



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Healthcare Systems Bureau

Rockville, MD 20857

JUN 10 2013

Ms. Maureen Testoni
General Counsel
Safety Net Hospitals for Pharmaceutical Access
1101 15th Street, NW, Suite 910
Washington, DC 20005

Dear Ms. Testoni:

The Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) has had discussions with Amgen Inc. (Amgen) regarding the distribution of Neulasta® to 340B covered entities.

Amgen has informed HRSA that it plans to distribute Neulasta through specialty distributors for 340B covered entities and other non-340B customers. Amgen has also assured HRSA that in no point in time, either in the past or under the new distribution plan, will 340B covered entities have issues with accessing the product at the 340B statutorily defined 340B ceiling price. HRSA believes that this practice will not violate the 340B statute, as Amgen is providing the 340B ceiling price to covered entities and this distribution plan is in place for both 340B and other non-340B customers. HRSA will continue to monitor Amgen to ensure 340B covered entities have access to Neulasta® at 340B discounted pricing.

Thank you for your continued support of the 340B Drug Pricing Program.

Sincerely,

Krista M. Pedley, PharmD, MS
CDR, USPHS
Director, Office of Pharmacy Affairs