



May 2013

Commander Krista Pedley, Director  
Office of Pharmacy Affairs ("OPA")  
Health Resources and Services Administration ("HRSA")  
Department of Health and Human Services ("HHS")  
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03  
Rockville, Maryland 20857

**Re: Temporary Limited Distribution System for Skyla®**

Dear Commander Pedley:

Bayer HealthCare Pharmaceuticals Inc. ("Bayer") distributes Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg (National Drug Code ("NDC"): 50419-422-01), a new hormone-releasing system that is placed in the uterus for the prevention of pregnancy for up to three (3) years ("Skyla"). Skyla received the Food and Drug Administration's ("FDA's") approval on January 9, 2013. Skyla was available for purchase on February 11, 2013.

Since Skyla's recent launch date, the demand for Skyla has been much greater than Bayer originally anticipated. At the same time, there has been a temporary delay in Skyla's production. Accordingly, we are currently unable to meet the demand for Skyla. We are, however, working hard to address Skyla's current limited inventory levels and to avoid such limited inventory levels going forward.

In the meantime, in order to ensure that all of our customers and their patients, have an equal opportunity to access Skyla, we are instituting a temporary limited distribution system. This temporary limited distribution system will apply to all customers, regardless of status, purchase pathway preference, or prior Skyla purchase history. The temporary limited distribution system will impact all customers in a fair and consistent fashion by limiting every customer (340B, commercial or other) to three (3) Skyla units per month beginning with orders placed on and after May 20, 2013. Skyla's temporary limited distribution system will be in place until the production delay has been resolved and Bayer believes that it will no longer be unable to meet the demand for Skyla.

Under this temporary limited distribution system, customers' orders for Skyla will be filled on a first-in, first-out ("FIFO") basis, until a customer reaches its three (3) unit per month limit. The temporary limited distribution system's "monthly" period will run from the 20<sup>th</sup> day of each month until the 19<sup>th</sup> day of the following month (*e.g.*, May 20, 2013 – June 19, 2013; June 20,

2013 – July 19, 2013, etc.). A customer that reaches its monthly limit may place additional orders for Skyla at the beginning of the next monthly period, again subject to the three (3) unit per month limitation.

Bayer will not require minimum purchase amounts per transaction and the three (3) unit per month limitation will apply equally to customers that previously placed orders for Skyla and new customers that have not previously placed Skyla orders with Bayer or its approved Skyla distributors. Most importantly, a customer's 340B participation status and the price a customer pays for Skyla will not affect its monthly allotment.

Customers may continue to order Skyla through their normal distribution pathway (either directly from Bayer or indirectly through a Skyla approved distributor) under the temporary limited distribution system. We have advised and requested that our approved distributors implement the three (3) unit per month (*i.e.*, 30 days beginning the 20<sup>th</sup> of each month) limitation for all their customers ordering Skyla, effective May 20, 2013. We will also immediately notify all our existing direct Skyla customers of the temporary limited distribution system. If customers have questions they may call Medical Information Services at 1-888-842-2937.

Without immediate implementation of this temporary limited distribution system, we will not be able to ensure equitable customer access to Skyla, because of greater-than-expected Skyla demand and an unexpected delay in production. We believe this temporary limited distribution system will help ensure that we are able to meet the existing needs of all our current and future Skyla customers, including 340B covered entities, the Medicaid program, the Department of Veteran Affairs, and Federal Supply Schedule entities. We also believe this will, in turn, ensure that patients interested in Skyla have an equal opportunity to access the product through their customary healthcare provider.

Very Truly Yours,

Bayer HealthCare Pharmaceuticals Inc.