July 15, 2020

Ms. Sarah McIntyre, Sr. Director, Trade Strategy & Operations
Mr. Matthew C. Smith, Associate Director, Wholesaler Operations
Sanofi-Aventis U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

Ms. Aneta Kantcheva, PharmD
Global Medical Information Manager
Sanofi Genzyme
50 Binney St.
Cambridge, MA 02142

Sent via electronic mail

Re: FDA Guidance on packaging of insulin products

Dear Ms. McIntyre, Mr. Smith and Ms. Kantcheva:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, ANSI-Accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

Recently it was brought to the attention of the NCPDP Work Group 2 Product Identification that the FDA issued guidance regarding the packaging of insulin products. According to the language in the guidance, there is a new labeling requirement for new insulin pen packages instructing the dispenser to: “dispense in the original sealed carton.”

NCPDP is concerned these unbreakable packaging dispensing instructions will have significant patient safety and increased costs impact. This labeling change is problematic for prescribers, pharmacies and payers for the following reasons:

- Patients may not be able to obtain their prescription if they require less than what the package contains, e.g., 1 or 2 pens for a 1-3 month’s supply when the package contains 3 or 5 pens. The dispensing of the full package exceeds the prescribed and/or plan benefit allowed days supply. This could prevent the patient from obtaining the necessary medication resulting in a delay in treatment and potentially significant negative health impacts.

- Patients may not be able to obtain their prescription if the pharmacy cannot break open packaging to fill the prescription based on the prescribed quantity or calculated days supply. This could also result in patient therapy delays with associated healthcare risks.
- Adjustments to days supply to meet both plan benefit limitations and original sealed carton requirements may result in conflicts of documented utilization measures, affect rebate processing, and create downstream audit risk.

To assist with managing both patient safety issues and limited healthcare resources, NCPDP asks you to consider adding single unit packaging to your insulin pen product line to avoid these potential patient safety risks and administrative burdens. Single unit packages would allow the pharmacist to dispense the appropriate quantity of the drug based on the individual patient's needs without overburdening the patient with excess drug or drug costs.

NCPDP looks forward to working with Sanofi-Aventis U.S. LLC to establish practical ways to ensure the safety and proper dispensing of these important and lifesaving products.

For direct inquiries or questions related to this letter, please contact:

Terry Fortin
Assistant Senior Manager, Standards Development
NCPDP
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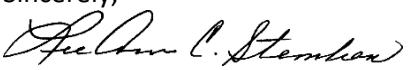
Sincerely,



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cc: NCPDP Board of Trustees