

LIST OF PEDIATRIC DRUGS AND BLOOD CLOTTING FACTORS

The Affordable Care Act (ACA) establishes several new rebate calculations for those National Drug Codes (NDCs) covered under the Medicaid Drug Rebate Program, effective January 1, 2010. Under this section, most single source and innovator multiple source drugs are subject to a minimum rebate of 23.1 percent. Section 2501(a)(1)(B) of the ACA added a new section 1927(c)(1)(B)(iii)(II)(bb) to the Social Security Act (the Act) to require a new minimum rebate of 17.1 percent of the average manufacturer price (AMP), effective January 1, 2010 for a drug approved by the Food and Drug Administration (FDA) exclusively for pediatric indications.

We plan to interpret this provision in accordance with Federal regulations published by the FDA regarding labeling requirements for prescription drugs and to further define such drugs as indicated for pediatric use required on such labeling. In accordance with regulations at 21 CFR 201.57, 21 CFR 201.56 and 21 CFR 201.80, the FDA defines pediatric use for such drugs as for pediatric populations and pediatric patients. The FDA further defines pediatric populations and pediatric patients as the pediatric age group from birth to 16 years, including age groups often called neonates, infants, children and adolescents. Accordingly, we plan to apply the 17.1 percent minimum rebate to such drugs as indicated by the FDA only for pediatric use for children from birth to 16 years of age. Drugs that are not labeled exclusively with indications for pediatric use or that receive a supplemental indication for pediatric use will not qualify for the minimum rebate provisions in section 1927(c)(1)(B)(iii)(II)(bb) of the Act.

Until CMS's systems can be updated to include an identifier for these drugs and others specified in ACA, we have compiled a list of those pediatric drugs we have been able to identify that appear to meet the above-mentioned definition. This list will also be posted on the Bulletin Page in the Drug Data Reporting for Medicaid (DDR) application for State and labeler use. If you are aware of other drugs that meet the pediatric definition specified above, please contact the data and operations email resource box at mdoperations@cms.hhs.gov so that CMS can review this submission and, if appropriate, the list can be updated accordingly.

Additionally, the ACA added a new section 1927(c)(1)(B)(iii)(II)(aa) establishing a minimum rebate of 17.1 percent for clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. The minimum rebate of 17.1 percent of AMP will be applied beginning in the quarter in which such factors were included on the list. CMS has obtained this data from Medicare Part B and will also post the list of clotting factor NDCs on the Bulletin Page in DDR for State and labeler use. If you have any questions or corrections to this list, please contact the data and operations email resource box at mdoperations@cms.hhs.gov so that we can review this submission and, if appropriate, the list can be updated accordingly.