



MAR 29 2017

Ms. Kerry Rothschild
Assistant General Counsel
Celgene Corporation
86 Morris Avenue
Summit, New Jersey 07901

Dear Ms. Rothschild:

The Health Resources and Services Administration (HRSA), Healthcare System Bureau (HSB), Office of Pharmacy Affairs (OPA) acknowledges that Celgene has been continuing to utilize a limited distribution network of specialty pharmacies and providers for its covered outpatient drugs Revlimid, Pomalyst, and Thalomid, as described in a letter on our website. (See: <https://www.hrsa.gov/opa/programrequirements/manufacturereletters/2015/celgeneletter.pdf>.) However, OPA has been notified by a 340B covered entity of the inability to purchase these covered outpatient drugs at or below the 340B ceiling price since 2015, even after contracting with the specialty pharmacies in the network established by Celgene (Accredo and Walgreens Specialty Pharmacy).

The covered entity stated the explanation given for not providing these drugs at the 340B ceiling price was that access to these drugs is restricted to a limited distribution network of specialty pharmacies. As a reminder, Celgene is obligated to make all of its products available to covered entities that seek to purchase the drugs under the 340B Drug Pricing Program (340B Program) in a manner that is no more restrictive than that required for non-340B entities. Celgene must ensure that the 340B ceiling price is available to covered entities that wish to purchase through one of the specialty distribution network pharmacies, or must accept into network any covered entity or covered entity's contract pharmacy that is willing to abide by requirements that Celgene has established. The inability of this covered entity to purchase these covered outpatient drugs at the 340B price through the specialty pharmacies in the network established by Celgene seems to run counter to the letter from Celgene posted on the HRSA website.

In accordance with 42 U.S. C. 256b(a)(1), manufacturers participating in the 340B Program enter into a Pharmaceutical Pricing Agreement with the Secretary to "offer each covered entity outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." HRSA established guidelines in 1994 (59 Fed. Reg. 25110 (May 13, 1994)) to state "manufacturers may not single out covered entities from their customers for restrictive conditions that would undermine the statutory objective" and "manufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program."

HRSA subsequently released a Policy Notice in 2011 to clarify this non-discrimination policy, which requests that manufacturers provide, in writing, an implementation plan of the limited distribution arrangement of their covered outpatient drugs. (See: Release No. 2011-1.1, May 23, 2012). HRSA requests this information in an effort to reduce the potential for disputes and ensure alternate distribution procedures are transparent to all stakeholders.

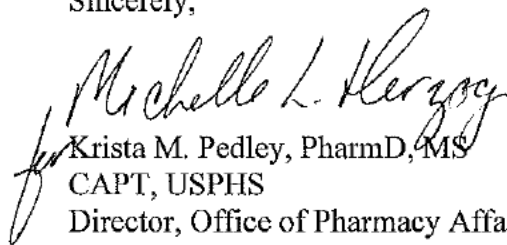
Within 30 days of receipt of this letter, please provide HRSA an update on your limited distribution plan for Revlimid, Pomalyst, and Thalomid. In addition, HRSA recommends manufacturers and 340B covered entities work together in good faith to resolve issues regarding the unavailability of the 340B ceiling price for a drug. The issue of the unavailability of the 340B price for Revlimid, Pomalyst, and Thalomid was brought to HRSA's attention by the 340B covered entity identified below. Please contact Aurora Healthcare Metro and provide HRSA an update on the outcome of those efforts.

Entity: Aurora Healthcare Metro Inc. DSH520138
Attention: Ms. Angela De Ianni
Phone: 414-382-1854
Email: angela.de.ianni@aurora.org

Please provide a written response to CDR Joshua E. Hardin MBS RN/BSN, MLT (jhardin@hrsa.gov) at HRSA's Office of Pharmacy Affairs, 5600 Fishers Lane, 8W05A, Rockville, MD 20857. Please include the update on your limited distribution plan and a status of your communication with Aurora Healthcare Metro at that time.

We appreciate your participation in the 340B Program.

Sincerely,


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



Gerald F. Masoudi
Executive Vice President
General Counsel & Secretary

Celgene Corporation
86 Morris Ave
Summit, NJ 07901
Tel (b) (6)
Fax (b) (6)
(b) (6)

May 19, 2017

Sent Via Email and Federal Express

Joshua E. Hardin
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 8W03A
Rockville, MD 20857

Dear Mr. Hardin:



¹ HRSA's March 29, 2017 letter was directed by email to Kerry Rothschild, an attorney who is no longer with Celgene, as we advised HRSA in May 2016. Unfortunately, the letter was not received by Celgene's current employees until May 11, 2017. We immediately prepared our response to the issues raised in HRSA's letter as soon as we learned about them.

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Gerald Masoudi
Executive Vice President, General Counsel and Corporate Secretary
Celgene Corporation
86 Morris Avenue
Summit, New Jersey 07901

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This letter and all enclosed documents are hereby designated Proprietary & Confidential information of Celgene and are not subject to disclosure under the Freedom of Information Act pursuant to 5 U.S.C. § 552(b)(4). We value our relationship with HRSA and look forward to hearing from you regarding the matters explained in this letter and in our prior correspondence.

(b) (4), (b) (6)