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-5545-P – Global Benchmark for Efficient Drug Pricing (GLOBE) Model
90 Fed. Reg. 60244 (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 Global Benchmark for Efficient Drug Pricing (GLOBE) 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 GLOBE Model demonstration would require pharmaceutical manufacturers of selected drugs to pay rebates for Medicare Part B 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. ACS CAN greatly appreciates the intent of the Model, which is to address the increasing cost of Medicare Part B prescription drugs while preserving and enhancing Medicare beneficiaries' quality of care. As discussed in more detail below, the Model represents a fundamental shift in the Part B program and would particularly impact oncology care. According to the Centers for Medicare & Medicaid Services (CMS), almost 40 percent of the top 50 percent of Part B drugs are used in oncology.[1]

ACS CAN has a number of questions about the operationalization of the Model and its potential downstream impact as it relates to oncology care. We caution that the proposed implementation date of October 1, 2026, provides the agency limited time to address these issues and urge the agency to postpone implementation of the Model until the below questions are resolved.

II. Provisions of the Proposed Regulations

A. Proposed Model Test Period (§§513.100 and 513.200)

CMS proposes that the GLOBE Model would have a seven-year test period with five performance years beginning October 1, 2026, and ending September 30, 2031.

ACS CAN is deeply concerned that the implementation timeline would be difficult to meet given the magnitude and complexity of the proposed Model. If the Model test period begins on October 1, 2026

[1] 90 Fed. Reg. at 60253 (Table 2).

(as stated in the proposed rule) and the final rule must be displayed at least 60 days prior to the effective date[2,3], this would leave CMS a very limited window to review and synthesize all the stakeholder comments, make 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 little opportunity to develop and implement a beneficiary educational campaign, which is vitally important to inform beneficiaries about the Model and to explain how to report access issues. As detailed in the proposed rule, CMS would rely on beneficiary complaints to monitor compliance and protect access.

CMS proposes to implement the GLOBE Model concurrently with the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (which impacts the Part D program), 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.

A tight timeline increases the risk of beneficiary confusion and creates 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 GLOBE Model cannot begin until the Model is finalized, yet the proposed timeframe does not allow sufficient time to educate beneficiaries, physicians, and manufacturers or to ensure appropriate beneficiary protections are in place.

B. Proposed GLOBE Model Drugs (§513.130)

CMS proposes a number of criteria related to determining drugs eligible for the Model:

Selected Drug Categories: CMS proposes to identify the single-source drugs and biologic products in the following drug categories: antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, and ophthalmic agents.

ACS CAN questions the operationalization of the Model and the cumulative impact of concurrent models. We are concerned that implementing such change, particularly given the implementation timeline, may result in unintended consequences that could negatively impact cancer patients' ability to access medically necessary prescription drugs, such as antineoplastics for cancer treatment, in a timely manner. Medicare beneficiaries living with cancer rely on oncology drug therapies for life-saving treatment, and any payment model intended to reduce prescription drug spending must not impede beneficiary access to these therapies. Inclusion of a drug in the Model could result in its manufacturer limiting production of that drug to avoid reducing prices or facing high rebates, increasing risk of a shortage. Individuals with cancer need regular access to care and cancer treatment services, and when

[2] We note that it can often take days – if not weeks – for a display copy of a rule to be published in the *Federal Register*. At the very least, any deadlines should be imposed based on the date of publication in the *Federal Register* and not the availability of the display of the rule.
[3] 5 U.S.C. 801a-3.

that access is disrupted, the effectiveness of the treatment could be jeopardized, and the individual's chance of survival could be significantly reduced. Alternative treatments may not be as efficacious, and postponing or forgoing treatment could result in negative health outcomes and even death for the beneficiary. Therefore, if CMS were to pursue the Model at the proposed timeline, we would urge the agency to at least exclude oncology drugs from the selected drug categories.

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 GLOBE Model on beneficiaries with rare diseases, including rare cancers. Congress saw fit to exempt these drugs from price negotiations under the Medicare Drug Price Negotiation Program because of a recognition that models addressing drug pricing have the potential to impact patient access, and for many patients with rare diseases, including rare cancers, these drugs are the only viable treatment option.[4] We encourage CMS to adopt a similar exemption for the GLOBE Model if the Model is implemented.

Cell and Gene Therapies: CMS is considering excluding cell and gene therapies, as well as plasma-derived products, from the GLOBE Model and seeks comments on factors that warrant their inclusion or exclusion.

ACS CAN strongly urges the agency to exclude cell and gene therapies from the Model. These therapies have revolutionized cancer treatment by altering a specific patient's cells or genes to help target that patient's cancer cells, enabling treatment of cancers previously thought to be untreatable and serving as an alternative to existing treatments. Additionally, their preparation and administration often require very site-specific infrastructure, invalidating cost comparisons with other countries. Including these therapies in the Model could undermine incentives for continued research and development, ultimately limiting patient access to these innovative, tailored treatments.

C. Proposed Defined Population (§513.120)

CMS proposes that the cohort of beneficiaries must have traditional Medicare Part B as their primary payer and must not be enrolled in a Medicare Advantage plan, Section 1876 cost plan, or Section 1833 healthcare prepayment plan. Beneficiaries must not have other group coverage that is a primary provider and be identified by CMS for inclusion in the Model based on the beneficiary's address.

ACS CAN questions the downstream impact of this approach. Excluding beneficiaries who are enrolled in the Medicare Advantage program (which encompasses more than half of all beneficiaries) further exacerbates the inequities between beneficiaries who are enrolled in traditional Medicare versus those enrolled in a Medicare Advantage plan. We fear that some beneficiaries who may have concerns about maintaining access to their prescription drugs might use the Model as a reason to enroll in a Medicare Advantage plan, which would have long-term implications for the stability of traditional Medicare and beneficiaries may encounter significant barriers if they choose to later return to traditional Medicare.

It is also unclear the extent to which the Model will impact Medigap programs. Approximately 20

[4] 42 U.S.C 1320f.

percent of Medicare beneficiaries opt to enroll in a Medigap plan.[5] Significantly altering the payment structure for selected prescription drugs covered under the Part B program will have actuarial implications for Medigap plans because Medigap plans' liabilities change when Medicare alters beneficiary cost sharing. Before CMS embarks on such a fundamental shift, we urge CMS to provide additional information about how the Model will impact Medigap plans and urge CMS to seek input from stakeholders, including the National Association of Insurance Commissioners (NAIC).

F. Proposed GLOBE Model Test Design and Geographic Areas (§513.110)

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 GLOBE Model geographic areas. Beneficiaries would be identified as a GLOBE Model beneficiary if their address of residence is in one of the chosen ZCTAs.

ACS CAN has questions regarding the operationalization of the GLOBE Model related to the ZCTAs. If, as the Model intends, the Zip Code of the beneficiary's residence is used as the selection criteria, beneficiaries who travel outside their immediate residence may encounter problems. Some beneficiaries maintain multiple residences, seasonally relocate, or may receive care outside of the ZIP Code associated with their primary residence. It is conceivable that providers who practice in an area that is not subject to the GLOBE Model may be unaware of the reduced cost sharing provided to beneficiaries who are assigned to the Model. Cancer patients often travel to receive specialized care. If a beneficiary were to seek care outside the immediate vicinity of their residence, they may be charged traditional cost sharing (20 percent of allowable charges), rather than the reduced cost sharing envisioned under the Model. The provider would later have to undergo a reconciliation process and refund the beneficiary the difference between the Medicare-allowed amount and the cost sharing as provided under the Model. This can create confusion and an administrative burden on patients and providers.

G. Proposed Model Payment Test for GLOBE Model Drugs (§§513.310, 513.410, 513.430, 513.510, 513.520, 513.600, 513.610, and 513.620)

CMS proposes several steps in calculating the GLOBE Model benchmark, including:

Identifying Reference Countries: 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, the Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. CMS then proposes two methods for calculating the GLOBE Model benchmark: 1) calculating the country-level average price for each reference country and selecting the 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.

[5] MedPAC, *Medicare Beneficiary Demographics*, July 2025 Data Book, Section 2 (2025) https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_Sec2_SEC.pdf.

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 – Quality Adjusted Life Years (QALYs) when evaluating a drug's cost effectiveness.[6] 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 when determining coverage or reimbursement.[7] Importing drug prices from countries that rely on QALYs would effectively apply these harmful measures 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.[8,9] These disparities reflect, in part, differences in access to life-saving treatments, and any model that incorporates international reference pricing, including the GLOBE Model, must carefully consider how pricing changes could impact access, and ultimately, patient outcomes and survival.

Identifying International Analogs: CMS proposes to identify the set of international analogs for each GLOBE Model drug based on scientific or nonproprietary name, dosage form, and route of administration.

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

---

[6] 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/.
[7] 42 U.S.C. 1320e-1.
[8] 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.
[9] OECD. Health at a Glance 2025.

into account.

J. Proposed Quality Measures

CMS proposes to use quality measures to monitor and evaluate the impact of the Model on quality of care. CMS proposes to rely on claims-based measures and is considering including voluntary surveys of providers who administer Part B drugs, as well as a beneficiary survey. Proposed measures may include Part B drug utilization, beneficiary out-of-pocket costs, frequency of drug administration, changes in site of service, changes in prescriber, and downstream health care utilization.

ACS CAN appreciates that the proposed rule outlines the agency's intent to evaluate the quality of care delivered under the Model. However, quality measures by definition measure care that was already provided, covering a far broader range of aspects of care delivery that will not achieve the stated goal. Moreover, quality measure 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 are unlikely 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 to care and overall quality.

K. Proposed Beneficiary Protections

CMS proposes several options to support beneficiary protection:

Reporting System: CMS is considering the creation of a GLOBE Model reporting system that would allow beneficiaries and providers to notify the agency of difficulties obtaining specific drugs. CMS is also considering sending letters to eligible GLOBE Model beneficiaries with instructions on how to submit reports.

While we appreciate efforts to enable beneficiary reporting, ACS CAN is concerned that the proposed reporting system is limited to drug access issues and does not propose to capture other types of beneficiary complaints, particularly in light of our concerns regarding the proposed use of the existing Medicare appeals process described below. CMS should not rely on beneficiary reporting alone to determine whether access problems exist.

In addition, we urge CMS to develop clear beneficiary education tools that explain how the Model operates and outline beneficiary protections, and we encourage CMS to tailor the educational tools to the Medicare population and to provide multiple, accessible avenues for reporting issues. Such educational efforts will take time, and we urge the agency to undergo robust outreach to stakeholders in developing the beneficiary education tools. Once these tools have been developed, CMS will need significant time to fully implement them.

Conducting Investigations: CMS proposes conducting investigations based on information submitted through the reporting system, which may include requesting additional information and determining whether further action by CMS or other governmental entities is warranted.

ACS CAN is concerned about the lack of detail regarding CMS's plan for investigating beneficiary complaints. We encourage CMS to outline the explicit contingency plan and actions it will take if the real-time evaluation reveals beneficiary access problems. Although diversionary practices could occur regardless of the geographic unit, we urge CMS to establish safeguards to ensure that beneficiaries are not steered to a particular site of care depending on the reimbursement structure under the GLOBE Model.

Beneficiary Opt-Out: CMS considered including a beneficiary opt-out within the GLOBE Model as an additional protection but ultimately decided not to implement it. CMS seeks comments on this decision, noting that beneficiaries will receive reduced coinsurance under the Model and that the Model is expected to have minimal impact on access.

While we appreciate CMS's efforts to address affordability, ACS CAN remains concerned that the proposed Model lacks sufficient patient-centered safeguards. Inclusion of a beneficiary's most appropriate therapy in the Model could disrupt established treatment plans, and CMS has not provided adequate information regarding plans to educate beneficiaries about the changes or how the agency will monitor and address beneficiary complaints. We strongly encourage CMS to establish a beneficiary opt-out process, as uninterrupted access to appropriate therapies is critical for cancer patients who often rely on individualized treatment regimens. Any policy that increases the risk of drug shortages or disruptions in access would be harmful for cancer patients.

L. Proposed Monitoring and Compliance Actions

CMS proposes to monitor changes to beneficiary access, including changes in site of service and prescriber, changes in drug list prices, and potential impacts on drug innovation and shortages. CMS also proposes to rely on the existing Medicare appeals process.

ACS CAN reiterates the importance of monitoring beneficiary access and quality of care under the Model. We strongly urge CMS to devote significant 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.

With respect to the appeals process, we note that beneficiaries historically underutilize their appeals rights. As a result, ACS CAN is concerned about beneficiaries' awareness of their ability to appeal decisions or submit complaints related to the Model. Given historically low utilization of the Medicare appeals process, we strongly urge CMS to undertake robust education and outreach efforts for both beneficiaries and providers, particularly regarding real-time monitoring and the appeals process. We also urge CMS to establish a process to use real-time data to actively monitor how beneficiaries engage with the review and appeals process.

M. Interaction with Other Models and Programs

CMS proposes not adjusting the GLOBE Model in cases where it overlaps with other models, programs, and initiatives. Instead, CMS proposes that other CMS Innovation Center models and CMS programs and initiatives, as determined by the agency, would adjust to accommodate the GLOBE Model test.

ACS CAN is concerned about the interaction between the GLOBE 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 GLOBE Model can reduce costs for Part B beneficiaries enrolled in the traditional program 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. Concurrent implementation also complicates the ability to accurately assess the impact of other CMMI models. ACS CAN strongly urges CMS to clarify how the GLOBE Model would interact with existing CMMI models and the Medicare Drug Price Negotiation Program, with particular attention to impacts on beneficiaries.

P. Evaluation

CMS proposes to conduct an evaluation that would analyze quality of care and Medicare spending under the GLOBE Model, using data from manufacturers, providers, and beneficiaries. CMS is considering several populations of interest for this evaluation, including those defined by recent diagnoses – including those diagnosed with cancer– and/or those likely to receive a GLOBE Model drug based on recent diagnoses, in order to understand the Model's impact on these beneficiaries.

ACS CAN appreciates CMS's acknowledgement of beneficiaries with cancer as a key patient population, particularly since oncology treatments are among those most affected by this model. 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.

CONCLUSION

Thank you for the opportunity to comment on the Global Benchmark for Efficient Drug Pricing (GLOBE) Model proposed rule. 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