GRIFOLS

November 14, 2019

AGO.highcostprescriptiondrugs@vermont.gov

Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(b)

Dear Office of the Vermont Attorney General,

Grifols USA, LLC ("Grifols") is issuing this notice pursuant to 18 V.S.A. § 4637(b), which asks prescription drug manufacturers to provide the Office of the Attorney General (the "Office") written notice within three calendar days of releasing a drug in the commercial market whose wholesale acquisition cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

On November 12, 2019, Grifols released the following drug products into the commercial market:

Xembify® immune globulin subcutaneous, human-klhw, 20%

The WAC for the drug product(s) identified above exceeds the threshold set for a specialty drug under the Medicare Part D Program.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Grifols is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

Grifols interprets "release of the drug in the commercial market" to mean the date the drug was made available for purchase in Vermont.

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Grifols reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Grifols does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

Sincerely,

Sam Talarico
Assistant General Counsel