May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Slavitt,

On behalf of the Cancer Support Community (CSC) and the thousands of patients we touch each year, I would like to thank you in advance for the opportunity to formally comment on the proposed rule change to Medicare Part B.

CSC acknowledges CMS for elevating the discussion about issues in reimbursement for cancer care. By way of this letter, CSC formally expresses its concern about the way in which this discussion is presented in the form of the Part B proposed rule as well as several concerns about the proposed rule recommendations. It is the position of CSC that CMS should not move forward with the rule in its current form. It is clear by reading the rule that the realities faced by a multitude of stakeholders were not included in the current version of the rule; of highest priority to CSC is the patient as a stakeholder.

In 2009, The Wellness Community and Gilda’s Club joined forces to become the Cancer Support Community. CSC is the largest, nonprofit provider of social and emotional support for people with cancer and their families, reaching nearly one million people through our telephone helpline, our vibrant online community and our 170 locations across the country. Serving people with all types of cancers, it is our mission to ensure that all people impacted by cancer are empowered by knowledge, strengthened by action and sustained by community.

In addition to our direct services, CSC also works tirelessly to make sure that the voices of patients, families, caregivers, friends and colleagues are heard through the research we perform. One example, our Research and Training Institute’s Cancer Experience Registry®, is a place where nearly 10,000 individual and collective voices of people impacted by cancer can be heard and measured. The goal of the Cancer Experience Registry is to better understand the full impact of the cancer journey on patients, families and caregivers and leverage those lessons to create new programs and services and inform policymakers.

Given the complexities of the cancer patient experience throughout each step of the patient journey, policy decisions must be made with some level of consideration to the impact such decisions will have on those most vulnerable. In today’s environment, as seen in CSC’s Cancer...
Experience Registry and other published data, patients are experiencing significant challenges accessing treatment and accessing health care professionals. There remains a deficit in the provision of comprehensive care due to these challenges and the lack of reimbursement for current services. And, finally, patients are living with chronic and long-term collateral damage (biomedical and psychosocial), which are often not addressed.

Again, thank you in advance for your attention to the following comments.

**Lack of stakeholder feedback**
CSC shares the concern of many in the cancer community that this proposed rule lacks broad stakeholder engagement. It is unclear who comprised the panel within CMS to formulate the rule, what reference material was used as a part of the decision-making process and whether or not the concepts noted in the rule were actually tested with stakeholders. While the rule may, in theory, provide CMS with the savings it hopes to achieve, the recommendations presented in the rule may result in collateral damage which will lead to an actual increase in overall spending. Thorough feedback sessions with patients, families, providers and payers would help inform CMS on the real world experiences of the complex cancer journey and engagement with this same stakeholder community could deliver broad change that would more closely meet the objectives of improved quality and lower cost.

**Risk to comprehensive, quality cancer care**
Cancer, as well as other chronic and life-threatening illness, creates a delicate ecosystem for patients, their families and their caregivers. The needs of patients extend well beyond the cost of medication as a part of treatment. The current reimbursement system with its significant limitations on reimbursement for services, including a lack of reimbursement for pharmacy and nursing time to mix and administer treatment and a lack of reimbursement for coordination/planning of care, distress screening and social and emotional support creates an environment whereby patients struggle to receive comprehensive, quality cancer care. In fact, CSC’s own *Insight into Patient Access to Care in Cancer* study demonstrated that in the current environment, 71 percent of patients did not receive social or emotional support services, and nearly 20 percent indicated they did not have enough time with their physicians. CSC is very concerned that a reduction of payment to providers without the addition of adequate reimbursement for all necessary services will lead to a further reduction in available services to patients, including treatment decision counseling, nutritional support, psychosocial support and others. Ironically, as demonstrated by the work of Dr. Linda Carlson and Dr. Barbara Anderson these are services which have demonstrated a reduction in cost to the overall system and also improved patient outcomes, which is exactly what CMS indicates it hopes to accomplish.

**Patient access to care providers**
There has been much discussion in the cancer community about the potential impact of the proposed rule on health care professional practice patterns, including the potential closing of physician offices, private practice integration into medical facilities and early physician retirements. In addition to the potential increase in cost to the overall health care system by this level of integration, consolidation and potential shortage, patients and families will bear the additional burden of relocating to new sites of care delivery that may be outside of their immediate community. In the current reimbursement environment, patients and families often
speak about the burdens they face as a result of the need to travel significant distances to care. These include extended time away from work and/or family obligations, the cost of gasoline and increased expenses for parking to name a few.\textsuperscript{iv} If implementation of this rule bears the same results in provider consolidation, as has been seen since the implementation of the Medicare Modernization Act in 2003, the burden on patients will continue to increase, in some cases creating an insurmountable barrier to access to care.

**Timeline for implementation**

There are two separate concerns with the timeline outlined in the current proposed rule. First, phase I of the final rule is set to go into effect “in the fall of 2016” and phase II will follow “no sooner than January 1, 2017.” With comments due on May 9, CMS could not possibly perform a thorough analysis, integrate stakeholder feedback and implement a patient-centered program within this abbreviated timeline.

Additionally, the model is proposed to be in place for five years without mention of a timeline for evaluation and adjustment based on findings. CMS has the ability to monitor practice patterns, patient access and costs burdens throughout the proposed timeframe. In any such pilot program, CMS must work with the broad stakeholder community to identify metrics and performance thresholds which would indicate either success or unintended consequences and implement a robust surveillance process to identify early signals which would require intervention. Additionally, CMS should work with the stakeholder community to perform a thorough interim analysis. All findings should be made publicly available.

**Transparency**

CSC is concerned about the general lack of transparency associated with the proposed rule, a potential final rule and the implementation of the rule. In particular, the proposed rule communicates in vague terms, such as “overprescribing,” “successfully manage,” “therapeutically equivalent,” etc., without identification of clear metrics and points of reference. CSC recommends that all decision points be grounded in evidence, formed with input from the broader stakeholder community and analysis and benchmarks be made available to all.

**Primary care service areas (PCSAs)**

The current model for implementation of this program via the PCSA’s is also of concern to CSC and to the patients we serve. An emerging body of evidence continues to grow indicating that patient outcomes can be directly correlated with the areas in which they live. Dr. Otis Brawley recently presented a summary of work demonstrating the relationship between education levels, geographic origin and cancer incidence which contributed to the body.\textsuperscript{v} Additionally, work published by Zeng et al. reported disparities in outcomes associated with patients living in rural vs. urban areas.\textsuperscript{vi} While CMS noted that the intent of the program is to realize cost saving, CMS should work with stakeholders in diverse geographies and communities to ensure that patients who are already at risk are not placed in further jeopardy as a result of this, or other new practices.

**Benchmarks**

There are several sections of the proposed rule which reference the potential use of benchmarks. In helping CMS to maintain a high level of transparency, CMS should define who is setting the benchmarks, what evidence is being used for the benchmarks, and how the patient’s voice will
be adequately included in benchmarks’ creation. CSC is happy to offer its expertise to CMS on the cancer patient experience as well as access to both patients and the ample research in this field to help develop a framework to address this issue, ensuring that patients have a voice in the process.

CSC encourages CMS to work with a diverse set of stakeholders to ensure that the benchmarks used for this rule are, in fact, accurate and reflect the realities of the cancer patient experience. CSC is concerned about the use of the Consumer Price Index (CPI) to calculate the flat fee adjustments as it may not provide an accurate reflection of cost and utilization across the full spectrum of users and, in fact, disadvantages patients in particular geographies.

CSC is concerned about the language in the proposed rule which says: “providing equal payment for therapeutically similar drug products is one form of value-based pricing that we propose to implement as part of phase II of the model.” The current language is unclear on the definition of “therapeutically similar.” Given the personalized nature of cancer treatment and response to interventions, CSC discourages the broad use of “therapeutically similar.” As a general principle, CMS should at least use the following formal Food and Drug Administration (FDA) definition, “Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.” Additionally, CMS should work with the broad stakeholder community to better understand the potential use of this as a benchmark given the difference in specific toxicities, including long-term side effects, which are experienced as a part of the unique patient response to treatment.

CMS references the guidance of professionally set guidelines and value models as a part of the decision framework for Phase II of the proposed rule. Specifically, CMS lists NCCN and ICER recommendations as potential benchmarks. CSC reminds CMS that many of the value models, including NCCN and ICER, have received significant feedback regarding shortcomings of the models. These shortcomings include the lack of the patient engagement as a part of the development, lack of adequate research and testing to support the models and concern regarding utilization of the correct benchmarks for patients, to name a few. CSC has been transparent in our comments on these models, which can be found on cancersupportcommunity.org.

**Value-based purchasing models**

CSC is concerned about the intent of CMS to use private industry value-based purchasing models without thorough analysis, feedback from patients and consideration of the impact this change will have on patients.

The proposed rule reads, “The market today uses the term ‘value-based’ to encompass a wide variety of different options designed to improve clinical results, quality of care provided, and reduce costs.” However, this perspective of “value-based care” does not take into account the patient’s quality of life or level of engagement in his or her care. Patients often define value differently than the other “market” participants. According to a 2015 study of 769 patients with metastatic breast cancer who participate in CSC’s Cancer Experience Registry, only 5.46 percent felt that value in care could be defined in an economic exchange context. When defining care,
nearly 40 percent of patients felt that valuable care meant care of a personal value, including time with their physician, quality of life and engaging on the decision-making process. Patients wrote in their responses of being concerned about quality of life, comfort during treatment or how their treatment would affect their relationships with others. vii When utilizing the perspective of “value-based care,” CSC strongly urges you to remember the patients in this definition, as every value-based model or framework developed thus far has not adequately represented the concerns of the patients who receive these treatments.

While many celebrated the removal of restrictions on lifetime caps and pre-existing conditions seen with the passage of the Affordable Care Act, private industry, in some cases, has replaced these once discriminatory practices with a new set of practices which could be considered discriminatory. As one example, generic medications used for breast cancer risk reduction have been placed as high as tier four in some private industry plans’ specialty tier systems. These types of tactics place a high degree of financial burden on patients and families and often lead to the unsafe practices of medication non-adherence. It could be argued that some value-based purchasing practices could pose a legal and ethical dilemma by shifting undue cost to patients with serious and life-threatening illness in a way that represents a discriminatory practice toward these special populations. CMS should work with the stakeholder community to establish models which ensure patient access to the medications determined to be the best treatment option for them.

CSC will not comment here on the specific challenges of each of the potential value-based purchasing models. CSC will raise its objection to the broad application of these processes to patients with cancer. As mentioned above, the combination of the complex cancer care environment and the degree to which the science is advancing personalized medicine, on both the response to treatment and also the predictability of toxicities, make this general application of particular concern. Value-based purchasing tools have not proven to be effective for these highly personalized scenarios and these tools and the standards established are the result of competitive business modeling versus patient feedback and outcomes.

Clinical Decision Support (CDS) Tool
The language used to describe the CDS tool in the proposed rule is particularly problematic and highlights the lack of consideration of the patient as an oncology care partner. The metrics described in the proposed rule are not patient-centered, and in fact, omit real world issues impacting patient care, including disruption to work/family life, need to travel, etc. Additionally when thinking about the tool in the context of cost conversations, the 2014 Journal of Clinical Oncology article by Shrag and Hanger provides insight into the reality that many doctors are not prepared or comfortable with having discussions regarding costs of care. Forty-three percent of doctors surveyed were aware of their patient’s financial well-being either only some of the time or none of the time. When it came to actually discussing the costs related to cancer care, 32 percent of oncologists discussed it some of the time, and 26 percent of oncologists rarely or never discussed the cost with patients. viii

CSC does note the use of the Agency for Healthcare Research and Quality definition of CDS tools, and CSC certainly supports the intent of including “patient specific information in real time” as a part of the tool. The CMS outline of two key components to the tool, “clinical decisions through education and feedback based on drug utilization in Medicare claims” does
give CSC pause due to the lack of representation of objective, comprehensive, patient-centered care measures. Additionally, the language, “High quality evidence is comprehensive, relies on randomized trial designs where possible and measures outcomes” further removes patient engagement from the discussion.

Finally, the lack of broad access to CDS tools is of concern. If such tools are used in clinical decision-making, the tool should be made available to the patients whose care is governed by the tool.

CSC challenges CMS to think more broadly on this issue and move its work away from CDS tools designed to shape thinking largely based on biomedical and research-specific measures to treatment decision counseling tools which facilitate a discussion between the physician and the patient and lead to decisions based on a more comprehensive profile of patient-centered expectations.

**Appeals**
CSC appreciates that CMS has offered a pre-appeals process as a part of the proposed rule. CSC is concerned that providers may not realize this as a viable option due to an increase in administrative burden. The potential result could include the patient experiencing delays in treatment or limited or no access to the therapy that is the most optimal to their individual needs is of particular concern to CSC.

**Oncology Care Model**
CSC recognizes the perspective of CMS that the proposed rule may be an opportunity to interplay with the Oncology Care Model. Given the interest expressed by CMS to move away from a pay for performance model toward a model which improves quality and reduces cost, it would seem helpful to work with stakeholders to create a comprehensive system which would evaluate and reimburse patient care in totality. The current models, which detach medication reimbursement from overall care delivery, will not provide the complete information needed to evolve quality cancer care of the future. Simply creating a system to influence prescribing behavior independent of overall patient care and quality outcomes poses a significant barrier to delivering meaningful solutions. CMS should work with the broader stakeholder community to create a comprehensive care delivery model which includes adequate reimbursement for appropriate, evidence-based, patient-valued treatment AND support services. CMS should also work with the stakeholder community on appropriate quality metrics which would govern or trigger reimbursement. Finally, CSC strongly believes that a pilot project which creates such a significant change in practice must be done with some level of financial stability and security for both the health care and patient community until relevant outcomes are confirmed.

**Definition of Success**
Other than achieving cost savings, there is no clear indication of how success will be measured in this proposed rule. Such a narrowly focused aim in a high stakes situation like cancer, is not only concerning, but is a missed opportunity. As CMS considered replacing the current rule with a rule formulated with input from the broader stakeholder community, CMS should identify clear metrics which strike the balance between improved patient outcomes and cost. It will only be with the input of patients and their families that these comprehensive measures can be derived.
Conclusion
In summary, CSC acknowledges CMS for attempting to tackle the important issue of ensuring that patients receive quality, affordable care via the Medicare Part B program. However, this rule, as it stands, does not adequately account for the needs and perspectives of patients in either Phase I or Phase II and, in fact, will create an environment that disenfranchises patients even further.

It is the position of CSC and the patients we serve that CMS should withdraw this rule, take time to engage the stakeholder community—especially patients—and work to deliver a solution in 2017 which would preserve comprehensive, quality and affordable health care.

Thank you for your consideration.

Warm Regards,

Linda House, MSM, BSN, RN
President
Cancer Support Community

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