



2/28/2022

Notice Regarding Offer of Refunds to 340B Covered Entities

Kala Pharmaceuticals, Inc (“Kala”) has recently recalculated 340B Ceiling Prices for the NDC referenced below for the time period of January 1, 2019 through December 31, 2019 and July 1, 2020 through December 31, 2020. As a result of the recalculated 340B Ceiling Prices, Kala has determined that, pursuant to 42 U.S.C. § 256b(d)(1)(B)(ii) and 42 C.F.R. § 10.11(b)(4), a refund is or may be owed to 340B Covered Entities that purchased the below NDC during the time period January 1, 2019 through December 31, 2019 and July 1, 2020 through December 31, 2020.

The table below identifies the NDC and purchase time period that is subject to a refund. The recalculated Ceiling Prices are the result of revised pricing data that were submitted to the Centers for Medicare & Medicaid Services.

NDC 11	NDC Description	Quarter/Year
71571-0121-28	INVELTYS / 2.8mL / Dropper Bottle	1Q19, 2Q19, 3Q19, 4Q19, and 3Q20 4Q20

Based on the recalculation for the product noted above, Kala intends to refund any amount equal to or in excess of \$50 for the periods listed directly to the 340B Covered Entity of record. Separate correspondence including a check and details of the payment will be sent to the 340B Covered Entity.

For 340B Covered Entities who may be owed less than \$50 in aggregate or who have questions about the above-referenced recalculation for this period, Kala invites interested parties to contact the company via email at contract.operations@kalarx.com, with a reference to the NDC and time period.

Kala has asked the Health Resources and Services Administration (HRSA) to post this Notice on the HRSA’s public website to ensure transparency to all 340B Covered Entities regarding the Ceiling Price recalculations for the NDC identified above and to offer a refund to any of the 340B Covered Entities that may have purchased the above NDC during the relevant time periods. Please direct any questions and/or requests for additional information to Kala at the following email address: contract.operations@kalarx.com