August 12, 2020

Dr. Jacqueline Corrigan-Curay, Office of Medical Policy
Lubna Merchant, Office of Medication Error Prevention and Risk Management
Lonnie Smith, Office of Health Informatics
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Sent via electronic mail

Re: Patient Safety Concerns with Insulin Pen Package Limitations

Dear Dr. Corrigan-Curay, Ms. Merchant, and Mr. Smith:

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.

Current packaging limitations force pharmacies to choose among compliance with FDA requirements, state board of pharmacy rules and Office of Inspector General (OIG) fraud, waste, and abuse policies.

To mitigate risk within the pharmacy industry, NCPDP strongly urges the FDA to require manufacturers to produce smaller package sizes. 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.

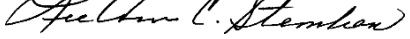
NCPDP requests the FDA proactively partner with NCPDP experts on future proposed changes to FDA guidance on drugs already approved and distributed in the marketplace. Such changes affect the dispensing of medications and the associated NCPDP Standards with which the majority of US pharmacy systems must comply. Where that partnering is precluded by law, allow for public comment on proposed changes to minimize negatively impacting patient care and safety.

NCPDP looks forward to working with the FDA 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
E: standards@ncpdp.org

Sincerely,



Lee Ann Stember
President & CEO
NCPDP
9240 East Raintree Drive Scottsdale, AZ 85260
(480) 477-1000, ext. 108
(602) 321-6363 cell

cc: NCPDP Board of Trustees