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URGENT MEMBER ALERT:

FDA Requests Updated Product Labeling on Insulin Pens

Stop Breaking Insulin Pen Boxes

The pharmacy industry has long debated whether one box of insulin pens is considered "unbreakable". The debate **appeared** to be settled January 22nd, 2019 when the U.S. Department of Justice issued a **press release** stating Walgreens agreed to a $209 million fraud settlement with the federal government regarding its billing and dispensing of insulin pens to Medicaid, Medicare Part D and TRICARE patients. Prior to the settlement, Walgreens' policy was to not dispense any insulin pens in quantities less than one full box, forcing their staff to falsely understate the days' supply on thousands of claims. They then enrolled many of these patients on its refill reminder program, causing patients to get early refills. The government labeled that billing activity as widespread **FRAUD** and required Walgreens to enter into a Corporate Integrity Agreement with the Office of the Inspector General. Consequently, both Walgreens and CVS have been breaking insulin pen boxes when appropriate.

Since that time, PAAS has seen OptumRx, Express Scripts, Humana, Prime Therapeutics, and EnvisionRx dramatically increase their audit recoupments on insulin pens being dispensed that exceed plan limits.

To complicate the matter, the FDA got involved June 20th, 2019 when it sent a "Safety-Related Supplement Request" to Eli Lilly, Sanofi, and Novo Nordisk requesting:

> *"…**updates to the Prescribing Information (PI) and carton labeling to specify that pens be dispensed in the original sealed carton**…"*

Consequently, the manufacturers submitted supplemental new drug applications (sNDAs) to update the information accordingly and **on November 15, 2019 the FDA published updated labeling**. PAAS National® has been in correspondence with the FDA and manufacturers to better understand the June 20th request (and ensuing conversations on October 10th between the FDA and manufacturers). We are presently awaiting a Freedom Of Information Act (FOIA) request through the FDA to gain further clarity. Conjecture leads us to believe it's related to a lack of *Patient Instructions for Use* being provided in the carton, or a possible increase in reported medication dispensing errors.

Regardless, it is important to note that PBMs are aware and will likely enforce the revised standard during audits (i.e. **do not break insulin pen boxes**). PAAS just received audit results where the PBM expected insulin pen boxes to have been broken between 1/22/2019-11/15/2019, and post-11/15/2019 they are expecting full insulin pen boxes to be dispensed. The absurdity is not lost on PAAS, but PBMs will use anything they can to deny paying claims - especially high dollar insulin claims.

Updated Section 16.2 of the package insert, and the exterior carton, will now state to dispense in the original sealed carton. Your supply chain and inventory management will dictate when you start seeing the revised product labeling, if you haven't already.

PAAS has been able to confirm ALL insulin pen products on our **Insulin Medication Chart** have updated product labeling on the Carton and in Section 16.2 (with the exception of Insulin Lispro (AG) and Novolog Cartridges). This includes combination products, Soliqua® and Xultophy®. We have not seen any revisions with GLP-1 Receptor Agonist products (e.g. Victoza, Trulicity, etc).

PAAS Tips:

- Pharmacies should always try to first bill an accurate days' supply based on the prescribed quantity– many insurers have accommodated days' supply limits well in excess of 90 days
- If plan limits are exceeded follow the guidance below:
    - Multiple cartons – reduce the # of cartons and corresponding days' supply until the claim will adjudicate. Document *Insurance Limits Quantity* (e.g. ILQ = 30 days) on the hard copy.
    - Single carton (in order of preference):
        - Call the help desk and request an override
        - If no override is available, adjust the days' supply to the Plan Limit
            - Best practice: note the actual days' supply in the patient sig – and make patients/staff aware of the process
            - Do NOT refill the product early. When overriding the accurate days' supply to meet plan limits, pharmacies can no longer rely on adjudication to properly reject claims that are refill too soon. All PBMs (including Caremark) will recoup for early refills on an audit. Since the original claim was rejected with an accurate days' supply, PBMs know the actual day's supply and will be looking for pharmacies that refill it earlier than allowed.
- Open boxes in inventory – PAAS recommends using up any open boxes as soon as possible prior to transitioning. Be sure to include a *Patient Instructions for Use*.

PAAS members, please log-in to find updated versions of our popular tip sheets:

1. Can You Bill It As 30 Days?
2. Insulin Medication and Injectable Diabetic Medication Charts
3. Diabetic Injectables FAQs

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