A publication of the North Dakota Insurance Department

## New programs offering prescription assistance

- Actelion Pharmaceuticals
- Ventavis Patient Assistance Program Added: Ventavis
  - Program details and contact information added
- Bayer
- Kogenate Factor Solutions Added: Kogenate Program details and contact information added Form will be available on RxAssist shortly
- Blairex Laboratories (new company)
- Blairex Laboratories Indigent Program This is an informal program Added: Simply Saline Nasal Mist Spray, Wound Wash, Zinc Oxide Cream Program details added
- Genzyme
- Renal Patient Assistance Program Added: Renvela, Hectorol Program details and contact information added

Application available online

- Sanofi-Aventis
- Hyalgan Hotline and Patient Assistance Program Added: Hyalgan Program details and contact information added Form available online
- Tibotech Therapeutics (new company)
- Prezista Patient Assistance Program Added: Prezista Program details and contact information added Form available online
- Validus Pharmaceuticals (new company)
- Equetro Patient Assistance Program Added Equetro (no longer Shire product) Program details and contact information added Form available online

#### New or updated applications

Abbott Diabetes—Instructions



Adam Hamm Insurance Commissioner

Welcome to the RxConnector newsletter!

Dear friends.

This newsletter is designed to keep you upto-date about the Prescription Connection for North Dakota program and to keep you in the know about the various prescription assistance programs that are available. From time to time, we may also include other items of interest related to Medicare and the State Health Insurance Counseling (SHIC) program.

As always, thank you so much for all that you do for the Prescription Connection program.

Without your help, our work would be that much harder. Your efforts are valued and appreciated.

If you have items of interest that you think should be included in this newsletter, we would love to hear about them. Please contact Sharon St. Aubin at sstaubin@nd.gov or call her at 1.888.575.6611.

#### Adam Hamm Insurance Commissioner





continued ...

RxConnector is a publication of the Prescription Connection for North Dakota program.

Contact us at:

1.888.575.6611 insurance@nd.gov www.nd.gov/ndins Abbott Diabetes—Application Abbott—Lupron Instructions Abbott-Lupron Application Astellas—Amevive Application Bayer-Kogenate Application Bayer-Nimotop Application Bayer—Precose Application **Biovail**—Application Centocor-Remicade Application Centocor-Remicade Spanish Eisai—Fragmin Application Eli Lilly-Lilly Cares Application Eli Lilly-Patient One Application Genzyme-Renal Application Graceway—Instructions Millenium-Velcade Application Novartis—Instructions Novartis—Application Pfizer—First Resource Application Pfizer—Somavert Application Pfizer-Sutent Application Sanofi-Aventis-Instructions Sanofi-Aventis—Application Sanofi-Aventis-Hyalgen Application Shire—Pentasa Application

Shire—Carbatrol Instructions Shire—Carbatrol Application Shire—Fosrenol Application Shire—Lialda Instructions Shire—Lialda Application Solvay—Application Takeda—Prevacid Instructions Takeda—Prevacid Application Teva—Azilect Instructions Teva—Application Teva-Clozapine Patient Registration Teva-Clozapine Physician Registration Tibotech—Application UCB—Keppra Instructions UCB—Keppra Application UCB-Neupro Instructions UCB-Neupro Application UCB—Parcopa Instructions UCB—Parcopa Application Validus—Instructions Validus—Application Wyeth—Instructions Wyeth—Application

## 12 tips to prevent health care fraud

1. Only visit your personal doctor, hospital or clinic for medical help. Only they should make referrals for special equipment, services or medicine.

 Never show anyone your medical or prescription records without first talking to your doctor or pharmacist.
 If someone calls and tries to threaten or pressure you into something—simply hang up the phone.

4. If someone comes to your door and says they are from Medicare or some other health care company, shut the door ... It's shrewd to be rude!

5. Do your homework and talk to your health care provider before buying or investing in internet "cure-all" or "miracle" products or services.

6. Don't keep mail in your mailbox for more than one day. People can steal personal information right out of your mailbox.

7. Rip up or shred your Medicare or other health care papers and other important documents before throwing them away. Crooks go through the trash!

8. Treat your Medicare and Social Security numbers like credit cards. If someone offers to buy your Medicare or Social Security number, don't do it ... it's simply not

worth it.
9. Remember that
Medicare doesn't sell anything.
10. Follow your instincts—if it seems too good to be true, it usually is.
11. If you suspect an

error, fraud or abuse related to health care, gather the facts and report it. 12. Always read your



Medicare Summary Notice or health care billing statement. Your Medicare Summary Notice is the piece of mail stamped "This is Not a Bill" that comes in after you get medical care.

This information is provided by the NDSMP project at NDCPD in Minot. If you believe you are the victim of Medicare fraud, call 1-800-233-1737.

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#### 2008 Medicare Part D events

The North Dakota Insurance Department is putting on several free events around the state, offering assistance in switching or enrolling in a Medicare prescription drug plan. All sessions are held 9 a.m.–5 p.m. Due to significant changes in Part D plans, beneficiaries are strongly encouraged to attend.

Nov. 17	Bismarck	Doublewood Inn, Heritage Room, 1400 E. Interchange Ave.
Nov. 20	Dickinson	Grand Dakota Lodge, Lewis and Clark Room, 532 15th St. W
Nov. 24	Williston	Senior Center, 18 Main St.
Nov. 25	Minot	Sleep Inn, 2400 10th St. SW
Dec. 1	Fargo	Ramada, Crystal Ballroom, 1635 42nd St. SW
Dec. 2	Wahpeton	NDSCS, Red River Valley Room, 900 6th St. N.
Dec. 9	Jamestown	Gladstone Inn, 111 2nd St. NE
Dec. 16	Grand Forks	C'Mon Inn, 3051 32nd Ave. S.
Dec. 17	Devils Lake	Lake Region College, Heritage Room, 1001 College Dr. N.

#### Applying for low-income subsidy

Applications for Extra Help or Low Income Subsidy (LIS) are sent to Social Security for processing. If an applicant receives a denial because of excess resources such as bank accounts, investments or real estate and has decreased their assets since the application, they need to reapply.

The process of reapplication requires the individual to fill out a new application and submit it to Social Security.

For example, Mary applied for the LIS and her savings account balance was \$10,500. She lived in her own home, but the home she occupies is not counted. The savings account, combined with her bank account, showed that Mary's total bank account balances exceeded the \$11,990 limit for eligibility for the low income subsidy. Her income was within the LIS range, but her assets were over. Her application for LIS was denied.

However, from the time she applied for LIS until the LIS denial arrived, she had to have part of her roof shingled, so she spent \$6000. When she received her denial, she only had \$4,500 in her savings account. She could now verify that her total savings, bank account, investments, and real estate were valued at less than \$11,990. However, she cannot appeal the LIS decision, she needs to file a completely new application.

Source: Kaiser Daily Health Report

## MeritCare makes rare move to no longer accept UniCare

In an unprecedented move, MeritCare Health System has decided to no longer provide services to seniors that have their health insurance coverage via Unicare, a commercial payer that is part of Medicare's advantage program. This means that as of Jan. 1, 2009, patients that choose to continue to receive their health insurance coverage via Unicare will no longer be able to be seen at MeritCare. Visit newsroom.meritcare.com to learn more.



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#### Want to learn how to find a Part D plan?

SHIC staff will hold training via IVN (interactive video network) **1–2:50 p.m. Friday, Nov. 14, 2008** at these locations:



To register, contact Jan Frank at 701-328-9611 or janfrank@nd.gov.

## Getting ready for the flu season

Vaccination is the key component of influenza prevention. Commonly called the flu, influenza is a virus-induced, contagious respiratory illness. The Food and Drug Administration (FDA) plays a key role in protecting Americans against seasonal strains of flu.

Assuring the safety of influenza vaccine is one of the agency's top priorities. So is ensuring that there's enough vaccine for everyone who wants it—especially for people who are at risk of complications of influenza.

There are two kinds of influenza vaccines:

• The flu shot contains inactivated, or killed, influenza viruses.

• The nasal vaccine is known by the trade name of Flu-Mist. It contains weakened, live viruses and is sprayed into both nostrils. Autumn is the best time to get vaccinated, although getting the vaccine in the winter months when flu season often peaks is also recommended.

Source: FDA



## Medical tourism business projected to grow eightfold by 2010



The number of people in the U.S. who plan to travel abroad for medical care, where the costs for various medical and surgical procedures often are comparatively lower, is projected to increase by eight times by 2010, according to a recent study by the Deloitte Center for Health Solutions, the Pittsburgh Post-Gazette reports.

For the study, researchers spent about 1,900 hours analyzing the mechanics of medical tourism. The researchers estimated that the number of people who travel internationally for medical procedures will increase from 750,000 to six million over the next two years. The study also found that U.S. patients contribute an estimated \$2.1 billion in business to the medical tourism industry.

The Joint Commission International, which accredits health systems and hospitals abroad, has certified more than 250 hospitals in 30 countries, according to David Jaimovich, JCI's chief medical officer. He said that he expects to see twice the number of JCI-approved hospitals by 2012.

Source: Kaiser Daily Health Policy Report

#### Sanofi-Aventis patient assistance program

Lantus U-100 Injection 100 units/ml (insulin glargine) is available to patients who do not have prescription insurance and who are ineligible for any federal or state programs and have an income at or below 200 percent of the Federal Poverty Level. The patient must also be a US

# Medication/medical supplies/PAPs

Two websites for coupons and rebates on prescription medications:

www.internet drugcoupons.com www.prescriptioncouponsandrebates.com

## Medline Plus

MedlinePlus is a service of the U.S. National Library of Medicine and the National Institutes of Health. It is the world's largest medical library. One of the sections of Medline Plus is named Drugs and Supplements. The reader can select a medication by clicking on the first letter of the name of the medication. The site will provide the following information about the medication.

- Why is this medication prescribed?
- How should this medicine be used?
- Other uses for this medicine
- What special precautions should I follow?
- What special dietary instructions should I follow?
- What should I do if I forget a dose?
- What side effects can this medication cause?
- What storage conditions are needed for this medicine?

resident. Sanofi Aventis may help patients in the donut hole. They will initially deny patient assistance but the applicant should submit an appeal and state (s)he is in the donut hole and has no coverage.

The AARP Bulletin from April 15,2008 notes the website Optimizerx.com (requires registration) and warns for all such sites to "read the small print—coupons offering rebates can't be used by those insured through most state and federal programs, including Medicare."

- In case of emergency/overdose
- What other information should I know?
- Brand names
- Brand names of combination products

The site also has a section on herbs and supplements. The information in this section is based on the Natural Standard. For each therapy covered by Natural Standard, a research team systematically gathers scientific data and expert opinions. Validated rating scales are used to evaluate the quality of available evidence. Information is incorporated into comprehensive monographs which are designed to facilitate clinical decision making. All monographs undergo blinded editorial and peer review prior to inclusion in Natural Standard databases. Natural Standard is impartial; not supported by any interest group, professional organization, product manufacturer. Institutional subscriptions, custom content and licensing are available.

It is easy to look for archived news articles in MedlinePlus. For example, on Sept. 25, there is an

# VA to provide full benefits for all veterans with ALS

The Department of Veterans Affairs in September announced that all veterans with amyotrophic lateral sclerosis, or Lou Gehrig's disease, will receive full disability, lifetime health and death benefits, a move that effectively acknowledges a general link between the condition and military service, the New York Times interesting story about a drug that fights diabetic eye disease. Under the title Current Health News, click on More News and a chart of dates will appear. Click on the date to find the articles published on that date. Then click on the article to read the news.

reports. According to VA, all veterans with ALS will qualify for disability benefits, regardless of when or where they served.

Source: Kaiser Daily Health Policy Report

## Nearly 2/3 of prescriptions initially filled were for brand-name drugs

Medicare beneficiaries enrolled in the prescription drug benefit are more likely to ask pharmacists for generic medications when they pay for them and for more expensive brand-name treatments when the program provides coverage, according to a study released on

#### FDA approved

"FDA approved": Maybe you saw the words on a company's website or in a commercial promoting a new product or treatment. Some marketers may say their products are "FDA approved," but how can you know for sure?

An FDA webpage serves as a gateway to information about approvals of FDA-regulated products: www.fda. gov/opacom/7approvl.html. You can search for FDA approval information by product type.

FDA is responsible for protecting the public health by regulating human and animal drugs, biologics (e.g. vaccines and cellular and gene therapies), medical devices, food and animal feed, cosmetics and products that emit radiation.

But not all of these products undergo premarket approval—a review of safety and effectiveness by FDA experts and agency approval before a product can be marketed. In some cases, FDA's enforcement efforts focus on products after they are already on the market. This is determined by law.

The following facts can shed light on when the term

Thursday by Medco Health Solutions, the AP/San Francisco Chronicle reports.

Source: Kaiser Daily Health Policy Report

"FDA approved" is appropriate after such a determination is made by the agency.

FDA does not approve companies.

FDA does not "approve" health care facilities, laboratories, or manufacturers. FDA does inspect product manufacturers to verify that they comply with good manufacturing practices.

Owners and operators of domestic or foreign food, drug and most device facilities are required to register with FDA. Blood and tissue facilities also must register with the agency.

Mammography facilities must be FDA certified. Mammography facilities are required to display their FDA certificates where patients can see them. The certificate indicates that the facilities have met stringent standards and can provide quality mammography.

FDA approves new drugs and biologics.

FDA uses a risk-based, tiered approach for regulating medical devices.

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FDA classifies devices according to risk. Only the highest-risk devices, such as mechanical heart valves and implantable infusion pumps, require FDA approval before marketing.

FDA approves certain foods.

FDA field investigators inspect food companies, examine food shipments from abroad, and collect samples. Laboratory scientists analyze samples. Compliance officers recommend legal action and follow through on enforcement issues.

FDA approves additives in food for people.

New food additives, including substances added intentionally to food and substances that may migrate to food because they contact food (e.g., food packaging) must be shown to be safe to FDA's satisfaction before companies can market them.

Certain food ingredients, such as those with a long history of safe use in food, do not require premarket approval. FDA approves drugs and additives in food for animals. FDA is responsible for approving drugs and food additives given to, or used on, over one hundred million pets, plus millions of poultry, cattle, swine and minor animal species. (Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs and cats.)



FDA does not approve pet food, but rather approves the food additives that are used in pet food.

FDA approves color additives used in FDA-regulated products.

This includes those used in food, dietary supplements,

drugs, cosmetics, and some medical devices. These color additives (except coal-tar hair dyes) are subject by law to approval by the agency, and each must be used only in compliance with its approved uses, specifications and restrictions.

FDA does not approve cosmetics.

Examples of cosmetics are perfumes, makeup, moisturizers, shampoos, hair dyes, face and body cleansers and shaving preparations.

Cosmetic products and ingredients do not require FDA approval before they go on the market, with one exception: color additives (other than coal tar hair dyes.) Cosmetics must be safe for their intended use and properly labeled.

FDA does not approve medical foods.

A medical food is used for the dietary management of a disease or health condition that requires special nutrient needs. An example of a medical food is a food for use by persons with phenylketonuria, a genetic disorder. A person with this disorder may need medical foods that are formulated to be free of the amino acid phenylalanine. A medical food is intended for use under the supervision of a physician.

Medical foods do not have to undergo premarket approval by FDA. But medical food firms must comply with other requirements, such as good manufacturing practices and registration of food facilities. Medical foods do not have to include nutrition information on their labels, and any claims in their labeling must be truthful and nonmisleading.

FDA does not approve infant formula.

FDA does not approve infant formulas before they can be marketed. However, manufacturers of infant formula are subject to FDA's regulatory oversight.

FDA does not approve dietary supplements.

Unlike new drugs, dietary supplements are not reviewed and approved by FDA based on their safety and effectiveness. Most dietary supplements that contain a new dietary ingredient (a dietary ingredient not marketed in the United States before Oct. 15, 1994) require a

notification to FDA 75 days before marketing.

FDA does not approve the food label, including Nutrition Facts.

FDA does not approve individual food labels before food products can be marketed. But FDA regulations require nutrition information to appear on most foods, including dietary supplements. Also, any claims on food products must be truthful and non-misleading, and must comply with any special requirements for the type of claim.

FDA does not approve structure-function claims on dietary supplements and other foods.

Structure-function claims describe the role of a food or food component (such as a nutrient) that is intended to affect the structure or function of the human body. One

## OAC: Obesity Action Coalition

The OAC was formed in 2005. The mission of OAC is to elevate and empower those affected by obesity through education, advocacy and support.

The OAC's primary focus is toward the patient. They offer resources for the overweight, obese and morbidly obese population. They also provide childhood obesity resources. Their resources are a great tool for healthcare professionals to use when talking to patients; however, the resources are also very patient-friendly for individual use as well.

#### Patient assistance community gathers for national conference

Among the more than 300 conference attendees at the Center for Business Intelligence's 9th Annual Patient Assistance Conference were 40 professional and volunteer patient advocates from 22 states who were recipients of Astra-Zeneca Educational Scholarships.

A highlight of the conference was the opening session that featured the heartfelt personal stories of two patients who depend on patient assistance programs to stay well. James is a Medicare Part D beneficiary who takes 16 medications daily, including two injections. His experience underscores the challenges faced by persons with a example is "calcium builds strong bones."

Misuse of FDA's logo may violate federal law.

FDA's logo should not be used to misrepresent the agency nor to suggest that FDA endorses any private organization, product or service.

This article appears on FDA's Consumer Health Information webpage (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

For more information: Approvals of FDA Regulated Products www.fda.gov/opacom/7approvl.html

For more information check out www.obesityaction.org. One of the items at the website is listed below:

WHAT: The 3rd Annual World Congress on Obesity WHEN: Nov. 20–21, 2008 WHERE: Omni Shoreham Hotel, Washington DC CONTACT: Patrick Golden, Director of Communications 781-939-2511 or Patrick.golden@worldcongress.com CONGRESS AGENDA: www.worldcongress.com/ obesity

disability covered by Medicare Part D who cannot afford the co-insurance levels for their specialty medicines. The second patient, Lossel, spoke about the important role her community clinic and MedBank of Maryland in helping her access the medicines she needs to manage her diabetes, high blood pressure and GERD.

To access presentations visit: http://www.cbinet.com/ Presentations/PC08027\_post.zip. For CBI 10th Annual Patient Assistance Conference educational attendance scholarships information visit: http://www.cbinet.com.