## CANCER LEADERSHIP COUNCIL

# A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

September 27, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1717-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective

Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting

**Programs** 

Dear Administrator Verma:

The undersigned organizations representing cancer patients, health care professionals, and researchers appreciate the opportunity on the hospital outpatient prospective payment system proposed rule for calendar year 2020. In our comments below, we offer advice regarding provisions of the rule that may affect cancer patient access to quality health care.

### **Hospital Price Disclosure**

We commend the Centers for Medicare & Medicaid Services (CMS) for the steps it has taken to strengthen the disclosure of health care cost information by hospitals. In the proposed rule, CMS would require release of negotiated price information in addition to chargemaster rates and would also release of the rates for a list of 300 "shoppable" services, including services specified by CMS and others identified by the hospital.

As we have consistently maintained in connection with health care cost transparency, we support efforts to enhance the amount and quality of information about health care costs but question the usefulness to patients of much of this information. All of the signatory organizations are engaged in efforts to assist patients in making informed decisions about their care, managing their treatment and side-effects of cancer and treatment, and addressing the financial burdens associated with their care. At the current time, cancer patients are generally not "shoppers" when it comes to the location of their care or the elements of their care. Instead, patients are seeking detailed information about their diagnosis, including perhaps a molecular diagnosis, and then evaluating treatment options, which may include targeted therapies.

If cancer patients are to add health care cost data to the analysis leading to treatment decisions, those data must be of higher quality than currently available data. To be meaningful to patients, cost data should be presented for an episode of care or treatment cycle, and data should be presented in a way that is comparable across care sites. Patients making treatment decisions and managing their care are not able to or interested in evaluating cost data for all separate elements of care they are receiving. The burden of doing this sort of cost analysis and comparison is simply too great with currently available cost information.

We urge that the movement toward transparency in health care cost information take into consideration the needs of patients. However, even if the quality of health care cost data are significantly improved and can be compared and utilized by patients, these improvements will not address the issue of health care affordability for cancer patients. Currently, even those cancer patients with adequate health insurance coverage have significant cost-sharing responsibilities. These patients can assume that comprehensive and multi-disciplinary cancer care will cause them to hit their out-of-pocket maximum spending thresholds – possibly for multiple years == which also reduces their incentive to shop.

The solution to health care affordability for cancer patients is not simply greater health care cost transparency. The solution must also include access to insurance coverage that offers greater protection from the financial toxicities of cancer care.

### Laboratory Date of Service Policy

It is increasingly important for cancer patients to receive biomarker testing to guide decisions about their treatment. If a cancer patient is recommended to receive biomarker testing, that testing should be performed in timely fashion. If there are delays in testing, patients may commence treatment without testing results and receive treatment that is not properly targeted. In addition, patients may miss the opportunity to enroll in a clinical trial appropriate to their biomarker status. In short, biomarker testing results must be delivered in timely fashion to guide treatment and assure delivery of targeted therapy, where appropriate.

We are concerned about the changes in date of service standards for laboratory tests that the agency has proposed, including the proposed physician certification requirement and the proposed limitation of the Laboratory Date of Service Exception to Advanced Diagnostic Laboratory Tests (ADLTs), for their potential adverse impact on timely access to biomarker testing.

We recommend instead that the agency leave in place the revision of the Date of Service (DOS) rule that was included in the CY 2018 OPPS final rule. That standard set the DOS for molecular tests as the date of test performance instead of date of specimen collection. It is our hope that this DOS standard will address the delays that occurred when the date of service was the date of specimen collection and when some patients experienced delays in their diagnostic testing until

more than 14 days after their discharge. However, additional experience with this standard – included in the CY 2018 OPPS rule and therefore in place for a limited period -- is necessary to assess its impact on patients and before any changes to it are considered.

We recommend that CMS leave the current policy in place and also institute methods for assessing its impact on patients. Only then, and on the basis of data about the policy's impact, should any changes in the laboratory date of service policy be considered.

#### Supervision Policy for Hospital Outpatient Therapeutic Services

For a number of years, direct supervision has been required for hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals. However, beginning in January 2010, and extended for a number of years, CMS implemented a non-enforcement standard with regard to the direct supervision policy for therapeutic services provided to outpatients in Critical Access Hospitals (CAHs) and rural hospitals. The agency instructed Medicare contractors not to enforce direct supervision requirements in CAHs and rural hospitals, after these entities indicated that they would have serious difficulties meeting the direct supervision requirements.

In the CY 2020 OPPS proposed rule, the agency recommends changing the minimum required level of supervision from direct to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs.

The undersigned organizations represent patients who often prefer to receive their cancer care — or at least some elements of it — in facilities near their homes, as that may minimize travel and maximize the ability of family caregivers to be involved in care. As a result, we are sympathetic to the burdens on rural hospitals and CAHs related to direct supervision, burdens that may affect cancer patient access to care in those institutions. However, of greater concern is that the care cancer patients receive in these institutions be of high quality and provided safely.

It is with this concern in mind that we recommend that direct supervision be required for radiation therapy services provided in the hospital outpatient department. As patients receiving these services and health care professionals providing them, we believe that radiation therapy services – increasingly targeted and precise and requiring complex equipment and processes – should be subject to direct supervision. This means that radiation oncology providers should be present during treatment planning and delivery, able to furnish assistance and direction throughout the performance of the procedure.

We understand that this issue requires evaluating and balancing issues of access, quality, and safety. In our analysis, direct supervision of radiation oncology services is in the best interest of patients.

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We appreciate the opportunity to comment on several proposals in the OPPS proposed rule that affect cancer patient access to quality care.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
CancerCare
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
LUNGevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivors
Sarcoma Foundation of America
Susan G. Komen