April 14, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Administrator LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions, which will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

As CMS implements Medicare drug price negotiation, ACS CAN offers recommendations to ensure Medicare beneficiaries realize the full potential of this new program. Every Medicare beneficiary is either a cancer patient, survivor, or at risk of developing the disease and the affordability and availability of cancer prevention, early detection, treatment, and survivorship is critical to reducing the significant nationwide cancer burden.

Drug therapies play an integral role in cancer treatment and survival. Both cancer patients and survivors rely on medications to treat their cancer and prevent recurrence. Over the course of the last few years there has been a remarkable increase in the number of new cancer drug therapies. In 2022 alone, 10 out of the 37 new drug therapies approved by the Food and Drug Administration (FDA) were for cancer.[1]

Advances in research have significantly improved our understanding of cancer at the molecular level – leading to the development of more precise detection and diagnostic tools and the corresponding therapies that can attack cancer. However, if patients likely to benefit from these advancements face barriers of affordability or accessibility, the opportunity to reach the national goal of eliminating death and suffering

[1]U.S Food and Drug Administration, New Drug Therapy Approvals 2022, https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2022.

from cancer is greatly hindered. Access to a full range of prescription drug therapies is, therefore, a key determinant in successful cancer outcomes.

The affordability of cancer therapies, however, remains a serious obstacle for many cancer patients. Even with Medicare coverage, beneficiaries who need access to innovative cancer drugs may find their out-of-pocket costs running into thousands of dollars each year. For those battling cancer, skipping pills, or abandoning prescribed drug therapies because of cost can have serious health consequences. Other patients go into significant debt, even bankruptcy, to pay for their treatments.[2]

The newly enacted cap on Medicare Part D out-of-pocket drug costs will help to make prescription drugs more affordable. As CMS begins to negotiate lower prices for select drugs in Medicare, there is the potential for further savings for millions of beneficiaries if the program is administered in a manner to ensure that access to new and innovative therapies is protected and savings directly reach beneficiaries, not just overall savings for the program. Given historical Medicare spending data, it is highly likely that cancer drugs will account for a substantial proportion of the drugs to be negotiated. If this is the case, it is even more critical that CMS consider the many unique oncology considerations to ensure critical therapies and future innovation is not impeded.

ACS CAN appreciates the opportunity to comment on the initial program memoranda. We offer some general recommendations for ensuring that patients benefit the most out of the negotiations as well as specific comments in direct response to questions CMS has raised in different sections of the draft.

The Importance of Patient Guardrails

ACS CAN views affordability and access as equally critical for ensuring that cancer patients receive the best treatment to survive their disease. As CMS moves forward with implementation of the new prescription drug negotiation program, we urge you to carefully balance the need to lower the cost of drugs offered through Medicare with ensuring patient access to new drug therapies. To this end, ACS CAN asks you to consider several patient "guardrails" that could help to achieve that goal.

Monitoring and Reporting

ACS CAN encourages CMS to carefully monitor and publicly report on the implementation of the negotiation process as it pertains to beneficiary access and cost, specifically:

- We urge CMS to ensure that Medicare enrollees realize the savings related to drugs that are the subject of negotiation and in no case pay more out-of-pocket for a drug that is subject to negotiation than they were paying previously. Absent clear directive from CMS, a drug that is subject to negotiation could be placed on a higher formulary tier (for example, a non-preferred brand) and enrollees could pay higher cost-sharing as a result.

- As CMS identifies the drugs subject to negotiation, we urge the Agency to determine whether a particular disease (like cancer) represents a majority of drugs subject to negotiation. If a majority of

[2] Liz Szabo, "Sticker Shock Forces Thousands Of Cancer Patients To Skip Drugs, Skimp On Treatment", Kaiser Health News, March 15, 2017, https://khn.org/news/sticker-shock-forces-thousands-of-cancer-patients-to-skip-drugs-skimp-on-treatment/view/republish/.

drugs subject to negotiation pertain to one disease or condition, CMS should consider (as part of the factors related to negotiation) the impact on long-term research, investment, and unique characteristics of innovation for that disease. For example, drugs with a single orphan designation are exempt from negotiation, but the protection is not extended to products with multiple orphan designations. This seems to provide a powerful disincentive for drug sponsors to explore new, lifesaving uses in rare diseases, of which most cancers are, for drugs already proven safe and effective.

- While the guidance document pertains to the Medicare negotiation process for Part D covered drugs and the guidance related to Part B drugs is forthcoming, we also recognize that CMS has a vested interest in adopting similar rules pertaining to both programs (in order to reduce administrative complexity for both the program, manufacturers, and plans). Therefore, we urge CMS to monitor the prescribing patterns of drugs subject to negotiation to determine whether prescribing patterns are generally on trend after the negotiation process. If prescribing patterns fall beyond a statistically significant measure, we urge CMS to conduct independent analysis to determine why prescribing has changed. This may be more of an issue with respect to Part B negotiation given the direct impact of physician reimbursement, but we recommend that CMS put in place monitoring processes for both programs to ensure beneficiary access.

Review the Potential for Steering

CMS should monitor plan formularies to determine the extent to which plans are using more utilization management tools for non-negotiated drugs, which can hinder access to these medications. ACS CAN is concerned about the extent to which beneficiaries could be steered towards negotiated drugs. For cancer patients who have found a specific drug that works for treating their cancer, being steered towards another – potentially less effective drug – could be detrimental. Medicare Part D is administered entirely through private plans which have a financial incentive to steer beneficiaries toward a drug with the lowest price the plan is able to negotiate. To the extent that providers have a choice of drugs to prescribe (e.g., several drugs available in the same therapeutic category and class) the Part D plan could steer beneficiaries toward the negotiated drug and may impose barriers (such as more rigorous prior authorization or step therapy requirements) on non-negotiated drugs.

Examine Impact on Launch Prices

CMS should examine any potential increase in launch prices as a result of negotiation and the overall impact on beneficiary costs and determine the extent to which higher launch prices potentially negate some of the potential beneficiary savings from negotiation. CMS should monitor and publicly report this information as part of the transparency of the Medicare negotiation process. This will help inform stakeholders as they seek to make refinements through the program, some of which may require Congressional action.

Monitoring Access Issues

Cancer is not just one disease it is hundreds of diseases. As such, there are many FDA-approved cancer drugs that are used for cancers not indicated in the formal label. According to the Agency for Healthcare Research and Quality (AHRQ) one in five prescriptions written today are for off-label use.[3] There is a statutory recognition of the appropriateness of such prescribing by covering oncology drugs for off-label use when

[3] Agency for Healthcare Research and Quality. Off-label drugs: What you need to know. Available at https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html#:~:text=Off%2Dlabel%20prescribing%20is%20when,are%20for%20off%2Dlabel%20use .

included in a recognized compendia.[4] Given this important feature of oncology drug use, CMS should consider not only the FDA-approved label indication of the drug but also the extent to which the drug is prescribed as an off-label use for another cancer. If the negotiation process unintentionally results in barriers to accessing medications (e.g., overuse of utilization management tools) or prescribing changes, there is a concern that beneficiary access to non-negotiated drugs may be negatively impacted. Therefore, CMS should begin to monitor any potential beneficiary access problems to establish a baseline for future comparison.

Examine Impact on Research and Development of New Therapies
While the overall cancer mortality rate continues to decline, there is still enormous unmet need for the development of therapies to treat cancer. Because the creation of negotiation processes will have downstream impact on research and development, we encourage CMS to work closely with the FDA, particularly on issues related to the trends in the number of new cancer therapies brought to market.

Specifically, we ask CMS to closely monitor two provisions that may negatively impact research and development of new therapies - the implications on research of additional indications for new therapies and the impact on the development of small-molecule therapies since they are eligible for negotiation after only seven years on the market.

Many oncology medicines approved a decade ago also received approvals for additional indications in later years, and most of those were seven or more years after initial FDA approval. Often times these indications are for earlier stage cancers when cancer is more treatable, and many expanded indications are for rare cancers. We ask CMS to work with the FDA to monitor and report on the implications of this new price negotiation program on the submission of applications for new indications of existing therapies and to identify negative trends.

Small-molecule oral oncology drugs are very important tools in the treatment of cancer. These therapies can be taken by patients at home, which can reduce patient time and transportation burdens. We ask CMS to work with FDA to monitor the implications of this new price negotiation program on the submission of applications for small molecule therapies.

Future Revisions to the Negotiation Process
We recognize that given the statutory deadlines, CMS was not able to obtain stakeholder input regarding the Medicare Part D negotiation process through rulemaking and instead is implementing the program through guidance. We thank the Agency for its willingness to release the draft guidance and for solicitation of stakeholder input.

At the same time, we recognize that the negotiation process is new to the Medicare Part D program and there are bound to be opportunities for improvements to the program moving forward. CMS should consider undergoing rulemaking in future years to formalize the negotiation process. CMS could also use this process to establish a timeline by which the Agency intends to revisit the rules regarding the negotiation process. Using the rulemaking authority will provide stakeholders clear direction regarding the process for negotiation and will ensure an open and transparent process for any subsequent changes to the negotiation process.

[4] 42 U.S.C. §§13952w-102(e)(4).

Recommendations on Specific Sections of the Memoranda

CMS is soliciting comments on specific issues raised in the memoranda. ACS CAN offers the following comments and recommendations in response to some of the questions CMS raised.

Section 50.2 – Evidence about Therapeutic Alternatives for the Selected Drug

To determine the maximum fair price of a selected drug CMS is required by law to consider evidence about alternative treatments including the comparative effectiveness of the selected drug and therapeutic alternatives, and the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations). CMS is prohibited from using comparative clinical effectiveness research – including quality-adjusted life years (QALYs) in a way "that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."

ACS CAN supports comparative effectiveness research because it provides clinicians with information regarding the relative clinical effectiveness of a given intervention and potential differences in side effects. We appreciate CMS clearly stating that it will "not use evidence in a manner that treats extending the life of any individual as lower value than the life of another individual; this includes QALYs when used in association with life extension."

ACS CAN strongly opposes the use of quality-adjusted life years to determine whether to provide coverage or to set patient cost-sharing for a given treatment. Doing so fails to consider the value an individual may place on the quality of life provided to them for a given treatment. ACS CAN believes that cancer treatments should be patient-centered and ensure a patient's preferences in treatments and outcomes.

Section 60.3.3.1 – Analysis for Selected Drugs with Therapeutic Alternatives

To compare the effectiveness and clinical benefit between a selected drug and its therapeutic alternatives, CMS indicates it intends to:

- Identify outcomes to evaluate for each indication of the selected drug, and consider the safety profile of the selected drug and the therapeutic alternative;
- Consider health outcomes, intermediate outcomes, surrogate endpoints, patient-reported outcomes, and patient experience;
- Focus the review of clinical benefit on outcomes of particular importance to the condition or disease being treated by the selected drug;
- Consider the effects on specific populations, as required by section 1194(e)(2)(C);
- Consider if the selected drug fills an unmet medical need; and
- Examine improvements in outcomes with the selected drug as compared to its therapeutic alternative to determine whether a selected drug represents a therapeutic advance.

We remind CMS that in oncology, there are very few drugs that are truly equivalent with respect to the FDA-approved label indication and the scientific evidence supporting the efficacy of a given drug. For example, both Keytruda and Opdivo are FDA-approved to treat lung cancer, but the efficacy of both drugs is not the same across all patients with lung cancer. Lung cancer itself is not a single disease but is subdivided into small-cell lung cancer and non-small cell lung cancer, which is further defined by up to 10 distinct biomarker-driven subtypes. We urge CMS to consider the real-world use of a particular medication across all types and subtypes of a disease for purposes of determining whether a drug has a therapeutic alternative.

ACS CAN supports the use of both patient-reported outcomes and patient experience data. Patients have first-hand knowledge of the effectiveness of a treatment as well as the impact on quality of life. We also support CMS considering health outcomes such as cure, survival, progression-free survival, or improved morbidity when comparing the selected drug to therapeutic alternatives. We support CMS considering whether a selected drug fills an unmet medical need such as treating a disease or condition in cases where extremely limited or no other treatment options exist as this is particularly important for cancer patients.

Section 60.7 – Exclusions from Negotiation Process
Under the new law, negotiation is delayed for those drugs where there is a high likelihood that a biosimilar will be licensed and marketed in the next two years.

ACS CAN has long supported the appropriate use of generic drugs and has been a staunch supporter of bringing more biosimilars to market. This is another way of both expanding options for cancer patients and lowering costs for their drugs. While outside the direct scope of implementing the new negotiation program, ACS CAN urges CMS to work with FDA to expedite approval of generics and biosimilars.

Section 90.2 – Monitoring Access to the MFP
ACS CAN supports CMS' intent to require Primary Manufacturers to establish safeguards to ensure information about the maximum fair price for selected drugs is available to eligible individuals, pharmacies, mail order services, and other dispensers. Program transparency and, in this case, price transparency will be key to overall success of the negotiation program.

We support the proposal for CMS to publish the information on its website and recommend that it be done in an easy to read, easy to access, consumer-friendly format. We also recommend that CMS update the Medicare Plan Finder with information for those drugs that are subject to Medicare negotiation. In reviewing Part D plan formularies, CMS should ensure that enrollees' cost sharing is based on the Medicare negotiated rate. We further suggest CMS consider other avenues consumers generally use to get information on coverage including:

- the Medicare toll free line and call center;
- insurance plan websites;
- pharmacies and pharmacy applications;
- patient navigators; and
- patient advocacy organizations.

We support CMS' proposal to establish a process by which beneficiaries can report violations. This system should be easy to use – such as a toll-free number or an online notification system – and widely publicized. We urge CMS to set a time limit – no more than 48 hours – for responding to beneficiaries reporting violations and guidance as to the steps they should take. CMS should also report the number of complaints it receives and the number of complaints which resulted in CMS action. Finally, we urge CMS to consider creating an Ombudsman that serves as a direct point of contact for beneficiaries.

Conclusion

ACS CAN appreciates the opportunity to comment on the implementation of the new prescription drug negotiation program. If you have any questions or need additional information, please feel free to contact me directly or Kirsten Sloan, Managing Director, Public Policy at Kirsten.Sloan@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network