Centers for Medicare & Medicaid Services

Center for Medicare and Medicaid Innovation

Seamless Care Models Group (SCMG)

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GENEROUS Model

(GENErating cost Reductions fOr U.S. Medicaid Model)

Request for Applications from Applicable Manufacturers

Version: 1.2

Last Modified: November 14, 2025

Contents

1. Background and General Information

1.1 Model Scope

The Centers for Medicare & Medicaid Services (CMS) is seeking applications for the voluntary Generating Cost Reductions for U.S. Medicaid Model (GENEROUS or "the model"). The model will test whether a CMS-led approach, in which manufacturers provide supplemental rebates to state Medicaid programs that result in Most Favored Nation (MFN) international pricing for a manufacturer's Covered Outpatient Drugs (CODs), reduces costs for the Medicaid program, while it preserves or enhances beneficiaries' quality of care, consistent with the purpose of model tests under Section 1115A of the Social Security Act (the Act).

This request for applications (RFA) is for pharmaceutical manufacturers that participate in the Medicaid Drug Rebate Program (MDRP)[1] and market U.S. Food & Drug Administration (FDA)-approved CODs (hereinafter, "manufacturers").[2] The RFA outlines model design elements, model eligibility criteria, and additional model details. Manufacturers who submit a timely and complete response to this RFA will be eligible to participate in negotiations with CMS under this model, and may, upon successful conclusion of negotiation, be eligible to become a model participant.

CMS anticipates issuing an RFA for interested states in December 2025. At this time, interested states can learn more about the model by accessing general information at the model website and reviewing the details contained in this RFA.[3] CMS looks forward to engaging with interested states in this model and application process.

1.1.1 General Approach

The Innovation Center is testing the impact of a voluntary model wherein CMS facilitates the provision of supplemental rebates between states[4] and manufacturers to effectuate MFN drug pricing for a manufacturer's CODs. Within this model, CMS will negotiate standard coverage criteria with manufacturers for each of their model drugs. Participating states will use these criteria to develop their Preferred Drug Lists (PDLs) as well as the utilization management criteria for the CODs.

Upon agreement regarding the standard coverage criteria terms and other terms (hereafter Key Terms) between CMS and the manufacturer, the manufacturer will enter into a participation agreement (PA) with CMS, and formally become a participant in the model. CMS will then communicate the agreed upon standardized Key Terms to all states, who may, at their option, execute a state PA with CMS, thus also becoming participants in the model. Participating states will adopt the Key Terms through a supplemental rebate agreement (SRA) with a participating

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[1] Under section 1927 of the Social Security Act.

[2] "Manufacturer" means an entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for a Covered Outpatient Drug.

[3] Additional information regarding the model may be found on the Model website, available here.

[4] "State" means any state, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate Program (MDRP). 42 CFR 447.502

manufacturer.[5] See Section 2.4 for a description of the legal relationships between CMS, manufacturers, and states.

CMS will support implementation of the model by facilitating the provision of manufacturer data to states to effectuate MFN pricing. In addition, the Innovation Center will conduct a robust model evaluation by an independent contractor. CMS will conduct monitoring activities to ensure compliance with all aspects of the model by states and manufacturers. These activities will focus on monitoring the impact of the model on drug spending, quality of care, access to medications and total health care costs. CMS retains the right to modify any model policy or parameter on an annual basis, or more frequently, in accordance with procedures to be agreed upon in the applicable agreement with the model participant (as described in Section 2.6). CMS may modify the terms of the model or cancel it entirely. The terms set forth in this RFA may differ from the terms set forth in the finalized PAs for the model test.

The Innovation Center is testing this model for five performance years, beginning on a rolling basis on January 1, 2026, and ending on December 31, 2030. The model is limited to manufacturers of single source and innovator multiple source CODs that have a signed rebate agreement with the Secretary of HHS under Section 1927 of the Act. Additional information regarding the model timeline is set forth in Section 5.4.

1.2 Statutory Authority

The authority for the model is Section 1115A of the Act (42 U.S.C. § 1315a, added by section 3021 of the Patient Protection and Affordable Care Act). Section 1115A of the Act authorizes CMS to test innovative healthcare payment and service delivery models that have the potential to lower Medicare, Medicaid, and CHIP spending while maintaining or improving the quality of beneficiaries' care.

Section 1115A(b)(4) of the Act requires the Innovation Center to evaluate changes in federal spending and quality of care (including patient-level outcomes and patient-centeredness criteria) in each model. The Secretary of HHS is authorized to expand the scope and duration of successful models, through rulemaking, that reduce spending without reducing quality of care, or that improve the quality of patient care without increasing spending, if such expansion would not deny or limit provision of benefits for the applicable individuals.[6]

Under section 1115A(d)(1) of the Act, the Secretary of HHS may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of testing models. CMS believes such waivers are not necessary to test this model.

[5] The State-specific contracts will comport with applicable laws and regulations.
[6] Social Security Act § 1115A [42 U.S.C. § 1315a], "Center for Medicare and Medicaid Innovation."

2. Description of Model

2.1 Purpose and Concept

Under the MDRP, State Medicaid agencies obtain rebates from manufacturers in return for coverage of the manufacturer's branded covered outpatient drugs (single source and innovator multiple source drugs) that are estimated as the sum of: (1) a basic rebate, which for brand drugs equals the greater of 23.1% of the Average Manufacturer Price (AMP)[7] or the difference between the AMP and the "Medicaid Best Price"; and, (2) an inflation rebate that is calculated to offset increases in list prices above inflation.[8] As defined in CMS regulations,[9] Medicaid Best Price is effectively the net price at which the manufacturer sells its drug to "any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity" in the United States, excluding certain enumerated transaction types, but including all "applicable discounts, rebates, or other transactions that adjust prices" either directly or indirectly to eligible entities." These formulas for the calculation of rebates under the Medicaid program also apply to the establishment of 340B ceiling prices under the 340B Drug Pricing Program.

In addition to these statutory rebates, almost all states negotiate supplemental rebates with manufacturers over and above the Section 1927 statutory rebates. Unlike certain defined statutory discounts that a manufacturer has to consider in the determination of its "best price," rebates provided under Section 1927 of the Act, as well as supplemental Medicaid rebates that are provided pursuant to a CMS-authorized supplemental rebate agreement, do not affect 340B ceiling prices.

There may be the potential for significant savings on some CODs if states' net costs for single source or innovator multiple source CODs could be set at MFN pricing. An Innovation Center model could facilitate the process of an interested manufacturer voluntarily offering states MFN pricing on its products.

The model will require that the following documents be executed by the model participants: (1) a CMS agreement with a manufacturer regarding the negotiated Key Terms of supplemental rebate agreements that the manufacturer will offer to states to effectuate MFN pricing; (2) a CMS agreement with participating states wherein states enter into supplemental rebate agreements aligned with those CMS-negotiated Key Terms; and, (3) a CMS-authorized SRA between a state and a manufacturer, reflecting CMS-negotiated Key Terms for supplemental rebates.

For state participants, the model aims to reduce the burden of pursuing SRAs for high-cost brand name drugs where there may be few or no supplemental rebates available from manufacturers.

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[7] See Section 1927(k)(1)(A) of the Act, which defines AMP. "Average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and, (ii) retail community pharmacies that purchase drugs directly from the manufacturer. AMP is the basis for Medicaid drug manufacturer rebates.

[8] See 42 CFR 447.509(a)(2)

[9] See 42 CFR 447.505

This model could also facilitate savings to states due to greater rebates for Medicaid CODs and long-term reductions in health expenditures.

For manufacturers, participation in the model may provide several advantages. For example, manufacturers often have to navigate different coverage criteria processes for their CODs among the various state Medicaid programs, which can be time consuming and may lead to varying requirements for access to the CODs among the states. Through the development of standardized coverage criteria policies for a manufacturer's CODs across participating states for MFN drugs, this model also may ease burdens on beneficiaries and providers by improving efficiency in navigating utilization management in the patient's care journey.

Finally, CMS will take a central role in facilitating data exchange and monitoring to encourage the adoption and implementation of MFN pricing for CODs, helping to relieve both manufacturers and states of some of that burden. Overall, the model aims to reduce the burden to states and manufacturers of developing coverage criteria, while maximizing the value of pharmaceutical therapies for Medicaid beneficiaries.

This RFA outlines the elements that must be included in a manufacturer's application to join the model. The application template is attached to this RFA as Appendix A. Eligible respondents to this RFA will be invited by CMS to participate in the model pre-implementation period (outlined below), including negotiation of Key Terms. While this RFA may result in subsequent negotiation, a response to this RFA constitutes a formal offer to CMS regarding all aspects of the model described herein. Responding to this RFA does not obligate the manufacturer to become a model participant.

2.2. Model Key Components

Under GENEROUS, the key model component is the calculation of the MFN price for each COD of the manufacturer. Under the model, manufacturers would provide the necessary international pricing data, in a form and manner specified by CMS, to support the calculation of the MFN price. This MFN price would be achieved for the states in the form of a guaranteed net unit price (GNUP) for each COD of the manufacturer subject to the model. The GNUP approach is commonly used in the supplemental rebate agreements that are currently negotiated between states and manufacturers. This approach guarantees a state will receive a net Medicaid price for each COD of a manufacturer, even with quarterly fluctuations in the Unit Rebate Amount (URA) due to changes in the pricing metric rebate components (such as AMP and "best price") for a COD. Under this model, a supplemental unit rebate amount value would be provided to the states for each COD based on the GNUP. This value would then be used by states to invoice manufacturers to effectuate the MFN.

- **Model Drugs**: Model drugs are limited to all the single source drugs or innovator multiple source drugs of a participating manufacturer, as described in 42 C.F.R. § 447.502. A "model drug" is defined at the level of the NDC-9, i.e., the active ingredient, dosage form and

strength. A manufacturer must provide international pricing data at the unique combination of dosage form, dosage strength, and route of administration, which would be at the NDC-9 level of the drug.

- **Model Participants**: While there are no minimum number of manufacturers or states that are needed to participate in the model for it to move forward or continue to operate, we would seek to engage as many manufacturers that are interested in providing MFN pricing to the states.

- **Country Selection**: For purposes of determining the MFN price, the country basket includes G-7 countries other than the United States (United Kingdom, France, Germany, Italy, Canada, and Japan), plus Denmark and Switzerland. The list of countries would be stable over the course of the five-year model test period.

- **MFN Price**: The benchmark used to calculate the MFN price for a COD (at the NDC-9 level) would be the second lowest country-specific manufacturer-reported net price, adjusted by gross domestic product per capita using a purchasing power parity method. For a given country, the manufacturer-reported net price for a COD would be calculated at the NDC-9 level as the average net price in each country for the previous twelve month period, after all rebates, discounts, and other price concessions provided by the manufacturer are deducted from the list price.[10]

- **Provision of International Pricing Data and Calculation of the MFN GNUP:** For the first model year of 2026, the manufacturer would begin providing data to CMS to determine the MFN price no later than 30 days after the manufacturer PA agreement is in effect. For each subsequent model year, the manufacturer would provide data no later than the end of the third quarter for the preceding calendar year, meaning the average net prices for the previous twelve months must be reported by September 30th. Therefore, for calendar year 2027, the average net price in each specified country needs to be reported by September 30, 2026, and for calendar year 2028, data must be reported by September 30, 2027. A GNUP value would be determined based on this MFN price, and states would invoice the manufacturers on a quarterly basis for the supplemental rebates necessary to effectuate the MFN. The supplemental rebate will be based on the WAC[11] value of the drug. The sum of the GNUP

[10] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug prices in the proposed GENEROUS Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

[11] Wholesale acquisition cost" means, "with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." Social Security Act Section 1847A(c)(6)(B). Under most current SRAs, the values of the GNUPs are calculated based on the WAC values of the drug, since WAC is a public and transparent benchmark. Each state may pay the pharmacy a different amount for

and the URA value would be subtracted from the WAC, which would result in the supplemental rebate that the manufacturer would have to pay to the state for that quarter to effectuate the MFN price.

Supplemental Rebate = WAC – (GNUP plus URA)

For example, based on the international pricing data, the GNUP for a COD (reflecting the MFN price) may be determined to be 50 cents per tablet. The WAC of the drug is listed as $2.00 per tablet in U.S. pricing compendia. The URA for the Medicaid rebate for the COD for the quarter (that is, basic rebate plus any inflation rebates, as calculated by Centers for Medicaid and CHIP Services, CMCS, and provided to the states) is 25 cents per tablet. The manufacturer would have to pay a supplemental rebate of $1.25, so that the state's GNUP for the COD is 50 cents, which reflects the MFN for the drug.

$1.25 = $2.00 – (0.50 + 0.25)

States participating in the model would not be able to negotiate any further supplemental rebates for the CODs for which the state is accessing the MFN. This prohibition would not apply to any of the manufacturer's drugs that are not included in the model. Finally, CMS can make allowances in the final GNUP price established for each COD to account for certain unique manufacturer costs relating to the storage, handling, or distribution of the COD.

- **Time period:** The manufacturer would sign a minimum one-year Participation Agreement with CMS that could be renewed for up to 4 additional years beyond the first year. States would also sign a one-year agreement with CMS to participate in the model, which may also be renewed. States and manufacturers could specify the terms of the SRA timeline within that document, subject to any minimum time period or notification requirements included in the state or manufacturer PA.

- **COD Coverage Terms for States:** CMS will ask each manufacturer interested in participating in the model to propose uniform coverage terms for the manufacturer's CODs. These may include suggested criteria for utilization management, such as step therapy, quantity limits, and other terms for prior authorization. Manufacturers suggested criteria should reflect the current criteria that they have negotiated with the states for their CODs. Manufacturers should describe how the proposed access policy compares to the FDA-approved labeling and pivotal clinical trial inclusion criteria and provide a rationale for any differences. The final coverage terms would be negotiated between CMS and the manufacturer, with state input, and would become part of the model. These criteria would be adopted by the states if they choose to access the MFN pricing of the manufacturer's drugs.

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dispensing the drug, so use of a standard reimbursement benchmark such as WAC allows for transparency, uniformity and easier administration of the supplemental rebate programs.

It is possible that multiple manufacturers may offer MFN pricing for the same drug class. If states decide to choose multiple products with MFN pricing in the same category from different manufacturers, they cannot disfavor one manufacturer from the other. In other words, they will need to commit to the same coverage criteria. For states that contract with Medicaid managed care organizations that provide pharmacy benefits, CMS will provide a contract template for Medicaid Managed Care Organizations (MCOs) and/or their Pharmacy Benefit Managers (PBMs) regarding the use of the coverage criteria for the CODs as directed by the MFN agreement, but states can further tailor these contract addenda if they participate in the model.

- **Collection and Audit of Manufacturer Data:** CMS would engage a contractor which would, among other responsibilities relating to the effectuation of the model, assure appropriate rebate collection by the states, as well as audit the data reported by the manufacturer to CMS to assure that they are appropriately determining the international prices.

Steps in Reporting of Data and Invoicing of Manufacturers for Supplemental Rebates

Step 1 – Manufacturer reports international pricing data for each COD at the NDC-9 level (active ingredient, dosage form and strength) to CMS no later than 30 days after the manufacturer signs the agreement (for the first model year), and then updated international pricing data no later than end of the third quarter of the calendar year preceding the model year. CMS reports the relevant data to participating states;

Step 2 –States invoice manufacturers for supplemental rebates for the COD for the calendar quarter within 60 days of the end of each calendar quarter. Manufacturers have 37 days after receiving invoices to pay rebates to states, after which interest will accrue;

Step 3 – CMS shares in MFN supplemental rebates through a reduction in federal spending based on the state's federal medical assistance percentage (FMAP), as is current practice under the MDRP.

2.3 Model Participation

The GENEROUS Model is voluntary to all participants. While this RFA only applies to manufacturers, information regarding state participation is included within this document for the reference of manufacturers and to aid in responses to this RFA. The legal agreements described throughout this Section are outlined in Section 2.4.

2.3.1 Manufacturer Participation

To be eligible to submit an application in response to this RFA, a manufacturer must participate in the MDRP and be able to enter into supplemental rebate agreements with state Medicaid programs.

Manufacturers that satisfy the above requirements and submit a timely and complete application in response to this RFA will be eligible to participate in the model pre-implementation period.

The model pre-implementation application period begins November 10, 2025, and ends March 31, 2026. During the model pre-implementation period, CMS and manufacturers will begin to negotiate the standard coverage criteria for each of its CODs, as well as other terms of the agreement. If an agreement between parties is reached, then the manufacturer must execute a PA with CMS before June 30, 2026. See Section 5 for more details about the model timeline, including the dates for submission of applications in response to this RFA.

A manufacturer that participates in the model pre-implementation period and signs a PA with CMS before June 30, 2026, is considered a model participant. CODs that are included in the Innovation Center's Cell and Gene Therapy model will not be included in the GENEROUS model.

Manufacturer requirements for participation in the model are as follows:

1) Provide MFN pricing for their CODs with respect to all their associated labeler codes that are listed in the MDRP[12];
2) Participate in negotiations with CMS during the model pre-implementation period;
3) Enter into a PA with CMS before June 30, 2026;
4) Agree to provide MFN rebates for the CODs in the model retroactive to January 1, 2026, for states that participate in the model;
5) For model evaluation purposes, agree to provide pricing information to CMS surrounding existing supplemental rebate agreements that they have with the states outside of the model prior to the model's beginning; and,
6) Maintain compliance with the PA.

Participating manufacturers will provide MFN pricing on CODs for all their associated labeler codes listed in the MDRP to all states participating in the model in the form of a supplemental rebate that will be paid by the manufacturer in addition to any statutory rebates that must be paid under Section 1927 of the Act. Participating manufacturers will also agree that states are able to seek supplemental rebates outside the model for CODs for which the state is not accessing the MFN for the COD under the model. If a state accepts the Key Terms, the participating manufacturer must enter into a SRA incorporating the Key Terms with that state. Variation in Key Terms will only be permitted as necessary to comport with state laws and regulations and must be approved by CMS. A process for disclosure of variation in Key Terms by states, and approval, as necessary will be specified in the State RFA. A participating manufacturer may not exclude any states that elect to participate.

[12] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-national-drug-rebate-agreement-ndra

Additionally, as a condition of participation, manufacturers must also provide information to the CMS evaluation contractor, for states participating with respect to a manufacturer's model drug(s), information about existing supplemental rebate agreements with the state outside of the model prior to the beginning of the model. Model participants will report these data to CMS and reporting will be designed to ensure that the identities of both the state and manufacturer remain confidential and are not publicly disclosed. It is critical that the data be reported to evaluate whether the model will meet the statutory requirement that it will "reduce program expenditures under [Medicaid] while preserving or enhancing the quality of care."

2.3.2 State Participation

Model participation is open to all states, the District of Columbia, and all U.S. territories that participate in the MDRP. If a territory does not participate in the MDRP as of January 1, 2026, but joins the MDRP during the course of the model, CMS may open a new application cycle to allow the newly eligible territory to participate in the model with any participating manufacturer.

States will apply to participate in the model after the Key Terms have been negotiated and at least one manufacturer becomes a model participant (i.e., executes a PA prior to June 30, 2026). States will participate in the model by responding to a State Request for Applications (expected to be released in December 2025), executing a state PA with CMS, and entering into a rebate agreement with the manufacturer by no later than August 31, 2026.

A State must execute a SRAs with manufacturer(s) that reflect the negotiated Key Terms for the State's selected model drug(s)) and may change their selected model drug(s) at annual renewals of the SRA (see Section 2.6). The state must have included as part of its state plan the authorization to enter into a supplemental rebate agreement or agreements with manufacturers that reflect the parameter of this model. States that do not join the model by August 31, 2026, may be allowed to participate in the model at CMS discretion. For example, CMS could allow a state to join a model later if their state plan submission approval process to obtain the necessary supplemental rebate authorizations takes an extended period of time. CMS will inform the participating manufacturer upon acceptance of a new state participant. States that participate in this model may not alter or make additions to the Key Terms except as necessary to comport with state laws and regulations, as approved by CMS.

2.4 Legal Agreements

This model will include a partnership among CMS, participating manufacturers, and participating States. This partnership will be executed through multiple legal and contractual mechanisms. Legal relationships are enumerated in the table below.

1. CMS and Manufacturer: Manufacturer Participation in Model (Manufacturer Participation Agreement)

Effective Dates: No later than June 30, 2026

Description:

1) Formalizes manufacturer participation in the model.
2) Specifies "Key Terms" negotiated with CMS, which will be included in the agreements established with participating States. Key Terms will address, but are not limited to:
    a. Definition of MFN price and GNUP and associated manufacturer reporting requirements;
    b. Covered Outpatient Drugs (CODs) included in the model;
    c. Countries for which MFN pricing would have to be reported;
    d. COD Access Policy;
    e. CMS and Manufacturer Responsibilities;
    f. Rebate Documentation, Audits and Disputes;
    g. Termination, Renegotiation or Alterations
3) Specifies terms of CMS and manufacturer data exchange.
   Specifies terms of potential model renewal.

2. Manufacturer and State: Supplemental Rebate Agreements (SRAs) to Effectuate MFN Pricing

Effective Dates: As needed in order for states to collect SRAs, but no later than August 31, 2026.

Description:

1) Formalizes supplemental rebates and coverage terms as negotiated by CMS and the manufacturer.
2) Specifies "Key Terms" negotiated by CMS and the manufacturer. Key Terms will include, but are not limited to:
    a. Duration for which MFN pricing is applicable and Reconciliation Period;
    b. Pricing related to MFN Rebates, including the calculation of the GNUP;
    c. State Invoicing of Supplemental Rebates;
    d. COD Access Policy;
    e. State and Manufacturer Responsibilities;
    f. Rebate Documentation and Disputes;
    g. Termination, Renewals, Renegotiation or Alterations.

3. CMS and State: State Participation in Model (State Participation Agreement)

Effective Dates: State RFA Submission and Execution of SRA with manufacturers- January 2026 through August 31, 2026.

Description:

1) Formalizes state participation in the model.
2) Requires states to include Medicaid beneficiaries (both FFS and Managed Care) in the Model when Medicaid is the primary payer for a model drug;
3) Establishes state requirements for model participation. For instance, states must:
    a. Have, or obtain, the necessary authority to implement the model, including entering into a CMS authorized SRA;

b. Establish a standardized model drug access policy for each COD based on CMS-manufacturer negotiations;
c. Ensure that Medicaid managed care organization policies align with model requirement;
d. Execute a CMS-authorized SRA with a participating manufacturer that incorporates the CMS-manufacturer negotiated Key Terms.
e. Meet minimum data requirements as specified in the PA and conduct data quality activities.
f. Submit reports to CMS on model implementation.

2.5 Key Terms

Manufacturers that submit a timely and complete response to this RFA will be eligible to participate in negotiations with CMS to determine the Key Terms of the model. Key Terms means the central parameters of the agreement negotiated between manufacturers and CMS, including how rebates amounts will be calculated, access policies for the CODs of the manufacturer, the duration of the agreement, data sharing arrangements, and any options or variations that will form the basis for individual SRAs between the manufacturer and participating states. The full application template for this RFA is included as Appendix A.

Key Term	Description
Drug Coverage Access Policy*	The coverage policy that will be negotiated between CMS and the manufacturer for each of the manufacturer's CODs subject to MFN pricing, including utilization management policies, such as prior authorization criteria and Preferred Drug List (PDL) placement. States will use these policies in determining final coverage access policies for the manufacturer's drugs subject to an MFN price as part of their SRAs. States may create their own criteria and policies as long as they are no more restrictive than the standardized access policy.
Drugs Included in Model	Manufacturers' CODs that will be included in the model, which include single source and innovator multiple source drugs of all associated labeler codes of the manufacturer
Medicaid Unit Rebate Amount (URA)	The total rebate amount that is due to states from the manufacturer for a dosage form and strength of a COD (NDC-9 level) for a calendar quarter under Section 1927 of the Act (basic rebate and inflation rebate) based on pricing data reported by the manufacturer to CMS. The URA will continue to be calculated by CMS and be provided to the states.
CMS Responsibilities	CMS's role in operationalizing the model includes, but is not limited to, supporting states and manufacturers with the implementation of the model and MFN pricing,

	including securing an MFN implementation and evaluation contractor. CMS will be responsible for gathering, aggregating, and analyzing data, as well as assessing whether the model goals are met.
Guaranteed Net Unit Price (GNUP)	The net price to a state for a COD that will reflect the MFN price, adjusted by GDP through purchasing power parity. The GNUP will be effectuated through a formula that subtracts the sum of the GNUP plus the URA from the Wholesaler Acquisition Cost (WAC) value for the drug.
Most Favored Nation Countries	MFN countries include the G-7 countries other than the United States (United Kingdom, France, Germany, Italy, Canada, and Japan) plus Denmark and Switzerland.
Most Favored Nation Rebates	MFN rebates are those paid to states by manufacturers over and above the Medicaid basic URAs. These will be effectuated through a GNUP for each COD of a manufacturer that is participating in the model.
Most Favored Nation Pricing	The benchmark used to calculate the MFN price for a COD (at the NDC-9 level) will be the second lowest country-specific manufacturer-reported net price, adjusted by gross domestic product per capita using a purchasing power parity method. For a given country, the manufacturer-reported net price for a COD would be calculated at the NDC-9 level as the average net price in each country for the previous twelve month period, after all rebates, discounts, and other price concessions provided by the manufacturer are deducted from the list price.
Rebate Data and Documentation	The materials and data provided to CMS and the states that are required to confirm that a supplemental rebate is owed to the state by the manufacturer to effectuate the MFN price, and has been paid to the state by the manufacturer.
Reconciliation Period	The time period following the conclusion of the Rebate Period (calendar quarter or year) in which the manufacturer and states reconcile any outstanding rebates that are due to the states or owed to the manufacturer, through interim and final calculation and payment of refunds.
Termination, Renewals, Renegotiation or Alterations	Processes for any terminations, renewals, alterations, or renegotiations of the Key Terms throughout the duration

	of the model. This includes processes for manufacturer or state withdrawal from model participation.
Supplemental Rebates	Rebates that are provided by manufacturers over and above the basic Medicaid rebates paid to states (consisting of the basic rebate and inflation rebates) pursuant to Section 1927 of the Act.

* - indicates term is negotiable with the manufacturer.

2.5.1 Most Favored Nation (MFN) Rebates

In responses to this RFA, manufacturers interested in participating in the GENEROUS model must agree to provide supplemental rebates to participating states to effectuate MFN pricing for their CODs that are listed in the MDRP. In return, states will adopt the coverage criteria negotiated between the manufacturer and CMS. This coverage criteria will be negotiated between CMS and the manufacturer, with input from the states. In addition, states will agree not to negotiate additional supplemental rebates on drugs for which the state is accessing the manufacturer's MFN price.

Manufacturers must include in their application a list of CODs to which the manufacturer suggests that MFN pricing will apply. These include all CODs that are listed in the MDRP as either a single source drug (S) or an innovator multiple source drug (I) for all associated labeler codes of the manufacturer. States will make an individual determination of whether they want to access the MFN prices of a participating manufacturer's CODs. In this RFA, the manufacturer must also describe coverage criteria that it suggests be used by the states for each of its CODs that would be subject to MFN pricing. This proposed coverage criteria will be subject to negotiation with CMS.

2.5.2 Guaranteed Net Unit (GNUP) Price Rebates

To effectuate MFN pricing, a manufacturer participating in the model would be required to provide a supplemental rebate to the state to guarantee a net unit price (GNUP) amount for each quarter for each COD of the participating manufacturer. The supplemental rebate would be calculated as follows:

$$\textit{Supplemental Rebate} = \textit{WAC} - (\textit{GNUP plus URA})$$

Within 30 days of entering into a PA with CMS for the first model year, for each COD listed in the MDRP, the manufacturer would report to CMS its relevant international prices. This will serve as the basis of the supplemental rebate paid by the manufacturer to the state. For subsequent model years, the international pricing would be due no later than the end of the third quarter of the calendar year preceding the model year.

When calculating supplemental rebates under the model, situations may arise where an exact dosage form and strength match does not exist between the reference MFN country prices and the corresponding U.S. drug product. In such cases, the model will seek to align pricing information between products where appropriate as determined by CMS with input from

manufacturers during the negotiation process. For example, a 20 mg cartridge formulation available in the United Kingdom could be appropriately matched to a 20 mg pen formulation in the U.S. That is, CMS may be able to determine that differences in certain identifying characteristics between products can be considered not significant, for example, if attributable to record keeping practices or country specific considerations.[13]

2.5.3 Rebate Documentation & Reconciliation

States will be responsible for invoicing manufacturers for supplemental rebates, based on state utilization data and additional data provided by CMS, to achieve MFN pricing for each COD of a participating manufacturer. States must keep adequate documentation of the units of a manufacturer's drug for which it invoiced supplemental rebates. Manufacturers must provide to CMS, in a form and manner specified by the agency, the data that will allow states to achieve the GNUP for each selected COD of the manufacturer. These data must be at the NDC-9 level for each COD. Participating manufacturers must pay such rebates to the states in the same timeframe as they would pay rebates under the MDRP.

Subsequent to manufacturer payment of supplemental rebates to states to effectuate MFN pricing, adjustments might be made by the state to the number of units that were invoiced for supplemental rebates in a quarter. States should provide any updated data to the manufacturers as soon as possible so adjustments can be made to the rebates that the states have invoiced to effectuate MFN pricing. Manufacturers and states are required to retain rebate documentation consistent with requirements under Section 1927 of the Act and the implementing regulations.

Consistent with the dispute resolution process used by the MDRP, manufacturers and states participating in the model may advance to the state-based dispute resolution process outlined in their SRA, such as the Medicaid Drug Rebate Dispute Resolution Program (DRP).

2.6 Changes to Model Design in Current or Future Model Years

CMS retains the right to modify any model policy or parameter on an annual basis, or more frequently, in accordance with procedures to be agreed upon in the PAs.

2.6.1 Modification of Key Terms

CMS understands that participating states may have nuanced and individualized contracting processes that may require, among other accommodations, annual renewals for the SRA. These annual renewals are allowable under the model, as long as the Key Terms are adopted at each renewal (barring exceptions as described in Section 5.1). The manufacturer must agree to offer the Key Terms, as agreed by the manufacturer and CMS, each year to states for the duration of the term of model participation.

[13] As stated above, individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug prices in the proposed GENEROUS Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

CMS and manufacturers will negotiate standard language regarding termination and renewals of the Key Terms, and the manufacturer may propose such terms in their response to this RFA. The manufacturer will agree to offer the Key Terms to states, subject to annual SRA renewals. A participating state may include additional language regarding termination and renewals in their SRA as required by state laws or regulations.

CMS and the manufacturer may renegotiate coverage criteria for a COD that would occur as a result of updates to the FDA labeling for the COD or new clinical evidence regarding the use of the drug that are consistent with Section 1927 requirements. If renegotiation between CMS and the manufacturer results in prospective change to the Key Terms, participating states would have an opportunity to execute new SRAs or amend existing SRAs.

2.6.2 Termination

The PA resulting from this RFA shall commence when executed, and be eligible for renewal each year through the end of the 5-year model test period on December 31, 2030. CMS reserves the right to terminate a manufacturer's PA at any point during the model for reasons associated with poor performance, new safety or efficacy data regarding the COD, program integrity issues, non-compliance with the terms and conditions of the applicable PA, or as otherwise specified in the PA or required by Section 1115A(b)(3)(B) of the Act. A participating manufacturer may voluntarily terminate their PA and participation in the model, subject to terms that will be outlined in the PA.

3. Quality and Performance Monitoring

The goal of the GENEROUS Model is to reduce costs for the Medicaid program while preserving or enhancing quality of care. The proposed quality measurement strategy is consistent with Section 1115A(b)(4) of the Act, including the measurement of patient-level outcomes and patient-centeredness criteria. CMS proposes to implement robust monitoring activities to identify any unintended consequences and ensure that access to medications is not impeded and that quality of care is preserved or improved.

Under their Medicaid programs, states are required to cover the CODs of manufacturers that have Medicaid rebate agreements. However, states will often use prior authorization or other utilization management techniques to manage the coverage for certain medications, especially high-cost medications for which they are not receiving supplemental rebates from manufacturers. Thus, while the drug is covered by the state, a beneficiary may not be able to obtain it until prior approval requirements for its use are satisfied. While states can develop criteria around the use of CODs, these might impede access to these drugs and delay treatment for a beneficiary with that particular COD.[14] For example, states may require that another COD be used before the COD being prescribed can be used, which is a widely accepted utilization management strategy called step therapy.

[14] https://psychiatryonline.org/doi/full/10.1176/ps.2009.60.5.601

This model aims to improve quality of care for Medicaid beneficiaries through the possible inclusion of more CODs on a state's PDL or deployment of fewer utilization management criteria that could result in enhanced access to necessary medications. These coverage changes may result in: 1) a wider range of accessible drug treatment options for the patient; 2) enhanced compliance with medication regimens, for example, if a daily dosage form is now available compared to a dosage form needed to be taken multiple times a day; and, 3) enhanced access to newer, more expensive but more effective drug therapies. These potential changes are expected to result in a decrease in hospital admissions, a decrease in emergency room visits, and an increase in quality or length of life.

CMS proposes primarily utilizing claims-based measures to monitor the quality of care in a way that directly reflects patient-level factors. CMS will measure the impact of this model on patient care and health care expenditures by examining the following trends:

- Changes in Medicaid FFS and managed care prescribing patterns (e.g. drug substitution effects, use of certain drug formulations or therapeutic alternatives over others, high-risk medication prescribing);
- Changes in state PDLs and utilization management criteria for model drugs;
- Patients experience measures for prescription drugs within the state, and across patient groups (e.g. medication access, refills, changes in prescribed drugs);
- Impact on hospital admissions, emergency room visits, and quality or length of life.
- Medication adherence (e.g. proportion of days covered);
- Changes in generic drug substitution rates;

A contractor will work with the Innovation Center and the states to develop a monitoring strategy that will assess the impact on quality of care of making medications more accessible to Medicaid beneficiaries by reducing their costs to the states.

4. Evaluation

CMS will use an independent contractor to conduct an evaluation of the model, which will examine the model's implementation and assess the model's impact on Medicaid program spending and the quality of care. All model participants will be required to participate in any evaluation activities if requested. CMS anticipates primarily relying on the data sources also utilized in for determining rebates in the evaluation of the model.

In certain situations, model participants will be required to cooperate with primary data collection activities, which may include participation in surveys, interviews, and other activities that CMS determines necessary to conduct a comprehensive formative and summation evaluation. When the evaluation uses non-publicly available data, only aggregated results would be reported.

5. Application

5.1 Application Process and Selection

Manufacturers seeking to participate in the model must complete and submit the application template in Appendix A in either PDF or Word format by 11:59pm EDT on March 31, 2026, according to the instructions provided in Appendix A. CMS will acknowledge receipt of the application to the Primary Application Contact (see Appendix A) and will, within 30 days of the submission response to this RFA by an eligible manufacturer, respond to the manufacturer with a request for a meeting and, if applicable, a counterproposal to the coverage criteria for the CODs submitted by the manufacturer. All eligible manufacturers that submit a response to this RFA will be individually invited to participate in Key Term negotiations with CMS, and, if, upon conclusion of negotiation an agreement is reached, will be selected to participate in the model.

To participate in the model, a manufacturer will be required to execute a PA with CMS on or before June 30, 2026. States will be required to submit an RFA, and must sign a PA with CMS by August 31, 2026. States that do not join the model by August 31, 2026, will not be allowed to participate in the model except at CMS discretion as discussed in Section 2.3.2.

5.1.1 Meetings between CMS and Manufacturers

Representatives of CMS and manufacturers may meet as needed, subject to agreement between parties, between the submission of the manufacturer's response to this RFA and March 31, 2026, to discuss the manufacturer's application or subsequent offers provided by either CMS or the manufacturer. After the manufacturer has submitted a response to this RFA, either CMS or the manufacturer may, at any point, request an in-person, virtual, or hybrid meeting prior to the end of the model pre-implementation period.

5.2 Rights in Data and Intellectual Property

CMS may use any data obtained pursuant to the model to evaluate the model and to disseminate quantitative results to states and to the public. Data to be disseminated may include savings information, results of beneficiary experience of care and quality of life surveys, as well as measures based upon claims and medical records. Participating states and participating manufacturers will be permitted to comment on evaluation reports for factual accuracy, where appropriate, but may not edit conclusions or control the dissemination of reports.

Notwithstanding any other provision in the PA, all proprietary trade secret information and technology of the manufacturer is, and shall remain, the sole property of the manufacturer and, except as authorized by federal law, shall not be released by CMS without express written consent. The regulation at 48 CFR § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into this RFA. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property rights or other rights to the manufacturer's proprietary information or technology.

CMS will be permitted to disclose information that a manufacturer has already made public. If the manufacturer maintains any information that should not be publicly disclosed because the manufacturer considers such information to be proprietary and confidential, the manufacturer should submit to CMS a form, using either the template attached as Appendix B, or a form substantially the same as Appendix B, identifying specific examples of information the manufacturer considers to be proprietary and confidential. The manufacturer must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the participating manufacturer does not submit such a form, it will be deemed to be confirmed that the manufacturer has no information in its response to this RFA it considers proprietary and confidential.

CMS will engage in independent negotiations with manufacturers regarding the terms of participation and the PA. To ensure compliance with applicable antitrust laws, sharing information on these discussions, negotiations, pricing and rebate terms or other contractual provisions with other manufacturers, competitors, and other applicants is strictly prohibited.

5.3 Submission Information

Information required by CMS in response to this RFA regarding the Key Terms and parameters of model participation is included in Appendix A. While Appendix A includes the minimum information required per this RFA, manufacturers may, at their discretion, include additional information or Key Terms they wish to present to CMS.

5.4 Model Timeline

A summary of the Model's timeline is provided below:

Milestone	Target Date
Release of Manufacturer Request for Applications (RFA)	November 2025
Manufacturers RFA submission period	November 2025-March 31, 2026
CMS—Manufacturer Ongoing Negotiations and Execution of Manufacturer Participation Agreements	December 2025-June 30, 2026
Release of State RFA	December 2025
State RFA/ Participation Agreements	January-August 31, 2026
Model End	December 31, 2030

5.5 Withdrawal of Application

Prior to 11:59 pm EDT March 31, 2026 and before executing a PA, a manufacturer that submitted an application may withdraw from participating in the pre-implementation period by submitting a written request on the organization's letterhead that is signed by one of the following: (1) the chief executive officer (CEO) of the manufacturer, (2) the chief financial officer (CFO) of the manufacturer, (3) an individual other than a CEO or CFO, who has authority

equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Once a manufacturer has submitted an RFA, to submit a withdrawal request, the manufacturer must send the request in a PDF format by email to GENEROUSModel@cms.hhs.gov.

Appendix A: Application Template

The Centers for Medicare & Medicaid Services (CMS) is seeking applications for a voluntary Model (the GENEROUS Model) that tests whether a CMS-led approach to achieving Most Favored National (MFN) pricing for Covered Outpatient Drugs of a manufacturer enrolled in the Medicaid Drug Rebate Program (MDRP) through a supplemental rebate approach reduces Medicaid program costs and preserves or enhances Medicaid beneficiaries' quality of care. This approach may result in improved health outcomes for Medicaid beneficiaries and a reduction in total health care expenditures.

CMS will safeguard the information provided in submitted applications in accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a).

CMS provides no opinion on the legality of any contractual or financial arrangement that the applicant may disclose, propose, or document in this application. The receipt by CMS of any such information during the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, the Department of Health and Human Services (HHS), the HHS Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

CMS will provide manufacturers with a secure platform where the completed application template and supporting documents must be submitted. Manufacturers must contact CMS at GENEROUSmodel@cms.hhs.gov to receive instructions regarding accessing the secure application platform and may do so at any time following the release of this RFA.

Manufacturers seeking to participate in the Model must submit the completed application template and any supporting documents in PDF or Microsoft Word format by 11:59pm EDT on March 31, 2026. Text responses in the application template are limited to no more than 1,000 words for each response.

Questions about the application for the Model should be directed to GENEROUSmodel@cms.hhs.gov.

I. BACKGROUND INFORMATION

a. Applicant Company Information

Please provide the following information regarding your company. The information provided in this application must be the same information as provided for participation in the Medicaid Drug Rebate Program (MDRP).

FIELD	RESPONSE FORMAT
Manufacturer Name:	*Text*
Doing Business As (DBA):	*Text*
Prior DBA(s) if applicable:	*Text*
Organization TIN/EIN:	*Text*

Organization DUNS:	*Text*
Website, if applicable:	*Text*
MAILING ADDRESS:	
Street Address:	*Text*
City:	*Text*
State:	*Text*
ZIP Code:	*Text*

b. Contact Information

Please include information for the Primary Application Contact and Secondary Application Contact. These two individuals will be whom CMS will contact to confirm receipt, direct follow up questions, and schedule meetings regarding the Model. The primary means of communication will be via E-mail.

For Primary Application Contact

FIELD	RESPONSE FORMAT
Full Name:	*Text*
Title/Position:	*Text*
Business Phone Number:	*Text*
Business Phone Number Extension:	*Text*
Alternate Phone Number:	*Text*
Email Address:	*Text*

For Secondary Application Contact

FIELD	RESPONSE FORMAT
Full Name:	*Text*
Title/Position:	*Text*
Business Phone Number:	*Text*
Business Phone Number Extension:	*Text*
Alternate Phone Number:	*Text*
Email Address:	*Text*

II. PROPOSED COVERAGE CRITERIA FOR CODs SUBJECT TO MFN SUPPLEMENTAL REBATES:

Please refer to the template on the following pages to identify the CODs of each of the associated labelers of the manufacturer that are listed in the Medicaid Drug Rebate Program. The manufacturer should identify each drug at both the NDC-9 and NDC-11 levels, as well as suggest possible coverage criteria for the drug that would be negotiated with the

manufacturer. These may include suggested criteria for utilization management, such as step therapy, quantity limits, and other terms for prior authorization. Manufacturers should describe how the proposed access policy compares to the FDA-approved labeling and pivotal clinical trial inclusion criteria and provide a rationale for any differences.

Negotiations between CMS and the manufacturer would have to be completed before a PA could be signed between the manufacturer and CMS. The drugs listed should only be those that have been approved under an NDA or BLA and meet the definitions of "single source drug" and "innovator multiple source drug" as found in Section 1927(k) of the Social Security Act and 42 CFR 447.502.

Product Information and Proposed Coverage Criteria

US Proprietary Name of Drug	US Generic Name of Drug	NDC-9	NDC-11s	Proposed Coverage Criteria

III. CURRENT COVERAGE CRITERIA FOR CODs:

The manufacturer should identify each distinct coverage criteria for each drug product using most recently available data, as well as the number of states that follow each distinct coverage criteria. These may include current criteria for utilization management, such as step therapy, quantity limits, and other terms for prior authorization.

US Proprietary Name of Drug	US Generic Name of Drug	NDC-9	Coverage Criteria 1	Number of States with Coverage Criteria 1	Coverage Criteria 2	Number of States with Coverage Criteria 2	Coverage Criteria n	Number of States with Coverage Criteria n

IV. REBATE DOCUMENTATION & RECONCILATION

a. Please include any comments regarding the reconciliation process described in the RFA.

RESPONSE FORMAT
Text

V. TERMINATION, RENEWALS, RENEGOTIATION OR ALTERATIONS

a. Please review the language below regarding the duration and renewals of the Model PA between CMS and manufacturer.

"This Agreement shall commence on XXXX, X, 2026, and manufacturers may renew the agreement for additional one (1) year terms for 4 additional years. The agreement will expire unless the manufacturer provides written notice of its intent to renew at least ninety (90) days prior to the end of any renewal term, subject to earlier termination as provided herein.

CMS, or the manufacturer, may terminate this Agreement upon written notice to the other Party: (i) if the other Party breaches any term of this Agreement and such breach is not cured within sixty (60) days of written notice thereof; or (ii) if the manufacturer files a petition in bankruptcy, is adjudicated bankrupt, makes a general assignment for the benefit of its creditors, or is voluntarily or involuntarily dissolved."

b. Is this language regarding duration and renewal of the contract resulting from this RFA acceptable?

RESPONSE FORMAT
Yes [ ] No [ ]

c. If no, please propose alternative language:

RESPONSE FORMAT
Text

VI. **ADDITIONAL KEY TERMS (OPTIONAL):** If desired, please describe any additional Key Terms that you would like to propose to CMS for consideration. Additional Key Terms are not to exceed more than 2 pages

VII. **SIGNATURE**

a. An individual eligible to certify this submission on behalf of the Manufacturer must be one of the following: (1) the chief executive officer (CEO) of the manufacturer, (2) the chief financial officer (CFO) of the manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes [ ]
No [ ]

[DATE]
[Signature block]

Appendix B: Manufacturer Proprietary and Confidential Information

The following are specific examples, without limitation, of what the manufacturer considers proprietary and confidential information currently maintained by the manufacturer that should not be publicly disclosed:

1)

2)

3)

In accordance with Section 5.2 of the RFA, this information shall remain the sole property of the manufacturer and, except as authorized by federal law, shall not be released by CMS without the express written consent of the manufacturer.