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FDA NEWS

Opioid Labels to Include Naloxone Info

The FDA has released a Drug Safety Communication regarding the addition of new recommendations about naloxone to the prescribing information and patient Medication Guides of all opioid analgesics. The agency is also asking healthcare professionals to routinely discuss the availability of the opioid antagonist with their patients when prescribing or renewing an opioid analgesic or medication to treat Opioid Use Disorder (OUD). As a reminder, New York State offers co-pay assistance for naloxone prescriptions through the **N-CAP** program, which covers up to \$40 of a patient's insurance co-payment. The processing information for pharmacists is as follows:

Rx Bin: 610490

Rx PCN: NCAP

ID #: N10001

Rx Group: UCPNCAP

Both nasal and injectable forms are covered.

.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

CDC Advice on Influenza Vaccination for 2020/2021 Season

The United States Centers for Disease Control and Prevention (CDC) has issued wide-ranging guidelines addressing the upcoming influenza vaccination season in the context of the current Coronavirus pandemic. The document, updated on August 14, 2020, includes advice for patients, as well as for healthcare professionals who will be administering the seasonal influenza vaccine. The major points, discussed in an FAQ format, include:

- **Will there be flu along with COVID-19 in the fall and winter?** CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be spreading. In this context, getting a flu vaccine will be more important than ever. CDC recommends that all people 6 months and older get a yearly flu vaccine.
- **Do we need to get a flu vaccine early this year (i.e., July/August)?** Getting vaccinated in July or August is too early, especially for older people, because of the likelihood of reduced protection against flu infection later in the flu season. September and October are good times to get vaccinated.
- **Can I have flu and COVID-19 at the same time?** Yes. It is possible to have flu, as well as other respiratory illnesses, and COVID-19 at the same time. Health experts are still studying how common this can be.
- **Is there a test that can detect both flu and COVID-19?** Yes. CDC has developed a test that will check for A and B type seasonal flu viruses and SARS CoV-2. This test will be used by U.S. public health laboratories. Initial test kits were sent to public health laboratories in early August, 2020.
- **Should a flu vaccine be given to someone with suspected or confirmed COVID-19?** No. Vaccination should be postponed for people with suspected or confirmed COVID-19, regardless of whether they have symptoms, until they have met the criteria to discontinue their isolation (10 days since symptom onset, 24 hours fever-free without medication, etc.).
- **What steps can healthcare personnel take to safely give flu vaccine during the COVID-19 pandemic?** Minimize chances for exposures, including steps such as these:
 - ◇ Screen patients for symptoms of COVID-19 and contact with persons with possible COVID-19 prior to and upon their arrival at the facility.
 - ◇ Install barriers, such as clear plastic sneeze guards, to limit physical contact at triage.
 - ◇ Implement policies for adults and children over the age of 2 to wear cloth face coverings.
 - ◇ Ensure staff follow standard precautions, including hand hygiene and cleaning the environment between patients.
 - ◇ All staff wear a medical facemask at all times.
 - ◇ Ensure staff wear eye protection based on level of community transmission of the virus that causes COVID-19:
 - ⇒ *Moderate-to-substantial transmission:* Healthcare providers should wear eye protection given the increased likelihood of encountering symptomatic COVID-19 patients.
 - ⇒ *Minimal-to-no transmission:* Universal eye protection is considered optional.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Matching Origin Codes to Serial Numbers

The New York State Medicaid Program has announced that many pharmacies have been billing prescriptions with incorrect origin code/serial number information. Below is the list of acceptable origin codes and the appropriate corresponding serial number data which should be attached, depending upon the situation.

Code 1: Written Prescription

- **Unique ONYSRx #:** Number printed on Official New York State Rx (ONYSRx) form
- **ZZZZZZZZ:** For out-of-state providers or prescribers within Federal institutions

Code 2: Telephone Prescription

- **99999999:** Prescription drugs obtained by telephone
- **SSSSSSSS:** Fiscal orders obtained by telephone (follow-up written or electronic cover required)

Code 3: Electronic Prescription

- **EEEEEEEE**

Code 4: Facsimile

- **Unique ONYSRx #:** Non-controlled prescription and fiscal on ONYSRx orders obtained by fax
- **SSSSSSSS:** Fiscal orders *not* on ONYSRx obtained by fax (follow-up written or electronic cover required)
- **NNNNNNNN:** Non-controlled prescriptions for **nursing home** patients obtained by fax

Code 5: Pharmacy

- **TTTTTTTT:** Covers any situation where a new Rx number must be issued (transfers, file buys, software upgrades, etc.)
- **99999999:** Covers *pharmacy dispensing*, such as Plan B and non-patient specific immunizations
- **DDDDDDDD:** Covers prescriptions dispensed under a Declared State of Emergency (non-controls)

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State



To Break or Not to Break: That is the Insulin Pen Question

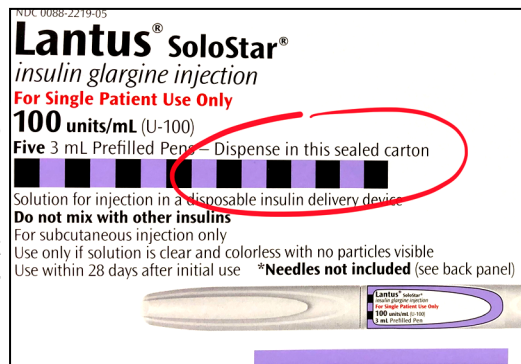
Since the introduction of **Lantus Solostar** in 2007, the prefilled insulin pen has become the most popular and widely-used insulin delivery method in the United States. For most of the thirteen years since those first pens reached the market, it had been standard practice among pharmacists to dispense only full boxes of insulin pens, the majority of which contain 5 pens, providing 1500 units of insulin. Recent events, however, have called that practice into question and left pharmacists divided on the question of "to break or not to break."

Walgreens Fined \$209 Million Over Insulin Pen Policy

In January of 2019, Walgreens agreed to pay \$209 million to settle fraud allegations brought by the U.S. Department of Justice (DOJ). The case alleged that the pharmacy chain had inappropriately billed Medicare and Medicaid for full boxes of insulin pens when, in many cases, those quantities exceeded the plan's maximum allowable days' supply. Walgreens' policy at that time, like many pharmacies', was to *not* open boxes of insulin pens. The problem was compounded by the fact that many of these prescriptions were enrolled in the company's refill reminder program, leading to early refills being processed. As a result of this fine, Walgreens and many other pharmacies, including CVS, instituted policies and software stops to direct that only the exact number of pens needed for a 30 or 90 day supply be dispensed, and pharmacists started breaking open insulin pen boxes. Third-party payers also took note, and their auditors started recouping payments made for full boxes of pens which exceeded plan limits on days' supply.

Enter the FDA: "Don't Break Boxes"

Just when the question of to break or not to break seemed to have been settled, the FDA, in June, 2019, sent a request to all insulin pen manufacturers that they relabel their products to "*specify that pens be dispensed in the original sealed carton.*" And on November 15, 2019, the change became official with the FDA's publication of the updated labeling (see Lantus Solostar package pictured here.) That would seem to put us back where we started, where pharmacists always dispense full boxes of insulin pens to patients, even when such dispensing might exceed an insurance plan's maximum days' supply. However, there is still the issue of third party audits, and the possibility of loss of payments.



PAAS Suggestions to Avoid Loss on Audit

Pharmacy Audit Assistance Service (PAAS), a leader in the field of organizations which help pharmacies avoid unfair penalties assessed by third party audits, has published some helpful tips on handling the insulin pen box dilemma. They include the following:

- **Always try first to bill an accurate days' supply and reduce the number of whole boxes dispensed to conform with the plan limits.**
- **When even a single carton exceeds the plan limit, do the following:**
 - ◊ **Call the help desk and request an override.**
 - ◊ **If no override is available, dispense the whole box, adjust the days' supply to the plan limit, and note the *actual days' supply* in the sig on the label.**
 - ◊ **DO NOT refill earlier than the actual days' supply calls for!**

Update on Vaccines for the 2020-21 Flu Season

Flu Season is rapidly approaching, and this year, in the context of the ongoing Coronavirus pandemic, it is more important than ever before to protect our patients from contracting influenza, the symptoms of which mimic COVID-19 in many respects. We are focusing this year's report specifically on prefilled quadrivalent vaccine products, since these are the doses most often administered by pharmacists in the community pharmacy setting.

Quadrivalent Influenza Vaccine

The 2020-21 quadrivalent egg-based influenza vaccines contain the following 4 antigens:

- **A/Guangdong-Maonan/2019 (H1N1)pdm09-like virus**
- **A/Hong Kong/2671/2019 (H3N2)-like virus**
- **B/Washington/02/2019-like virus (Victoria lineage)**
- **B/Phuket/3073/2013-like virus (Yamagata lineage)**

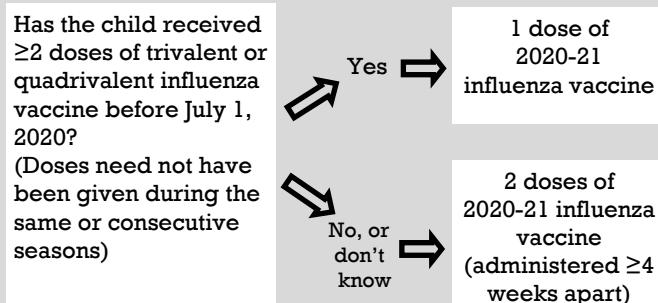
This year, for the first time, both influenza vaccines recommended for people 65 years of age and older (**Fluzone High-Dose** and **Fluad**) will be quadrivalent (previously these vaccines were trivalent.) All of this year's egg-based standard dose quadrivalent vaccines are now indicated for patients 6 months of age and older

The 2020-21 quadrivalent cell- or recombinant-based— influenza vaccines (**Flucelvax** and **Flublok**) contain slightly different "A" components:

- **A/Hawaii/70/2019 (H1N1)pdm09-like virus**
- **A/Hong Kong/45/2019 (H3N2)-like virus**

Special Considerations for Pediatric Patients

Legislation signed into law in 2018 authorizes pharmacists in New York State to administer influenza vaccine to patients 2 years of age and older (previously, pharmacists were limited to patients 18 years old and up). There are several clinical issues pharmacists must familiarize themselves with in regard to vaccinating this population. For example, children under the age of 9 **may** require 2 doses of the influenza vaccine, administered at least 4 weeks apart, depending on prior history. Here is an algorithm to determine if a child under age 9 will need 2 doses of vaccine¹:



Quadrivalent Influenza Vaccines (prefilled) for the 2020-2021 Season

| Vaccine Trade Name (Manufacturer) | Presentation | Age Indication | Egg/Latex/Thimerosal Presence |
|--|---|----------------|----------------------------------|
| AFLURIA (Seqirus) | 0.25 mL Prefilled Syringe 0.5 mL Prefilled Syringe | ≥6 months old | Yes / No / No |
| FLUAD (Seqirus) | 0.5 mL Prefilled Syringe | ≥65 years old | Yes / No / No |
| FLUARIX (GlaxoSmithKline) | 0.5 mL Prefilled Syringe | ≥6 months old | Yes / No / No |
| FLUBLOK (Sanofi Pasteur) | 0.5 mL Prefilled Syringe | ≥18 years old | No / No / No |
| FLUCELVAX (Seqirus) | 0.5 mL Prefilled Syringe | ≥4 years old | No / No / No |
| FLULAVAL (ID Biomedical) | 0.5 mL Prefilled Syringe | ≥6 months old | Yes / No / No |
| FLUZONE (Sanofi Pasteur) | 0.5 mL Prefilled Syringe | ≥6 months old | Yes / No / No |
| FLUZONE HIGH-DOSE (Sanofi Pasteur) | 0.7 mL Prefilled Syringe | ≥65 years old | Yes / No / No |



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Are New York State's restrictions on pre- scribing and dispensing hydroxychloro- quine still in effect?

No. On March 23, 2020, Governor Cuomo issued Executive Order 202.10, which prohibited the dispensing of hydroxychloroquine for the treatment of COVID-19, except under certain special circumstances, and limited all hydroxychloroquine prescriptions to a 14 day supply with no refills. The days' supply and refill limitations were subsequently lifted under Executive Order 202.11. On July 7, 2020, Executive Order 202.11 expired, removing restrictions on the prescribing and dispensing of hydroxychloroquine in New York State.

At the height of the Coronavirus pandemic in New York State the governor issued numerous Executive Orders affecting the practice of pharmacy. Are any of these orders still in effect?

Yes. The following Executive Orders have been extended until September 4, 2020:

- Executive Order 202.18, which permits pharmacists and pharmacy technicians to practice at an alternate location, including their home, as long as there is adequate security to prevent any Personal Health Information from being compromised.
- Modifications which allow for the extension of the triennial registrations of pharmacy establishments which are currently registered and whose registration is set to expire on or after March 31, 2020. An application for re-registration of such establishments must be submitted no later than 30 days after the expiration of the Executive Order.
- Certified or registered pharmacy technicians may continue to assist pharmacists in compounding drugs for a home infusion provider, through a home care agency licensed under Article 36 of the Public Health Law.

GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that Armour Thyroid was originally developed, produced, and sold by the Armour meat packing company? Armour, famous for the "Armour Hot Dog," was at one time among the largest pork producers in the United States, known for making commercial use of many of the by-products of meat production (including the introduction of Dial soap in 1948). Armour Thyroid is made from the dried thyroid glands of pigs raised for human consumption, and is currently marketed by Allergan, Inc. The Armour company, after a long series of mergers and acquisitions (it was once part of the Greyhound Bus conglomerate!), is now a division of Smithfield Foods, the largest producer of pork products in the world.

PHARMACY FUN

It's time for our annual back-to-school quiz, and for this edition we will test your knowledge of common pharmacy acronyms. For each of the following, spell out in full what each letter of the acronym stands for (e.g., ASA is acetyl salicylic acid).

- | | | | |
|----------|--------|--------|----------|
| 1. APAP | 4. BCG | 7. NPH | 10. SSKI |
| 2. 5-ASA | 5. INH | 8. AA | 11. QS |
| 3. AZT | 6. KOW | 9. PRN | 12. SS |

The first reader to submit the correct answer to puzzle@prnnewsletter.com will win a \$25 gift card from Amazon, which will be sent electronically to the winner's Amazon account.

Answers to last month's **PHARMACY FUN**:

Number each carton of weights from 1 to 10. Take 1 weight from carton #1, 2 weights from carton #2, 3 weights from carton #3, etc. Place all 55 weights on the scale at once. If all the weights were accurate, the total would be 55 grams, so if the total is 10 mg short, carton #1 is defective; if it is 20 mg short, carton #2 is defective; if it is 30 mg short, carton #3 is defective, etc.

References:

1. Adapted from CDC Morbidity and Mortality Weekly Report. August 23, 2019. Retrieved from www.cdc.gov/mmwr