P.R.N.

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What's Inside…

MEDICAID NEWS

Effective February 15, 2008, the New York State Medicaid program will no longer accept claims from pharmacies in which a **hospital's or facility's Medicaid number** is used in the *ordering provider field*. In the past, this practice had been acceptable in the case of a prescription written by an intern or resident working in a hospital when the supervising physician's license number was unavailable. Going forward, prescriptions written by physicians without license numbers (interns and residents) must be billed using **the Medicaid number or profession code and license number of the supervising physician.** In addition, in the case of restricted recipients, the Medicaid number of the primary physician or clinic must appear in the *referring provider field*.

Effective February 25, 2008, all prescriptions written in N.Y. State, including those from exempt hospitals, will contain a state-issued serial number (see **Law Review** in the February, 2008 issue of ***PRN***). In billing Medicaid, the only exceptions to entering the serial number on prescription claims are for out-of-state prescriptions (enter all 'Z's), electronic prescriptions (enter all 'E's) and oral prescriptions (enter all '9's).

……RX NEWS……RX NEWS……RX NEWS……RX NEWS……

Pediatric Asmanex Approved: The FDA has approved a new, lower strength version of Schering-Plough's **Asmanex** (mometasone furoate) for use in children aged 4 to 11 years. Asmanex is an inhaled corticosteroid (ICS) indicated for maintenance treatment of asthma as prophylactic therapy and is currently available as a 220 mcg Twisthaler®, a propellant-free inhalation device, for adults and children aged 12 and over. The new product, **Asmanex 110 mcg**, is approved for use in children 4 to 11 years old and the recommended dose is 1 inhalation (110 mcg, which delivers 100 mcg mometasone furoate) once daily in the evening. Patients should be advised to rinse their mouth after each use to reduce the possibility of fungal infections of the mouth or throat. The inhaler should be discarded 45 days after being removed from its foil pouch, or when the dose counter reads '00', whichever comes first.[1] In a 12-week clinical trial in pediatric patients, the most common adverse reactions were: fever (7%), abdominal pain (6%), allergic rhinitis (4%), and vomiting (3%). Asmanex 110 mcg represents the first ICS approved for once daily dosing in children as young as 4 years old (although **Pulmicort** [budesonide] may be used either once or twice daily in children 1 year of age and older). A spokeswoman for Schering-Plough informed ***PRN*** that Asmanex 110 mcg is expected to be available in the second half of 2008.

New Combo Anti-Lipid: Abbott Laboratories has received approval to market a new combination antihyperlipidemic product called **Simcor**. Simcor is a fixed-dose combination of the HMG-CoA reductase inhibitor **Zocor** (simvastatin) and the time-released formulation of niacin, **Niaspan**. Simcor is indicated for use in patients with primary hypercholesterolemia and mixed dyslipidemia and patients with hypertriglyceridemia when statin or niacin monotherapy has proved inadequate. In a 6 month study of 403 patients, the most common adverse effects noted were flushing (59%), headache (4.5%), back pain (3.2%), nausea (3.2%), pruritis (3.2%), and diarrhea (3%). The manufacturer suggests that taking aspirin or an NSAID 30 minutes before dosing can minimize flushing.[2] Simcor is available in the following strengths of niacin/simvastatin: 500mg/20mg, 750mg/20mg, and 1000mg/20mg. Tablets should not be broken, crushed, or chewed. The recommended dose is 1 tablet daily, taken at bedtime with a low-fat snack. The dosage should be titrated according to the following chart:

SIMCOR TITRATION SCHEDULE	
Week(s)	**Daily Niacin Dose**
1 to 4	500 mg
5 to 8	1000 mg
If response is inadequate	Increase 500 mg q 4 weeks up to 2000 mg

Heparin Recall Linked to Uninspected Chinese Factory

In January of this year, Baxter Healthcare Corp., maker of approximately 50 percent of the heparin used in the U.S., recalled nine lots of its multi-dose vials containing 1000 units/ml heparin sodium injection. The company subsequently agreed to recall virtually all of its heparin products, including single-dose vials and lock flush solutions. This action was prompted by 448 reports of adverse effects since mid-December (as compared with only 100 reports in all of 2007). The reactions, which occurred after bolus dosing, included difficulty breathing, hypotension, nausea, vomiting, and diaphoresis; 21 patients died during this period, though it is uncertain whether the drug directly caused these deaths.[3] The New York Times has reported that a plant in Changzhou, China is the source of much of the active ingredient for the Baxter product. But that plant, Chanzhou, SPL, is registered as a chemical company, not as a pharmaceutical supplier, and as such was never certified to make pharmaceutical products. The Times also reports that the FDA violated its own policy by approving the drug for sale without first inspecting the plant in question. Baxter's chief rival in the heparin market, APP Pharmaceuticals, Inc., also imports ingredients for their product from China, but from a different company, Shenzhen Hepalink Pharmaceutical Co., according to a report in the Los Angeles Times.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Medicaid Coverage of Over-The-Counter (OTC) Items

The New York State Medicaid program covers a wide array of non-prescription (OTC) drugs, medical/surgical supplies, and durable medical equipment. This month we review the policies relevant to the dispensing of OTC *drugs*.

Non-Prescription Drugs

Prescriptions for OTC drugs are called *fiscal orders*. As of April 19, 2006, all fiscal orders must be written on the official NY State prescription (ONYSRx). Fiscal orders may be refilled, if indicated by the prescriber, up to 5 times within 6 months of the date of issuance. Pharmacies must keep fiscal orders on file for 6 years from the date of dispensing. Other key policies include:

Fiscal orders are valid for 60 days from the date written

Telephone orders are allowed and may have refills

Fax orders are allowed and may have refills (fax orders must be on the ONYSRx)

No follow-up hard copies are required for either telephone or fax orders

Electronic transmission (terminal to terminal) of fiscal orders is permitted (ONYSRx is *not* required)

If a fiscal order calls for a quantity that does not match the quantity of a pre-packaged unit, the pharmacist may dispense the pre-packaged unit that most closely approximates the quantity ordered

A complete listing of all OTC (non-prescription) drugs covered by Medicaid, including NDC numbers and current reimbursement rates, is available at:

www.emedny.org/info/formfile.html

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Rules and Regulations on Hypodermic Syringes and Needles

In New York State, the sale and possession of hypodermic syringes and needles are regulated under Title 10 of New York Codes, Rules and Regulations (NYCRR), sections 80.131 and 80.137. The statutory authority for these regulations resides in section 3381 of Article 33 of the Public Health Law. Below are some of the key points of these regulations.

Written prescriptions for syringes and/or needles must contain the name, address and age of the patient, as well as the name, address, telephone number and signature of the prescriber. Pharmacists dispensing syringes and/or needles must **sign** and **date** the face of the prescription, and retain the prescription for a period of 5 years.

Refills are allowed if authorized on the prescription for a specific **number** of times (*not* for a period of time, such as "1 year") and provided that no more than 2 years have elapsed since the date the prescription was written. When refilling a prescription for syringes and/or needles, pharmacists must record, on the reverse of the prescription, their signature, the date, and the quantity dispensed.

Emergency oral prescriptions for hypodermic syringes and/or needles must be reduced to writing and contain all the information required on a written prescription, as well as the notation that it is a telephone order. Such prescriptions may authorize the dispensing of **up to 100** syringes and/or needles. A follow-up official prescription must be sent to the pharmacy within 72 hours and, when received, should be attached to the oral memorandum. The face of the follow-up prescription must be signed, and the date of filling, prescription number, and fact that it is a follow-up to an oral order recorded thereupon. On the reverse should be recorded the statement: "Follow-up prescription to oral prescription, pharmacy prescription number_____, filled on_____, prescription received_____," with the appropriate information filled in. Refills of emergency oral prescriptions are not permitted.

Refill transfers are **not** permitted on prescriptions for hypodermic syringes and/or needles.

PRN has confirmed with the Bureau of Narcotic Enforcement that all of the above regulations, including those concerning oral prescriptions and refill transfers, also apply to any prescription product that contains a pre-filled syringe, such as **EpiPen, Byetta Pen, NovoLog FlexPen, Humalog Pen, Pegasys Convenience Pack,** etc.

Expanded Syringe Access Demonstration Program (ESAP)

Effective January 1, 2001, New York State instituted ESAP as a public health measure to prevent the transmission of blood borne diseases such as HIV/AIDS and Hepatitis B and C. The program allows for the sale of hypodermic syringes and needles without a prescription under the following circumstances:

- The provider has registered with the Department of Health
- The purchaser must be 18 years of age or older
- Each sale is limited to a quantity of 10 or less
- The sale shall be accompanied by the required safety insert developed by the Department of Health

The ESAP program was originally scheduled to end on September 1, 2007, but an amendment to the Public Health Law signed into law on April 9, 2007 extended the program's life to the new expiration date of September 1, 2011.

Feature Article..

A REVIEW OF OVER-THE-COUNTER PRODUCTS FOR GASTROINTESTINAL SYMPTOMS

Upset stomach. Constipation, diarrhea, heartburn. These are among the most common conditions which send patients to their pharmacist for advice. Therefore it is vital that professionals keep up with the latest changes in product ingredients, dosages, and contraindications. Recently, a number of well-known brand names have been reformulated, leading to confusion among patients and prescribers. For example, Kaopectate, which originally consisted of kaolin and pectin, then attapulgite, now contains bismuth subsalicylate, which, since the FDA final rule of 2004, is no longer approved for over-the-counter pediatric (<12 yo) labeling.

Constipation

Product (active)	Type	Pediatric Dose	Adult Dose	Precautions, etc
Dulcolax (Bisacodyl 5 mg)	Stimulant	2-11 yo: 5 to 10 mg QD	5 to 15 mg QD	Do not use > 1 week
Fleet Enema (Sodium phosphates)	Saline		1 bottle	Do not use if abdominal pain, nausea, or vomiting
Fleet Pedia-Lax Enema (Sodium phosphates)	Saline	2-5 yo: 1/2 bottle 5-11 yo: 1 bottle		Do not use if abdominal pain, nausea, or vomiting
Fleet Glycerin Suppositories (Glycerin 2 g)	Osmotic	≥6 yo: 1 suppository	1 suppository	Do not use if abdominal pain, nausea, or vomiting
Fleet Pedia-Lax Suppositories (Glycerin 1 g)	Osmotic	2-5 yo: 1 suppository		Do not use if abdominal pain, nausea, or vomiting
Little Tummies Laxative Drops (Sennosides 8.8 mg/mL)	Stimulant	2-5 yo: 0.5 to 0.75 mL 6-11 yo: 1.0 to 1.5 mL QD to BID		Do not use > 1 week
Magnesium Citrate (1.75 g/30 mL)	Saline	2-6 yo: 60 to 90 mL 6-12 yo: 90 to 210 mL on empty stomach with water	300 mL on empty stomach with 8 ounces of water	Do not use if abdominal pain, nausea, or vomiting
Phillips Milk of Magnesia (Magnesium Hydroxide 400 mg/mL)	Saline	2-5 yo: 5-15 mL QD 6-11 yo: 15-30 mL	30-60 mL QD	Do not use if abdominal pain, nausea, or vomiting
Senokot (Sennosides 8.6 mg)	Stimulant	2-6 yo: 1/2 tab QD (max 1 tab BID) 6-11 yo: 1 tab QD (max 2 tabs BID)	2 tabs QD (max 4 tabs BID)	Do not use > 1 week

Diarrhea

Product (active)	Type	Pediatric Dose	Adult Dose	Precautions, etc
Imodium A-D (Loperamide 2 mg/tab, 1 mg/7.5 mL liquid)	Opiod	6-11 yo: 2 mg x1, then 1 mg after each loose stool (max = 4 mg /day 6-8 yo, 6 mg/day 9-11 yo)	4 mg x1, then 2 mg after each loose stool (max = 8 mg/day	Do not use if bloody or black stool
Kaopectate (Bismuth subsalicylate 262 mg/15 mL, 262 mg/caplet)	Antisecretory		Adults and children ≥12 yo: 30 ml or 2 caplets, may repeat every 1/2 to 1 hour, maximum of 8 doses/day	Do not use if bloody or black stool, ulcers, or bleeding problems
Pepto-Bismol (Bismuth subsalicylate 262 mg/15 mL, 262 mg/caplet, 262 mg/chewable tablet)	Antisecretory		Adults and children ≥12 yo: 30 mL or 2 caplets or 2 tablets, may repeat every 1/2 to 1 hour, maximum of 8 doses/day	Do not use if bloody or black stool, ulcers, or bleeding problems

Acid Reflux (Heartburn)

Product (active)	Type	Pediatric Dose	Adult Dose	Precautions, etc
Children's Mylanta (Calcium CO_3 400 mg) **Children's Pepto** (Calcium CO_3 400 mg)	Antacid	2-5 yo: 1 tab prn (max = 3/day) 6-11 yo: 2 tabs prn (max = 6/day)		Do not use > 2 weeks
Maalox (Aluminum & Magnesium OH 200mg) **Mylanta** (Aluminum & Magnesium OH 200mg, Simethicone 20 mg)	Antacid		2 to 4 tsp QID	Do not use > 2 weeks
Pepcid AC (Famotidine 10 mg, 20 mg) **Tagamet HB** (Cimetidine 200 mg) **Zantac** (Ranitidine 75 mg, 150 mg)	H2 blocker		10 to 20 mg QD to BID 200 mg QD to BID 75 to 150 mg QD to BID	Do not use if trouble swallowing, vomiting with blood, or bloody or black stool
Prilosec OTC (Omeprazole 20 mg)	PPI		20 mg QD	Same as above

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NATURAL PRODUCTS: GINSENG

Uses/claimed benefits: Ginseng has been used to increase stamina, as a tonic in cases of fatigue and debility, to increase cognitive performance, and to improve memory and concentration. It has come to be known as an "adaptogen," defined as an herbal product that improves the body's ability to handle stress, trauma, and fatigue. Ginseng has also been used to lower blood glucose in diabetics.

Evidence: A review of relevant studies indicates good evidence for the use of ginseng to improve cognitive function, reduce feelings of fatigue, and lower blood glucose. The evidence is lacking, however, for its use to improve athletic performance. A 2006 study done in the United Kingdom compared the effects of ginseng, when taken with or without glucose, on cognitive performance and blood glucose levels. The study used a double-blind, placebo-controlled, balanced-crossover design. The results in 27 healthy young adults showed both ginseng extract (200 mg) and glucose (25 mg) enhanced performance of a mental arithmetic task and reduced subjective feelings of mental fatigue experienced by participants during the later stages of the sustained, cognitively demanding task performance.[4] In another double-blind, placebo-controlled study, volunteers received ginseng (200 mg) every morning 30 minutes prior to breakfast for 21 days and were evaluated for exercise performance at baseline and after 21 days using heart rate, blood pressure, and other measures. There was no significant improvement in aerobic exercise performance in the ginseng group.[5] *Editors Note: The above referenced studies used* Panax Ginseng*, also known as* Asian Ginseng*. Some studies done with* American Ginseng*, which contains differing proportions of ginsenosides, believed to be the active component of ginseng, have shown it to have an even greater ability to lower blood glucose*. Siberian Ginseng*, now known as* Eleuthero*, is not a true ginseng and is not closely related to Panax or American ginsengs.*

Precautions: Use caution in patients with cardiovascular disease or diabetes. Ginseng should not be taken during pregnancy or used while breastfeeding.

Interactions: Ginseng may interact with anticoagulant and anti-platelet drugs, such as **warfarin, aspirin, clopidogrel, ticlopidine, heparin, enoxaparin, and dalteparin**. There are some reports that ginseng may also interact with **antidiabetic agents, furosemide**, **MAOIs, conjugated estrogens,** and **nifedipine**.

PHARMACY FUN

The following clues refer to commonly prescribed medications. After solving for all 11 (using generic names), collect the first letter of each correct answer and rearrange them into a well-known phrase appropriate for the season. The first reader to submit the correct answer to *puzzle@prnnewsletter.com* wins a custom-printed P.R.N. binder.

1. A 51 amino acid pancreatic hormone
2. Short-acting IV Beta Blocker
3. Anti-wrinkle toxin
4. Melatonin agonist
5. Respiratory Fluoroquinolone (320 mg)
6. A 29 amino acid pancreatic hormone (opposite of 1)
7. The latest generic ACE
8. Skin bleaching agent
9. Desmethylamitriptyline
10. First PPI
11. Acetyl Salicylic Acid

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

1. Ambien (Ambient) 2. Sular (Insular) 3. Colyte (Acolyte) 3. Lyrica (Lyrical)

References:
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5. Allen J McLung J Nelson A Ginseng supplementation does not enhance healthy young adults' peak aerobic exercise performance. *J Am Coll Nutr* 1998 Oct; 17 (5): 462-6.