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January 16, 2018

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4182-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [CMS-4182-P]

Dear Administrator Verma,

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [CMS-4182-P].

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of over 40 licensed affiliates, more than 120 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than \$40 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

CSC applauds CMS for its efforts to support flexibility and efficiency within the Medicare Advantage (MA) and Part D programs. Many cancer patients are Medicare beneficiaries and will therefore be directly impacted by the proposed changes. As such, we submit the following comments in an effort to ensure that any changes to the programs are finalized and implemented in a manner that balances plan flexibility with beneficiary protections in a fair and transparent manner. CSC is pleased to submit comments on the following areas:

***Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale***

CSC applauds CMS' proposed efforts to reflect manufacturer rebates and pharmacy price concessions for Part D covered drugs in the negotiated price at the point of sale and we strongly support efforts to limit beneficiary cost sharing. We also support a portion of manufacturer rebates being shared with the patient. Historically, beneficiaries have not enjoyed direct or indirect remuneration (DIR) cost savings directly, but rather depended on plans to utilize DIR savings to offset overall expenditures such as premiums. CSC

encourages beneficiary cost sharing to be based on the negotiated price. We also encourage CMS to work to ensure that such changes do not create other incentives for plan sponsors to make up the difference through alternative cost sharing mechanisms, particularly if DIR received is above plan projections. We ask CMS to require sponsors to include all pharmacy price concessions received and ensure that patient cost sharing is reflective of the lowest price. Beneficiaries should not only experience lower premiums, but also avoid high cost sharing whenever possible. We also support a standardized approach that is consistent and transparent across plans so that patients can consider cost sharing impacts as they make personal decisions. Further, we ask CMS to explore avenues to identify and reward high performing pharmacies that go above and beyond to improve patient outcomes.

#### ***Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations***

CMS has proposed lengthening the adjudication timeframe from 7 to 14 days in cases where the enrollee has received the drug, paid for the prescription out of pocket, and is requesting reimbursement. This change would be detrimental to beneficiaries, particularly those with limited incomes, which is the case for many Medicare beneficiaries. If beneficiaries pay these costs out of pocket, wait for an adjudication response, and are denied, they must then continue to pay out of pocket (which may not be possible) or seek a different treatment which may cause a delay in care and/or additional expense. Ultimately, this change will impact both patient access and cause additional financial toxicity.

#### ***Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§422.254, 422.256)***

While CSC supports plan options that allow beneficiaries to find the plan that fits their unique needs, the elimination of meaningful differences has the potential to lead to confusion as patients make these selections among several similar plans. Plan offerings should be accompanied by detailed, understandable information and decision aids geared at thoroughly educating consumers as they make plan selections.

#### ***Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)***

CSC does not support non-medically necessary medication substitutions, particularly if it occurs in the middle of a benefit year and without the full knowledge and understanding of both the patient and provider. This is particularly relevant for cancer patients and survivors who often take complex and/or combination therapies that carry with them various side effects. Patients and providers engage in shared decision making processes to determine the best medication for that particular patient based on their values, needs, and preferences. Patients have differing responses to treatments, and personalized medicine is offering more targeted options. It is critical that providers have the autonomy to exercise discretion in treatment recommendations, incorporating both clinical evidence as well as patient input through shared decision making. Medication substitutions can interfere with this process. If patients are stable on a certain therapy, changes to their medications can cause serious negative repercussions including declines in health outcomes, increased costs (if the patient must switch medications several times or if they are faced with higher out-of-pocket costs if they must be treated with the original medication), and increased distress. Finally, if patients are required to undergo substitutions, it is essential that they receive ample notification of any changes, that they are provided with timely and understandable information on ways to appeal such a decision, and that decisions in response to appeals are made within seven days.

#### ***Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)***

CSC understands the goals of the Comprehensive Addiction and Recovery Act of 2016 (CARA) and supports efforts to curb opioid abuse. However, we also applaud CMS for proposing to exclude individuals with a diagnosis of cancer from the proposed CARA provisions as outlined in this rule. Many cancer patients and survivors deal with pain associated with their disease and/or treatments for the disease. When medications are clinically appropriate and necessary, it is ill-advised to put barriers in the way of patients in need.



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Further, CSC would like to ensure that patient rights and requests for transparency are respected as CARA is implemented. We are concerned that the proposed single pharmacy and single provider lock-ins may have negative implications for patients. Patients should have the authority to choose their preferred pharmacy and provider, particularly if they are going to be locked into utilizing a single provider or pharmacy. Any decisions that are made for patients must be done so in a transparent way that acknowledges and considers patient preferences.

Finally, as CMS develops and implements programs to stop the abuse and misuse of opioids, CSC would like to offer ourselves as a resource. Our Research and Training Institute (RTI) will soon be fielding a cross sectional study on pain management among cancer patients. This will offer critical insights into the ways in which cancer patients experience pain, approach pain management, and address challenges associated with limits on access to opioid pain medications.

***Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100, 422.101)***

CSC encourages CMS to use its authority to limit plans' ability to increase their Maximum Out-of-Pocket (MOOP) limits. The out-of-pocket costs incurred by cancer patients are a major contributing factor to financial toxicity. Depending on the plan, out-of-pocket costs for cancer patients can go upwards of \$10,000 before comprehensive insurance coverage kicks in (Banegas et al., 2016), putting beneficiaries at risk of skipping doses of life-saving medications, suffering from physical or emotional stress, or facing bankruptcy (Bach & Pearson, 2015). Any changes to the MOOP must balance plan flexibility with necessary protections for the beneficiaries. This estimated annual savings of this proposed rule total \$195 million and we strongly support those savings being passed along to beneficiaries.

CSC thanks CMS for the opportunity to provide comments on this proposed rule and we stand ready to serve as a resource to CMS as we work together to ensure that patients have affordable access to comprehensive coverage through Medicare. Please reach out to me at [linda@cancersupportcommunity.org](mailto:linda@cancersupportcommunity.org) if you would like to discuss any of the above in more detail.

Sincerely,

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