



### Announcements

#### *GSHP Webinar*

**April 14, 2016 – 12 noon-1:00pm**

#### **New Treatment on the Block? Overview of Treatment for Calcium Channel Blocker and Beta-Blocker Overdoses**

1. Describe the epidemiology and pathophysiology of calcium channel blocker (CCB) and beta-blocker overdoses
2. Discuss the clinical presentation of a patient with a CCB and/or beta-blocker overdose
3. Review the treatment options available for patients presenting with CCB and beta-blocker overdoses
4. Determine an appropriate treatment plan for a patient with a CCB and a beta-blocker overdose

Speaker: Samantha Rosenthal, PharmD, BCPS

St. Joseph's/Candler Health System

PGY-2 Emergency Medicine Pharmacy Resident

There is no charge for members to attend. Non-members will be charged \$20.

To register: <https://attendee.gotowebinar.com/register/7463761280182584324>

### Headlines

#### **GSHP News**

### March 2016

#### About GSHP



Georgia Society of Health-System Pharmacists (GSHP) is a professional society of pharmacists and related personnel practicing in organized healthcare settings.

Mission Statement  
Helping our members become better practitioners.

Motto  
Bringing pharmacy practice into focus.

#### **Georgia Society of Health-System Pharmacists**

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- 'Adherent' Patients May Not be Better Than 'Non-Adherent' Peers at Taking Their Medication
- Program Helps Patients Improve Medication Adherence
- Wisconsin Pharmacies Will Pilot Making Prescription Bottles Easier to Read
- RxSafe, Datarithm Team to Streamline Pharmacy Inventory Management

## GSHP News

### Poster Presenters at the GSHP Spring Meeting

Around 30 posters were presented at the Spring Meeting. Thank you to all of our presenters. Coming in the April issue, a look at the poster contest winners.

To view the abstracts: [Poster Abstracts](#)

## PTCB

### New Recertification Deadlines Take Effect for Active PTCB Certified Pharmacy Technicians

This is a reminder that effective January 2016, PTCB has changed the recertification schedule for active PTCB Certified Pharmacy Technicians (CPhTs). All CPhTs are affected by the changes. Most active CPhTs have a new certification expiration date, while a small percentage are keeping the same expiration date. All are required to apply for recertification by the first day of their expiration month or they will be charged a late application processing fee of \$25.

## What's New

**New Window:** The new 'Recertification Window' opens 60 days (reduced from 100 days) before a CPhT's certification expiration date. For example, the recertification window opens on March 1 for CPhTs who have an April 30 certification expiration date. View the [new deadline chart](#) for more examples. Applicants have 30 days to submit their application before a late application processing fee will be charged.

**New Deadline:** Applications must be submitted by the first day of the certification expiration month; this day is the 'Application Deadline' (previously the 'Renew by Date'). A \$25 late application processing fee is charged for applications submitted after Application Deadline.

**New \$25 Late Fee:** Applications submitted after the Application Deadline (the first day of the certification expiration month) will incur the \$25 late fee.

During 2015, PTCB notified individual CPhTs by email of their new certification expiration date, their new Application Deadline, and information on the new recertification deadline schedule. CPhTs may check their certification expiration dates by logging into their PTCB Account. This information is

ASHP is a 35,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems. ASHP is the only national organization of hospital and health-system pharmacists and has a long history of improving medication use and enhancing patient safety.

### American Society of Health-System Pharmacists

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Bethesda, MD 20814  
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### Calendar

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#### GSHP Summer Meeting

7/15/16 - 7/17/16

Omni Amelia Island  
Plantation, FL

displayed on their individual account homepage and can also be viewed by printing an official certificate. They can quickly find out if their certification date has changed by visiting PTCB's web page, "[What's my certification expiration date?](#)".

### **Why is PTCB implementing the new recertification deadlines?**

PTCB has added nine additional recertification deadlines for a total of 12 recertification deadlines per year. The increased number of recertification deadlines is more consistent with PTCB's continuous nationwide testing and helps facilitate recertification application submission and processing. The change is designed to help reduce potential disruptions that could affect an individual's employment or state registration. The new recertification deadlines are intended to improve the customer service experience and enhance the recertification process for CPhTs.

[Read more and view the deadline chart.](#)

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### *Clinical Article*

## **An Updated Profile of Afrezza®**

Authors: Danielle McLendon, Student Pharmacist Mercer University, and Kendra Manigault, Pharm.D., BCPS, BCACP, CDE

Diabetes mellitus (DM) is a chronic, multifactorial disease which requires substantial consumption of healthcare resources.<sup>1</sup> When untreated, hyperglycemia that results due to insufficient insulin production or sensitivity, can predispose a patient to microvascular complications (e.g. retinopathy, neuropathy) or lead to macrovascular complications (e.g. cardiovascular disease, cerebral vascular disease, peripheral vascular disease) that can decrease quality of life and increase mortality.<sup>2</sup>

Diabetes is increasing in prevalence with 29.1 million people in the United States living with the disease in 2012.<sup>3</sup> Diabetes also presents vast economic challenges. The total cost of diagnosed DM in the US was \$245 billion in 2012 and is anticipated to increase in the future.<sup>4</sup> The cost and complexity of DM warrants continual care with therapeutic lifestyle changes as well as a variety of pharmacological and non-pharmacological therapies. Type 1 diabetes results from autoimmune destruction of insulin-producing pancreatic beta cells. These patients generally require more stringent management and are typically limited to insulin therapy in addition to nutrition and exercise management.<sup>1</sup> Type 2 diabetics commonly possess glucose intolerance and insulin resistance due to beta cell dysfunction. Lifestyle modifications, oral medications, or insulin can be utilized for management in these patients. Due to the progressive nature of diabetes, insulin is increasingly being utilized as pancreatic beta cell destruction continues.<sup>1</sup> Several potential barriers to insulin include fear of painful injections, hypoglycemia and weight gain.<sup>5</sup>

In January 2006, the US Food and Drug Administration (FDA) approved Exubera®, the first inhaled insulin option for patients requiring insulin therapy. Exubera® was manufactured by Pfizer with anticipation that it would be a blockbuster drug due to its novel formulation.

Although Exubera® was well-tolerated and provided glycemic control comparable to conventional subcutaneous regimens, market sales were much lower than expected potentially due to its cost, bulkiness, and ambiguity surrounding potential effects on lung function.<sup>6</sup> In October 2007, Exubera® was removed from the market following poor sales. Despite the market failure of Exubera®, Afrezza®, another inhaled insulin product was FDA-approved in June 2014.<sup>6</sup> Afrezza® is a rapid-acting insulin manufactured by Mannkind approved to improve glycemic control in adult patients with diabetes mellitus. As with any insulin, it works by stimulating peripheral glucose uptake by inhibiting hepatic glucose production and glucose uptake by skeletal muscle and fat. In type 1 diabetics, it must be used in combination with a long-acting insulin but may be utilized as the only insulin in type 2 diabetics.<sup>7</sup>

Clinical trial data for Afrezza® is currently only available in a briefing document from the Endocrinology and Metabolic Drug Advisory Committee of Mannkind Corporation.<sup>8</sup> Clinical trial 171 consisted of 344 type 1 diabetics randomized to receive inhaled insulin or insulin aspart in addition to their basal insulin for 24 weeks. Results indicated patients with type 1 diabetes had an adjusted mean reduction in Hemoglobin A1c (HbA1c) from baseline with basal insulin plus inhaled insulin that was non-inferior to the reduction with basal insulin plus insulin aspart (-0.21% vs. -0.4%, respectively) because it met the established non-inferiority margin of 0.4. The difference between the Afrezza® group and the aspart group was 0.19% with a 95% CI [0.02-0.36].<sup>8</sup> Clinical trial 175 consisted of 479 type 2 diabetics randomized to receive inhaled insulin or placebo in addition to their current therapy of metformin monotherapy or 2 oral

antidiabetic medications for 24 weeks.<sup>8,9</sup> Study results showed the addition of inhaled insulin significantly reduced the adjusted mean HbA1c from baseline compared with placebo (-0.82% vs. -0.42%, respectively). The adjusted mean difference in HbA1c reduction between the Afrezza® group and the oral medication alone group was -0.4% with a 95% CI (-0.57, -0.23),  $p < 0.001$ .<sup>8</sup> At week 24, twice as many patients treated with Afrezza® and oral medications achieved an A1c  $\leq 7\%$  (32.2%) vs. placebo and oral drugs (15.3%).<sup>8,9</sup>

Afrezza® should be administered at the beginning of each meal with a single inhalation per cartridge. It is available in 4, 8, and 12 unit cartridges. Cost ranges from \$271.27 to \$380.11 for 90 cartridges of varying units.<sup>10</sup> Dosing is individualized and adjustment may be needed when switching from another insulin to Afrezza®. Before beginning treatment with Afrezza®, a detailed medical history, physical exam, and spirometry must be performed in all patients to identify potential lung disease.<sup>11</sup> Additionally, Afrezza® use requires a communication plan through a Risk Evaluation and Mitigation Strategy (REMS) program due to potential risks. A black box warning exists for use in chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD) due to risk of acute bronchospasm.<sup>11</sup> It was shown to cause a decrease in lung function as measured by forced expiratory volume in one second (FEV<sub>1</sub>). In clinical trials lasting up to 2 years, patients experienced a small (40 mL) but greater FEV<sub>1</sub> decline than comparator-treated patients. Therefore, pulmonary function with spirometry should not only be assessed at baseline, but after the initial 6 months of therapy and annually thereafter even in the absence of pulmonary symptoms.<sup>11</sup>

Hypoglycemia, cough, and throat pain were the most common adverse effects reported with Afrezza®. Diabetic ketoacidosis (DKA) has also been reported and there is an increased risk in patients with acute illness or infection. Hypokalemia may occur particularly in patients taking potassium-lowering medications. In patients with hepatic and renal impairment, monitoring and dosage adjustment may be necessary.<sup>11</sup> In clinical trials, 2 cases of lung cancer were reported in patients exposed to Afrezza® while no cases were reported for the comparators. Two additional cases of lung cancer (squamous cell) were reported in non-smokers exposed to Afrezza® after the trial completion. Although lung cancer developed in more patients taking Afrezza® compared to other DM medications, there are currently too few cases to suggest a causal relationship. Nonetheless, there should be consideration whether the benefits of Afrezza® outweigh the risks in patients with active lung cancer, prior history of lung cancer, or at risk of lung cancer.<sup>11</sup>

Patient understanding as well as recognition of signs and symptoms of hypoglycemia (sweating, confusion, light-headedness, blurred vision etc.) should be ensured during counseling. As with any diabetic regimen, Afrezza® patients should adhere to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1c testing and assessment for diabetes complications. Although Afrezza® has been proven to be well-tolerated, further studies regarding long-term safety and efficacy must be established. Afrezza® has improved some of the limitations associated with Exubera® (i.e. size, dosing, etc.) which may improve its appeal as an alternative to traditional insulin therapy.<sup>6</sup> Before beginning therapy, the risks and benefits of Afrezza® use and alternative modes of therapy should be discussed.

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## ASHP News

### ***Pharmacy Students Push for Provider Status on Capitol Hill***

2/26/2016

Nearly 50 students visited 31 congressional offices on Capitol Hill earlier this month as part of ASHP's Student Advocate Training & Legislative Day. The two-day conference, also known as SSHPTakesDC, gives student pharmacists hands-on experience in how to directly affect public policy.

During meetings at the U.S. Capitol with members of Congress and legislative staff, the students made the case for provider status legislation, the [Pharmacy and Medically Underserved Areas Enhancement Act](#) (H.R.592 and S.314), by emphasizing how the pharmacy school curriculum and postgraduate residency training prepare future practitioners to be patient care providers.

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### ***FDA Addresses ASHP Concerns in Pre-Published Guidance***

2/26/2016

The Food and Drug Administration (FDA) today announced the availability of a guidance for industry entitled "Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy."

The guidance specifically addresses concerns raised by ASHP and its members over the ability of hospitals to supply first responders with medications in anticipation of emergent use or specific patient need.

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### ***Companies Use Value-Based Pricing for Single-Source Off-Patent Drugs***

[March 15, 2016, AJHP News]

Cheryl A. Thompson

BETHESDA, MD 25 Feb 2016 - The behind-the-scenes decisions on prices for single-source off-patent drugs came center stage on February 4 when two company executives explained business strategies to the House Committee on Oversight and Government Reform.

Valeant Pharmaceuticals International, Inc.'s Howard B. Schiller and Turing Pharmaceuticals' Nancy Retzlaff faced a panel of congressional representatives who took turns questioning the executives on their companies' conduct.

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### ***ASHP Expresses Major Concerns with Proposed Revisions to Chapter <797> Standards, Offers Recommendations***

2/22/2016

A number of proposed changes to the U.S. Pharmacopeial Convention (USP) General Chapter <797> Pharmaceutical Compounding - Sterile Preparations standards are incompatible with the medication-use process in patient care environments, ASHP stated in comments submitted to a USP expert panel earlier this month.

In its comment letter, ASHP points out that many of the new requirements are more appropriate for making drugs from bulk chemicals in compounding pharmacies or outsourcing facilities than for preparing medications for administration in patient care settings. The letter urges the expert panel to revise the proposals to better meet the urgent and unpredictable demands of the typical acute patient care setting.

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### ***Baxter Recalls 0.9% Sodium Chloride Irrigation Lot G120162***

Cheryl A. Thompson

BETHESDA, MD 19 Feb 2016 - Baxter International Inc. on Wednesday announced the recall of lot G120162 of the company's 500-mL 0.9% Sodium Chloride Irrigation product because an insect was found in one bottle of solution from the lot.

The product's labeling states that the solution is "for irrigation only." The company said the solution may be used to flush or rinse medical equipment, such as catheters.

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## Pharmacy News

### **Health-System Pharmacists Empower the Team**

*Drug Topics (02/10/16) Vecchione, Anthony*

Health-system pharmacists are increasingly involved in patient care and interact regularly with physicians, nurses, and other caregivers. They evaluate trends in medication use and physician prescribing, develop guidelines for medication use, and implement and maintain drug distribution systems. In some hospitals, they provide specialized services in areas such as pediatrics, oncology, infectious diseases, nutrition support, and drug information. As patient safety experts, they are responsible for the automation systems that control drug distribution. In collaboration with nursing, they help to ensure that patients receive the right medication, in the correct form and dosage, at the right time, in order to prevent adverse events. "Hospital pharmacists have long embraced the roles that practice standards, residency training, credentialing and privileging, and specialty certification play in achieving optimal patient care outcomes," says Kasey K. Thompson, PharmD, MS, MBA, vice president, ASHP Office of Policy, Planning, and Communications. Thompson notes that pharmacy technician education, training, and certification, along with the enhanced use of information technology, have also played important roles. "These advancements and others in hospitals have served as examples for other practice settings, many of which are now seeking to adopt similar pharmacy practice models," Thompson says. As the role of the health-system pharmacist continues to expand

beyond clinical duties, the pharmacy executive, a relatively new position, is also gaining ground. According to ASHSP, it behooves hospitals and health systems to have a pharmacy executive responsible for the strategic planning, design, operation, and improvement of the organization's medication management system.

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### **Hospitals' Medicine Mistakes Spike, but More Mysteries Revealed**

*Minneapolis Star Tribune (02/19/16) Olson, Jeremy*

The Minnesota Department of Health has identified 4 deaths and 10 serious injuries caused by medication mix-ups at hospitals statewide during the 12 months ended October 6. The tally reflects the highest total in more than a decade of "adverse event" reporting there, despite greater use of computerized order entry and robotic drug dispensers. "There are many transition points" in prescribing," acknowledges Rahul Koranne, MD, chief medical officer for the Minnesota Hospital Association. "The medicine is ordered by the physician, so there is room for human error there. The medication is then checked off by the nurse ... and evaluated by the pharmacist." However, collecting error data has helped to expose specific weak spots—showing blood thinners and cardiac drugs to be particularly problematic, along with medication checks and changes following patient discharge. While the report found that monitoring and recordkeeping systems can backfire by alerting patients too often for non-urgent matters, some hospitals have had success with programs that post pharmacists in the emergency room, where they interview patients and review prescription histories. The visits often lead to adjustments in patients' drug regimens.

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### **UA College of Pharmacy Developing Dry Powder Inhalers to Treat Pulmonary Diseases**

*News-Medical.Net (02/24/16)*

Research recently published in *Expert Opinion on Drug Delivery* details the development of dry powder inhalation aerosols to treat and prevent pulmonary diseases. The report, by University of Arizona College of Pharmacy assistant professor Heidi M. Mansour, discusses currently available dry powder inhalers for inhalable powder drug formulations used in the treatment of COPD, asthma, and pulmonary infections. Mansour says delivering drugs to the lungs is the best method of treatment, but there are a variety of complications involved. "The lung is the organ of life that we're targeting, so there are added regulations and added safety limits that we have to work within," she says.

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### **Drug Shortages Forcing Hard Decisions on Rationing Treatments**

*New York Times (01/29/16) Fink, Sheri*

In recent years, shortages of a wide variety of drugs have become increasingly common in American medicine. The American Society of Health-System Pharmacists currently lists inadequate supplies of more than 150 drugs and therapeutics, for such reasons as manufacturing problems and federal safety crackdowns. The rationing that results from such shortages has been largely hidden from patients and the public. Medical institutions across the country have faced choices about who gets drugs. Some institutions have formal committees that include ethicists and patient representatives; in other places, individual physicians, pharmacists, and drug company executives decide which patients receive a needed drug—and which do not. Marc Earl, a Cleveland Clinic pharmacist, says children are not favored over adults during chemotherapy shortages. But at other hospitals, they have been, because of their potentially longer life span or because they sometimes require smaller doses of a drug. At Cleveland Clinic, decisions about conserving, substituting, and allocating scarce drugs typically are made by small groups of doctors and pharmacists.

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### **Embracing Pharmacy Care Management for High-Value Care Delivery**

*Drug Store News (02/12/16) Biczak, Laureen*

Pharmacists have played a greater role in clinical care in recent years, thanks to two key trends. Medication adherence and the rising cost of generic and brand-name drugs have thrust pharmacists into the clinical spotlight and created a need for a multi-pronged approach to care. Non-adherence costs the United States about \$290 billion each year, with only 50 to 70 of every 100 prescriptions being filled by patients, according to industry statistics. Only 25 to 30 of those

are properly taken. These numbers can put a strain on value-based goals, so pharmacy care management has become a tool to address the issue. This management allows patients to receive consultation immediately after receiving a medication, which permits the pharmacist to evaluate the drug's potential effect on a patient and educate the patient on how to properly take the drug. "Pharmacies that capitalize on the unique knowledge base and expertise that [pharmacists] bring to care delivery can have greater success in moving the needle on outcomes and performance in the value-based health care landscape," writes Laureen Biczak, medical director of Goold Health Systems, a Change Healthcare company.

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### **New 'Smart Pill Bottle' Knows When You've Taken Your Medication**

*ABC7Chicago.com (02/08/16) Fleischer, Tim*

A "smart pill bottle" from AdhereTech alerts patients to when they have not taken their daily medications. "Patients just aren't taking their meds," said AdhereTech CEO Josh Stein. "It's one of the biggest problems in health care." The smart bottle signals a blue light and sounds an alarm when a person has missed his or her medication, sends the information to the individual's health care provider, and even directs a message to the patient's phone. Stein and his partners are working with hospitals to offer the bottles to patients taking expensive medication, where each dose is especially valuable. AdhereTech is also working with pharmacies to provide the technology for free and for use in clinical trials.

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### **New Study Highlights Risks of Combining Benzodiazepines and Opioids**

*Pain Medicine News (02/10/2016) Holzman, David C.*

The risk of overdose from taking opioid analgesics at the same time as benzodiazepines is four times the risk from taking opioids by themselves, according to new research. The study used VA documentation and the National Death Index to identify 422,786 veterans prescribed opioids for nonterminal cancer pain, about a quarter of whom also were on benzodiazepines. Approximately 2,400 people in the study sample suffered a fatal overdose, and about one-half of them were patients taking both drugs. "If you are going to prescribe benzodiazepines [to people on analgesic opioids], you should understand that there may be an increased risk of overdose, and you should consider what disorder you are attempting to treat," said coinvestigator Tae Woo Park, MD, of Brown University. "Typically, benzodiazepines are prescribed for anxiety disorders and insomnia, and these are pretty common in patients with pain problems. You want to ensure that you are prescribing in an evidence-based manner, and carefully weigh the risks and benefits of treatment." Park also identified high opioid doses, a history of mental health and/or substance abuse problems, and having more than one doctor prescribing opioids or more than one pharmacy filling them as other warning signs of high risk for overdose.

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### **'Adherent' Patients May Not be Better Than 'Non-Adherent' Peers at Taking Their Medication**

*News-Medical.net (02/16/2016)*

According to researchers the Universidad Miguel Hernández (UMH) in Spain, patients who are considered "adherent"—those who pick up their prescriptions each month—are not statistically any better than "non-adherent" patients at actually taking their medicine. The study also found that if changes are made to the size, shape, or color of the capsule, patients are more likely to stop taking their medication. UMH researchers and pharmacy lecturers Elsa López Pintor and Blanca Lumbreras Lacarra studied about 600 patients in Alicante who were being treated for hypertension. They discovered that lack of adherence even among patients who regularly collected their medication was as high as 32%. Those taking five or more different medications and long-term outpatients were better at following their prescribed treatments. Adherence was strongest when the medication did not interfere with the patient's daily activities.

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### **Program Helps Patients Improve Medication Adherence**

*Rapid City Journal (SD) (02/06/16) Gahagan, Kayla*

Approximately 50% of patients do not take their medications as prescribed, according to Prescriptions for a Healthy America, and at least 125,000 Americans die each year as a result of poor medication adherence. A new program from the Medicine Shoppe aims to help, enabling

patients with multiple medications to sync all of their medications to be picked up at the same time and sending a reminder the day before they are ready. Curt Rising, owner and pharmacist at the Medicine Shoppe, said that "on their own, patients typically fill meds 6 to 8 times a year," but with this program, patients are "filling 11 to 12 times a year." Rising said the patients' relatives are often relieved when the patient receives a med box to help organize medications, or they use a program such as med sync. Other ways to help increase adherence include setting alarms, using cellphone apps designed for prescriptions, and writing reminders on a calendar. Dana Darger, director of pharmacy at Rapid City Regional Hospital, said the best thing a patient can do is sit down with their pharmacist and work out a schedule for medications.

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### **Wisconsin Pharmacies Will Pilot Making Prescription Bottles Easier to Read**

*Wisconsin Public Radio News (02/15/16) Mills, Shamane*

In Wisconsin, 46 pharmacy locations are participating in a campaign to boost prescription adherence by making medicine bottles easier to read and understand. Based on recommendations from the nonprofit U.S. Pharmacopeial Convention, the 2-year pilot program will include more white space and enlarged print on labels; use numerals instead of spelling numbers out; avoid type in all capital letters, which is more difficult to read; and be more specific about what the medication treats and when to take it. "One of the challenges that we have with current labels is that sometimes the most important things are not the things that are emphasized most," acknowledges Steve Sparks of Wisconsin Literacy, noting that pharmacy logos or prescribing doctors' names often claim the most space. He says pharmacies report that patients, especially those with multiple prescriptions, often ask for additional information to be written on their medicine label. The new standards, he says, will benefit all patients but older adults in particular as well as those with poor reading skills.

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### **RxSafe, Datarithm Team to Streamline Pharmacy Inventory Management**

*Drug Store News (02/11/16) Salazar, David*

In an effort to streamline inventory for pharmacy owners, pharmacy automation company RxSafe and inventory software company Datarithm are entering into a partnership. RxSafe's real-time inventory combined with Datarithm's software, which delivers optimized order points, can quickly identify surpluses and offer pharmacies solutions for handling them. "The result is a game-changing model that eliminates cycle-counting, frees up cash, and allows pharmacies to focus on patient care and services," said William Holmes, RxSafe president and CEO. Datarithm has also declared its eagerness to work with RxSafe: "Their RxSafe 1800 System, and all that it does, combined with Datarithm's customizable Rx inventory software, and all it does, makes for a very flexible, powerful, and automated solution," said Datarithm VP sales and marketing Dan Sullivan.

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