State Letter of Intent (LOI) for Medicaid GENEROUS Model

Thank you for your interest in the GENErating cost Reductions for U.S. Medicaid (GENEROUS) Model. The GENEROUS Model proposes a process by which an interested manufacturer can offer states most favored nation (MFN) pricing on its Covered Outpatient Drugs (CODs) in exchange for negotiated coverage criteria. It will test whether MFN pricing can reduce state expenditures for CODs, while maintaining or improving quality of care for Medicaid patients. Manufacturers will offer supplemental rebates to states for drugs in the model, aligning Medicaid net prices with what other international countries pay. These prices will be provided by manufacturers in exchange for states adopting standard COD coverage criteria. States can then review these prices and coverage criteria to decide if they want to participate for a particular manufacturer's drug or not. States can still seek supplemental rebates outside the model for CODs for which the state is not accessing the model MFN prices. Any state, the District of Columbia, or U.S. territory that participates in the Medicaid Drug Rebate Program (MDRP) and has authority in its State Plan to enter into a supplemental rebate agreement is eligible to participate in the model.

Please complete this non-binding Letter of Intent (LOI) to help us understand your interest in the model. The LOIs will assist the Center for Medicare & Medicaid Innovation ("Innovation Center" or "CMMI") in understanding state goals and challenges, facilitating a smooth application process, and informing negotiations with drug manufacturers on pricing and coverage terms.

While you are encouraged to submit an LOI, this form is not required to apply for participation in the model and more application details will be available at a later date. Please submit the complete LOI in PDF or Microsoft Word format to GENEROUSModel@cms.hhs.gov at your earliest convenience. If feasible, returning the LOI by <u>January 15, 2026</u>, would greatly support our planning process. However, submitting after January 15, 2026, will not affect your ability to participate. We will continue to accept submissions beyond this deadline. All questions are required unless marked otherwise.

Part 1: Administrative Background

- 1. Provide the name of your state.
- 2. Provide the name of your agency.
- 3. Provide the name and contact information for the person who CMMI should contact if there are questions or comments about your LOI, and a secondary point-of-contact.
- 4. Please indicate the number and percentage of Medicaid covered lives that are enrolled in Medicaid fee-for-service (FFS) and Medicaid managed care respectively in the state.

Part 2: State Interest

- 5. What interests you in this model?
- 6. What are your top priorities or goals that you hope to achieve by participating in this model?

- 7. Please indicate if there are any laws or regulations in your state that may (i) interfere with participation in this model, or (ii) require CMMI to make allowances in contracts with manufacturers to accommodate. Similarly, are there established policies that may interfere (such as a set process for when rebate offers must be reviewed by the state) or conflicts with the timing of MFN offers? Does the state use P&T committees/DUR boards/purchasing pools to determine clinical criteria? If so, how would those work with model requirements?
- 8. For which drugs or classes of drugs are you most interested in obtaining the MFN price?

Part 3: Medicaid Supplemental Rebate and Drug Coverage Policies

- 9. Does your state have a current CMS-authorized supplemental rebate agreement or agreements? Please describe these agreements. Do they apply to both FFS and managed care claims?
- 10. Does your state belong to a multistate supplemental rebate negotiating pool? If so, how do you see your participation in the GENEROUS Model affecting your continued participation in the rebate pool?
- 11. Please describe your state's process for annual or periodic updates of your Preferred Drug List (PDL) and utilization management criteria, including timing and updating deadlines.
- 12. For states that utilize Medicaid Managed Care Organizations (MCOs), do you utilize a single preferred drug list (PDL)? Please describe how drug coverage decisions are made under these arrangements including:
 - a. How are criteria aligned across MCOs when a single PDL is not used?
 - b. Drug categories that require similar coverage/criteria.
 - c. Which drugs, if any, are carved out of managed care and reimbursed through FFS?
 - d. Any other state specific drug payment mechanism that could influence this model.
- 13. What administrative challenges does the state anticipate in participating in the model (e.g., billing and collecting supplemental rebates, integrating model data from CMMI for invoicing and potential updates to coverage criteria, seamless integration of supplemental rebates for MFN pricing with the conclusion of existing Medicaid supplemental rebate agreements, etc.)
- 14. Does the state anticipate that the MFN model will affect state Medicaid policies toward the 340B Drug Discount Program?
- 15. What is your state's anticipated timeline for requiring additional information to support informed PDL decisions? For example, how many months in advance of a model year (i.e., the next calendar year), would you need pricing and coverage information to make a decision regarding participation in the model for that calendar year?

Thank you for your interest in the <u>GENEROUS Model</u>. We anticipate a Request for Application (RFA) for participation in the model will be made available to the states in December 2025. Questions about the application for the model should be directed to <u>GENEROUSmodel@cms.hhs.gov</u>. We look forward to your continued collaboration.