

Summer 2009

THE “RED FLAGS” RULE**What Pharmacies Need to Know About Complying with New Requirements for Fighting Identity Theft**

The expression “Red Flag” signals “**Danger: Be alert to problems ahead.**” For millions of consumers every year, identity theft is more than a threat—it is their reality. Businesses often bear the biggest part of the monetary damage from identity theft. But the economic, psychological and emotional harm to victims can be devastating. When the identity theft involves health information, the consequences can be particularly severe!

It is everyone’s responsibility to do what they can to fight identity theft. Healthcare providers can be the first to spot the **Red Flags** that signal the risk of identity theft, including suspicious activity indicating that identity thieves may be using stolen information like names, Social Security numbers, insurance information, account numbers and birth date to open new accounts or get medical services.

Under the **Red Flags** Rule, certain businesses, organizations and healthcare providers—including pharmacies—are required to spot and heed the **Red Flags** that often can be the telltale signs of identify theft. Pharmacies that regularly offer patient charge accounts, also known as house accounts, must develop a written “**Red Flags** program” to comply with the new **Red Flags** rule. This program must be put into effect by August 1, 2009.

The definition of “creditor” is broad and includes businesses that regularly defer payment for goods or services and bill customers later. “Healthcare providers are creditors if they bill consumers after their services are completed.” according to the Federal Trade Commission. Most pharmacies that regularly offer their patient charge accounts fall under a category of covered accounts, which the FTC calls consumer accounts. Consumer accounts are primarily for personal, family or household purposes that involve or are designed to permit multiple payments or transactions.

The Rule does not specifically outline what the Pharmacy’s **Red Flag** program must look like. Instead, it gives the Pharmacy flexibility to implement a program that best suits the needs of the business, as long as it meets the Rule’s requirements.

The best starting point for developing a program is the Guidelines issued with the **Red Flags** Rule, available at www.ftc.gov/os/fedreg/2007/november/071109redflags.pdf

(The Guidelines are on pages 63773-63774 of the document.) Said Guidelines list the issues you must consider in developing and maintaining a program appropriate for the Pharmacy’s business. The Pharmacy Owner/Manager should also draw on his/her own experience and knowledge about identity theft risks in developing the program. There are four basic steps to designing a program to comply with the Rule:

1. Identify relevant **Red Flags**
2. Detect **Red Flags**
3. Prevent and mitigate identity theft
4. Update the program periodically

The program must also spell out how it will be administered. The program should be appropriate to the size and complexity of the Pharmacy, as well as, the nature of the business operations.

The Guidelines also describe the categories of warning signs—**Red Flags**—that the program must identify and address with regard to possible identity theft in connection with covered accounts. Said categories are as follows:

- Alerts, notifications or warnings from a consumer reporting agency
- Suspicious documents
- Suspicious personally identifying information
- Suspicious activity related to a covered account
- Notices from customers, victims of identity theft, law enforcement authorities or other entities

Once the relevant **Red Flags** are identified, the Pharmacy must establish policies and procedures to detect them in their day-to-day operations. NCPA posted questions and answers in the Members Only section of their website, as well as, provided a sample policy.

SURETY BONDS

The Centers for Medicare and Medicaid Services (CMS) confirmed that surety bond requirements will continue to move forward as stated. Businesses offering Durable Medical Equipment and Prosthetics, Orthotics and Supplies (DMEPOS) must post a minimum \$50,000 surety bond for each National Provider Identifier (NPI) number that they have.

EXEMPTION**SECRETS TO MANAGING ALL THAT PAPER**

Eliminate the Phrase “Just for Now.” One of the biggest reasons that paper quickly gets out of hand is that it is put in a pile, “just for now.” That ‘temporary’ place often turns into a permanent place. The paper piles grow and grow until they are completely out of control. **Do It** (take action on it), **Delay It** (file it in your filing system), **Delegate It** (give it to someone else to take care of it) or **Dump It** (80% of the paper we get on a daily basis can be recycled).

File, Don’t Pile. It is okay to have a TO FILE box, as long as you file on a daily or every other day basis. Many people put filing items aside as a low priority item. Beware of this. Filing should always be a high priority item on your list because when you don’t file, the result has the potential to really affect your productivity later.

Don’t Make Lots of Extra Copies. If you have easy access to a copy machine, don’t be tempted to make more copies of a sheet of paper than you really need.

Go Through Your Mail Over the Recycle Can. Each day when you get your mail, whether you are at home or in the office, open your mail over your recycle can. Immediately get rid of any junk mail so it doesn’t have a chance to pile up somewhere.

Write Things Where They Belong. Rather than writing things on scraps of paper, write them where they belong. Put events or scheduled appointments in your calendar. Put ideas, checklists, to do items and other important information into one concise organizing system that works for you.

WRIST SAVER

Relax your wrists and relieve the pain and strain that can result from typing and other repetitive motions. Rest your elbow on a hard surface

EXEMPTION

CMS reiterated the list of exempt providers included in the final rule and indicated that Pharmacies are **NOT** exempt from this rule. In addition, **Pharmacies that only furnish drugs under Part B are NOT exempt.**

NEW SUPPLIER REQUIREMENTS

As of May 4, 2009, suppliers that enroll for the first time, suppliers that seek change of ownership, or existing suppliers that are establishing new practice locations must submit proof of a surety bond. In these cases, the National Supplier Clearinghouse (NSC) will reject the CMS-855s application if it is not submitted with evidence of a surety bond.

EXISTING SUPPLIER REQUIREMENTS

Enrolled DMEPOS suppliers, subject to the bonding requirement, are required to obtain and submit \$50,000 bond for each National Provider Identifier (NPI) by October 2, 2009 to the National Supplier Clearinghouse (NSC).

BOND AMOUNT

The bond amount is \$50,000 per location based on the National Provider Identifier (NPI). However, for suppliers that have a Final Adverse Action (defined below) within 10 years before enrollment, revalidation or reenrollment, the surety bond amount will be based \$50,000 plus \$50,000 for each adverse event. Final Adverse Action means one or more of the following:

- (i) Medicare-imposed revocation of any Medicare billing privileges
- (ii) Suspension or revocation of a license to provide health care by any state licensing authority
- (iii) Revocation or suspension by an Accreditation Organization (AO)
- (iv) Conviction of a federal or state felony offense [as defined in 42 CFR § 424.535 (a)(3)(i)(A)] within the last 10 years preceding enrollment, revalidation or reenrollment
- (v) Exclusion or debarment from participation in a federal or state health care program

SINGLE BOND

CMS indicated that it will allow suppliers with multiple locations to obtain a single bond to cover all of their locations, as long as the total bond amount equals \$50,000 per location. For example, a chain with 10 locations may obtain one bond of \$500,000 instead of 10 separate bonds for \$50,000 each.

AUTHORIZED SURETY COMPANIES

CMS will only accept bonds obtained through authorized surety companies. PRS Pharmacy Services has partnered with an insurance firm with 50 years experience in helping Pharmacy owners with their professional insurance needs. They will provide this Medicare DMEPOS Surety Bond for \$250* annually. This will save a Pharmacy thousands of dollars over the years. For more information, call:

Mayer & Steinberg, Inc.
1-800-454-3040

**A small number of Pharmacies will have a higher bond and/or premium due to individual circumstances such as fraud convictions, previous exclusion from federally funded programs and other underwriting considerations. This will not affect the majority of Pharmacies.*

PFIZER UPDATES CHANTIX® (varenicline) LABELING IN THE UNITED STATES

Pfizer Inc announced that it has updated the U.S. product labeling for Chantix® (varenicline), a prescription aid to smoking cessation treatment, to communicate important safety information in a boxed warning, as well as, in revised warnings and precautions. These updates are based on post-marketing reports and are being made in agreement with the U.S. Food and Drug Administration (FDA).



The updated label highlights safety information about reports of serious neuropsychiatric events in a boxed warning; updates the warning about reports of neuropsychiatric symptoms and suicidality; adds warnings about reports of allergic reactions and serious skin reactions; and updates precautionary information about driving or operating machinery to include details about reports of accidental injury.

“The labeling update underscores the important role of health care providers in treating smokers attempting to quit and provides specific information about Chantix® and instructions that physicians and patients should follow closely,” said Dr. Briggs W. Morrison, senior vice president, Primary Care Development Group at Pfizer. “Quitting smoking is one of the best things people can do for their health, but the quitting process is both difficult and complex.”

BOXED WARNING HIGHLIGHTS IMPORTANT SAFETY INFORMATION

Certain information on neuropsychiatric symptoms has been included in the Chantix® label since November 2007 and is based on post-marketing reports. The boxed warning instructs health care providers to observe patients being treated with Chantix® for the possibility of certain serious neuropsychiatric events and to advise patients to stop taking Chantix® and contact their doctor immediately if these symptoms occur. It also states that the safety and efficacy of Chantix® in patients with serious psychiatric illness have not been established. The update advises

motions. Rest your elbow on a hard surface (i.e. desk) with your hand hanging over the edge. Gently stretch your fingers back with your other hand and hold for five seconds. Repeat for the other hand.

EMAIL ADDRESS



Please keep us informed of any changes to your email address.

“QUOTE IT”

If I believe I cannot do something, it makes me incapable of doing it. But when I believe I can, then I acquire the ability to do it, even if I did not have the ability in the beginning.

– Mahatma Gandhi

MAXIMIZE STRENGTHS, MINIMIZE WEAKNESSES

Good managers know how to ferret out the strengths and weaknesses of their employees—then figure out how to build those strengths and minimize those weaknesses. This is a big job and the reason managers are such an important aspect of successful businesses.

Of these two jobs, the most important is to recognize the strengths of employees and to help reinforce self-assurance. To do this, a really great manager won't praise an employee for working hard. Instead, the manager will tell that employee that her success is due to her growing ability to use specific strengths on the job. Doing this will give the employee an optimistic outlook on her effect on the workplace and will give her more confidence in facing future challenges.

If the employee repeatedly fails at the goal, it may be that some weakness needs to be strengthened. First the manager must assess whether the failure is due to a lack of skill or knowledge. If this is the case, all the manager needs to do is provide the education, experience, etc. necessary to bring the

symptoms occur. It also states that the safety and efficacy of Chantix[®] in patients with serious psychiatric illness have not been established. The update advises physicians to provide ongoing monitoring and support for patients who exhibit neuropsychiatric events until symptoms resolve.

The boxed warning also provides important information about the quitting process. It states that some smokers who are making a quit attempt – including those who are not using medication – may experience nicotine withdrawal symptoms, such as depressed mood. Additionally, the boxed warning communicates that the health benefits of quitting smoking are immediate and substantial, the risks of Chantix[®] should be weighed against the benefits of its use, and that Chantix[®] has been demonstrated to increase the likelihood of quitting for as long as one year compared to placebo.

Pfizer is conducting clinical trials of Chantix[®] in multiple populations, including in patients with psychiatric disorders and chronic lung disease.

Safety Information in Warnings and Precautions Sections

The Chantix[®] label updates existing warning information regarding serious neuropsychiatric symptoms to include the types of reports received. It also adds warnings about allergic reactions, such as angioedema, and rare, but serious, skin reactions, such as Stevens-Johnson Syndrome. Existing precautionary information about driving and operating machinery has been updated in the Chantix[®] label to include details about accidental injury.

For more information, visit www.pfizer.com/files/products/uspi_chantix.pdf for [full Prescribing Information](#) and http://www.pfizer.com/files/products/ppi_chantix.pdf for [Patient Medication Guide](#).

education, experience, etc. necessary to bring the employee up to snuff. However, if the failure is due to the lack of talent, then the manager will have to find a way of managing around the problem. One thing that can be done: The manager can find a partner whose strength balances the weakness of the failing employee. If this tactic is not a possibility, then the manager will want to help the employee develop a discipline that will help her overcome her weakness. For instance, if she has trouble being direct with others, then a visualization exercise, in which she imagines how her mentor might handle the situation, might help.

—adapted from “Great managers understand their people,” by Marcus Buckingham in the *Harvard Business Review*

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