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 States

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Contents

1. Background and General Information

1.1 Model Scope

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from state Medicaid programs 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)[1], reduces costs for the Medicaid program, while preserving or enhancing 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 any state, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate program (MDRP) (hereinafter, "states")[2]. This RFA outlines model design elements, model eligibility criteria, and additional model details. States that submit an application in response to this RFA, and that meet other conditions of eligibility, including having authority under the state plan to enter into supplemental rebate agreements, will be eligible to become model participants.

CMS looks forward to engaging with states interested 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 establishment of supplemental rebates between states 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 then review the CMS negotiated criteria and select individual CODs for inclusion on their Preferred Drug Lists (PDLs). Participating manufacturers are required to provide Most Favored Nation (MFN) pricing on all eligible CODs. However, states will have the discretion to choose the specific CODs for which they wish to access the MFN pricing.

Upon agreement regarding the standard coverage criteria terms and other terms (hereinafter 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

[1] "Covered Outpatient Drug" shall have the meaning set forth in Section 1927(k) of the Social Security Act.

[2] The specific state entity that may apply to participate in the model (and ultimately enter into a state Participation Agreement) may be a state Medicaid agency, state health department, or other state agency with appropriate authority over the state Medicaid program (and CHIP, if applicable).

manufacturer.[3] See Section 2.4 for a description of the legal relationships between CMS, manufacturers, and states.

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. Certain operational and evaluation activities will extend beyond the designated five-year performance period to ensure continued compliance and proper execution of the model until all necessary processes are completed. 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 models that meet the statutory criteria for expansion under Section 1115A(c), 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.

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.

[3] The State-specific agreements will comport with applicable laws and regulations.

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 CODs (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)[4] 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.[5] Blood clotting factors and drugs approved exclusively for pediatric indications get a lower minimum rebate, that is, 17.1% of AMP, with both types subject to additional inflationary rebates, while generics have a 13% base rebate.[6] As defined in CMS regulations,[7] Medicaid Best Price is the lowest price available from the manufacturer during the rebate period 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, states may 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," supplemental Medicaid rebates that are provided pursuant to a CMS-authorized supplemental rebate agreement do not affect best price or 340B ceiling prices.

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 (SRAs) that the manufacturer will offer to states to effectuate MFN pricing; (2) a CMS agreement with participating states establishing states would enter into SRAs aligned with those CMS-negotiated Key Terms; and, (3) a CMS-authorized SRA, 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. This model could also facilitate savings to states due to greater supplemental rebates for

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[4] 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.

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

[6] See 42 CFR 447.509(a)

[7] See 42 CFR 447.505

Medicaid CODs and long-term reductions in health expenditures. The model does not alter any features of statutory rebates under Section 1927 of the Act.

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 reducing Medicaid spending on pharmaceutical therapies.

This RFA outlines the elements that must be included in a state's application to join the model. The application template is attached to this RFA as Appendix A. An application submitted in 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 state 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 will provide the necessary international pricing data, in a form and manner specified by CMS, to support the calculation of the MFN price by CMS. This MFN price will 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 SRAs 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. Model drugs also include blood clotting factors and drugs approved exclusively for pediatric indications. A "model drug" is defined at the level of the National Drug Code (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 will seek to engage as many manufacturers as 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 (the United Kingdom, France, Germany, Italy, Canada, and Japan), plus Denmark and Switzerland. The list of countries will remain 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) 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 will be calculated at the NDC-9 level as the average net price in each country for the reporting period (see Section 2.5.2), after all rebates, discounts, and other price concessions provided by the manufacturer are deducted from the list price.[8]
- **Provision of International Pricing Data and Calculation of the MFN GNUP:** For the first model year of 2026, the manufacturer will 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 will provide data according to the schedule provided in Section 2.5.2. A GNUP value will be determined based on this MFN price, and states will invoice the manufacturers on a quarterly basis for the supplemental rebates necessary to effectuate the MFN. The supplemental rebate will be based on the Wholesale Acquisition Cost (WAC)[9] value of the drug. For each drug in the model, the GNUP and other negotiated Key Terms will be provided to the state by CMS, the manufacturer, or another entity as designated by CMS, to allow the state to assess which model drugs they wish to select. In order to accommodate variations in state Medicaid pharmacy program negotiation and Preferred Drug List (PDL) timelines, the MFN price is guaranteed to the state for at least 12 months from the effective date of the SRA and longer times may be permitted at the discretion of a manufacturer.

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[8] 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.

[9] **"**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 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.

The sum of the GNUP and the URA value will be subtracted from the WAC, to result in the supplemental rebate that the manufacturer will 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 Center for Medicaid and CHIP Services (CMCS) and provided to the states) is 25 cents per tablet. The manufacturer will 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 will not be able to negotiate any further supplemental rebates for the CODs for which the state is accessing the MFN price. 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 will sign Participation Agreements with CMS for the duration of their participation in the model. States will also sign a state Participation Agreement with CMS to participate in the model. A participating State may choose to begin their individual model implementation (meaning, effectuate an MFN pricing SRA) at any point following the execution of their individual CMS Participation Agreement and prior to December 31, 2030.
- **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. The final coverage terms are to be negotiated between CMS and the manufacturer, with state input, and will become part of the model. These criteria will be adopted by the states if they choose to access the MFN pricing of the manufacturer's drugs.
  It is possible that multiple manufacturers may offer MFN pricing for the same drug class. If more than one offer exists for a given class, states would need to refer to the negotiated Key Terms to determine how those products would be treated. 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. [10] For states that contract with Medicaid managed care plans (i.e., managed care organizations, prepaid inpatient health plans, and prepaid ambulatory health plans) that provide pharmacy benefits, CMS will provide a contract template for managed care plans) and/or their Pharmacy Benefit Managers (PBMs) regarding the use of the coverage criteria for the CODs as reflected in the Participation Agreements, but states can further tailor these contract addenda if they participate in the model.

- **Collection and Audit of State and Manufacturer Data:** CMS will engage a contractor which will, among other responsibilities relating to the effectuation of the model, ensure appropriate rebate collection by the states, as well as audit the data reported by the manufacturer to CMS to ensure 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 participation agreement (for the first model year) and then reports updated international pricing data according to the schedule provided by CMS (see Section 2.5.2). CMS, the manufacturer. or a separate entity identified by CMS, reports the relevant data to participating states in accordance with each state's established process for receiving supplemental rebate offers If enhanced MFN prices on drugs take effect during a period in which a state has already implemented a prior MFN price, the state may elect to adopt the enhanced MFN price and implement the Key Terms associated with that MFN price. ;

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 states, information regarding manufacturers participation can be found in the manufacturer RFA which was released on November 6, 2025, at this link. The legal agreements described throughout this Section are outlined in Section 2.4.

[10] For the purposes of this model, a product is not considered to be disfavored if all products within the same class are operating within the scope of their approved FDA labels, even if the approved labels of competing products are more expansive than the approved label of that product.

2.3.1 Manufacturer Participation

To be eligible to submit an application in response to the manufacturer RFA released on November 6, 2025, a manufacturer must participate in the MDRP and be able to enter into SRAs with state Medicaid programs.

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

The model pre-implementation application period for manufacturers began 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 the manufacturers' 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 the manufacturer 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[11];
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 according to the direction to be provided by CMS.;
5) For model evaluation purposes, agree to provide pricing information to CMS on existing SRAs 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 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. MFN pricing and other negotiated Key Terms will be provided to states by CMS, the manufacturer, or another entity as designated by CMS in accordance with each state's established process for receiving supplemental rebate offers. Participating manufacturers will also agree that states or their designee are able to seek supplemental rebates outside the model

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

for CODs for which the state is not accessing the MFN price 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.

We seek to allow the model to accommodate the various timelines that states currently have with respect to the bids received through supplemental rebate purchasing pools, as well as states not in such pools. In that regard, states will be able to access the MFN price that was in effect as of the day of execution of the SRA for at least twelve months from that effective date, in order to accommodate variations between state PDL timelines. For the first year of the model (2026), states may access the MFN prices through 2026, and MFN prices remain valid for at least twelve months after signing the SRA. For following model years, states may access the MFN price received the previous year (e.g., the new MFN pricing for 2027 that becomes available after June 30th 2026) at any point during the following calendar year, that is 2027. Those prices would be effective for at least twelve months from the time of the execution of the SRA.

Variation in Key Terms will only be permitted as necessary to comport with state laws and regulations and must be approved by CMS. The state must submit any proposed variations in writing to CMS for review and approval and provide a copy to the relevant participating manufacturer. A participating manufacturer may not exclude any states that elect to participate.

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 SRAs 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 be eligible to sign a state PA if the State submits a timely and complete application in response to this RFA, and CMS accepts the State's application. Upon signing a state PA a state becomes a model participant.

States will be able to participate in the model after the Key Terms have been negotiated and at least one manufacturer becomes a model participant (i.e., manufacturer executes a PA prior to June 30, 2026). States will participate in the model by responding to this state RFA by no later than July 31, 206 and executing a state PA with CMS by August 31, 2026. A state must execute 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 in its approved state plan the authorization to enter into a supplemental rebate agreement or agreements with manufacturers that reflect the parameters 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 all participating manufacturers 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.

State obligations will be detailed in state Participation Agreements and are described in Section 2.3.3 of this RFA. A state may not obtain additional supplemental rebates on a drug for which it is receiving the MFN price. Meaning, the state must either modify or terminate existing SRAs upon implementation of a model SRA for a model drug. CMS will offer direct technical assistance to all state participants in the model to support them in implementing these model requirements.

2.3.3 Operational Requirements

State participants must comply with the following legal/policy, operational, and system requirements to support the model:

1) Have, or obtain, the necessary authority for states to participate in the model, including CMS approval of a State Plan Amendment (SPA) to enter into a SRA;
2) Establish a standardized model drug access policy consistent with the CMS-manufacturer negotiated Key Terms;
3) Ensure that applicable Medicaid plan policies align with model requirements for both FFS and Managed Care are included
4) Execute a CMS-authorized SRAs incorporating the CMS-manufacturer negotiated Key Terms.
5) Meet minimum requirements as specified in the PA and conduct data quality activities.
6) Submit reports to CMS on model implementation and overall model operations, as required.

2.3.3.1 Legal Authority for States to Participate in the Model

State participants must have an approved SPA allowing them to enter into SRAs for both Fee-for-Service (FFS) and Managed Care drug claims (if applicable). States are welcome to contact CMS to discuss state-specific program requirements. In the application submitted in response to this RFA, state applicants must indicate whether they will need a SPA, or other program waiver or demonstration approval to implement the model (see Application Item 5a). If a SPA is necessary to allow a state to participate in the model, the state should meet with CMCS as early

as possible to begin the approval process. States do not need to wait until submitting a model application or becoming model participants to apply for any necessary SPA authority.

In the application submitted in response to this RFA, state applicants must also indicate whether the state would need to enact new state legislation or establish new regulations to participate in the model and describe the anticipated timeline for doing so (see Application Item 5b). By the earliest date by which the state intends to include both FFS and managed care beneficiaries in the model for a model drug, the state participant must submit documentation showing that any necessary state laws or regulations are in effect.

Information included in the model application will be used solely for the purpose of application review and does not represent a formal request for a SPA, waiver, or demonstration approval on the part of the state; nor a commitment to approval on the part of CMS. Rather, the identification of current and planned Medicaid authorities will help support state and federal planning and communication efforts related to the model and the potential submission of requests for new or revised SPAs.

2.3.3.2 Standardized Access Policy

For each model drug, a standardized access policy will be described in the Key Terms and will include prior authorization policies, any utilization management processes, provider qualifications, and patient eligibility criteria for the model drug. The aim of the access policy described in the Key Terms is to standardize access to model drugs across all participating states for the COD unless variations are necessary to comply with state law.

State participants must establish an access policy for the model drug(s) that is consistent with the standardized access policy described in the Key Terms negotiated with the manufacturer. States may create additional criteria and policies within their access policy only as necessary to comport with state law or regulation, as approved by CMS. State criteria and policies must be uniform across all beneficiaries enrolled in FFS Medicaid and Medicaid managed care plans within the state.

2.3.3.3 Managed Care Alignment

For model drugs, state participants must ensure that applicable Medicaid managed care plan policies are consistent with model requirements, such that the Key Terms apply equally to FFS Medicaid and Medicaid managed care beneficiaries. For example, managed care plans must apply the standardized access policy described in the Key Terms, including any additional related criteria and policies created by the state (see Section 3.1.2). State participants must submit documentation showing that applicable Medicaid managed care plan policies align with model requirements (e.g., managed care contracts/rates, memoranda of understanding, communications with managed care plans). States are encouraged to meet with CMCS as early as possible for technical assistance.

Some states have existing policies in which they exclude certain drugs (e.g., high cost gene therapies) from applicable Medicaid managed care contracts while providing coverage for these drugs via the FFS delivery system instead. If a state participant excludes model drug(s) from its managed care contracts in this manner and its managed care plans retain responsibility for providing other services for beneficiaries receiving model drugs, the state must ensure that the managed care plan covers services in accordance with the access policy in the Key Terms. Prior to a state beginning implementation of any model SRA, state participants must inform CMS as to whether they have excluded any model drug(s) from managed care contracts, and if so, describe their process for coordinating prior authorization for managed care beneficiaries' drug(s) that are excluded from managed care contracts. States must ensure that their managed care plans are applying the model negotiated Key Terms.

2.4 Legal Agreements

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

1. CMS and Manufacturer: Manufacturer Participation in Model (Manufacturer Participation Agreement (PA))
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. 4) Specifies terms of potential participation renewal.
2. Manufacturer and State: Supplemental Rebate Agreements (SRAs) to Effectuate MFN Pricing

Effective Dates: As needed in order for states to implement SRAs.

.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 (PA))

Effective Dates: State RFA application no later than July 31, 2026; execution of the state Participation Agreement no later than 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 for states to participate in the model, including CMS approval of a SPA to enter into SRAs.
    b. Establish a standardized model drug access policy for each COD based on CMS-manufacturer negotiations;
    c. Ensure that Medicaid managed care plan (as applicable) policies align with model requirements;
    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

States that submit a timely and complete application to this RFA will be eligible to participate in model. CMS will negotiate with manufacturers to determine the Key Terms of the model, which states will then have an opportunity to review before signing state Participation Agreements. 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.
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. States will have the option to select individual CODs from the included list for the purposes of executing a model SRA.
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 GNUP will be based on the second lowest country-specific manufacturer-reported net price (reported at the NDC-9 level), adjusted by gross domestic product per capita using a purchasing power parity method. 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 (the 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 reporting 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

Manufacturers participating in the GENEROUS Model, will agree to provide supplemental rebates to participating states to effectuate MFN pricing on selected CODs.. States will make an individual determination of whether they want to access the MFN price for a given COD of a participating manufacturer. States will adopt the coverage criteria negotiated between the

manufacturer and CMS for the selected model drugs. 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.

2.5.2 Guaranteed Net Unit (GNUP) Price Rebates

To effectuate MFN pricing, a manufacturer participating in the model is 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:

Supplemental Rebate = WAC – (GNUP plus URA)

Within 30 days of entering into a PA with CMS for the first model year, for each COD, the manufacturer would report to CMS its international prices for the reporting period between October 1, 2024, and September 30, 2025. This will serve as the basis of the supplemental rebate paid by the manufacturer to the state for SRAs implemented in the first model year (2026) and the price will be guaranteed for at least 12 months from the SRA effective date. For subsequent model years, the reporting period will span from Apri1 1 to March 31, and the state may implement at any point during the following calendar year. For example, MFN prices will be calculated using international pricing data from the following schedule:

- ***In model year two (2027),*** the MFN price reporting period will be April 1, 2025, to March 31, 2026. Data from the reporting period must be shared with CMS no later than May 31, 2026. CMS, the manufacturer, or another entity as designated by CMS, will share calculated MFN prices with -participating states no later than June 30, 2026. States will then implement the MFN prices between January 1, 2027, and December 31, 2027, depending on their standard PDL timelines. The price will be guaranteed for at least 12 months from the SRA effective date.
- ***In model year three (2028),*** the MFN price reporting period will be April 1, 2026, to March 31, 2027. Data from the reporting period must be shared with CMS no later than May 31, 2027. CMS, the manufacturer, or another entity as designated by CMS, will share calculated MFN Prices with participating states no later than June 30, 2027. States will then implement the MFN prices between January 1, 2028, and December 31, 2028, depending on their standard PDL timelines. The price will be guaranteed for at least 12 months from the effective date.

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.[12]

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 that the state has chosen to access the MFN price. 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 model drug 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.

CMS and manufacturers will negotiate standard language regarding the Key Terms (including termination and renewals). The manufacturer will agree to offer the Key Terms to states, subject

[12] 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.

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 state's PA at any point during the model for reasons associated with poor performance, 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 state 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, under the provisions of Section 1927 of the Act, states may use utilization management techniques, or limit the number of preferred medications, 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. 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.

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 CODs 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 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.

To ensure that data from the GENEROUS Model can be accurately evaluated and are not affected by potential distortions or confounding variables from overlapping participation in other models, CMS may, at its discretion, waive or modify the applicability of other CMMI Models or Model requirements. Any such waivers shall be provided for in GENEROUS Model PAs.

5. Application

5.1 Application Process and Selection

States seeking to participate in the model must complete and submit the application template in Appendix A in either PDF or Word format by 11:59 pm EDT on July 31, 2026, according to the instructions provided in Appendix A.

To participate in the model, a state will be required to execute 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.

CMS encourages states to engage with CMS as early as possible regarding potential participation in the model. States may contact the GENEROUS model at GENEROUSModel@cms.hhs.gov.

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.

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, states 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 Due	July 31, 2026
State Participation Agreements Due	August 31, 2026
Model End	December 31, 2030

5.5 Withdrawal of Application

Prior to signing a Participation Agreement, a state that submitted an application in response to this RFA may withdraw its application by submitting a written request on the state's letterhead that is signed by one of the following: (1) the State Governor, (2) the State Secretary of Health, or official in equivalent position, (3) the State Medicaid Director, 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).

To submit a withdrawal request, the state applicant 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, 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).

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 will provide states with a secure platform where the completed application and supporting documents must be submitted. The application portal will be open from January 2026 through July 31, 2026. CMS provides this appendix as a reference for the questions to be asked in the application portal, and all applications must be submitted through the application portal.

States seeking to participate in the model must submit a complete application and any supporting documents by 11:59pm EDT on July 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 Information

Please provide the following information regarding your state Medicaid agency.

FIELD	RESPONSE FORMAT
Name of state, D.C., or territory:	*Text*
Name of state agency:	*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. CMS will contact these two individuals 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*
Phone Number:	*Text*
Phone Number Extension:	*Text*
Alternate Phone Number:	*Text*
Email Address:	*Text*

For Secondary Application Contact

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

II. START OF MODEL PERFORMANCE

a. Please specify the Performance Period Start Date – the earliest date by which the state intends to include both FFS and managed care beneficiaries in the model for a model drug.

RESPONSE FORMAT
Date

III. ADOPTION OF KEY TERMS

Based on the information currently available, will the state need to vary any of the Key Terms described in this RFA to comport with state laws and regulations? If so, please identify those terms and the source of the state level conflict. Also indicate whether the state will propose changes to any conflicting state laws and regulations.

RESPONSE FORMAT
Yes [ ] No [ ]

RESPONSE FORMAT
Text

IV. LEGAL AUTHORITY

a. Will the state need to obtain a state plan amendment (SPA) or other program waiver to implement the model? Please specify whether the state has already submitted a SPA or met with Center for Medicaid & CHIP Services (CMCS) to discuss a request for a SPA/demonstration/waiver.

RESPONSE FORMAT
Yes [ ] No [ ]

RESPONSE FORMAT
Text

b. Will the state need new state law or regulations to implement the model? If yes, please describe the type of changes that are needed and the anticipated timeline for implementing them.

RESPONSE FORMAT
Yes [ ] No [ ]

RESPONSE FORMAT
Text

V. SIGNATURE

a. An individual eligible to certify this submission on behalf of the state must be one of the following: (1) the State Governor, (2) the State Secretary of Health, or official in equivalent position, (3) the State Medicaid Director, 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.

RESPONSE FORMAT
Yes [ ] No [ ]

[Signature block]