



Safety Net Hospitals for Pharmaceutical Access

May 29, 2013

Via E-Mail (robert@amgen.com) and First-Class Mail

Robert A. Bradway
Chairman and Chief Executive Officer
Amgen Inc.
One Amgen Center
Thousand Oaks, CA 91320

Re: Limited Distribution Plan for Neulasta

Dear Mr. Bradway:

Safety Net Hospitals for Pharmaceutical Access (SNHPA), which represents nearly 1,000 hospitals that participate in the 340B federal drug discount program, is writing to express concern regarding Amgen's limited distribution plan for the drug Neulasta. One of our member hospitals recently received the attached notice from its wholesaler AmerisourceBergen (ABC) stating that, beginning June 1, Amgen would require the hospital to purchase all 340B-priced Neulasta through the wholesaler's specialty drug division, ASD Healthcare. The notice clarifies that the new requirement does not apply to non-340B purchases of Neulasta. SNHPA is concerned that Amgen's distribution plan violates federal policy by imposing substantial administrative and financial burdens on 340B hospitals that would not apply to non-340B hospitals. For these reasons, SNHPA requests that Amgen withdraw this distribution plan. If Amgen does not do so, SNHPA will ask the Health Resources and Services Administration (HRSA) to investigate this issue. (SNHPA has already shared its concerns with HRSA's 340B Prime Vendor Program (PVP), and we understand that that PVP has already been in touch with Amgen about this issue.)

HRSA prohibits manufacturers from "singl[ing] out [340B] covered entities from their other customers for restrictive conditions that would undermine the [340B program's] statutory objective. Manufacturers [may] not place limitations on transactions ... which would have the effect of discouraging entities from participating in the ... program."¹ Amgen's distribution plan violates this policy because it imposes a "restrictive condition" that only applies to 340B entities and creates significant administrative and financial challenges that could deter entities from participating in the 340B program.

For example, hospitals' split-billing software programs, which hospitals rely on for 340B compliance purposes, automatically load purchases made from wholesalers into their system.

¹ Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

Robert A. Bradway

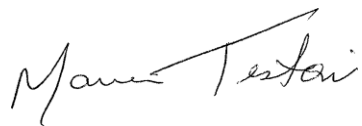
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Purchases made from specialty distributors, however, often must be entered manually, increasing staff costs as well as the risk of noncompliance due to human error when entering the information. SNHPA has also been informed that the restriction will force entities to pay more for Neulasta because wholesalers normally sell the drug at a lower price than specialty distributors. One SNHPA member hospital reported that the restriction would cost the hospital approximately \$200,000 annually. Finally, we understand that shipments will take longer under the proposed distribution model. These are all burdens that the new distribution plan will impose on 340B hospitals, but not on non-340B hospitals.

Again, we urge Amgen to withdraw this distribution plan for Neulasta. The plan violates federal policy prohibiting restrictions that create significant administrative and financial challenges for 340B providers. If Amgen moves forward with this plan, SNHPA will ask HRSA to look into the matter. Please feel free to contact me at 202-552-5851 or maureen.testoni@snhpa.org if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Maureen Testoni". The signature is written in black ink and is positioned above the typed name and title.

Maureen Testoni
General Counsel



AmerisourceBergen Corporation
P.O. Box 959
Valley Forge, PA 19482

May 16, 2013

Dear Valued Customer,

Amgen has recently informed us of a new policy regarding distribution of Neulasta® which affects your pharmacy.

Beginning June 1, 2013, pharmacies that purchase Neulasta at 340B pricing will need to do so through our specialty pharmaceutical business unit, ASD Healthcare, as a drop ship item.

In order to facilitate a seamless transition of your Neulasta purchases from Drug Corporation to ASD Healthcare, a member of our customer service team will call you before June 1 to ensure that you are aware of this change in distribution policy and that you are set up to order from ASD Healthcare.

As such, there is no need for you to do anything at this time. Please note there will be no change to the ordering and distribution of Neulasta that is not at 340B pricing.

Should you have questions about Amgen's decision or need clarification on any aspect of these new policies, please contact your Amgen account representative.

We appreciate your understanding as we make this transition to comply with Amgen's new policy and, as always, we greatly value your business and your support.