February 23, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-5546-P – Guarding U.S. Against Rising Drug Costs (GUARD) Model
90 Fed. Reg. 60338 (December 23, 2025)

Dear Secretary Kennedy and Administrator Oz:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Guarding U.S. Against Rising Drug Costs (GUARD) Model proposed rule. 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 that will reduce the cancer burden. As the American Cancer Society's (ACS) nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

The GUARD Model demonstration would require pharmaceutical manufacturers of selected drugs to pay rebates for Medicare Part D if their prices exceed an international benchmark. Drug therapies are the bedrock of cancer care, and ACS CAN has long fought for public policies that support both the affordability and availability of medically necessary prescription drugs. We are concerned that the GUARD Model as proposed would raise costs for cancer patients because CMS expects manufacturers to respond by increasing point-of-sale prices under the Medicare Drug Price Negotiation Program, thereby impeding patient access to life-saving oncology treatments.[1] The Model's projections for higher premiums and increased cost sharing run counter to the goal of improving drug affordability and lowering costs for Medicare Part D beneficiaries.

Our letter provides greater detail of our concerns, which in sum include:

- The implementation timeline would be difficult to meet given the magnitude and complexity of the Model.
- The Model would increase beneficiary cost sharing and premiums over the course of the Model.
- Inclusion of a beneficiary's most appropriate therapy, which may differ from established treatment regimens, in the Model could result in the manufacturer limiting production of that drug to avoid reducing prices or facing high rebates, increasing risk of a shortage. As a result, the Model could disrupt ongoing treatment, and since oncology care is highly individualized, alternatives may not be clinically appropriate or effective. This concern is especially acute for

[1] 90 Fed. Reg. at 60352, ("Addressing Deficits of Care Among Part D Enrollees").

patients with rare cancers, as the Model fails to exclude orphan drugs, which are often their only viable treatment option.

- The Model fails to account for a drug's specific indication when calculating the benchmark based on international reference pricing, resulting in comparisons that are not clinically equivalent.
- Many of the reference countries used for the GUARD Model benchmark calculations, while economically comparable, have health care systems substantially different from that of the United States (U.S.) and often rely on Quality Adjusted Life Years (QALYs) to set prices – an approach that undervalues the lives of cancer patients.[2] Due in part to their pricing reimbursement structures, many of these reference countries have more limited access to effective therapies, resulting in worse patient outcomes and survival.[3,4]
- The Model fails to include sufficient beneficiary protections to ensure unencumbered access to medically indicated prescription drugs.

Given these concerns, we urge CMS to reconsider its proposal to begin the Model on January 1, 2027, and to withdraw the proposed rule at least until these issues are fully addressed. Rather than moving forward with the GUARD Model, we encourage CMS to strengthen existing programs that directly improve drug affordability for Medicare beneficiaries, such as promoting the Medicare Prescription Payment Plan and other initiatives that could provide meaningful financial relief and support access to treatment.

IV. Detailed Description of Provisions in the GUARD Model

A. Proposed Model Performance and Test Period (§§514.1, 514.5, and 514.110)

CMS proposes that the GUARD Model would have a seven-year test period with five performance years beginning January 1, 2027, and ending December 31, 2031.

ACS CAN is deeply concerned that the implementation timeline would be difficult to meet given the magnitude and complexity of the proposed Model. The proposed timeline would leave CMS with a very limited window to review and synthesize all the stakeholder comments, make any revisions to the proposed rule based on those comments, and complete the necessary administrative clearance processes required to issue a final rule. This also leaves a limited opportunity to develop and implement a beneficiary educational campaign, which is vitally important to inform beneficiaries that the Model could cause treatment disruptions and to explain how to report access issues. As detailed in

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[2] National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series. Nov. 6, 2029. Available from https://www.ncd.gov/assets/uploads/reports/2019/ncd_quality_adjusted_life_report_508.pdf.

[3] U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; https://www.cdc.gov/cancer/dataviz, released in June 2025.

[4] OECD. Health at a Glance 2025: OCED Indicators. Nov. 13, 2025. Available from https://www.oecd.org/en/publications/health-at-a-glance-2025_8f9e3f98-en/full-report/cancer-incidence-and-mortality_efaedf06.html.

the proposed rule, CMS would rely on beneficiary complaints to monitor compliance and protect access.

This concern is heightened by recent proposals in the Contract Year 2027 Medicare Part C and Part D proposed rule, in which CMS proposes to remove State Health Insurance Programs (SHIPs) as a source of information from the disclaimer requirements for Third-Party Marketing Organizations (TPMOs).[5] Medicare can be complex, and beneficiaries often need unbiased, one-on-one counseling to understand their Medicare options, which SHIPs provide. If finalized, this change would eliminate an important avenue for educating beneficiaries about the Model.

CMS proposes to implement the GUARD Model concurrently with the Global Benchmark for Efficient Drug Pricing (GLOBE) Model, both of which fall under the purview of the Center for Medicare & Medicaid Innovation (CMMI), while simultaneously carrying out other major agency programs such as the Medicare Drug Price Negotiation Program. Each of these models represents a significant operational and administrative undertaking, straining agency resources and making the proposed timeline difficult. Given the size and scope of the GUARD Model, it is anticipated that CMS will receive numerous detailed comments, which could further impede CMS's ability to meet the proposed timeframe.

A tight timeline has direct patient impact as it increases the risk of beneficiary confusion and could potentially create barriers to access for medically necessary prescription drugs. Given the scope and complexity of this particular Model, CMS should consider a longer timeframe for implementation to ensure that the Model minimizes any unintended consequences for cancer patients. Additionally, meaningful education and outreach regarding the GUARD Model cannot begin until the Model itself is finalized, and the proposed timeframe does not allow sufficient time to educate beneficiaries, physicians, and suppliers or to ensure appropriate beneficiary protections are in place.

B. GUARD Model Drugs (§§514.100 and 514.120)

CMS proposes a number of criteria related to determining drugs eligible for the model –

Selected Drug Categories Include Six Protected Classes Drugs: CMS proposes to identify the single source drugs and biologic products in the following specific therapeutic categories: analgesics; anticonvulsants; antidepressants; antimigraine agents; antineoplastics; antipsychotics; antivirals; bipolar agents; blood glucose regulators; cardiovascular agents; central nervous system agents; gastrointestinal agents; genetic or enzyme or protein disorder: replacement or modifiers or treatment; immunological agents; metabolic bone disease agents; ophthalmic agents; and respiratory tract/pulmonary agents.

The Model as proposed would include four of the six protected classes drug categories – antineoplastics, antidepressants, antipsychotics, and anticonvulsants. ACS CAN urges CMS to exclude from the Model any drugs that are included in the Part D category and classes of clinical concern (the so-called "six protected classes"). Since the program's inception, CMS has required all Part D plan

[5] Centers for Medicare & Medicaid Services. Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program. 90 Fed. Reg. 54894 (November 28, 2025).

sponsors to cover all or substantially all drugs within these classes. CMS created the six protected classes policy to ensure that beneficiaries who needed these drugs would have access to them. In fact, CMS's current Medicare Prescription Drug Policy manual clearly states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[6]

Including these drugs in the model could jeopardize access to therapies that are critical for patients with cancer, undermining protections designed to prevent treatment interruptions for vulnerable populations.[7] Medicare beneficiaries living with cancer rely on oncology therapies for life-saving treatment, and any payment model intended to reduce prescription drug spending must not impede beneficiary access. The GUARD Model, however, risks doing just that by creating barriers to timely cancer treatment. In oncology, alternative treatments may not be as efficacious, and postponing or forgoing treatment could lead to serious health consequences, which could increase care costs and result in additional spending for the Medicare program.

Beneficiary Out-of-Pocket Costs: CMS states that although the GUARD Model does not directly impact Part D enrollees' out-of-pocket costs for selected drugs, the agency believes that the GUARD Model has the capacity to address deficits of care experienced by the populations who take drugs that fall within the selected categories.

ACS CAN is deeply concerned that while the proposed rule cites financial toxicity among Medicare beneficiaries as rationale for the Model and notes nine percent of this population decided not to fill a prescription in 2025 due to cost, the Model would not generate beneficiary savings.[8] As addressed in the Regulatory Impact Analysis of the proposed rule, the Model would actually increase cost sharing and premiums for beneficiaries over its duration.[9] This result runs counter to the Model's stated goal of improving drug affordability and lowering costs for Medicare beneficiaries.[10] Any drug pricing payment model with the goal of improving affordability should reduce costs for Medicare beneficiaries rather than imposing additional financial burden.

Total Medicare Part D Spend: CMS proposes to identify Part D rebatable drugs with more than $69 million in total Medicare Part D spending over a 12-month period for inclusion in the Model.

While ACS CAN supports efforts to improve drug affordability, we are concerned that this threshold for defining a high-cost drug – which would apply to 38 percent of sole-source drugs and biologics – could significantly affect cancer patient access, as many oncology treatments are likely to be included based upon this approach. Moreover, this proposal's threshold is substantially lower than the $200 million baseline used in the Medicare Drug Price Negotiation Program. As a result, the Model could include a broader range of drugs, increasing the likelihood that beneficiaries' medications will be subject to the

[6] Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.
[7] Id.
[8] 90 Fed. Reg. at 60352, ("Addressing Deficits of Care Among Part D Enrollees").
[9] 90 Fed. Reg. at 60411 (Table C4).
[10] Id.

Model and raising the risk of unintended consequences for beneficiary access.

Orphan Drugs: CMS does not propose an exclusion for orphan drugs.

ACS CAN is concerned because many orphan-designated drugs are used to treat rare cancers, and for these patients, such drugs may be the only available treatment. We urge CMS to carefully consider the impact of including orphan drugs in the GUARD Model on beneficiaries with rare diseases, including rare cancers. The Medicare Drug Price Negotiation Program exempts these drugs from price negotiations, and we encourage CMS to adopt a similar exemption for the GUARD Model if the Model is implemented.

C. Proposed Model Test Design, Geographic Selection, and Beneficiary Population (§§ 514.110, 514.130, and 514.5)

CMS proposes a design in which CMS, through simple random selection, would identify 25 percent of all ZIP Code Tabulation Areas (ZCTAs) in the U.S., excluding territories, as GUARD Model geographic areas. Beneficiaries would be identified as GUARD Model beneficiaries if their address of residence is in one of the chosen ZCTAs.

ACS CAN has several concerns and questions regarding the operationalization of the GUARD Model. CMS should clarify how it intends to account for beneficiaries who maintain multiple residences or who seasonally relocate and, as a result, frequently receive care and fill prescriptions outside of the ZIP Code associated with their primary residence. This aspect of the Model's design introduces significant administrative complexity for both patients and providers. Cancer patients often travel to receive specialized care, and circumstances in which a beneficiary resides in a demonstration area but receives care and fills a prescription outside that area could create additional challenges.

ACS CAN also has concerns regarding geographic selection and how the Model will operate from the plan perspective. In the initial year, Medicare Part D plans likely will not know which, if any, ZCTAs will be included in their plan area, which will complicate their ability to develop accurate bids. In creating the Part D program, Congress required Part D plans to submit their bids based on an entire Prescription Drug Plan (PDP) region.[11] Without clarity on the number of covered lives included in the Model, Part D plans will be unable to assess which drugs – or how many beneficiaries using those drugs – will be impacted. This information is critical for plans to develop actuarially sound benefit designs that balance beneficiary costs and coverage, and without it, plans may inaccurately project costs and could experience financial losses. For cancer patients, this is concerning because it could translate to plans reducing the generosity of their benefits and greater costs for beneficiaries.

Additionally, we encourage CMS to clarify how cost-sharing information under the Model will be reflected in the Medicare Plan Finder. Medicare Plan Finder is a crucial tool for beneficiaries – allowing them to view and compare plan options, including monthly premiums, deductibles, and cost sharing, which helps them make informed enrollment decisions. It is therefore important for plans to understand how Model cost-sharing information will be incorporated and displayed on Medicare Plan Finder.

[11] 42 U.S.C. 1395w-11.

E. Proposed Existing International Drug Pricing Data and Reference Countries (§§ 514.5 and § 514.210)

CMS proposes selecting a large group of non-U.S. Organization for Economic Cooperation and Development (OECD) countries with a real GDP per capita of at least 60 percent of the U.S. level and an annual real GDP of at least $400 billion. Based on these criteria, CMS identified the following potential reference countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

ACS CAN is concerned that the proposed approach for selecting reference countries permits inclusion of countries with health care systems that differ fundamentally from that of the U.S., including countries that operate under single-payer models with government-imposed price controls as well as those with more market-oriented approaches. Although these countries may be economically comparable, their health care financing mechanisms, regulatory structures, and approaches to drug prices vary significantly. These systemic differences directly influence how prescription drug prices are set and negotiated, making cross-country price comparisons potentially misleading and insufficiently reflective of the realities of the U.S. health care market.

Additionally, all but one of these countries explicitly consider – or may consider – QALYs when evaluating a drug's cost effectiveness.[12] Using QALYs to assess a drug's value is problematic because they tend to undervalue the lives of individuals with pre-existing and chronic conditions, such as cancer, and the health benefits they gain from treatment. QALY-based assessments often favor treatments that restore individuals to "perfect" health, rather than those that extend or improve the quality of life for patients who are already ill. Notably, Medicare is prohibited from using health outcomes measures that assign lower value to extending the lives of ill patients compared with healthy individuals – such as QALYs – when determining coverage or reimbursement.[13] Importing drug prices from countries that rely on QALYs would effectively apply this harmful methodology to U.S. coverage and reimbursement decisions.

Pricing and reimbursement policies play a critical role in determining patient access to oncology treatments, which in turn impacts patient outcomes. Limited access to effective therapies has dire consequences for patients in many countries. In the U.S., the age-adjusted cancer mortality rate in 2023 was 141.5 per 100,000, while across all OECD countries, the cancer mortality rate was 191 per 100,000, highlighting significant differences in patient outcomes.[14,15] These disparities reflect, in part, differences in access to life-saving treatments, and any model that incorporates international reference pricing, including the GUARD Model, must carefully consider how pricing changes could impact access,

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[12] Office of Health Economics. How Widely are QALYs Used in OECD Countries? A Snapshot of International Practices. June 11, 2025. Available from https://www.ohe.org/insights/how-widely-are-qalys-used-in-oecd-countries-a-snapshot-of-international-practices/.

[13] 42 U.S.C. 1320e-1.

[14] U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; https://www.cdc.gov/cancer/dataviz, released in June 2025.

[15] OECD. Health at a Glance 2025.

and ultimately, patient outcomes and survival.

G. Determination of the GUARD Model Applicable International Benchmark (§§ 514.5 and § 514.410)

CMS proposes two methods for calculating the GUARD Model benchmark: 1) calculating the country-level average price for each refence country and selecting lowest of those prices, after adjusting for purchasing power parity (GDP), as the default benchmark; or 2) if the manufacturer submits net price data, calculating a volume-weighted average price across all reference countries. CMS also proposes to identify the set of international analogs for each GUARD Model drug based on active ingredients, dosage form, route of administration, and strength.

ACS CAN is concerned because, although prescription drugs may be approved in different countries, the labeled indication may differ depending upon the regulatory pathway under which the sponsor sought approval. A drug's approved indication has a bearing on the price under which the product will be reimbursed, and comparing a drug's reimbursement from one country to another fails to take this into account.

L. Quality and Monitoring Strategy (§ 514.720)

CMS proposes to use quality measures to monitor and evaluate the impact of the Model on quality of care. CMS proposes relying on claims-based measures and is considering including voluntary surveys of beneficiaries. Proposed measures may include Part D drug utilization, beneficiary out-of-pocket costs, changes in Part D plan premiums, changes in drug formularies and tiering, medication adherence, and patient experience (e.g., medication access, refills, and communication with prescribers).

ACS CAN reiterates the importance of closely monitoring beneficiary access and quality of care under the Model. ACS CAN appreciates that the proposed rule outlines the agency's intent to evaluate the quality of care delivered. We strongly urge CMS to devote resources to utilize real-time claims data to ensure that beneficiaries' access to oncology medications is not hindered – including monitoring the extent to which beneficiaries are unable to access their oncology services in a timely manner. Quality measures by definition measure care that was already provided and that reporting is often delayed because the required process – including data collection, data cleaning, and validation – can be time intensive, undermining both its accuracy and timeliness. Quality measures may not be able to identify emergent issues such as beneficiary access problems.

Therefore, while quality measures are important in making a post-hoc review of a new proposal, if and when CMS implements this model, we urge the agency to include patient-reported outcome measures and to implement a beneficiary survey to better understand how the Model affects patient access and overall quality of care.

CMS anticipates that manufacturers may respond to the Model by reducing rebates they pay to plans. As such, we are concerned that the Model may incentivize plans to restrict formularies or increase utilization management to offset lost revenue. We appreciate CMS's inclusion of formulary and tiering changes as a potential quality measure and strongly encourage CMS to prioritize this area, as utilization management practices can have significant consequences for patient access.

M. Beneficiary Protections and Compliance Related Activities (§ 514.710)

CMS proposes several options to support beneficiary protection –

Complaint Tracking Module (CTM): CMS proposes to record and track complaints submitted to CMS from beneficiaries related to the GUARD Model using the CTM.

ACS CAN is concerned about the limited transparency into beneficiary complaints related to the Model. CTMs are generated when a beneficiary contacts the 1-800-MEDICARE hotline or when a plan initiates a CTM. There is no GUARD Model-specific mechanism for beneficiaries to submit complaints, and CMS lacks visibility into complaints raised with plans unless the plan creates a CTM. We therefore encourage CMS to develop a more direct pathway for beneficiaries to submit complaints to CMS regarding the program so that these can be more directly addressed by the Model and to develop beneficiary education tools that clearly explain program protections and how to report program concerns.

Conducting Investigations: CMS proposes conducting investigations based on information submitted through the CTM to determine if any drug access issues are occurring.

ACS CAN is concerned about the lack of detail regarding CMS's plan for investigating beneficiary complaints received through CTMs. It is unclear how CMS plans to evaluate the severity and patterns of complaints and what standards will be used to determine whether access issues are occurring. We encourage CMS to outline the explicit contingency plan and actions it will take if the real-time evaluation reveals beneficiary access problems, including the timelines for response, specific actions CMS will take if beneficiary access issues are identified, and safeguards to prevent ongoing harm.

Research and Development: CMS states that it may consider examining any changes in drug innovation, research and development, timing of drugs coming to market, and launch prices.

ACS CAN is concerned about how the Model could hamper investment in research and development of novel, advanced therapies. While the overall cancer mortality rate continues to decline, there is still an enormous unmet need for the development of therapies to treat cancer. As such, we encourage CMS to clearly articulate how it will evaluate the Model's potential impacts on drug innovation and research and development.

N. Interaction and Coordination with Other Models and Programs

CMS outlines the plan to address model interactions –

Model Interactions: CMS did not identify any models that would have significant overlap with the GUARD Model. CMS also states that the GUARD Model avoids significant interaction with the Medicare Drug Price Negotiation Program by excluding drugs with a Maximum Fair Price (MFP) in effect. CMS seeks comment on the proposed approach to addressing overlap between the GUARD Model and other programs.

ACS CAN is deeply concerned about the interaction between the GUARD Model, other CMMI models, and the Medicare Drug Price Negotiation Program. It is unclear how CMS plans to educate beneficiaries for the GLOBE and GUARD Models concurrently, particularly if the selected ZCTAs used in the models do not align, creating potential for confusion among beneficiaries and challenges in ensuring access to accurate information. Aside from excluding drugs selected for the Medicare Drug Price Negotiation

Program, the proposed rule does not address the potential impacts on beneficiaries or the market from implementing the programs concurrently. The purpose of the demonstration is to evaluate whether the GUARD Model can reduce costs for Medicare Part D beneficiaries while maintaining quality of care. However, accurately assessing the Model's effects on beneficiary affordability, access, and overall Medicare program savings is difficult when other factors are present that may influence the results. ACS CAN strongly urges CMS to clarify how the GUARD Model would interact with existing CMMI models and the Medicare Drug Price Negation Program, with particular attention to impacts on beneficiaries.

Additionally, the Consolidated Appropriations Act, 2026 included several provisions that establish new requirements for Part D plan sponsors' contracting with pharmacies and introduce substantial reforms affecting sponsors' relationships with pharmacy benefit managers (PBMs). These provisions – including the requirement that sponsors allow any pharmacy that meets standard contract terms to participate in their networks and the requirement that PBMs fully pass through rebates to Part D sponsors and comply with enhanced transparency and reporting standards – have the potential to significantly reshape the Medicare Part D program and were not considered in the development of the GUARD Model. As such, CMS should first implement the provisions required by the Consolidated Appropriations Act, 2026 before considering the implementation of any new drug pricing model within the Part D program.

Part D Market Impacts: CMS seeks feedback on the potential impact of the Model on the Part D market with respect to unintended changes to market competition, Part D plan benefit and network offerings, and Part D plan bids and premiums.

ACS CAN is concerned that the Model could prompt manufacturers to reduce the rebates they pay to plans, which could have significant implications for Part D plans. Reduced rebates could lead plans to tighten formularies and increase utilization management requirements, which can significantly impact patient access to lifesaving therapies. Additionally, plans could respond by submitting higher bids, and ultimately increase premiums for Medicare beneficiaries. We urge CMS to closely monitor potential increases in beneficiary out-of-pocket costs and changes in Part D plan benefit designs and offerings.

P. Limitations on Review (§ 514.720)

CMS proposes to deploy multiple mixed-method strategies to analyze quality of care and Medicare Part D drug spending under the GUARD Model, using data from manufacturers, providers, and beneficiaries. CMS is considering several populations of interest for this evaluation, such as beneficiaries who are likely to receive a GUARD Model drug based on recent diagnoses or other patient populations.

ACS CAN appreciates CMS's acknowledgement of the necessity of analyzing the impacts of the Model on population subgroups. We encourage CMS to assess the specific impacts of the Model on drug access and patient out-of-pocket costs, particularly for populations with complex care needs. Cancer patients often rely on complex, tailored treatment regimens that require timely access to therapies and coordinated care. Cancer is not just one disease – it is more than 200 different diseases. As such, cancer treatment often requires access to specialized treatment. Even more common cancers like breast cancer have many different treatment options. Given this complexity, CMS will need to ensure

that its evaluation is robust and considers the unique treatment needs of this patient population. We urge CMS to specifically evaluate the Model's impact on beneficiaries with cancer diagnoses, including any effects on access to treatments, continuity of care, and out-of-pocket costs. In addition, we support CMS's plan to assess the Model's market impact by evaluating its effect on the Part D market and plans, including potential changes to formulary design, benefit structures, and cost-sharing requirements.

V. Collection of Information Requirements

VI. Regulatory Impact Analysis

D. Estimated Impacts of the Proposal

According to CMS's own estimates, the Model will generate $14.1 billion in savings for the Medicare Trust Fund[16] but will increase Part D enrollee costs by $3.6 billion over the Model's duration, including $3 billion in higher cost sharing and $600 million in increased premiums.[17] CMS's estimate of Part D enrollee costs assumes that the change in manufacturer negotiations for the Medicare Drug Price Negotiations will impact beneficiaries' cost sharing due to higher point-of-sale prices and will also impact beneficiary premiums after the end of the Inflation Reduction Act (IRA)'s premium stabilization provisions.

ACS CAN is deeply concerned that the Model is predicted to increase both cost sharing and premiums for Part D enrollees, particularly given that CMS cites financial toxicity among the Medicare population as a primary justification for the Model. Many Medicare beneficiaries live on fixed or limited incomes and already struggle to cover basic living expenses, making it difficult to absorb high out-of-pocket costs at the pharmacy. These added costs can force patients to forego or delay taking critical medications. This burden is especially pronounced for cancer patients and survivors who are particularly vulnerable to high prescription drug costs, with 65 percent expressing concern about their ability to afford the medications they need.[18] Any policy intended to address drug affordability should deliver meaningful financial relief to beneficiaries, not worsen cost barriers. These concerns are exacerbated by the likelihood of larger premium increases after 2029, when the cap on average Part D base premium growth established by the IRA is set to expire.

While ACS CAN supports efforts to achieve savings for the Medicare program, we strongly oppose models that generate savings by shifting costs from the Medicare program to beneficiaries, especially individuals with chronic conditions such as cancer. We are particularly concerned about the risk that the savings could be achieved through increased utilization management and restricted formularies as a direct consequence of the Model. Utilization management in oncology can have serious unintended consequences for patients, including delays in access to medically necessary treatments and imposing substantial administrative burdens on patients. Restrictive formularies also create barriers to clinically

[16] 90 Fed. Reg. at 60411 (Table C4).
[17] Id. (Table C5).
[18] American Cancer Society Cancer Action Network. Survivor Views Cancer & Medical Debt. February 2022 Survey Findings Summary. Available from https://www.fightcancer.org/sites/default/files/national_documents/survivor_views_cancer_debt_0.pdf.

appropriate treatment and force patients to bear additional costs to obtain the therapy best suited for their care. It is essential that beneficiaries with cancer can access the right medication as quickly as possible to avoid preventable disease progression. The projected increases in beneficiary costs and risks to patient access raise substantial concerns regarding implementation of the GUARD Model, and we believe these potential harms warrant further assessment by CMS before proceeding with implementing the proposed rule.

CONCLUSION

Thank you for the opportunity to comment on the Guarding U.S. Against Rising Drug Costs (GUARD) Model. If you have any questions, please feel free to contact me or have your staff contact Allie Babyak, Policy Fellow, Access to Care and Prescription Drugs at Allie.Babyak@cancer.org.

Sincerely,

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