

42 C.F.R. § 10.20

Administrative Dispute Resolution Panel.

The Secretary shall establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the Office of the General Counsel (OGC) from which Administrative Dispute Resolution Panels (340B ADR Panel) of three members shall be selected by the HRSA Administrator (to review claims and, pursuant to authority expressly delegated through this rule by the Secretary, and to make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers). There shall also be one ex-officio, non-voting member chosen from the staff of the HRSA Office of Pharmacy Affairs (OPA). HRSA and CMS Board members shall have relevant expertise and experience in drug pricing or drug distribution. OGC Board members shall have expertise and experience in handling complex litigation.

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