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Proposed Rule: Global Benchmark for Efficient Drug Pricing (GLOBE) Model (CMS-5545-P)

January 7, 2026

Background & Key Takeaways

On December 19, 2025, the Centers for Medicare & Medicaid Services (CMS) issued the proposed rule, Global Benchmark for Efficient Drug Pricing (GLOBE) Model (hereinafter, "Proposed Rule"). Under the Proposed Rule, CMS, through the Center for Medicare and Medicaid Innovation (CMMI), will implement and test a new mandatory model in certain geographies that uses an alternative method for calculating Part B inflation rebate amounts for certain separately payable Part B drugs and biological products. CMMI is interested in determining whether the GLOBE Model will reduce costs for Medicare fee-for-service (FFS) beneficiaries and the Medicare program while preserving quality of care.

In addition, on December 19, 2025, CMS issued a separate proposed rule, "Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model". The GUARD Model is similar to the GLOBE Model, as it also tests an alternative payment method for calculating inflation rebates. However, the GUARD Model is limited to a subset of Part D rebatable drugs, among other differences. More information regarding the GUARD Model is available here.

Comments must be submitted by February 23, 2026. Vizient looks forward to working with clients to inform our letter to the agency.

Summary

To discourage manufacturers from increasing drug prices faster than the rate of inflation, the Inflation Reduction Act of 2022 (IRA) created the Medicare Part B Inflation Rebate Program ("Inflation Rebate Program"). Under the Inflation Rebate Program, if drug manufacturers raise prices for certain drugs faster than the rate of inflation for a calendar quarter, beginning with the first quarter of 2023, manufacturers must pay a rebate to the Medicare Part B account in the Federal Supplementary Medical Insurance Trust Fund while Medicare lowers beneficiary coinsurance amounts for applicable drugs accordingly. Under the GLOBE Model, CMS proposes to use international drug pricing information as a benchmark for an alternative Part B inflation rebate amount calculation for a subset for Medicare Part B rebatable drugs. CMS estimates that the GLOBE Model would result in overall savings of $11.9 billion in Medicare Part B net spending during the 7-year model.[1]

Proposed Model Test Period

CMS proposes a 7-year test period (7 payment years and 5 performance years[2]) for the GLOBE Model, beginning October 1, 2026. During the 5 performance years, monitoring activities would occur,

[1] CMS estimates that the GLOBE Model would result in overall savings of $11.9 billion in Medicare Part B net spending during the 7-year model, inclusive of $8.4 billion in Medicare Part B FFS, 7.5 billion in Medicare Advantage (MA) savings, and $4 billion in premium offset impacts. In this estimate, CMS assumes manufacturer behavioral changes and beneficiary utilization changes. Also, CMS estimates rate setting for 2028, and savings for the Medicaid program of around $1.0 billion, of which roughly $0.7 billion would be federal savings and roughly $0.3 billion would be state savings.4 When annualized over the 7-year period, we estimate that the GLOBE Model would result in overall cost savings in Medicare Part B FFS net spending of approximately $2.3 billion at both the 3 and 7 percent rates of discount.

[2] CMS proposes to define "performance year" as a 12-month period beginning on Octobre 1 and ending on September 30 during the first 5 years of the GLOBE Model test period.

while beneficiary coinsurance and adjusted payments to providers and suppliers would apply (as applicable). CMS proposes 7 payment years to include 2 payment years after the end of the final performance year to allow for rebate invoicing and reconciliation activities.

Proposed GLOBE Model Drugs

CMS proposes GLOBE Model drugs to include a set of Part B rebatable drug categories (single source and sole source biological products[3]) that are used to treat beneficiaries with conditions where access barriers (e.g., high costs) can negatively impact clinical outcomes and increase costs. As noted in Table 3 of the Proposed Rule (pg. 11), CMS aims to include the following non-exhaustive list of U.S. Pharmacopeia (USP) Drug Classification (DC)[4] categories when selecting GLOBE Model drugs: Antigout Agents; Antineoplastics; Blood Products and Modifiers; Central Nervous System Agents; Immunological Agents; Metabolic Bone Disease Agents; and Ophthalmic Agents. These seven categories represent 21 percent of the 34 possible Medicare Part B rebatable drug categories but most Part B spending (91 percent), according to CMS.

Also, CMS proposes that drugs eligible for the GLOBE Model must also have Medicare Part B FFS spending greater than $100 million over a 12-month period[5] and those that do not meet the proposed exclusion criteria.[6] For example, one of the exclusion criteria is drugs selected for the Medicare Drug Price Negotiation Program, for which a Maximum Fair Price (MFP) has been agreed upon and for which the manufacturer is required to provide access to the MFP. As proposed, the drug in that circumstance would be excluded from the GLOBE Model for the calendar quarters that MFP is in effect.

Table 4 of the Proposed Rule (pg. 17-18) provides an illustrative list of proposed performance year 1 GLOBE model drugs and model participants based on the agency's initial analysis. CMS indicates it will identify GLOBE Model Drugs and add them to the GLOBE Model Drug List (to be made available on the GLOBE Model web page). The GLOBE Model Drug List would be maintained quarterly to add and remove drugs, as appropriate.

Considerations Related to Cell and Gene Therapies and Plasma-Derived Products

Although not proposed, CMS indicates it is considering excluding cell and gene therapies (CGTs) from the GLOBE Model. **CMS seeks comments on the merits of excluding CGTs based on supply chain criteria, or if there are other factors that warrant their inclusion or exclusion.**

Also, CMS requests feedback on whether the GLOBE Model would exclude plasma-derived products, particularly because, according to CMS, these products may be more likely to

[3] Sole source biological means a biological product licensed by the FDA in under a BLA under section 351(a) of the PHS Act and that, at time of evaluating for inclusion into the GLOBE Model for each applicable ASP calendar quarter, is not the reference biological product, as defined in section 1847A(c)(6)(I) of the Act, for a biosimilar biological product licensed by the FDA in a BLA under section 351(k) of the PHSA Act. The biosimilar biological product must be recognized in the FDA's Purple Book and be identified as sold or marketed in FDA's NDC Directory. At the time of evaluating inclusion in the GLOBE Model for each applicable ASP calendar quarter, CMS uses FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to identify whether the biosimilar biological product is being sold or marketed for purposes of the GLOBE Model.

[4] The USP Drug Classification 2025 file can be found here: https://www.usp.org/health-qualitysafety/usp-drug-classification-system.

[5] CMS also proposes that Part B rebatable drugs would need to meet the spend threshold at least one time during the duration of the GLOBE Model to meet this criterion for the applicable ASP calendar quarter and subsequent applicable ASP calendar quarters

[6] CMS proposes that the following are excluded from the GLOBE Model: (i) A Part B rebatable drug for applicable calendar quarters prior to the first applicable calendar quarter for which CMS identifies a specified amount under 42 CFR 427.302(b). (ii) A Part B rebatable drug for which a maximum fair price under the Medicare Drug Price Negotiation Program is in effect. (iii) A drug or biological product that is no longer a Part B rebatable drug during the duration of the GLOBE Model is removed for the applicable calendar quarter in which it is no longer a Part B rebatable drug.

experience shortages and therefore, the rebate amount for these products may be reduced based on the existing Inflation Rebate Program and as proposed in the GLOBE Model.

Proposed Defined Population

CMS proposes that, prior to the model start, the agency would randomly identify the model geographic areas (based on ZIP Code Tabulation Areas). To determine the geographic areas that CMS would use as GLOBE Model eligible beneficiaries, CMS proposes to select geographic regions to represent 25 percent of Medicare FFS beneficiaries.

Also, prior to the model start and periodically thereafter, CMS would identify eligible Medicare FFS beneficiaries and update the GLOBE Model Eligible Beneficiary List, which would be effective when the Medicare claims processing system is updated with the GLOBE Model Eligible Beneficiary List information. CMS proposes various beneficiary exclusions, such as beneficiaries who do not have Medicare Part B FFS as their primary payer, and beneficiaries who are enrolled in a Medicare Advantage plan.

Proposed Model Participants

CMS proposes that model participation would be mandatory for all manufacturers of GLOBE Model drugs that are furnished to a GLOBE Model beneficiary during the GLOBE Model performance period. CMS proposes that there would be no specific enrollment activities for GLOBE Model participants; rather, their participation would be effectuated by the requirements under the Medicare Part B Drug Inflation Rebate Program, and where applicable, the application of the proposed GLOBE Model calculation for the GLOBE Model rebate amount. CMS seeks comments on factors CMS could consider in exempting certain manufacturers while maintaining sufficient model participation. **CMS seeks feedback on whether manufacturers would voluntarily participate in the proposed GLOBE Model absent a mandatory participation requirement. Also, CMS seeks feedback on evidence that could support a voluntary participation approach which would ensure sufficient model participation for a robust model test and evaluation during performance year 1 and thereafter.**

CMS also proposes various requirements for model participants (e.g., adherence to proposed GLOBE Model repayment instructions; participation in monitoring and evaluation activities and additional requirements if electing to submit international drug net pricing data). In addition, CMS proposes specific audit, record access and retention requirements for manufacturers participating in the GLOBE Model.

Proposed Criteria and Process for Identifying and the Set of Reference Countries

CMS proposes criteria and a process that the agency would use to identify the non-U.S. countries that would be included in the set of reference countries for purposes of identifying international drug pricing information available in existing data sources and calculating the per unit Method I Globe Model benchmark. Additional information regarding the criteria and process is in the Proposed Rule (pg. 27-30). Based on the agency's analysis using data that were available on October 1, 2025 from the United States Central Intelligence Agency (CIA) World Factbook, CMS identified the following potential set of reference countries for the model: Australia, Austria, Belgium, Canada, Czechia, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. **CMS welcomes comments on the criteria and process for identifying the set of reference countries, including comments on the timing that would be necessary to operationalize a change to the set of reference countries that would minimize impacts on the GLOBE Model.**

Proposed Model Payment Test for GLOBE Model Drugs

For GLOBE Model drugs furnished to GLOBE Model beneficiaries, CMS proposes to test an alternative rebate calculation and an alternative calculation to adjust the beneficiary coinsurance and Medicare Part B payment. CMS clarifies that these alternative calculations would expand upon the current Inflation Rebate Program methodology by incorporating additional drug pricing information.

CMS proposes to base the alternative rebate calculation on a per unit GLOBE Model benchmark which would be determined using two potential methods (Method I Globe Model benchmark or Method II Globe Model benchmark). CMS indicates it would compare the per unit benchmark for each method, if available, and the greater of the two would be identified as the per unit GLOBE Model benchmark for the GLOBE Model drug for the applicable calendar quarter.

- **Method I:** The per unit Method I Globe Model benchmark would be determined using existing data sources and would reflect the Gross Domestic Product (GDP) Purchasing Power Parity (PPP)[7] adjusted lowest country level price among a set of reference countries. To identify the per unit Method I GLOBE Model benchmark, CMS proposes to rely on existing data sources available (e.g., IQVIA MIDAS, GlobalData Pharmaceutical Prices (POLI), Eversana NAVLIN's Price & Access database) to CMS that contain international drug pricing information, including pricing information, sales and/or volume data (for example, package size and number of items or packages sold), as available. CMS indicates that "Confidential manufacturer rebates would not likely be accounted for within these available data sources; therefore, existing sources for international drug sales data may overstate actual prices realized by manufacturers." Addiitonal information regarding the data sources CMS is considering and proposed hierarchy for using existing data sources is available in the Proposed Rule (pg. 24-26). **CMS seeks comments on existing data sources for international drug pricing information that may be available to CMS and steps CMS could follow to best use such data sources for the GLOBE Model payment test.**
- **Method II:** The per unit Method II Globe Model benchmark would involve the manufacturer electing to submit international drug net pricing data. This benchmark would reflect the volume-weighted average of the GDP (PPP)-adjusted manufacturer's international drug net pricing for sales among a set of reference countries for the applicable ASP calendar quarter.[8] CMS proposes that manufacturers electing Method II would be required to execute a data agreement that must be effective prior to the manufacturer's first submission of voluntary international drug net pricing data. The data agreement would establish terms, conditions and requirements, including data completeness and validity requirements, and compliance responsibilities. CMS also proposes to conduct a verification review for validity to determine whether a manufacturer's submission meets the Proposed Rule's submission requirements.

For both Method I and Method II, CMS proposes to increase the per unit GLOBE Model benchmark by an applicable threshold percentage (102 and 105 respectively) to account for potential differences between the U.S. market and reference countries' markets. CMS believes a lower applicable threshold is appropriate for the Method I benchmark since it relies on the lowest country level prices, which do not reflect the full range of discounts and net pricing, unlike the Method II benchmark.

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[7] GDP (PPP) means purchasing power parity (PPP)-adjusted per capita GDP.
[8] Additional information regarding the proposed reporting requirements and process for voluntary manufacturer-provided data is in the Proposed Rule (pg. 44-53).

CMS also proposes to increase the per unit GLOBE Model benchmark by the add-on percentage amount that is included in the specified amount.[9] For example, if the per unit volume-weighted average sales price for a drug for an appliable calendar quarter is $100 and the 6 percent add-on applies, the statutory add-on amount per unit would be $6 and CMS would add $6 in the calculation of the per unit GLOBE Model benchmark amount.

Additional details regarding the proposed data and methodology for the Gross Domestic Product (GDP) (PPP) adjuster[10] and methodology to identify the per unit GLOBE Model benchmark for Method I and Method II are in the Proposed Rule (pg. 30-36).

The per unit GLOBE Model benchmark is used in the calculation of the per unit GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter. The proposed methodology for calculating the per unit GLOBE Model rebate amount, incremental per unit GLOBE Model rebate amount[11] and total GLOBE Model Rebate amount, among other metrics, is available in the Proposed Rule (pg. 39-41).

Also, CMS proposes to reduce the incremental GLOBE Model rebate amount for GLOBE Model drugs in shortage and when there is a severe supply chain disruption (Proposed Rule pg. 43-44). This proposal is similar to the framework for drugs in shortage and when there is a severe supply chain disruption in the Inflation Rebate Program.

Proposed GLOBE Model Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for GLOBE Model Drugs

Currently, for a separately payable Part B drug, the basic allowable charges that a participating provider or supplier may charge a beneficiary are the Part B annual deductible and 20 percent (i.e. coinsurance) of the Medicare allowed amount in excess of that deductible, subject to certain limitations. For a Part B rebatable drug, the basic allowable charges that a participating provider or supplier may charge a beneficiary are the Part B annual deductible and 20 percent of the inflation-adjusted payment amount for the rebatable drug in excess of that deductible, which is applied as a percent to the payment amount for such calendar quarter. For the GLOBE Model, CMS proposes to calculate the beneficiary coinsurance adjustment for GLOBE Model drugs using a methodology that is similar to the coinsurance adjustment under the Medicare Part B Drug Inflation Rebate Program.

However, CMS does propose to test an alternative calculation for beneficiary coinsurance for GLOBE Model eligible beneficiaries who receive a GLOBE Model drug for which separate Medicare Part B payment is allowed. Specifically, for a GLOBE Model drug for an applicable calendar quarter, to determine if the GLOBE Model beneficiary coinsurance adjustment applies, CMS would compare the provider payment amount (CMS would use the published payment amount in quarterly pricing files published by CMS as the payment amount in this determination) to the per unit GLOBE Model benchmark amount. CMS proposes the following two scenarios related to coinsurance and an illustrative example is provided in the Table 6 of the Proposed Rule (pg. 42):

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[9] The specified amount is determined based on 42 CFR 427.302(b).
[10] CMS proposes to use the following calculation to determine the GDP (PPP) adjuster: divide the U.S. real GDP per capita by the country's real GDP per capita and round the result to the third decimal place. In calculating the GDP (PPP) adjuster CMS proposes to apply the following limitations: (1) the country's real GDP per capita and U.S. real GDP per capita data from the same year; and (2) the real GDP per capita used must be for the same year as the data used to calculate the per unit country-level price (as defined in 42 CFR 513.410), or the most recent earlier year available; and (3) in cases where the resulting ratio is less than 1.000, the GDP (PPP) adjuster is set to 1.000.
[11] The incremental GLOBE Model rebate amount for a GLOBE Model drug for an applicable calendar quarter is equal to the product of the incremental per unit GLOBE Model rebate amount of such drug, as determined under § 513.510(b), and the total number of GLOBE Model billing units, as identified by CMS as set forth in § 513.520.

- If the payment amount exceeds the per unit GLOBE Model benchmark amount, the GLOBE Model beneficiary coinsurance adjustment would apply. In this scenario, the GLOBE Model beneficiary coinsurance would be calculated by multiplying the per unit GLOBE Model benchmark amount by 0.20. To apply this amount as a percent to the payment amount for an applicable calendar quarter, CMS proposes to then calculate the GLOBE Model beneficiary coinsurance percentage by dividing the result by the payment amount and rounding the result to the third decimal place.
- If the payment amount does not exceed the per unit GLOBE Model benchmark amount, CMS proposes that the GLOBE Model beneficiary coinsurance adjustment would not apply. In such cases, the GLOBE Model beneficiary coinsurance percentage would be calculated using the non-Model coinsurance.

CMS would determine and apply the GLOBE Model beneficiary coinsurance percentage to the payment amount when processing a claim for a separately payable GLOBE Model drug that was furnished to a GLOBE Model eligible beneficiary on a date of service within the applicable calendar quarter. CMS's calculation and application of the GLOBE Model beneficiary coinsurance percentage would not be subject to appeal.

Also, CMS proposes adjusting the Medicare payment to the provider or supplier for a separately payable GLOBE Model drug claim. To clarify, CMS proposes that the Medicare payment amount (the adjusted Medicare payment amount) would be equal to the allowed amount for the GLOBE Model drug minus the product of the GLOBE Model beneficiary coinsurance percentage and the allowed amount, assuming no other claim adjustment applies.[12] **CMS welcomes comments on this proposed approach.**

Proposed Payment Responsibilities

CMS proposes that the manufacturer of a GLOBE Model drug would be responsible for all GLOBE Model rebate payments for each applicable GLOBE Model drug. CMS proposes that manufacturers of GLOBE Model drugs with a total GLOBE Model rebate amount due of $0 or greater would be provided a rebate report which would serve as an invoice for the total GLOBE Model rebate amount due, using an incremental GLOBE Model rebate amount. In addition, CMS proposes to include the total GLOBE Model rebate amount and incremental GLOBE Model rebate amount in either the Preliminary Rebate Report and Rebate Report provided to the manufacturer (which would be the same rebate reports used for the Medicare Part B Drug Inflation Rebate Program) or in separate Preliminary GLOBE Model Rebate Report and GLOBE Model Rebate Report that CMS would provide to the manufacturer.

When there are multiple manufacturers linked to a single HCPCS Level II code for a GLOBE Model drug, CMS proposes to apportion the incremental GLOBE Model rebate amount, as appliable.

Proposed Program Compliance Requirements, Enforcement and Collection of GLOBE Model Rebate Amounts

CMS proposes policies related to enforcement of GLOBE Model rebate payments, civil monetary penalties and appeals procedures. CMS also notes that is could impose one or more enforcement actions (e.g., suspending or terminating the data agreement with the manufacturer; requiring

[12] For example, if the Medicare Part B allowed amount under the GLOBE Model is $100 and the GLOBE Model beneficiary coinsurance percentage is 10 percent (instead of the usual 20 percent), the Medicare Part B program payment to the provider or supplier would be adjusted and would be $90 (instead of the usual $80) and the beneficiary financial responsibility would be $10. The formula in this example is $100-(0.100 × $100) = $90.

additional information from the manufacturer; subjecting the manufacturer to additional monitoring, auditing, or both) for certain actions (e.g., submitting false data, being under investigation or action by HHS or the Department of Justice due to an allegation of fraud or significant misconduct).

In addition, CMS proposes systems collect GLOBE Model rebate amounts that align with those established under the Medicare Part B Drug Inflation Rebate Program. CMS proposes that the date of the receipt of the Rebate Report would be the calendar day following the day on which a report of a GLOBE Model rebate amount is made available to the manufacturer of a GLOBE Model drug by CMS. Payment is due 30 days after the date of the receipt of the Rebate Report.

Regarding monitoring and compliance, CMS indicates it intends to monitor major changes in beneficiary access, as viewed through changes in site of care, provider and quality measures, as discussed below. In addition, if, during implementation of the proposed GLOBE Model, CMS observes unintended impacts on beneficiaries or model operations (e.g., in GLOBE Model geographic areas there is an increase in Part D utilization of clinician-administered drugs), CMS intends to propose appropriate operational adjustments to the GLOBE Model through notice and comment rulemaking. CMS also proposes to collaborate with the Food & Drug Administration (FDA) to review shortage lists and determine whether the number of drugs or length of time on the shortage list changes over time.

Proposed Quality Measures

CMS proposes utilizing quality measures to monitor and evaluate whether quality of care, including as measured through patient-level outcomes, changes due to the proposed alternative Part B inflation rebate amount calculation approach for GLOBE Model drugs. CMS also noted it will consider Part B drug utilization and prescribing patterns, out-of-pocket costs for administered Part B drugs, changes in site of service and downstream healthcare utilization (e.g., hospitalizations or emergency room visits). CMS indicates that it may supplement claims-based measures with voluntary surveys to providers who administer Part B drugs to assess variables such as site of service of administration of clinician-administered drugs, prescribing changes and interactions between patient and prescriber. CMS may also implement a beneficiary survey. CMS clarifies that payments to manufacturers or providers would not be adjusted based on quality of care.

CMS welcomes comments on the proposed quality measures to monitor changes in the quality of care that may result from the alternative Part B inflation rebate calculation amount.

Proposed Beneficiary Protections

To help protect beneficiaries, CMS proposes developing a GLOBE Model reporting system open to providers and beneficiaries to notify CMS that a particular drug has become harder to source or obtain. CMS also aims to conduct investigations, as appropriate, based on information reported to the system. **CMS welcomes comments on a potential plan to build a GLOBE reporting and monitoring system for stakeholders and any other methods to protect beneficiaries.**

Interaction with Other Federal Programs

Regarding Medicaid, CMS does anticipate an impact on Medicaid “Best Price” as manufacturers seek to adjust prices to lower the amount of GLOBE Model rebates.

In addition, CMS anticipates Average Manufacturer Price (AMP) to decrease if the manufacturer lowers prices for GLOBE Model drugs. CMS provides that the resulting effect on the Medicaid drug rebate would depend upon the relationship of any AMP and best price changes. CMS also indicates that manufacturers would not include GLOBE Model rebates in the calculation of manufacturer’s average sale price, consistent with the Inflation Rebate Program.

Regarding the 340B Drug Pricing Program, CMS notes that billing units associated with claims for GLOBE Model drugs that are submitted with a 340B modifier and paid for under Part B would be excluded from the total GLOBE Model rebate amount. Regarding the 340B ceiling price, CMS notes that since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the proposed GLOBE Model may indirectly affect a drug's AMP and best price, the 340B prices would be affected.

CMS estimates that total Medicare Part B FFS savings would amount to $8.4 billion over the model test period (7 years), with an additional beneficiary premium savings of $1.4 billion. In addition, CMS indicates that if the ASP for a GLOBE Model drug exceeds the AMP for such drug, then 103 percent of AMP is substituted for ASP for reimbursement purposes. CMS also anticipates that manufacturers and providers would collaborate to increase the use of white-bagging, as drugs would be reimbursed under the Part D benefit, allowing the manufacturer to avoid owing a GLOBE Model rebate amount for those units.

For MA, CMS clarifies that the MA rate book calculations would reflect changes in actual FFS spending due to the impact of the GLOBE Model. As a result, MA benchmarks and bids may be lower and MA plans may reduce supplemental benefits and increase MA beneficiary out-of-pocket costs.

What's Next?

Comments on the Proposed Rule are due February 23, 2026.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued client feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.