are reimbursed at ASP plus six percent for separately paid Part B drugs. Although the statutory add-on rate is 6% the application of budget sequestration brings actual payment to ASP plus 4.3%. Medicare payments for chemotherapy are further eroded because the calculation of ASP includes prompt pay discounts negotiated between the manufacturer and the distributor – discounts that are not passed on to the oncology practice. By some estimates, this reduces the effective value of the ASP add-on by one-third for some community-based practices.

Despite these downward pressures, the ASP add-on helps cover a portion of the expenses associated with administering chemotherapy treatments that are not otherwise reimbursed by Medicare, including the expenses associated with the procurement, special handling and storage of cancer drugs. The CAP Demonstration Model must include a fair and adequate payment that replaces the drug margin for oncology practices. This margin is likely to disappear under a CAP program, and independent practices cannot absorb the entirety of costs for the management and handling of cancer drugs.

The CAP management fee should vary based on the class of drug administered to recognize that some drugs – such as the hazardous drugs used in chemotherapy treatment – have more resource intensive handling, storage and preparation requirements than others. The Administration should work with providers to determine the appropriate amount of a fixed fee to compensate practices for the costs of managing and administering chemotherapy drugs to their patients.

The CAP management fee must also be distinct and independent from management fees provided in other oncology payment reform programs. For example, both the Oncology Care Model (OCM) and ASCO's Patient Centered Oncology Payment Model (PCOP) use management fees as a mechanism to support high-value care coordination and patient management activities to reduce overall expenditures by avoiding unplanned emergency department visits and inpatient hospitalizations. Unlike the expenses associated with procurement, special handling and storage of drugs used in cancer treatment which are supported by the current buy-and-bill add-on payment, the services supported by the OCM and PCOP management fees are not currently reimbursed by Medicare. Failing to provide additional adequate resources to practices to support CAP Model participation would undermine incentives for practices to participate in any proposed demonstration and would stifle the Agency's overall goal of improving value and reducing costs.

A CAP Demonstration Model must protect patient access by avoiding interruptions in care when co-payment issues arise and allowing for common adjustments in prescribed drug regimens that occur on the same date of service as drug administration.

A CAP Demonstration Model must serve the best needs of patients and contain a mechanism for collecting Medicare beneficiary cost-sharing that does not place financial risk on practices The previous CAP program placed the responsibility for collecting Medicare cost-sharing on the CAP vendor and we observed that the CAP vendor was quick to interrupt or discontinue the coverage of oncology drugs for Medicare beneficiaries when problems arose with the collecting these payments. We do not support replicating this model. ASCO members support robust patient access to cancer care and many practices regularly work with patients to identify resources to support the financial challenges that accompany a cancer diagnosis. Despite these efforts, practices cannot absorb additional administrative burdens and the responsibility for collecting and processing co-payments should lie solely with CMS in any demonstration. When an issue with the collection of a co-payment arises, CMS must ensure that adequate safeguards are in place to protect patient access while records are checked, and options are addressed identified for securing payment from the beneficiary or on behalf of the beneficiary. Disruptions in care are not an acceptable outcome.

Any CAP Demonstration Model must also support streamlined and efficient patient care. In the previous CAP program, many oncologists experienced delays or were unable to administer treatments on the scheduled date of service because they were unable to make same-day changes to a patient's drug treatment regimen based on changed clinical circumstances. A CAP Demonstration Model must promote patient access to care by allowing physicians to easily substitute and make common changes in drug dosage or treatments on the scheduled date of

service. Oftentimes these changes in treatment are medically necessary and based on an oncologist's review of new clinical information.

The CAP Demonstration should restrict vendors from engaging in draconian or burdensome utilization management requirements.

There is concern that policymakers will either permit or require burdensome utilization management processes as part of a new CAP Demonstration Model. Medicare has a long and well-established history of providing robust patient access to cancer therapies without delay, which include statutory and regulatory protections.

There must be protections in place to ensure that oncologists and any potential CAP vendors share the primary goal of delivering high-quality care that is most appropriate for the patient. Many utilization management strategies flow from the assumption that there are clinically equivalent oncology drugs within each general category or class. However, in many cases, an equally effective and less expensive drug does not exist and the clinical reality is that there is often only one drug that is appropriate to treat a patient's condition.

ASCO is strongly opposed to the use of any step-therapy policies that require a cancer patient to try and fail on a therapy before they are able to access the preferred clinical therapy without delay. Step-therapy policies are often based primarily on considerations of drug cost rather than the best interest of patients, clinical evidence, or aggregate costs. Any CAP demonstration program must prohibit—and certainly not require—the use of step-therapy policies or other draconian utilization management techniques for oncology. Instead of step-therapy, restrictive formularies or other draconian utilization management approaches, CMS could consider the use of evidence-based, high-value clinical pathways in a CAP demonstration program.

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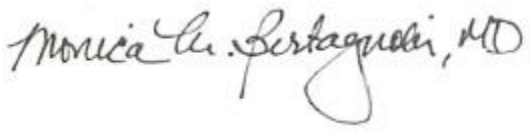
Thank you for the opportunity to provide comment on the CY2019 Hospital Outpatient Prospective Payment System proposed rule. Please contact Sybil Green at Sybil.Green@asco.org with any questions.

Sincerely,



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