

**Centers for Medicare & Medicaid Services
Office of the Administrator
Center for Medicare**

Medicare Drug Rebate and Negotiations Group (XXXX)

Division of Contract Support

- Develops short- and long-range contracting strategies necessary to support Part B and Part D drug price negotiation and inflation rebate activities.
- Procures the contracts necessary to support and operationalize the drug price negotiation and inflation rebate programs, including development of acquisition plans and processes.
- Manages the contracts critical to effectuate the application of inflation rebates to selected drugs covered under Part B and Part D.
- Manages the contracts critical to effectuate the negotiation of prices for selected drugs covered under Part B and Part D.
- Manages contract tracking, reporting, and oversight including coordination with the Office of Acquisition and Grants Management.
- Manages budget and budget call letter process for the Medicare Drug Rebate and Negotiations Group.
- Manages the Comprehensive Acquisition Management System approval process for the Medicare Drug Rebate and Negotiations Group.
- Works with Medicare Drug Rebate and Negotiations Group divisions in planning future budget needs and systems upgrades to address new program changes.
- Serves as a Liaison to the Office of Financial Management.
- Reviews and provides technical assistance on proposed legislation pertaining to the division's subject areas of responsibility.

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Division of Data Assessment and Analytics

- Conducts analyses to identify drugs eligible for, and excluded from, negotiation each year.
- Conducts analyses to identify drugs selected for negotiation each year.
- Conducts analyses to identify selected drugs subject to renegotiation.
- Determines maximum fair price ceiling category for each selected drug.
- Calculates maximum fair price ceiling (and, if applicable, maximum fair price floor) for each selected drug.
- To inform negotiations, analyzes information submitted by manufacturers of selected drugs, including research and development costs, market data, unit costs of production, prior Federal financial support, data on patents and exclusivity, sales data, and information on clinical trials.
- To inform negotiations, analyzes information on Parts B and D drugs including FDA-approved alternatives, comparative efficacy including in specific populations, and other information provided by external stakeholders.
- Performs other clinical and pharmacoeconomic analyses and research necessary to inform drug negotiation policies.
- Provides specialized clinical and pharmacological technical input to establish contracting requirements.
- Provides specialized clinical and pharmacological technical input to establish data collection criteria.
- Identifies drugs subject to Part B and Part D inflation rebates (including drugs subject to shortages and supply chain disruptions).
- Calculates applicable Average Manufacturer Price/Average Sales Price and inflation-adjusted payment amounts for drugs subject to inflation rebates.
- Reviews and provides technical assistance on proposed legislation pertaining to the division's subject areas of responsibility.

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Medicare Drug Rebate and Negotiations Group (XXXX)

Division of Manufacturer Compliance and Oversight

- Monitors manufacturer compliance with manufacturer agreement and reporting requirements under the drug price negotiation program for Medicare Parts B and D.
- Investigates and/or coordinates with other Federal agencies to investigate violations of manufacturer requirements reported by external parties and assesses civil monetary penalties, as appropriate.
- Monitors manufacturer compliance with reporting and payment requirements under the inflation rebate program for the Parts B and D programs and assesses civil monetary penalties, as appropriate.
- Reports information to the Secretary of the Treasury needed to determine application and amount of manufacturer excise taxes as applicable under the Parts B and D programs for selected covered drugs.
- Reviews and provides technical assistance on proposed legislation pertaining to the division's subject areas of responsibility.
- Develops and maintains Medicare Drug Rebate and Negotiations Group training program to support new and ongoing operations.
- Coordinates with Medicare Drug Rebate and Negotiations Group divisions and the Office of Strategic Operations and Regulatory Affairs on responses to Freedom of Information Act requests and Business Operations Staff responses to Strategic Work Information Folder Transfer requests.
- Coordinates responses to Office of Inspector General and Government Accountability Office reports and provides updates, as necessary, to the CMS Office of Financial Management.
- Coordinates Chief Financial Officer and other internal audit requests for Medicare Drug Rebate and Negotiations Group.

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Medicare Drug Rebate and Negotiations Group (XXXX)

Division of Manufacturer Data and Inflation Rebate Operations

- Develops business, technical, and systems requirements and manages information systems necessary to operationalize Part B and Part D drug price negotiation. This includes processes and systems to collect manufacturer agreements and manufacturer data and to support the negotiation process. The data collected from manufacturers may include, but are not limited to: non-Federal Average Manufacturer Price data, research and development cost data, market data (sales data and projected future revenue), unit cost of production and distribution data, prior Federal financial support information, and patent and clinical trial information.
- Develops business, technical, and systems requirements and manages information systems necessary to operationalize Part B and Part D inflation rebates.
- Coordinates with CMCS and other components within CMS to effectuate data collection, data sharing across programs, collaboration, and data analysis to calculate inflation rebates under the Parts B and D programs, as well as to inform negotiations as required.
- Calculates applicable inflation rebates under the Parts B and D programs for each applicable manufacturer.
- Invoices and collects applicable inflation rebates under the Parts B and D programs from manufacturers.
- Develops short- and long-range strategic plans necessary to support assessment activities regarding manufacturers' data submissions and develops the information systems necessary to support these activities.
- Provides standard and ad-hoc data analyses, files, and reports on manufacturer data collected in connection with drug price negotiations and inflation rebate policies under the Parts B and D programs and rebates invoiced and collected.
- Provides training for manufacturers, contractors, and other external stakeholders on the division's subject areas of responsibility under the inflation rebate and drug price negotiation programs.
- Reviews and provides technical assistance on proposed legislation pertaining to the division's subject areas of responsibility.

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Medicare Drug Rebate and Negotiations Group (XXXX)

Division of Policy

- Develops policies related to the application of inflation rebates for drugs covered under Medicare Part B and the Medicare Prescription Drug benefit (Part D).
- Develops policies related to the negotiation of prices for selected drugs covered under Medicare Part B and Part D.
- Prepares briefing memoranda for internal policy clearance.
- Coordinates with CMCS, CCIIO, the Medicare Plan Payment Group, the Medicare Drug Benefit and C & D Data Group, OACT and other components and programs within CM and CMS to ensure that cross-component policy development activities surrounding negotiation and inflationary rebate policies are cohesive.
- Drafts regulations, guidance, and technical policy requirements, as well as other instructional documents regarding programmatic requirements for drug price negotiation.
- Drafts regulations, guidance, and technical policy requirements, as well as other instructional documents regarding programmatic requirements for Part B and D inflation rebates.
- Develops manufacturer agreements in coordination with the Division of Drug Price Negotiations.
- Prepares annual Federal Register notice with explanation of maximum fair price for each selected drug.
- Prepares and provides training for manufacturers, contractors, and other external stakeholders on the division's subject areas of responsibility under the inflation rebate and drug price negotiation programs.
- Evaluates and reviews regulations, rulings, manuals, program guidelines, program memoranda, policy letters, and instructions developed by internal and/or external parties to determine their interaction and impact with the inflation rebate and drug price negotiation programs.
- Assists with technical assistance, as necessary, for Department and CMS staff, program contractors, health plans and representatives of the health delivery system, health policy community, standard setting organizations, manufacturers, pharmacy benefit managers, and other interested parties.
- Conducts regulatory clearance and manages Reports to Congress.
- Participates in the development and evaluation of proposed legislation pertaining to the division's subject areas of responsibility.

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Medicare Drug Rebate and Negotiations Group (XXXX)

Division of Rebate Agreements & Drug Price Negotiations

- Develops the methodology, processes and timelines for maximum fair price negotiations with pharmaceutical manufacturers for Parts B and D drugs selected for negotiation or renegotiation.
- Implements and manages the maximum fair price negotiation and approval process with manufacturers for Parts B and D drugs selected for negotiation or renegotiation.
- Executes agreements with manufacturers of selected drugs to support the negotiation process and make maximum fair prices available under the Parts B and D programs.
- Executes agreements with manufacturers of selected drugs, as needed, to implement inflationary rebates under the Parts B and D programs.
- Updates manufacturer agreements as needed.
- Prepares offers and evaluates counter-offers from manufacturers on drugs subject to negotiation under the Parts B and D programs.
- Prepares briefing materials on status/outcomes of negotiations during and following the negotiation/renegotiation period.
- Provides liaison with other government agencies, including the FDA, and other public and private groups.
- Coordinates with external parties, as necessary, as part of the negotiation and approval process with manufacturers.
- Reviews policies and procedures developed by other components to provide technical assistance and to review their impact on the division's subject areas of responsibility.
- Participates in the development and evaluation of proposed legislation pertaining to the division's subject areas of responsibility.

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- Develops policies related to the application of inflation rebates for drugs covered under Medicare Part B and the Medicare Prescription Drug benefit (Part D).
- Develops policies related to the negotiation of prices for selected drugs under Medicare Part B and Part D.
- Identifies negotiation-eligible drugs and drugs subject to inflation rebates and applicable price parameters for negotiation.
- Develops, drafts, and executes agreements with pharmaceutical manufacturers to implement negotiation and inflationary rebate policies.
- Designs, implements, and manages negotiations with manufacturers.
- Conducts analyses of Medicare, manufacturer, and other sources of data to support drug price negotiations and inflationary rebates.
- Develops business, technical, and system requirements to implement and administer the Part B and Part D drug price negotiation and inflation rebate programs, including collection of data from manufacturers and other parties and calculation and invoicing of rebates.
- Procures and oversee contracts necessary to support the drug price negotiation and inflation rebate programs.
- Monitors manufacturer compliance with the drug price negotiation and inflation rebate programs and implements compliance strategies including civil monetary penalties.
- Reports information to the Secretary of Treasury needed to determine manufacturer excise taxes for applicable drugs.
- Prepares regulations, guidance, business, technical, and systems requirements, as well as other instructional documents regarding programmatic requirements.
- Prepares Federal Register notices, reports, and other documents summarizing the performance and outcomes of the drug price negotiation and inflation rebate programs.
- Serves as liaison to external stakeholders regarding the drug negotiation and inflation rebate programs.
- Coordinates with other components within CMS and HHS, as well as other Federal Agencies as needed to administer the drug price negotiation and inflation rebate programs.
- Reviews and provides technical assistance on proposed legislation pertaining to the Group's subject areas of responsibility.