REMS and the Pharmacist

MUSIC CITY STANDOUTS • A PHARMACY LEGACY • OWNERSHIP OPTIONS •
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How We’re Doing

IT’S THAT TIME OF YEAR AGAIN when we release key trends and statistics from data collected from hundreds of independent community pharmacies of all sizes from across the country. The 2011 NCPA Digest once again is sponsored by Cardinal Health. The first NCPA members to see it are those attending the annual convention in Nashville.

I can’t thank Cardinal enough for supporting this longtime and important resource for NCPA members, and for all the other backing and service it provides community pharmacy throughout the year. Cardinal follows in a rich tradition of partnership between industry and independent community pharmacy begun by Lilly, which launched the Digest with NARD in 1932, and it has been continued over the last 20 years variously by Searle, Pharmacia, and Pfizer.

Some 41 percent of all retail prescriptions dispensed came from independent pharmacies.

In 2010 independent community pharmacy represented a $93 billion marketplace, with 92 percent of the sales coming from prescription drugs. Some 41 percent of all retail prescriptions dispensed came from independent pharmacies. The average independent dispenses about 64,000 prescription drugs a year. Average total sales were about $4 million per pharmacy.

The role of government programs such as Medicare Part D and Medicaid continues to increase while private third-party plans have been declining since 2005. Cash customers, of course, are disappearing. In 2010, 16 percent of prescriptions dispensed by independent community pharmacies were through Medicaid and 30 percent through Medicare Part D.

During these difficult economic times independent community pharmacists continue to help patients lower their costs by encouraging the use of generic drugs. About 71 percent of the prescriptions dispensed by independents were for generics, and their brand-to-generic drug switching recommendations to physicians were accepted 80 percent of the time.

Independent practitioners also continue to offer a wide array of patient-centric services and niche products to stay competitive:

- 86 percent set up patient charge accounts.
- 69 percent provided home delivery.
- 69 percent had durable medical equipment sections.
- 66 percent offered compounding.

Of independent community pharmacies that provided at least one disease state management service:

- 58 percent gave immunizations.
- 50 percent performed blood pressure monitoring.
- 48 percent offered diabetes training.

So what’s the real bottom line? As long as men and women like you continue to serve their patients, businesses, and communities, and work with partners such as NCPA and Cardinal Health, independent community pharmacy will remain a vibrant part of the health care delivery system.

Please help NCPA help you. Keep your membership up to date and make sure your colleagues are members, too.

B. Douglas Hoej, Pharmacist, MBA
NCPA Executive Vice President & CEO
NCPA Meets With White House On Crime, Drug Abuse

Twice this summer, NCPA leaders have been invited to separate White House meetings on the inter-related problems of prescription drug abuse and pharmacy crime. NCPA President Robert J. Greenwood represented NCPA in a White House Office of National Drug Control Policy meeting to discuss the pharmacist’s role in preventing prescription drug abuse. That same office later held a meeting on pharmacy crime that past president Joseph H. Harmison attended. The stakeholder meetings were convened in response to action items laid out in the Obama administration’s Prescription Drug Abuse Prevention Plan. Both men were able to provide the invaluable perspective of frontline practitioners.

There are many sobering statistics about the rampaging abuse of prescription drugs: seven million Americans reporting non-medical use; $56 billion in costs associated with abuse; $25 billion in direct health care costs, including 1.2 million emergency department visits annually; and that six of the top 10 abused substances among high school seniors are prescription drugs.

Crime figures are sobering, too, especially with in light of two robberies earlier this year that left five people dead, including

Continued on page 8

Adherence—It Only Takes a Minute

By Wendy Lantaff

The importance of adherence is often discussed regarding long-term medications for chronic conditions, but did you know almost 40 percent of patients on a short course of antibiotic therapy are non-adherent? Non-adherence during antibiotic therapy can result in decreased cure rates, increased health care costs, and the development of antibiotic resistant strains of bacteria. For a pharmacist, there are several easy ways to increase antibiotic adherence.

One way is through education. How many times have patients stopped taking antibiotics because they felt better or because they wanted to save a few for a future infection? Or maybe they were just simply misinformed. Make the dispensing of every antibiotic prescription an opportunity to talk with and educate every patient. Ask open-ended questions during counseling to understand what they already know. You can then reinforce important concepts while educating them about their prescription. Write down the counseling points discussed so the patient can easily refer back to them later. Written instructions, in addition to verbal counseling, have been shown to significantly increase adherence.

Keep it short and simple—the dose, that is. In study after study, the highest rates of adherence are associated with the shortest duration and simplest dosing schedule of antibiotics. Ask your patients if they are going to be able to follow their dosing schedule, especially if the antibiotic prescribed is to be taken three or four times a day or the duration is longer than seven days. If a specific therapy needs to be taken often and the patient knows they are going to have trouble taking some of the doses because they will be at work and won’t have access to food and water, or a place to store their medication, contact the doctor and try to collaborate on a therapy the patient can follow. If a complicated therapy...
**THE AUDIT ADVISOR**

**PRESCRIPTION BLANKS WITH RULES**

Q: Recently, audits of several pharmacies resulted in chargebacks because the prescriber did not fill out the prescription blank correctly. What are third parties taking monies back on?

A: In one case, the number of authorized refills was indicated as a number; the prescription form clearly stated that refills had to be written in letters and the auditor deemed all refills of the prescriptions to be Unauthorized.

Another pharmacy filled prescriptions written on a form that had the disclaimer “prescription void if more than one medication is prescribed.” This resulted in a full chargeback of the claim, as the prescription was considered Invalid. Auditors have also charged back on prescriptions when the prescriber has not filled out the field indicating how many medications were prescribed or if a quantity check-box is not checked.

Prescription blanks that present unique stipulations may be used against you in an audit. *It is imperative that pharmacists and technicians scrutinize all prescription orders carefully before filling!* Potential pharmacy saving—$100 or more.

By Mark Jacobs, RPh, PAAS National, the Pharmacy Audit Assistance Service. For more information call 888-870-7227 toll free.

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**INDEPENDENT PHARMACY TODAY**

Independent pharmacies using workflow technology:
- **Point of sale**—72%
- **Telephone IVR**—41%
- **Automated dispensing counter**—30%
- **Automated dispensing robotics**—24%

Source: 2011 NCBA Digest, sponsored by Cardinal Health

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should not be changed, which is the case with Helicobacter pylori eradication, work with the patient to overcome any barriers they foresee, while reminding them that adherence is crucial for success. You, the pharmacist, are first in line to identify and fix adherence issues before they occur.

Follow up. Some studies suggest adherence increases with a follow up phone call from the pharmacist midway through the antibiotic regimen. It has also been shown to increase patient satisfaction, along with giving the patient an opportunity to ask questions regarding medication-related issues that have come up. During follow up phone calls, pharmacists are dispensing advice about managing side effects, recommending over-the-counter medications and non-pharmacological treatments, and referring the patient to their physician when indicated. Rarely do patients seek out this valuable advice when not called. A simple follow up phone call provides the opportunity to enhance patient care and keep your patients on the adherence pathway!

While these adherence activities do take a little time, the results are worth it for both you and your patient. In addition to being healthier, your patient will see their relationship with you strengthening, while continuing to see you as the medication expert, accessible and available. It only takes a minute!

Wendy Lantaff is a 2013 PharmD candidate at the University of Colorado, and was an NCPA 2011 summer intern.
Drug abuse education in pharmacy (and medical) schools was a hot topic. An ONDCP slide said two-thirds of pharmacists surveyed reported receiving two hours or less of addiction or substance abuse education in pharmacy school, and nearly 30 percent reported receiving none at all.

ONDCP acknowledges that there is no single solution to combating the epidemic, but coordination and collaboration at the federal, state, and local levels are needed for success. Efforts will focus on education for patients, parents, and health care providers; PDMPs to flag questionable prescriptions; proper medication disposal; and enforcement, especially addressing “pill mills” and doctor shoppers.

Harmison represented NCPA in a Pharmacy Robberies Roundtable Discussion hosted by ONDCP and the Department of Justice Office of Community Oriented Policing Services. The purpose was to discuss prescription drug abuse and its impact on pharmacies and to share information regarding whether the recent increases in pharmacy robberies represents a trend and what action, if any, can be taken to address the issue.

NCPA provided helpful recommendations from the independent community pharmacy viewpoint, including ideas for increased penalties, educational efforts, and what can be done in situations when a pharmacist believes they can’t fill a controlled substance prescription for a particular reason yet feels threatened by the patient. NCPA also provided details on our efforts over the last several years involving the Protect Your Pharmacy Now initiative, which was developed to encourage pharmacists in all practice settings to take steps to protect staff and patients from pharmacy crime, including prescription drug theft.
Campaign to Block Express Scripts/Medco Merger Underway

NCPA and the National Association of Chain Drug Stores have sent two formal letters to the Federal Trade Commission in shared opposition to the proposed $29.1 billion merger of Express Scripts and Medco announced July 21.

The correspondence emphasized joint opposition because of the merger’s anticompetitive impact on patients, consumers, the market, and the entire health care delivery system. NCPA and NACDS offered to assist the FTC in its assessment, examination, and investigation into the merger’s anticompetitive nature and its consequences on patient access and consumer care.

In addition, NCPA has launched a congressional campaign to convince the FTC to reject the plan to join two of the nation’s biggest PBMs. All NCPA members are being urged to contact their members of Congress, state attorney general, insurance commissioner, state legislators, and governor and ask them to express their opposition to the merger with the FTC.

Approval of the merger could mean higher drug prices, less competition, more egregious PBM practices, fewer consumer choices, and more mail order. Please go to the NCPA website to contact your member of Congress today.

NCPA also has contacted numerous interest groups that represent different levels and sectors of state government. The goal of is to develop relationships that will assist NCPA’s state advocacy efforts in opposition to the merger. Groups contacted included the National Governors Association, Democratic Governors Association, Republican Governors Association, National Association of Attorneys General, National Conference of State Legislators, National Conference of Insurance Legislators, and Council of State Governments.

Make Part D Plans Pay, NCPA Recommends

NCPA has submitted comments to the Centers for Medicare & Medicaid Services on the burdens associated with the 2012 requirement that pharmacies provide Part D beneficiaries with a standard paper notice whenever their prescriptions cannot be filled. The notice will replace the signs, currently posted in pharmacies, which detail beneficiary appeal rights.

Members have expressed concerns about the time and financial burdens associated with meeting this new requirement. NCPA urged CMS to reevaluate the small business burdens imposed by the transition, and also requested that CMS reconsider the decision to make the transition, or at a minimum, to consider options for reducing the costs and burdens to community pharmacies associated with it. Moreover, NCPA urged CMS to mandate that Part D plans bear the costs associated with this transition to a paper-based standardized notice, not the pharmacies.
New Independent Pharmacist

Now that summer has come and gone, it is time to gear up for legislative advocacy on the campuses of pharmacy schools with your NCPA student chapters. One of the best ways to learn about advocacy and the legislative process is by attending the NCPA Conference on National Legislation and Government Affairs. The 43rd annual event was held May 23–25 in Washington, D.C. Provided is a brief recap of the first Future Pharmacists Programming session at the conference, along with ideas you can use at your school or college of pharmacy to encourage advocacy.

The first topic of discussion was “NCPA PAC and LDF — What You Should Know” presented by Karry LaViolette, director of Political Development for NCPA. The NCPAPAC (political action committee) relies on personal donations from NCPA members to go toward campaign contributions for pharmacy supporters in Congress. It is among the largest pharmacy organization PACs, and is among the top 40 association PACs nationwide. Donations to the LDF (Legislative Defense Fund) may come from members or non-members, through either personal or corporate funds. These funds support grassroots advocacy, outreach, independent research, and litigation. The PAC and LDF exist to fight on your behalf, so what can you do to keep them effective? Encourage your members to make personal donations to the NCPAPAC and your chapter to fundraise and contribute to the LDF.

The second topic was “Legislative Issue Briefing” by Chris Smith, director of policy and regulatory affairs for NCPA. This was a crash course on some of the issues we would be lobbying for on Capitol Hill: These include the Pharmacy Competition and Consumer Choice Act (H.R. 1971/S. 1058), which calls for pharmacy benefit manager (PBM) transparency and audit practice reform; the Medication Therapy Management (MTM) Benefits Act (H.R. 891/S. 274), which would promote and expand the provision of MTM services to Medicare Part D patients; the Medicare Access to Diabetes Supplies Act, exempting diabetes supplies sold in small pharmacies from the competitive bidding program; and the Pharmacy Fairness Act of 2011, allowing independent community pharmacies to collectively negotiate terms and conditions of insurance contracts for fairer plan designs and greater patient choice. For additional information on these topics and more, visit the NCPA Legislative Action Center website (www.ncpa-actioncenter.com/) where you can email your legislators to support these pharmacy initiatives.

The last topic was “How to Meet with Your Legislator—Pharmacy Visit Tips” by Deirdre Myers, RPh, of the Raabe College of Pharmacy at Ohio Northern University. As a student, you may be nervous about meeting with your congressman, senator, or a member of their staff, but it is actually a rewarding experience. I met with two pharmacists from my own state association and two other students from Ohio Northern University. We attended several office visits over the course of the conference. This gave us a chance to observe and take notes, help explain an issue, and then finally, lead the discussion. For a step-by-step guide on how to visit with your legislators, check out the Pharmacy Visit tips found in the Legislative Advocacy section of the NCPA website www.ncpanet.org.

Lauren Anderson is a 2013 PharmD candidate at Ohio Northern University’s Rudolph H. Raabe College of Pharmacy. She is also on the NCPA Student Leadership Council, senior member, Region 3.
When patients report medication errors to the Institute for Safe Medication Practices, they are usually more upset about the response, or lack of response, they receive from the pharmacist or pharmacy management than with the actual error itself. For example, a pharmacist incorrectly dispensed Zyrtec (cetirizine), an antihistamine, instead of the antifungal Lamisil (terbinafine). When the patient brought the possibility of an error to the pharmacist’s attention, the pharmacist did not investigate the situation and responded, “I would not have filled it if it wasn’t correct.” This, or something similar, is often the response patients receive when they question that the medication may ‘look different.’ The patient later took the wrong drug!

Patients are looking for open and honest communication from their health care providers on questions about their medications or when an actual error may have occurred. As patients are continually encouraged to be more active in their care and serve as a final check at the pharmacy, it is critical that pharmacy staff prepare for the inevitable occurrence of a medication error.

Every pharmacy should have written policies and procedures for handling medication errors. These procedures need to be seen, read, and understood by every member of the pharmacy team. The policies and procedures need to be reviewed regularly for appropriateness and updated to reflect changes in workflow and additions of technology. They should contain guidance about what to say and do as well as what not to say or do. General principles in written procedures regarding how to respond to an error include:

- Define staff roles in response to a possible or actual medication error, including a description of how staff should respond to a patient’s questions. Also define how management should respond and investigate.
- Have a written policy on disclosure that is agreed upon and followed by management and staff.
- Define when others (such as the prescriber) should be notified of an error.
- Respond to the report with truth and honesty. Be direct and open with the patient reporting the error. Assure the patient reporting a potential or actual error that it is important and a priority.
- Consider teaching everyone who is involved in responding to an error to use statements such as: “Please let me explain what we believe happened and how we plan to fix it,” or “At this point I cannot answer how this happened but I promise you I will look into it and get back to you.”
- Document and report the event and response. Some specific actions to consider include: document the date, time, and specifics of the event; report the event using the pharmacy’s internal reporting system; notify supervisors, risk management, and the prescriber when necessary; make a note in the patient’s profile so that staff is aware, especially when the patient returns to the pharmacy; and report the event confidentially to ISMP, when appropriate, to warn others outside of the organization of a possible error that may have been prevented.
- Alert staff to the situation. Share and discuss event details, possible contributing factors, temporary and subsequent prevention strategies, and procedural changes.
- Provide support to staff involved in the incident. Offer those involved with the error access to employee assistance programs.
- Practice and role play possible scenarios using the established guidelines.

This article is from the Institute for Safe Medication Practices (ISMP). ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.
Matt was in a car accident during his sophomore year in college. He went to the emergency room for evaluation and treatment and was discharged with a diagnosis of three broken ribs and a dislocated shoulder. He experienced significant pain while in recovery, and the short acting opioid the doctor initially gave him was replaced with a long acting opioid which allowed him better pain relief and rest at night. When he was ready to return to college, he needed to bring his medication with him. Most of Matt’s friends were worried about him, but a few wasted no time in asking him “what he got” for the pain. Some even offered to pay Matt for some of his medication, and he found one friend searching through his drawers looking for pills. Matt, concerned that his meds would be stolen, asked his dorm resident assistant if he could store his medication for him.

Reducing the potential risks of prescription opioid medications

By Kathryn L. Hahn, PharmD
A Loaded Gun

Although much of the public perceives prescription opioid medications as safe because a doctor is prescribing them and a pharmacy is dispensing them, statistics show us that they can have the same deadly potential as a loaded gun if not used as intended. If they are abused, not taken as directed, or taken by people for whom they are not prescribed, they can kill. In a perfect world, we don’t give guns to people without warning them about their deadly potential—and without making sure they understand the warning. The same should be true for prescription opioid medications. Luckily Matt was able to prevent the theft or misuse of his medication, but that is not always the case. Some studies estimate that up to two thirds of deaths related to prescription pain medications in the United States are caused by medications that are legally dispensed by a pharmacist with a valid prescription, but were not taken as directed, not taken by the person they were prescribed for, or that fell into the wrong hands.

According to the Institute of Medicine’s recent report, acute and chronic pain affects large numbers of Americans, with at least 116 million U.S. adults burdened by chronic pain alone. The annual national economic cost associated with chronic pain is estimated to be $560–635 billion. Pain is a uniquely individual and subjective experience that depends on a variety of biological, psychological, and social factors, and different population groups experience pain differentially. For many patients, treatment of pain is inadequate not just because of uncertain diagnoses and societal stigma, but also because of shortcomings in the availability of effective treatments and inadequate patient and clinician knowledge about the best ways to manage pain.

While there are a number of effective prescription pain medications available, the increasing misuse, abuse and diversion of prescription pain medications—especially among young adults—is having a major impact on physicians’ ability and/or willingness to treat pain. This impedes patient access to medicines and care. According to the National Institute on Drug Abuse, nearly 10 percent of high school seniors have abused short-acting combination hydrocodone products. The increasing misuse, abuse, and diversion of opioid pain medications have become widespread and pose a costly and significant public health issue in and of itself. In 2005, the estimated total cost associated with opioid abuse, including health care, justice, and work-related costs, totaled $9.5 billion.

However, opioids, which are so dangerous in the hands of abusers, are beneficial or even lifesaving for millions of people who otherwise would live with intractable pain. Nearly everyone seeks medical treatment to control pain at some point. Over the past two decades, there has been increasing awareness among health care providers that good pain management is an important component of ethically providing care for patients with chronic pain. The increased awareness about pain management practices has been accompanied by increased prescribing of opioids for the treatment of chronic nonmalignant pain. As the appropriate use of opioids gained an accepted role in the long-term treatment of chronic nonmalignant pain, the incidence of misuse and mortality also increased.

Recent studies have shown that patients recognize the value of, and are willing to receive, pharmacist delivered care. Ideally that care is delivered by a pharmacist with whom a patient has had an established relationship.

Predicting Aberrant Behavior

If pain treatment with opioids is to be successful, prescription misuse must be managed. To accomplish this, it is necessary to monitor, document and address a patient’s aberrant drug-related behavior. There are observable behavioral patterns that are indicative of potential
misuse or abuse of controlled substances. The goal is to ensure that opioid therapy is beneficial to the patient instead of a source of unmanageable difficulty.

**Pharmacist Role as Pain Team Member**

Pharmacists are often the first point of contact for patients complaining of pain. Given their extensive training and expertise, pharmacists are valuable resources for patients with a variety of painful conditions, providing education about drug administration, side effects, and the potential for drug interactions.

Abuse and diversion potential is an important topic of discussion because patients should be made aware that the sharing of medication is prohibited, both from a medical and legal perspective. In addition, patients must be taught to monitor, safely store, and properly dispose of their opioid medications. Having awareness about the diversion of easily accessed opioid prescription bottles is crucial. Contrary to the popular opinion of many in the general public, the bathroom medicine cabinet is actually the worst place to store medications because of heat, moisture and the knowledge by potential abusers that that’s the most likely spot to find highly sought after drugs. Pharmacists can teach patients to lock up their opioid prescriptions and keep them in a secure place such as a safe, drawer, or box. They should be keeping track of the amount of pills they currently use by regularly counting them.

Safe disposal of unused opioids is an important subject that community pharmacists are best suited to discuss with their patients. The FDA recently addressed this topic by coming out with recommendations for safe disposal of medications, including opioids. While most medications are safely disposed of by locating a disposal site (or mixing with kitty litter or coffee grounds if nothing else is available), most opioids have been placed on a list by the FDA, directing patients to flush them down the sink or toilet. FDA believes that any potential risk from flushing the drugs is outweighed by the real possibility of life-threatening risks from accidental or intentional ingestion of these medications. However, NCPA, through the Dispose My Meds program, discourages flushing meds mainly because of environmental concerns. Disposal of controlled drugs may be possible by locating a disposal site at a local police or sheriff’s station.

The FDA has recognized the role of the pharmacist as part of its recently-launched Safe Use Initiative. Pharmacists are prominently mentioned as part of the

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### Predictive Behavior Characteristics of Misuse (History of Misuse) | Patient Management Guidelines

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<th>Frequent loss of prescriptions</th>
<th>Highly structured approach:</th>
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<tr>
<td>Lack of effectiveness of non-controlled substances</td>
<td>• Frequent office visits</td>
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<tr>
<td>Specific drug requests</td>
<td>• Limited supply of medication</td>
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<tr>
<td>Diversion, dealing, stealing drugs</td>
<td>• Pill counts</td>
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<tr>
<td>Use of illicit drugs/alcohol</td>
<td>• Urine drug testing</td>
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<tr>
<td>Functional deterioration</td>
<td>• Written treatment agreement</td>
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<tr>
<td>Isolative behavior</td>
<td>• State prescription monitoring Program</td>
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<tr>
<td>Doctor or pharmacy shopping, frequent ER visits</td>
<td>• Referral to addictionologist</td>
</tr>
<tr>
<td>Flunks urine testing</td>
<td>• Multidisciplinary care, including psychologist</td>
</tr>
<tr>
<td>Manipulating tablet to snort, inject</td>
<td>• Maintain rigorous documentation</td>
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community of care providers necessary to help ensure safe medication use. NCPA member experiences with patients suggest that safe medication use is greatly enhanced through personal face-to-face interaction with a pharmacist. With the emergence of risk mitigation strategies to improve the safe and effective use of medications used for pain, undoubtedly there will be a parallel emergence of the prominent role of the pharmacist in this effort.

Pharmacists can prepare for the new REMS by educating staff, by preparing the workplace, (such as flagging pertinent drugs and storing or printing relevant educational materials), and by patient communication via written and face-to-face counseling.

**REMS for Certain Opioid Analgesics**

At a press conference on April 19, 2011, the United States government unveiled a multi-agency, multi-pronged master plan aimed at stemming the “nationwide epidemic” of prescription drug abuse. Part of the plan was the long-awaited FDA-backed Risk Evaluation and Mitigation Strategy, or REMS, focusing on reducing the misprescribing, misuse, and abuse of opioid analgesics. The new opioid-REMS requiring opioid-prescriber education and patient counseling applies only to long-acting and extended-release opioid analgesics at this time.

Because the long-acting, extended-release opioid analgesics—such as fentanyl, methadone, oxycodone, hydromorphone, and others that are indicated for the treatment of moderate to severe pain associated with cancer and other serious chronic conditions—are so prone to abuse and misuse, the case for greater REMS-related protections is undisputed.

A first part of the opioid-REMS program focuses on educating prescribers about proper pain management, patient selection and monitoring, and other aspects of opioid analgesic safety. There will be no cost to opioid prescribers to receive the education and CME/CE credits. At this time, participation is voluntary; there is “no requirement that prescribers have completed this training before they write a prescription for a LA/ER opioid, or before such a drug is dispensed,” the FDA states.

However, the FDA continues to seek legislation that would make prescriber education mandatory under the Controlled Substances Act (CSA) as a precondition for DEA registration. The agency further states: “If the voluntary program under the current REMS is found to be ineffective, FDA will also consider the possibility of developing a mandatory educational program or other measures under the Food and Drug Administration Amendments Act (FDAAA).”

Another major aspect of REMS requires prescribers to improve patient awareness about how to use opioids safely. The FDA wants manufacturers to develop a single, patient education sheet to assist prescribers in counseling patients. The prescriber also would be able to write in any necessary product-specific information on this sheet.

Additionally, new medication guides will be developed containing standard information on LA/ER opioids overall and information specific for each product. Presumably, these documents will be distributed by prescribers and also by pharmacies, which will need to keep an inventory of opioid-product medication guides on hand or preferably, programmed to print automatically upon dispensing in the pharmacy.

**Pharmacists’ Role in REMS**

While REMS are devised by the FDA and pharmaceutical manufacturers, implementation requires adherence of health care practitioners, including drug prescribers and dispensers. For drug risks to be “mitigated,” patients must understand the educational materials provided. Specifically, for medication guides to help prevent serious adverse effects, pharmacists must help patients understand serious risks (relative to benefits) and help patients’ adherence to a drug’s directions for use, patients must understand the safety issues discussed.

Recent studies have shown that patients recognize the value of, and are willing to receive, pharmacist delivered care. Ideally that care is delivered by a pharmacist with whom a patient has had an established relationship. While other approaches to delivering these services exist,
studies have shown that community pharmacists providing face-to-face patient interactions may have a greater impact on patient behavior compared to other methods of service delivery. Clearly, these services can be utilized to meet the goals of REMS programs.

Pharmacists can prepare for the new REMS by educating staff, by preparing the workplace (such as flagging pertinent drugs and storing or printing relevant educational materials), and by patient communication via written and face-to-face counseling.

The success of this initial voluntary program is of vital concern to pain care advocates, as failure might usher in a more restrictive, access-limiting strategy from the FDA. Pharmacists have an important role in assuring REMS success.

**Other National Efforts**

Gil Kerlikowske, director of the White House Office of National Drug Control Policy (ONDCP), said the new plan unveiled in April—a collaborative effort involving agencies of the departments of Justice (DEA), Health and Human Services (FDA), Veterans Affairs, Defense, and others—provides a national framework for reducing prescription drug abuse and the diversion of prescription drugs for recreational use. Four key elements of the plan include:

1. Expansion of state-based prescription drug monitoring programs (while recognizing that “more work needs to be done to maximize their effectiveness”).
2. Recommending convenient and environmentally responsible ways to remove unused medications from homes.
3. Reducing the number of “pill mills” and rampant doctor-shopping through law enforcement efforts.
4. Supporting education for health care providers and patients, particularly regarding controlled substances and especially opioid analgesics.

The DEA has also sponsored three drug take-back days in conjunction with state and local law enforcement agencies throughout the United States in September 2010, April 2011, and another scheduled for Oct. 29, 2011. The purpose of these national take-back days was to provide a venue for people who wanted to dispose of unwanted and unused prescription drugs. There were nearly 4,000 state and local law enforcement agencies throughout the nation that participated in the events. All told, the American public turned in more than 309 tons of pills during the combined events.

The DEA has also been instrumental in supporting the emergence of state-based prescription monitoring programs (PMPs) that are either up or in development in 48 states. The intention of PMPs, in terms of provider use, is to prevent diversion and abuse by helping clinicians identify patients who are getting controlled medications from multiple sources as a way of screening out people with criminal intent and/or identifying those who may have a substance use disorder related to opioids or other controlled drugs. Pharmacists should avail themselves of these programs when possible to help other members of the pain team monitor for potential problems.

It is quite apparent that our profession is entering a new era of pharmaceutical care. REMS represents perhaps the most significant change in U.S. drug regulation in many years. The pharmacist, as an educator and risk mitigator, is now considered an integral part of the health care team. We must embrace this role and focus our efforts on proper counseling, screening, and advocating for the appropriate care of people suffering from pain. We need to partner with the community to deliver effective methods of managing the REMS process. Ultimately, we can help bring the use of opioids for pain back into balance, minimizing risk while maximizing benefit.

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Six Super Southern Stores

A tour of some of the Music City’s standout pharmacies

By Bruce Kneeland
Editor’s note: Every reader of this article ought to make it a priority to join and otherwise support their state pharmacy association. It is at the state level that much of the future of the pharmacy profession will be determined and your input, cognitive and financial, are essential. You can locate your state association on the NCPA website at www.ncpanet.org.

ATLANTA MAY BE THE ECONOMIC HUB OF THE SOUTH AND NEW

Orleans more historic, but there is little doubt that Nashville embodies all that is distinctive in Southern culture. Also known as Music City, this central Tennessee locale is famous for its music industry, being the headquarters of 56 health care companies, and the home of Goo Goo Cluster’s (caramel, marshmallow nougat, peanuts, and chocolate).
As NCPA brings its 113th Annual Convention and Trade Exposition to Nashville, Oct. 8–12, we thought you’d like to learn about the ways community pharmacy owners are chasing their dreams in this dynamic metropolis. So, on June 8–9, after getting recommendations from several buying group and wholesaler representatives, I set out on a two-day tour that took me into six super pharmacies. Here is some of what I saw.

**B & B Pharmacy—New, Clean, Inviting**

Ahmad Adhami, PharmD, opened this 2,000-square-foot pharmacy, using his children’s first name initials as inspiration for the store name, early in 2010. He takes pride in providing consumers with an attractive alternative to the six chains that compete with him. A personable and outgoing individual, Adhami is well networked in Spring Hill, the town about 20 miles south of Nashville made famous as the corn field that Saturn selected to build its state-of-the-art auto factory 21 years ago.

The store is both cute and well organized. Upon entering, patients are greeted with colorful décor, well-merchandised OTC products, gifts, durable medical equipment, and an eye-catching blackboard announcing specials for the day. But while the store is attractive, it is in the pharmacy that Adhami is making a difference.

Discouraged by the lack of opportunity to talk with patients while working for several chains, Adhami has bent over backwards to make up for lost time. One way is with medication therapy management. While in the store I was able see him work with two MTM patients whose prescriptions had been brought to him in plastic bags filled with more than 20 empty containers each, many of which were from other pharmacies. Adhami points out that while many of his peers are reluctant to provide MTM due to low reimbursement, he says he is able to consolidate prescriptions filled at other pharmacies and thus turn this service into a growth vehicle. He also offers a free program where he arranges medications in special packaging to encourage adherence, and participates in an innovative medication reminder program that sends out text, emails or phone calls. Adhami says that compounding has become an important aspect of his professional service as it provides medications to people with special needs and gives him reason to get out of the store and talk with prescribers. To round out his practice he does immunizations, serves a 30-bed children’s home, a hospice, and provides a delivery service.

Adhami says one thing he believes has helped make his new pharmacy grow so rapidly is treating his employees with the same courtesy and respect he treats customers. He says, “If I treat my staff right, and train them well, they will treat my customers right, which will give my customers reason to recommend me to others.” It’s a philosophy that has served him well.

**Bradley Health Services—The Total Drugstore**

Bradley Health Services is one of the most amazing
drugstores I have ever seen. Phil Bradley, DPh, owner of this remarkable operation, has built what can easily be referred to as The Total Drugstore.

Opened by Bradley’s father in 1961, the store occupies about 15,000 square feet of a corner location on a busy commercial street in Nashville. Upon graduating from pharmacy school in 1980, Phil joined the family business and was given an opportunity to start its DME division. Given permission to explore new opportunities, Bradley excelled and today Bradley Health Services is a striking example of how today’s independent can thrive.

The practice consists of its original retail location with the pharmacy supported by a robot and providing a delivery service. The rest of the store is fairly traditional with an assortment of classic drug store departments such as OTCs, vitamins, cards, gifts, and seasonal items. Over the years Bradley has added a closed door pharmacy in the basement that services several thousand patients in both LTC and assisted living facilities. It also features two compounding labs, one equipped to support sterile compounding; Bradley also supports a number of hospices. The company also has a 20,000-square-foot warehouse a few blocks away. The entire operation is supported by a fleet of 18 delivery vehicles.

Recently the tire dealership that shared a wall with the drug store went out of business, and the entire space has been tastefully converted into a large DME showroom and a brand new venture called Everything Diabetic. This showroom features a variety of traditional diabetes products such as meters and strips. But that is only the tip of the iceberg as consumers can also shop for diabetes friendly food and choose from a large assortment of wound care, eye care, and a diabetes shoe department that has also found a following with joggers and serious runners looking for better foot care.

To top it off, it also features a state-of-the-art classroom, a fully functional kitchen to help teach patients and caregivers better ways to prepare food, an info kiosk and health book department. When you factor in the investment Bradley is making in technology supported by diabetes educators and nutritional experts, Everything Diabetic is a name that seems to fit.

Greenbrier Pharmacy and Fountain—A True Family Affair

I knew I wanted to visit this pharmacy in Greenbrier, Tenn., as soon as I checked out its website and learned about its fountain. Owner Misty Williamson, PharmD, is quick to point out that while she is not sure if the fountain is a major profit center, one thing is certain—it serves as a magnet attracting people to the pharmacy.

Williamson opened the pharmacy five years ago and it is a true family affair. Her husband is the general manager and also calls on doctors and community groups. Her mother manages the fountain and her husband’s father is the delivery driver. Their two children have their angelic faces on the store’s outdoor billboard and the pharmacy sponsors volleyball, basketball, and baseball teams.

Williamson says her “driving force” is spending time with patients and helping them understand all their medications to better manage their total health care
needs. And, she says, running a pharmacy in a small town of 6,000 people about 20 miles north of Nashville means the phone often rings after hours with patients expressing a need for a prescription or with a question or medical concerns.

She not only does flu shots but goes on site and does them in local schools and other businesses. She has a scheduled delivery service, Tuesday and Friday, but delivers at other times when specifically requested. The pharmacy has a drive up window, but Williamson makes sure her staff works extra hard with customers to ask questions, make OTC recommendations, and to insure they drive off knowing they are special.

Wednesday is Wellness Wednesday where pharmacy students staff a table and do blood pressure readings, provide meter training, or enhanced OTC counseling. Williamson is almost evangelical in her devotion to pharmacy students, bringing in 20–30 each year on a rotation, and she believes they provide a real touch of professionalism to the pharmacy.

Then there is the “med-box” service. It currently has about a dozen patients on the program where, for a modest fee, a patient’s medications are arranged into a plastic weekly pill box. Williamson says the fee almost covers the cost of the service, but she says the real payoff is in knowing patients are getting the right medication at the right time. And, she says, it doesn’t hurt that it gives her something special to talk about with doctors and concerned family caregivers.

Health and Wellness—Just Say No to Third Parties

Over the years I have heard tales of innovative pharmacists that have charted a different course and established a truly unique practice model. Now I have seen one in real life and I am both impressed and amazed.

Mark Binkley, PharmD, owns The Health and Wellness Pharmacy near a couple of major hospitals in downtown Nashville. He is a personable guy who has taken a common success attribute of most independents a notch higher—that being he listens to customer comments and

Misty Williamson’s two children smile down from a billboard in front of her pharmacy where personal service also includes a weekly med-box service.

TENNESSEE PHARMACISTS ASSOCIATION ON THE FRONT LINES FOR STATE PHARMACISTS

Being in Nashville provided me an opportunity to visit the offices of the Tennessee Pharmacists Association. TPA is among the top tier of pharmacy associations and this is due in no small part due to the talents of Executive Director Baeteena Black, DPh. Like most state associations TPA finds itself on the front lines of fighting for the rights of patients and for the right of community pharmacy to serve their needs. One recent victory Black mentions is formalizing a process for pharmacists to set themselves up in non-dispensing practice to contract with community pharmacies to provide MTM services to patients. According to Black, this will open the way for many more pharmacies to provide this service by bringing in pharmacists on an appointment basis to provide the service in and on behalf of the pharmacy. My thanks to Black and Micah Cost, PharmD, director of professional practice, for a pleasant and informative visit.
suggestions and then tries to respond to them.

The first thing you will envy Binkley for is that he bills no third-party plans. Currently about 80 percent of his revenue comes from compounding and the other 20 percent from nutritional counseling fees coupled with selling a variety of professionally recommended nutritional supplements. As part of his nutritional counseling he does cholesterol, A1c, and uses a sophisticated body composition analysis tool that measures body fat, basal metabolic rates, and other key metrics to establish a baseline and then documents improvement over time.

While he has always had a professional focus to his practice, and he started compounding with Professional Compounding Centers of America in 1983, the genesis for stepping out into this leading edge practice came from listening to customers ask about the value of various nutritional supplements such as glucosamine and CoQ10. After doing some research and then seeing how eagerly people accepted his recommendations, he decided to take the leap of faith and move into his current practice format.

Health and Wellness Pharmacy is housed in a suite of an office building designed for doctors who want to be right next to the hospitals. The patient reception area closely resembles that of a doctor’s office but also has a tastefully merchandized selection of nutritional items and patient information materials.

The compounding lab is full blown and impressive. It features a sterile room that is USP 797 compliant as well as a more traditional compounding lab. Binkley says one of the things he wishes for is that more of his colleagues would understand they can deal with doctors and other health care professionals as peers. And, he says one emerging area of practice he sees coming is gene therapy, where medications are tailored to meet the specific DNA of individual patients. Something tells me that as that starts to happen Binkley will be ready to take advantage of it.

Joelton Prescription Shop—A Really Nice Pharmacy

The first thing you are likely to notice about Joelton Prescription Shop is the amazing look of the store itself. In 1974, Ronnie Felts, DPh, and a partner opened their pharmacy from scratch in this bedroom community about 20 miles north of Nashville. A few years later Felts bought out his partner and then three years ago decided to upgrade and build this impressive 3,000-square-foot facility. Felts describes the new locations as his “tribute to pharmacy,” and with marble floors, large windows and beautiful wood cabinetry it is impressive.

But, the most appealing thing about Joelton Drug is the professionalism of the staff and the way they go about the practice of pharmacy. When asked about the most important thing he does to ensure success, Felts responds by saying, “I give patients the gift of my time.” Then he talks about the ways he does that and you begin to see that finding ways to find time is the central reason behind several things Felts does. For example he uses the reports and insights he gains from his wholesaler and listens to the advice his representative provides. He says,
“My wholesaler offers me a suite of services to ensure proper quantities are on hand, prescriptions are billed correctly, NDC codes are current and that price increases are accepted by third parties.”

Felts spends the bulk of his time doing prescription input and patient counseling. And even though the store has a modest front end, Felts says he has a point-of-sale system and that he believes is essential to the efficient operation of the pharmacy as it allows him to “close the loop” on prescription pickup, documentation, and proper billing.

Felts expresses strong opinions on a few points. First, he never runs the cash register. He consciously decided not to put a drive up window in his new store; and finally, even though he stocks a limited amount of OTC, he uses his wholesaler’s lowest OTC zone price. He says, “I don’t sell enough front end merchandize to matter, so I sell at prices competitive to Walmart just to make sure I have a low price image.”

Felts’ formula for success is to work hard, be efficient, have systems in place, train your staff to follow carefully designed protocols, and always make time to talk with patients, as this is what he believes sets independents apart from chain and mail order competition.

**Perkins Drugs and Gift—Gifts Galore and Much More**

Perkins Drugs and Gift is pretty much the iconic community drug store. Opened in Gallatin in 1895 (yes, nearly 120 years ago), it has become an institution in this quaint town about 25 miles northeast of Nashville.

Andrew Finney, PharmD, joined the company in 2004 and bought in as partner a few years later. Finney takes pride in mentioning he is a graduate of the NCPA Ownership Workshop program and encourages others with entrepreneurial aspirations to attend. The other two partners, Sam Rickman, RPh, and Ferrell Haile, RPh, have been around longer than they care to admit. Haile has a passion for public service and was appointed by Gov. Bill Haslam to fill out the remaining term of a state senator a few years ago.

One of the major features of Perkins Drugs and Gifts is its first-class gift department. The backbone of this department’s promotional program is the Annual Christmas Sale. They kick off the season on the second weekend in November with an open house complete with punch, cookies, and door prizes. To take full advantage of this department the staff also offers a baby and bridal registry, which Rickman says is a huge asset in attracting new customers. Many of the store’s gifts are featured on the pharmacy’s website. Rickman goes to three or four gift shows each year and devotes a great deal of time and attention to product selection, pricing, and its artful presentation.

All three partners say the major way they compete is by going the extra mile to make sure customers know they are appreciated. When pressed for details, Finney says the store is equipped with a POS system to help speed and simplify checkout and ensure that customers leave with all the prescriptions the pharmacy has filled for them. Using the reports they get from their pharmacy management system and POS system, they con-
Barry and his pharmacist staff are consistently staffed with more people than a cost accountant would recommend, and even have one person designated as a floater to go wherever they are needed during a hectic day. Then they provide the resources (time and tuition support) to get their pharmacy staff trained. To build on the personal attention theme, they have a formal program for sending out birthday cards and welcome messages to new customers. Finally, to help ensure compliance, they have a system that makes outbound refill reminder calls, which they believe is a much appreciated service.

Bruce Kneeland is a contributing writer for America’s Pharmacist and has an extensive background in working with independent pharmacy. He currently serves as the pharmacy development manager for Epicor, Inc. Kneeland lives in Royersford, Pa., and can be reached at bkneeland@epicor.com.
ENHANCING THE LEGACY
After Ryan Frerichs, RPh, received his doctorate of pharmacy degree from the University of Iowa College of Pharmacy in 2001, he moved to Colorado to manage a couple of pharmacy departments for national chain. The plan was to stay for a year or two before coming back to his home state of Iowa where he and his wife Kate hoped to start a family. Well, a couple of years was quickly becoming almost five, and Frerichs was not only yearning for a return to Iowa, but he was also looking for a more hands-on setting where he could work closely with patients and build long-term relationships. Fortunately, an opportunity arose that allowed him to realize both of those goals.

When he was in school at Iowa, Frerichs completed an internship at Meyer (Health Mart) Pharmacy in Waverly, Iowa, working for owner Tom Taiber. After graduating, Frerichs briefly considered a franchise arrangement with a pharmacy, but ultimately wasn’t sold on it.

“I was looking for some guidance so that’s when I called Tom,” Frerichs said. “He said that he was reaching the point when succession was something he would be open to discussing. That opened that door — when I contacted him I had no expectation of that.”
Taiber and Frerichs came to an informal agreement. “I would work there for a year, and he could evaluate me and I could evaluate the business, and make sure that this is what we wanted to do,” Frerichs says.

With this arrangement in place, Ryan and Kate moved back to their home state in August of 2005. It was a good match, and Frerichs bought the business on March 1, 2007.

When Frerichs assumed the reins, he wasn’t just acquiring a pharmacy, but also taking leadership of a local institution that had thrived in the Waverly community since 1913. Frerichs understood the importance of upholding the Meyer legacy.

“It takes years and years to build a good reputation, but it doesn’t take long to lose one,” Frerichs says, adding that a small business is an investment that grows based on steady nurturing—one that requires constant attention and care to customers evolving needs.

**Progressive Community**

For the Frerichs, Waverly is an ideal place to own a business and raise their three daughters. A community of nearly 10,000 residents, Waverly is located about 20 miles north of the larger Cedar Falls-Waterloo metropolitan area where Kate was raised. Waverly is home to Wartburg College and John Deere has a nearby manufacturing facility. The community also boasts a robust agriculture industry, with local farmers raising livestock and growing crops, primarily soybeans and corn.

“Because of the college, we view [Waverly] as a progressive and highly-educated [community],” Frerichs says. “We’re certainly affected by the agricultural business, and the industry gives it some nice balance.”

Frerichs describes Meyers’ staff, including its four full-time pharmacists, as “energized.” The pharmacists range from a recent graduate to Taiber (who works part time and has 41 years of professional practice in community and long-term care pharmacy).

“They are willing to take on new things,” he says. “It gives us a good feel for what we see as a current move in pharmacy toward patient-centered care and counseling. We have a staff that’s very open to new practice ideas.”

Overall there are about 35 people on staff, including full and part-time. The physical property covers 8,500 square feet, of which the pharmacy and retail space is about 6,000 square feet. On a daily basis Meyer will dispense almost 400 prescriptions. Meyer is also a Hallmark Gold Crown location, allowing customers to accrue rewards points, while the pharmacy enjoys exclusive access to products and gifts.

However, Frerichs is moving Meyer beyond the traditional prescription and gift retailer model. He is working to enhance Meyer’s presence in durable medical equipment (DME), long-term care (LTC), compounding, diabetes care, and immunization services, to name just a few. Frerichs also looks to “dovetail” pharmacy services with product areas when possible. He says that one growth area is baby items.

“When a patient comes to the pharmacy counter and they bring a prescription for an antibiotic for a child, the first thing we ask is, ‘How well does the child take medicine?’” Frerichs says. “For example, should we flavor it?”

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and they bring a prescription for an antibiotic for a child, the first thing we ask is, ‘How well does the child take medicine?’” Frerichs says. “For example, should we flavor it? We’ll also ask them for the child’s weight just to make sure everything is in line. It’s another way that we differentiate ourselves from other pharmacies. We keep all the pediatric products and a lot of the medications right next to the pharmacy, so we can go out and offer our expertise to those people who are shopping in that area.”

Building Revenue Streams

Just as Frerichs finalized the purchase of Meyer Pharmacy, Walgreen’s announced that it was going to build a store in Waverly as well. With five retail pharmacies in a town of 10,000 people, he asked himself, “Do we need to diversify? Do we need to shore up some of these other revenue streams, just to make sure we have a business that’s going to carry us on in the future in case times get tough in one of these areas?”

Frerichs decided that DME could be one of those other revenue streams, as there weren’t many other area pharmacies offering that service on a comprehensive level. The pharmacy had previously just dipped its toes into that market, but with the looming threat of stricter accreditation, Frerichs was thinking Meyer needed to be “all in” or drop out completely. Frerichs hired respiratory therapist Boualay Crow to manage the department. An additional delivery driver was also brought on board.

“Ultimately, we decided to make a full commitment because it was an unmet need in our area; nobody was servicing locally,” he says. “In Iowa if a local company offers a service, that goes a long way, especially in a small to mid-size town. That’s one of the reasons I think independent pharmacy can still be successful, especially in this state.”

Frerichs says the pharmacy eventually received its accreditation, “and we basically do full service DME” offering home oxygen, hospital beds, wheelchairs, walkers, roll aids, canes, support chairs, compression stockings, ostomy products, and full diabetes testing strips and supplies.

Frerichs says that DME accounts for about 5 percent of the pharmacy’s revenue, and he hopes to increase that to 10 percent within the next year. Securing a hospice contract for medical equipment helped build some momentum.

“It’s continuing to grow for us, because we are filling an unmet need in the community,” he says. “Just like anybody, when they see exceptional service, they’ll go back to the people who treated them right the first time.”

Further Diversification

To diversify even more, a 300-square-foot non-sterile compounding lab was completed in December of 2010. It is run by staff pharmacist Alisha Burrows. Located next to the pharmacy, it is called Custom Meds by Meyer Pharmacy, with a separate pharmacy license.

“We have a couple of physicians in the area and saw there was a need,” Frerichs says. “We were doing some BHRT, but this was more of a strategic move because third parties are requiring that if you hold a contract with them, then you need to submit those claims to them. We’re trying to ensure that we get adequately reimbursed for what we do as a compounder, so that’s the reason to set up with a separate license.”

At the same time, Frerichs was in the process of licensing a closed door, LTC pharmacy (about 500 square feet). “We had always run it out of the retail side,” he says. “It’s in the same area as the compounding lab; there’s another room, and that’s where we are doing closed door pharmacy. We’re located in a strip mall, so
we built a door between the two retail locations, and then built two rooms within that.”

Frerichs says there is additional space for activities such as patient education, continuing education for local area providers, and support group activities. Kate is a clinical dietician, and they are exploring options with NCPA’s Diabetes Accreditation Standards-Practical Applications (DASPA) program. DASPA offers community pharmacists training to expand their role into diabetes self-management education/training (DSME/T), which can be eligible for payment by the Centers for Medicare & Medicaid Services (CMS) for providing these services to persons with diabetes. DASPA was created through a partnership between NCPA and the American Association of Diabetes Educators. CMS only acknowledges programs that are accredited or “site recognized” to bill Part B for DSM/T services.

“I think we would be uniquely positioned for the [DSME/T] program, with a registered dietician and pharmacists on staff,” he says. “[Kate] has been doing detailed promotions with doctors about nutrition counseling, and meets with patients at the pharmacy, and receives referrals for diabetes education.”

**Technology**

Automation implementation has been a mixed bag for community pharmacists. Some have embraced it, while others have held back. Frerichs is in the former category.

“I like to use technology whenever possible,” he says. “I definitely think it’s the future of pharmacy. It’s the future of every industry right now. It allows fewer people to do more work. We’ve got an automated filling robot and we run the heck out of it. We use IVR, and are in the process of moving to a new system that has more functionality and has the ability to call out to people.”

Additionally, Frerichs says, “We’re looking at whether we can use text messages to send out refill reminders and that sort of thing. But you have to make the most of what you have, and maximize the potential within the business that you have. We do set up some people on auto-fill monthly. We do our LTC manually with bingo cards, and looking at the [potential] 7-day fill requirements, we’re considering some type of automation to make it easier. I think all of the solutions to the volume questions will be automated solutions. That’s just because of the way margins are going and the increasing cost of health care for employees, wages, and other factors.”

Frerichs says his point-of-sale system has been a benefit in analyzing gift and OTC sales data.

“That helps us know what’s moving,” he says. “You have to stay in tune with what the customer is buying—if you don’t you’re going to get left in the dust. If you don’t have things that people are buying, that will have a huge negative impact on your cash flow.”

E-prescribing is also picking up, Frerichs says.

“Some of the clinics here are still resistant to it, but once they start getting reimbursed more from Medicare, that will probably change. I’d say that we get maybe 20-25 percent of prescriptions done electronically with two major clinics.”

Frerichs also stresses a strong web presence for Meyer (www.meyerpharmacy.com). “We went to a CE session and heard the comment, ‘Your reputation is now the first blue line on a Google search,’” he says. “We’re not huge into social media, but we have a Facebook page. That might be a slippery slope, but I think you need to have a presence. You just can’t get left behind. It can be done very well, but it takes a lot of babysitting. Being an older business, you don’t want people to think you aren’t up to date. It’s a balance to market your business as a reputable and long-standing pharmacy that may be almost 100 years old, but that also continue to evolve and stay current.”
Meyer still does traditional marketing and advertising, including television, radio, newspaper, and a “Welcome Wagon” style publication for new residents. “The concern is that if somebody is new in town, Meyer Pharmacy doesn’t really mean anything to them, but Walgreens and Walmart do, because they are everywhere,” Frerichs says. “So we have to reach out to that patient base.”

**Constant Evolution**

Frerichs says the primary challenge for his pharmacy is competition. And like many of his colleagues, the brick and mortar variety rivals aren’t necessarily the biggest threat.

“Mail order is a huge problem, and mandatory mail order is as well” he says. “Some of our area’s major employers are going to mail order, and that’s a big concern of ours. I feel like that’s an uphill battle. You try to find a way to convince these employers that they are really not saving any money and that they are probably paying more. If we could figure out a way to get that message across, that would be great to get those prescriptions back into the community, to show them that not only are you probably spending less money to dispense, but you are probably avoiding other health care costs too. I think that if they continue to push mail order, there will be a backlash if they drive all this business out. We get calls weekly from people wanting our advice regarding their mail order medications. It really is ridiculous.”

Reacting to those concerns, diversifying and creating new revenue streams has helped Meyer stay competitive. It also helps to continuously look inward and see what can be improved. In other words, Frerichs doesn’t want the pharmacy to become complacent.

“It’s just a constant re-evaluation and an understanding that just because you have a successful business, you’re not perfect,” he says. “You can never sit there and say, ‘Oh, this is good enough.’ Your patients don’t deserve that either. You can’t just bank on the fact that they want to do business with you because you are a nice guy. You have to give them the best product day in and day out.”

Frerichs says he is looking at changing department layouts, and changing some of the fixtures, or at the least relocating them.

“By and large, a big part is due to our growth in medical equipment and creating those winning places in the store for the current merchandise that moves it,” he says. “If the last time you reset the pharmacy was 10 years ago the odds are you should probably re-allocate your resources to highlight your best, newest, and most innovative products.”

**Service Is Paramount**

In any endeavor, excellent customer service is synonymous with success. It’s no different for Meyer Pharmacy. It has built long-term equity in relationships with the community that span multiple generations. As Frerichs says, “They come here because their parents came here.”

He points out that, niche programs aside, Meyer essentially carries the same medications and products that the larger stores do. “So it has to be continually in front of each and every employee that [customer service] is the reason we stay in business,” he says. “That’s the first thing [staff] hear on the first day on the job, the first time they walk through the door and in the interviews. It has to be ingrained in the hearts and minds of every employee that it is the reason we’re successful. We’re in the pharmacy business, but above and beyond that we’re truly in the customer service business, and patient care business. It just so happens that we do that through pharmacy."

When asked what gives him the most satisfaction in his profession, Frerichs doesn’t hesitate to answer. “For me, by far it’s the relationships with the patients,” he says. “Knowing them by their name and knowing something about all of them gives you purpose to my daily work. They trust us, they know us, and we see them on a monthly basis, and sometimes it just takes a simple ‘how’s it going?’ Then they will open up to you a little bit, and you realize the impact that you can have on each and every patient.”

Chris Linville is managing editor for *America’s Pharmacist*. 
Start a new pharmacy or buy a ‘used’ one? It’s more challenging than picking a car—even one you’ve always wanted.

By Ed Webman, RPh & Brian Faulk

YOU KNOW YOU WANT A FORD MUSTANG, and that’s a given (or maybe a Corvette, a Porsche, or BMW). But do you buy an older, classic model or go with the very latest? Either way, you want it.

It’s the million dollar question for budding pharmacy owner: Do I buy an existing pharmacy, or do I start my own from scratch? Compelling arguments exist for both options. If you start from scratch, you do not incur a $1 million or more debt obligation. If you buy an existing pharmacy, you have stable operating income on day one to support your debt obligation. From the bank’s perspective, it is a relatively easy decision as historical repayment ability evidenced by an established pharmacy is much easier to finance than a start up operation where repayment is based on projections. It is a very daunting decision, but hopefully we can make it a much easier one by analyzing a startup investment and an acquisition investment.
As statistics in the 2010 NCPA Digest, sponsored by Cardinal Health, reflect, the average independent pharmacy generates approximately $4.02 million in gross revenue, with prescription drug sales being the primary income source. This average pharmacy fills some 64,000 prescriptions per year at an average price of $58. Now that we have this information in hand, we can begin the process of comparing a startup investment to an acquisition.

Buying an Existing Business

There are numerous methods to determine the value of the prescription records/goodwill/business of a going concern. These include a per script price, a multiple of EBITDA (earnings before interest, taxes, depreciation, and amortization), net present value of earnings, and several others. For simplicity’s sake, we will examine a pharmacy’s EBITDA and apply a multiplier to arrive at a value.

We determine the bottom line cash generated by the pharmacy that will be available to service the debt/loan incurred to acquire the pharmacy and still have ample excess cash to appropriately compensate you as the owner and operator. This bottom line cash figure is a cumulative of the following: seller’s salary, depreciation, interest on the debt the seller was servicing, amortization expense, net income, and any non-recurring expenses that will be eliminated following ownership transition. If you are working as an associate at the pharmacy being acquired we would also add your salary to the bottom line cash figure.

Experience has shown bottom line cash flow for a good pharmacy to be approximately 7–12 percent of the gross revenue generated by the pharmacy.

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Experience has shown bottom line cash flow for a good pharmacy to be approximately 7–12 percent of the gross revenue generated by the pharmacy. Likewise, a good pharmacy is often sold for three times bottom line cash plus inventory on hand at closing. Please note that there are several factors that can change this multiple including sales trends (up or down), and other pharmacy services such as compounding, durable medical equipment, and/or long-term care services.

We will now examine the acquisition of a typical independent pharmacy. (Table 1.) Gross revenue is $4.1 million and the bottom line cash being generated is approximately 9.5 percent. The store is generating about $389,000 to service acquisition debt and compensate the buyer. (The owner is working three quarters FTE as the second pharmacist, so three-fourths of his salary may be deducted from the true business earnings.) Multiplying ($389,000 minus $93,750) by three gives us, $885,750, and a goodwill purchase price of $900,000 plus inventory, of $300,000. We now have a total purchase price of $1.2 million due to the seller.

We are not quite finished funding the project, as funds need to be allocated for working capital and loan closing costs. You will need working capital to sustain your operation while you await payment from your third party payers (the seller will retain the AR). Typically you should request a working capital figure 17–30 DSO (days sales outstanding) representing the time it will take you to collect your receivables from PBMs and other third-party payers. Additionally, you will need to have some cash in the bank to ensure you are well capitalized from the start.

Loan closing costs include legal fees you and the bank will incur, business valuation fees, accounting fees, and loan fees. Closing costs can vary greatly and you should allocate to the high side for this category to ensure you have ample funds to cover all transaction-related expenses without having to dip into the working capital allocation. The closing costs on a $1 million plus transaction can run as high as $50,000. Any savings realized in this category will be diverted to additional working capital.

We have now arrived at the total financing cost of $1.55 million to acquire this $4.1 million gross revenue pharmacy: $900,000 for prescription records/goodwill/non-compete, $300,000 for inventory, approximately $300,000 in working capital, and $45,000 in closing costs. A very typical loan structure would be as follows: borrower cash equity injection of $75,000, seller financing of $150,000, and bank loan of $1.325 million.

The seller note is placed on complete standby for two
TABLE 1. ACQUISITION BUDGET

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<thead>
<tr>
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<th>EQUITY</th>
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<th>Seller</th>
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<td>$300,000</td>
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<td>WORKING CAPITAL WC</td>
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<td>GOODWILL P</td>
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<td>RECAP:</td>
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<td>4.84%</td>
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<td>9.68%</td>
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<table>
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<tr>
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<td>Inventory</td>
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<td>Interest Rate:</td>
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<td>TOTAL</td>
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<td>Payment</td>
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*Accrued interest
Prime rate plus 2.00% adjusted calendar quarterly

Acquisition Budget—Cash Flow

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<tr>
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<td>$125,000</td>
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<td>NOI</td>
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<td>$194,522</td>
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<td>1.19</td>
<td>1.23</td>
<td>1.36</td>
<td>1.36</td>
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</table>

years, which means no payments of principal or interest are made. The seller’s note accrues interest during this standby period and can be viewed very similarly to a CD investment by the seller. Request terms of two years standby followed by five years of principal and interest payments based on a 10-year amortization. The rate is normally around 7 percent and the loan matures seven years from original date of issuance. When payments due commence 25 months after closing, your payment would be approximately $1,994 per month.

The bank loan of $1.325 million amortized 10 years at prime rate (currently, 3.25 percent) plus 2 percent for a current effective rate of 5.25 percent would result in a monthly principal and interest payment of $14,216. Please note that the majority of business loans of this nature are variable rate loans that adjust on a calendar quarter basis. Fixed rates are available in certain situations; however they are in the 7–10 percent range, and most have an early call or balloon provision.

We know the pharmacy is grossing $4.1 million (or $341,667 per month), and that it
You are left with $16,248 in owner compensation, or $194,478 annually. You can pay yourself an owner’s salary of $125,000 and have $69,478 for a cushion.

Each year you accumulate considerable equity in your business as you reduce the principal debt obligation and in no less than 10 years, you have a $1 million plus asset owned free and clear. This all assumes that you operate the pharmacy status quo with little to no improvement in the margins or sales generated by the retiring seller.

### Starting a Startup

Now take your $75,000 cash savings and invest it in a startup independent pharmacy. (Table 2.) To begin you need approximately 1,500 square feet. Minimal leasehold improvement costs at $50 per square foot result in build out costs of approximately $75,000; another $75,000 for furniture, fixtures, and equipment; $150,000 for opening inventory; $17,625 for soft costs/loan closing costs; and no less than $200,000 in working capital to sustain the operation while you build your script counts.

We now have a total startup financing cost of $525,000 less your $75,000 equity injection upfront, requiring a loan of $450,000. A typical startup loan will provide six months of interest-only payments to accommodate building development and initial startup months of operation followed by 120 monthly payments of principal and interest. A total of $450,000 amortized 10 years at the prime rate plus 2.5 percent for a current effective rate of 5.75 percent creates a monthly principal and interest payment of $4,940.

To reach a break-even level of operation sufficient to service the loan payment and pay you an equivalent $100,000 annual salary, you have to fill approximately 100–120 prescriptions per day (27,600 per year) or approximately $133,333 per month and $1.6 million in gross revenues, and manage a 10 percent bottom line cash return. With a net operating income of $13,333 less the $4,940 monthly loan payment, that leaves you with a monthly officer compensation figure of $8,393 or $100,716 yearly.

### Comparing an Acquisition Versus Startup

Developing a pharmacy from scratch to dispensing more than 100 prescriptions per day is a daunting task.
This could take several years. Let’s consider your immediate ROI (total owner’s compensation) based upon your investment of $75,000 for each pharmacy. In the acquisition, if things remained the same as with the prior owner, in the first year ROI should be $69,478 over and above your salary of $125,000, or a return of 93 percent. In the startup example, the pharmacy can only afford a $100,000 salary, and it would be two years before the store is cash flow positive. In the third year, there is $27,561 over and above the $100,000 salary, an ROI of 37 percent. If you use the same base salary of $125,000, to compare, as in our acquisition, the ROI is then 3.4 percent.

You do have to consider your total debt obligation, and granted you have a much lower debt obligation on a startup after three years, which would be approximately $341,000 based on a straight line amortization of your original $450,000 note, but you have little to no business equity as your pharmacy has only just recently achieved a break-even status. You reduced your principal debt obligation by $109,000, but you have little to no market for the sale of your pharmacy with prescription counts just above 100 per day. In comparison, the acquisition opportunity has reduced the original debt obligation from $1.325 million to $997,500 million based on a straight line amortization, thus creating a minimum of $327,000 in equity via principal reduction. Also, since the acquisition pharmacy generates revenue of more than $4 million and has a substantially higher prescription count, it is much more marketable, thus providing you with an additional return on your investment.

Just like a classic car (new or old), it all depends on your preference. With either choice, you know you’ll love it and care for it. No two opportunities are alike as potential owners, practices, markets, and lenders are all different, but we hope this information will help you make your million dollar decision. 

Ed Webman, RPh, is a former pharmacy owner, a longtime NCPA member, and loan officer with Live Oak Bank. Brian Faulk is a loan officer with Live Oak Bank and a professional practice lender for veterinarians, dentists, and independent pharmacies. More information is available at www.liveoakbank.com.
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(As of Sept. 12, 2011)
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- Holly W. Henry
- Sharlea M. Leatherwood
- Forrest “Woody” Pack
- Nancy Pruitt
- Betty Schutte
- Andrew Stout

Visionary (individuals $5,000 and above/corporations $50,000 and above)
- AmerisourceBergen Corp./Good Neighbor Pharmacy
- Gary W. Boehler
- Cardinal Health Foundation
- Pharmacies Mutual
- Betty Schutte

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- Eric L. Graf
- Holly W. Henry
- Mike Henry
- Darden Heritage
- Daniel Horn
- Edmund R. Horton
- Carly Huffman Huie
- Larry D. Irwin
- Omar M. Jaladi
- John G. Kaiser Jr.
- Brian Komoto
- Minas G. Liristis
- Matt Mallinson
- McKesson Corp.
- Michael W. Minesinger
- Donald L. Moore
- W. Whitaker Moore
- William W. Moose Jr.
- Joseph A. Mioso Sr.
- Deinde L. Myers
- Randall S. Myers
- Boris Natenzon
- Howard Allan Pavia
- Mark Riley
- Ernest Rosales
- Gerald Shapiro
- David A. Shipman
- Todd Sondrup
- Harry Taubman
- Jay T. Thompson III
- Dirk White

Strategist (individuals $500–$999/corporations $5,000–$9,999)
- Mary Abharian
- Larry M. Ambroson
- AstraZeneca
- Frederick J. Bonchakosky
- Anthony T. Buddle Sr.
- Barry Christensen
- Tim Clark
- Jeffrey Danhauer
- Omololu Fatakiisu
- Marcz E. Finke
- Leon Galehouse III
- Fritz R. Glasser Jr.
- Robert Greenwood
- John C. Griffin
- Jagadeesh Gummella
- H. Edward Heckman
- John H. Higgins
- Brian Douglas Hoey
- Karen Isenimer
- Tom P. Kines
- Garry Levitsky
- Charles H. McWilliams
- Diane G. Milano
- Cynthia Nobles
- Andy Oaks
- Michael T. Ohnemus
- Thomas Pasternak
- PCCA
- QS1
- Fleet W. Richards Jr.
- Joanne Ryan
- Mark A. Salvatore
- Carol Smith
- Kendrick B. Smith
- Frank Southall Jr.
- Mehrele Trust
- Lynn Ung
- Gerard J. Volgraf
- Nancy B. Watson
- Chad Wiggins
- Allan Wong

Fellow (individuals $250–$499/corporations $2,500–$4,999)
- Julian R. Adams Jr.
- Kenneth J. Anderson
- Sam Bakar
- Gerald E. Beachy
- Ed Berg
- John S. Calhoun
- Cardinal Health
- John R. Carson
- John J. Cernac
- Clarence M. Clifton
- Steve L. Colabello
- Stephanie C. Smith Cooney
- Charles D. Cotton
- Robert B. Coulter
- Dianne V. Cruse
- Gerald Culler
- Janice Curry
- Joseph Devins
- Pamela Keil-Eilers
- Ira N. Freeman
- Freda Gezah Juergen
- Larry Halper
- Tyler Higgins
- Thomas R. Hodel
- Keith Hodges
- Thomas L. Hoskins
- Steve P. Karagiannis
- John Keller
- Hanna Leah Kim
- Dominick M. Leteri
- Jeff Liberman
- Robert L. Maher Sr.
- John K. McLellan
- Barbara McLellan
- Dave Miller
- Artie G. Mitchell
- National Community Pharmacists Association
- Van Nguyen
- Gerard O’Hare
- David J. Olig
- Elliot Pacheco
- Earl Wayne Padgett
- Mukesh G. Patel
- David Peters
- Douglas M. Pick
- Ivan Saiff
- Bryan Salazar
- Teva
- Adrian A. Thomas
- Tony Wellder
- Harold T. Wells
- R. Wayne West
- Lonny D. Wilson
- Stephen R. Wilson
- Jeffrey E. Young
- Denise Stiles-Yount

Patron (individuals $100–$249/corporations $1,000–$2,499)
- Buford T. Abeldt
- Robert Addison
- Titalayo Akinoyenewu
- Bill Atland
- Don Anderson
- Stephen Anderson
- Umar Uddin Ansari
- Calvin J. Anthony
- Ollice Arnold Jr.
- Edison Asonye
- Mark A. Aurit
- Rick Austin
- Larry Bailey
- Vince A. Bari
- Richard W. Barmore
- Harold Baumgarten
- Ted Beatty
- Beaver County Pharmaceutical
- Michele M. Belcher
- Stephen P. Bernardi
- Aj Biebly
- Timothy N. Bishop
- Daniel Blakeley
- Bill Bloodworth
- Edward L. Boyd Jr.
- Michael L. Boyd
- Richard Bradley
- Lanny Branstetter
- Grant H. Brown
- Joseph G. Brummer
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- Michael D. Butler
- Denis P. Campbell

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Harry Webb
Eugene Weinstein
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upon successful completion of this activity, the pharmacist should be able to:
1. Describe the essential elements of a business plan.
2. Compare and contrast the types of business structures available for pharmacy operations.
3. Describe federal legal issues associated with the hiring of pharmacy employees.
4. Identify lease and purchase concerns associated with facility acquisition.
5. Appraise payroll obligations and mandates based on state and federal requirements.
6. Explain specific federal law and business permit requirements for pharmacies.

INTRODUCTION
Most great businesses begin with an idea. However, simply having a great idea is not enough to begin a business. According to the Small Business Administration (SBA) Office of Advocacy, approximately half of all small businesses fail after five years. A small business is defined as "an independent business having fewer than 500 employees," (reference www.sba.gov/advo/research/rs188tot.pdf, accessed July 3, 2010).

So, what does it take to become a successful pharmacy owner? There are a variety of factors, many of which will be discussed in this article. However, before the decision is made to start or grow an existing business, the concept of entrepreneurship will be examined.

IS ENTREPRENEURSHIP FOR YOU?
In business, there are no guarantees. There is simply no way to eliminate all the risks associated with starting a small business—but you can improve your chances of success with good planning, preparation, and insight. In his book, "Awakening the Entrepreneur Within: How Ordinary People Can Create Extraordinary Companies," Michael Gerber states, “Everyone possesses the ability to be an entrepreneur.” In examining one’s likelihood of becoming an entrepreneur, consider each of the following questions:
1. Are you a self-starter? It will be entirely up to you to develop the business, organize your time, and follow through on details.
2. How well do you get along with different personalities? Business owners need to develop working relationships with a variety of people, including customers, vendors, staff, bankers, and other health care professionals. Can you deal with a demanding patient or an unreliable vendor if your business interests demand it?
3. How good are you at making decisions? Small business owners are required to make decisions constantly—often quickly, independently, and under pressure.
4. Do you have the physical and emotional stamina to run a business? Business ownership can be exciting, but it’s also a lot of work. Can you face six or seven 12-hour workdays every week?
5. How well do you plan and organize? Research indicates that poor planning is responsible for most business failures. Good organization of financials, inventory and schedules can help you avoid many pitfalls.
6. Is your drive strong enough? Running a business can wear you down emotionally. Some business owners burn out quickly from carrying all the responsibility for the success of their business on their own shoulders. Strong motivation will help you survive slowdowns and periods of burnout.
7. How will the business affect your family? The first few
years of a business startup can be hard on family life. It is important for family members to know what to expect and for you to be able to trust that they will support you during this time. There also may be financial difficulties until the business becomes profitable, which could take months or years. You may have to adjust to a lower standard of living or put family assets at risk in the short term. (Reference www.sba.gov/smallbusinessplanner/plan/getready/SERV_SBPLANNER_ISENFORU.html, accessed July 4, 2010#.)

Once the potential business owner and entrepreneur honestly answers these questions and desires to move forward, he must next develop a business plan. As described in the following section, a business plan forces the future owner to answer another set of important questions.

BUSINESS PLAN BASICS
A business plan precisely defines the business, identifies goals, and serves as its resume. The basic components include a current and pro forma balance sheet, an income statement, and a cash flow analysis. It helps allocate resources properly, handles unforeseen complications, and makes good business decisions. As it provides specific and organized information about the company and how the business will repay borrowed money, for example, a good business plan is a crucial part of any loan application. Additionally, it informs sales personnel, suppliers, and others about operations and goals.

PLAN YOUR WORK
The importance of a comprehensive, thoughtful business plan cannot be overemphasized. Much hinges on it, such as acquiring outside funding, obtaining credit from wholesalers, management of operation and finances, promotion and marketing of the business, and achievement of goals and objectives.

Despite the critical importance of a business plan, many entrepreneurs drag their feet when it comes to preparing a written document. They argue that their marketplace changes too fast for a business plan to be useful or that they just don’t have enough time, but just as a builder won’t begin construction without a blueprint, eager business owners shouldn’t rush into new ventures without a plan.

Before beginning to write a business plan, consider four core questions:
1. What service or product does your business provide and what needs does it fill?
2. Who are the potential customers for your product or service and why will they purchase it from you?
3. How will you reach your potential customers?
4. Where will you get the financial resources to start your business? (Reference www.sba.gov/smallbusinessplanner/plan/writeabusinessplan/SERV_BUSPLANBASICS.html, accessed July 4, 2010.)

WRITING THE PLAN
What goes into developing a business plan? The body can be divided into four distinct sections. The sections include: 1) Description of the business, 2) Marketing, 3) Finances, and 4) Management. Furthermore, the business plan should include an executive summary, supporting documents, and financial projections. Although there is no single formula for developing a business plan, some elements are common to all business plans. They are summarized in Table 1. A more complete description of the business plan elements can be found at www.sba.gov/smallbusinessplanner/plan/writeabusinessplan/SERV_ESSENTIAL.html.

TYPES OF BUSINESS STRUCTURES
During the process of developing a business plan, a prospective pharmacy business owner must determine the type of business structure to select. In selecting a business structure, an individual should consider factors such as the number of owners/partners in the business, ownership succession, legal liability issues, and tax implications. There are numerous options available, each with certain advantages and disadvantages. The following section will highlight several available options.

BASIC STRUCTURES
Sole Proprietorship
The sole proprietorship is a simple, informal
structure that is inexpensive to form; a single person or a marital community usually owns it. The owner operates the business, is personally liable for all business debts, can freely transfer all or part of the business, and can report profit or loss on personal income tax returns.

**Limited Liability Company (LLC)**
The LLC is generally considered advantageous for small businesses because it combines the limited personal liability feature of a corporation with the tax advantages of a partnership and sole proprietorship. Profits and losses can be passed through to its members, or the LLC can elect to be taxed like a corporation. LLCs do not have stock and are not required to observe corporate formalities. Owners are called members, and the LLC is managed by these members or by appointed managers.

**General Partnership**
Partnerships are inexpensive to form, and require an agreement between two or more individuals or entities to jointly own and operate a business. Profit, loss, and managerial duties are shared among the partners, and each partner is personally liable for partnership debts. Partnerships do not pay taxes, but must file an informational return; individual partners report their share of profits and losses on their personal return. Short-term partnerships are also known as joint ventures.

**C Corporation (Inc. or Ltd.)**
This is a complex business structure with more startup costs than many other forms. A corporation is a legal entity separate from its owners, who own shares of stock in the company. Corporations can be created for profit or nonprofit purposes and may be subject to increased licensing fees and government regulation than other structures. Profits are taxed both at the corporate level and again when distributed to shareholders. Shareholders are not personally liable for corporate obligations unless corporate formalities have not been observed; such formalities provide evidence that the corporation is a separate legal entity from its shareholders. Failure to do so may open the shareholders to liability of the corporation’s debts. Corporate formalities include:

- Issuing stock certificates
- Holding annual meetings
- Recording the minutes of the meetings
- Electing directors or ratifying the status of existing directors

A qualified attorney should always assist corporations.

---

### Table 1. Elements of a Business Plan

1. Cover sheet
2. Statement of purpose
3. Table of contents

#### I. The Business
- A. Description of business
- B. Marketing
- C. Competition
- D. Operating procedures
- E. Personnel
- F. Business insurance

#### II. Financial Data
- A. Loan applications
- B. Capital equipment and supply list
- C. Balance sheet
- D. Break even analysis
- E. Pro-forma income projections (profit & loss statements)
- F. Three-year summary
- G. Detail by month, first year
- H. Detail by quarters, second and third years
- I. Assumptions upon which projections were based
- J. Pro-forma cash flow

#### III. Supporting Documents
- A. Tax returns of principals for last three years
- B. Personal financial statement (all banks have these forms)
- C. For franchised businesses, a copy of franchise contract and supporting documents provided by the franchisor
- D. Copy of proposed lease or purchase agreement for building space
- E. Copy of licenses and other legal documents
- F. Copy of resumes of all principals
- G. Copies of letters of intent from suppliers, etc.

**Sub Chapter S Corporation (Inc. or Ltd.)**
This structure is identical to the C Corporation in many ways, but offers avoidance of double taxation. If a corporation qualifies for S status with the IRS, it is taxed like a partnership. The corporation is not taxed, but the income flows through to shareholders who report the income on their individual returns.


**SPECIAL STRUCTURES**
The following business structures are available in some states, but not all.

**Limited Liability Partnership (LLP)**
LLPs are organized to protect individual partners from personal liability for the negligent acts of other partners or employees not under their direct control. Partners report their share of profits and losses on their personal tax returns. Every state does not recognize LLPs. Those that do sometimes limit LLPs to organizations that provide a professional service, such as medicine or law, for which each partner is licensed. States may require that EACH partner is a licensed professional. Check with your secretary of state’s office to see if the state recognizes LLPs and if so, which occupations qualify.

**Professional Service Corporation (PS)**
A PS must be organized for the sole purpose of providing a professional service for which each shareholder is licensed. The advantage here is limited personal liability for shareholders. This option is available to certain professionals, such as doctors, lawyers, and accountants. Check with your secretary of state’s office to find out which occupations qualify.

**Limited Partnership (LP)**
LPs have complex formation requirements and require at least one general partner who is fully responsible for partnership obligations and normal business operations. LPs also require at least one limited partner, often an investor, who is not involved in everyday operations and is shielded from liability for partnership obligations beyond the amount of their investment. LPs do not pay tax, but must file a return for informational purposes; partners report their share of profits and losses on their personal returns.

**Non-Profit Corporations**
These are formed for civic, educational, charitable, and religious purposes and enjoy tax-exempt status and limited personal liability. A board of directors or trustees manages non-profit corporations. Assets must be transferred to another non-profit group if the corporation is dissolved.


**HIRING EMPLOYEES**
At first glance, this may appear as a relatively simple step in developing the business, especially compared with developing a business plan. In the movie *Field of Dreams*, the phrase heard repeatedly was “If you build it, they will come.” It is easy to believe this phrase may also apply to the business setting in that if a business (pharmacy) is built, patients will come. Can the same be said about quality employees? One would hope so, but as this section demonstrates, there are some potential pitfalls with which pharmacists must observe in order to avoid legal liability.

There are a number of federal laws relating to the employment process (recruiting, interviewing, hiring, termination). See Table 2 for a brief overview of the laws enforced by the Equal Employment Opportunity Commission (EEOC). A thorough discussion of the employment laws is beyond the scope of this article. However, any prospective employer should become very familiar with the federal regulations. The following governmental websites are excellent resources for describing these laws: www.eeoc.gov and www.dol.gov/opa/aboutdol/lawsprog.htm.

Once the federal and state employment laws are met, it may appear that this is the end of the story. For example, a pharmacist advertises for a pharmacy technician position in the local newspaper. After interviewing three
Table 2. Laws Enforced by EEOC

<table>
<thead>
<tr>
<th>Title VII of the Civil Rights Act of 1964 (Title VII)</th>
</tr>
</thead>
<tbody>
<tr>
<td>This law makes it illegal to discriminate against someone on the basis of race, color, religion, national origin, or sex. The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit. The law also requires that employers reasonably accommodate applicants’ and employees’ sincerely held religious practices, unless doing so would impose an undue hardship on the operation of the employer’s business.</td>
</tr>
<tr>
<td>• The Pregnancy Discrimination Act</td>
</tr>
<tr>
<td>This law amended Title VII to make it illegal to discriminate against a woman because of pregnancy, childbirth, or a medical condition related to pregnancy or childbirth. The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit.</td>
</tr>
<tr>
<td>The Equal Pay Act of 1963 (EPA)</td>
</tr>
<tr>
<td>This law makes it illegal to pay different wages to men and women if they perform equal work in the same workplace. The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit.</td>
</tr>
<tr>
<td>The Age Discrimination in Employment Act of 1967 (ADEA)</td>
</tr>
<tr>
<td>This law protects people who are 40 or older from discrimination because of age. The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit.</td>
</tr>
<tr>
<td>Title I of the Americans with Disabilities Act of 1990 (ADA)</td>
</tr>
<tr>
<td>This law makes it illegal to discriminate against a qualified person with a disability in the private sector and in state and local governments. The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit. The law also requires that employers reasonably accommodate the known physical or mental limitations of an otherwise qualified individual with a disability who is an applicant or employee, unless doing so would impose an undue hardship on the operation of the employer’s business.</td>
</tr>
<tr>
<td>Sections 501 and 505 of the Rehabilitation Act of 1973</td>
</tr>
<tr>
<td>This law makes it illegal to discriminate against a qualified person with a disability in the federal government. The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit. The law also requires that employers reasonably accommodate the known physical or mental limitations of an otherwise qualified individual with a disability who is an applicant or employee, unless doing so would impose an undue hardship on the operation of the employer’s business.</td>
</tr>
<tr>
<td>The Genetic Information Nondiscrimination Act of 2008 (GINA)</td>
</tr>
<tr>
<td>This law makes it illegal to discriminate against employees or applicants because of genetic information. Genetic information includes information about an individual’s genetic tests and the genetic tests of an individual’s family members, as well as information about any disease, disorder or condition of an individual’s family members (i.e. an individual’s family medical history). The law also makes it illegal to retaliate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit.</td>
</tr>
</tbody>
</table>


prospective employees, the owner decides to offer the position to Jane, a 21-year-old college student. Jane is very personable and is knowledgeable about pharmacy. So, it would appear this is “no-brainer” on the part of the owner, correct? Every pharmacist has heard of the Controlled Substances Act (CSA). This federal law regulates the various aspects of controlled substances, from ordering to dis-
pensing to various recordkeeping provisions associated with these medications. However, there is a provision that is often overlooked. This provision (21 CFR 1307.03) describes the requirements for hiring individuals who have committed a felony related to controlled substances. The following is a summary, taken from the Pharmacist’s Manual, An Information Outline of the Controlled Substances Act of 1970, a publication from the Drug Enforcement Administration’s (DEA) Office of Diversion Control.

“A pharmacy registrant (i.e., the registrant or corporation which owns the pharmacy) must not employ in a position which allows access to controlled substances, anyone who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. ‘For cause’ means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual’s handling of controlled substances.”

However, pharmacies desiring to employ an individual who meets this definition may request an exception to this requirement (see 21 CFR 1307.03) from the DEA. The employer must have a waiver approved before hiring the applicant. A waiver request should be sent to DEA Headquarters, Office of Diversion Control, Washington, D.C. 20537. A pharmacy registrant who applies for such a waiver should understand that the following factors will be considered:

1. A detailed description of the nature and extent of the applicant’s past controlled substances violations.
2. Activities of the applicant since the violation.
4. Extent of applicant’s proposed access to controlled substances.
5. Registrant’s proposed physical and professional safeguards to prevent diversion by the applicant if employed.
7. Other pertinent information uncovered by DEA in its investigation of the applicant’s or registrant’s handling of controlled substances.
8. Such a waiver should not be considered unless there are valid reasons to believe that diversion is unlikely to occur.

It is important to note that the felony could have taken place many years prior to applying for the position. Going back to our earlier example, has Jane been convicted of a controlled substances-related felony? From the facts of the case, we do not know. This becomes problematic for the pharmacy owner because if he hires Jane without knowing this information, he has violated the CSA if it is later determined that Jane, in fact, does have a felony on her record. So, how does the owner protect himself from this situation? After an employment offer is made to Jane, the offer must be conditioned on the fact that Jane successfully passes a criminal background check. If a felony appears as a result of the background check, the offer of employment must be revoked. Though a waiver may be obtained from the DEA (see the language above in the CSA), these waivers are very difficult to obtain, and if obtained, take a lengthy period of time.

In addition to the federal CSA, there may be state laws requiring the use of criminal background checks for pharmacy employees. For example, in Ohio, a law was recently enacted. Emily’s Law establishes standards for qualified pharmacy technicians, in addition to requiring them to undergo a criminal background check. Since pharmacists are ultimately held responsible for any actions a pharmacy technician makes, failure to conduct training and background checks will result in subsequent legal action against the pharmacist. There are numerous resources available that provide information regarding criminal background checks. It is imperative for employers to conduct these checks on all employees, while making sure to utilize a reputable service.

REGISTRATION, LICENSES AND PERMITS
Pharmacy Registration
Every pharmacy that intends to order, process or dispense controlled substances must be registered with the DEA. Registration is not optional. Application for initial registration can
now be made online. (U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Registration Applications. Found at www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp, accessed June 15, 2010) The current fee for pharmacy registration is $551, which is for a three-year period. Having already obtained a state license from the board of pharmacy for the pharmacy may expedite the approval of the DEA registration. One registration covers the dispensing of controlled substances in Schedules II through V. The federal regulations require separate registrations for each principal place of business for individual pharmacies regardless of the fact that the same individual or business organization may own them. In effect, each new pharmacy location requires a separate registration.

Registration typically extends for a period of three years. However, at the time a retail pharmacy is first registered, the pharmacy is assigned to one of 12 groups, which shall correspond to the months of the year. The expiration date of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to one of the twelve groups, the DEA may select a group expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration shall expire 36 months from the initial expiration date. (21 CFR § 1301.13(d))

In addition to registration with the DEA, most states also have an agency that may be separate from the board of pharmacy and also involved with controlled substances regulation. These agencies may have a variety of names, but often refer to a previous name of the DEA; Bureau of Narcotics and Dangerous Drugs. These state agencies may also require separate registration of the pharmacy before controlled substances may be ordered or dispensed.

Pharmacist Licensure
Boards of pharmacy are typically created by either a state constitutional provision or legislative mandate. Yet it is the state statutes that typically provide the board with certain powers, including the power to issue a pharmacist license. Successfully passing the North American Pharmacist Licensure Exam (NAPLEX) and Multistate Pharmacy Jurisprudence Exam (MPJE) are typical prerequisites to pharmacist licensure.

State rules commonly provide that only a state licensed pharmacist may be in charge of a licensed pharmacy. These same rules may provide that a certain pharmacist be designated as the pharmacist-in-charge (PIC). The PIC may then have certain responsibilities as delineated by board of pharmacy regulation. These responsibilities may include determining that those working in the pharmacy are properly licensed, that technician functions are monitored or that controlled substance inventories are conducted and records maintained. Pharmacist re-licensure is not automatic. Certain requirements, such as continuing education with specific guidelines, must be met in order for a state board to renew a license. Criminal activity by the pharmacist may prevent the board from renewing a license. In any event, the PIC should be assured that all individuals working in the pharmacy who need special credentials have current documentation of licensure.

Pharmacy Technician Permits
In most states, pharmacy technicians must be registered with their respective state board of pharmacy. Most states do not require technicians to be certified, but voluntary national certification is available through several private organizations. The Institute for the Certification of Pharmacy Technicians (ICPT) and the Pharmacy Technician Certification Board (PTCB) administer national examinations. To be eligible for taking either of the exams or obtaining licensure by a state that does not require national certification, candidates must have a high school diploma or its equivalent and no felony convictions of any kind. Under the exam programs, technicians must be recertified every two years. Recertification requires 20 hours of continuing education within the two-year certification period, with at least one of the hours being in the area of pharmacy law.

Pharmacists should recognize that national certifi-
cation of technicians indicates a measured degree of competency. More than 363,000 individuals have been certified through the PTCB since 1965. (Pharmacy Technician Certification Board. Found at www.ptcb.org/AM/Template.cfm?Section=Regulations&Template=/CM/ContentDisplay.cfm&ContentId=3095, accessed June 15, 2010.) While some states may provide areas of instruction for technicians to be trained prior to state certification, pharmacists must decide individually what educational and competency expectations their technicians will possess. Pharmacists must also ensure that a technician’s registration or license is current with the board of pharmacy. Performing technician functions without board authorization could result in an action by the board for allowing an unauthorized person to practice as a technician.

Business Permits
Most city, county and state governments require business owners to obtain specific business permits. Such permits may include a signage permit, which allows the owner to erect a sign for the business. Other permits may include an alarm permit, zoning permit, building or construction permit, or a general business license permit, which allows the organization to conduct business, collect taxes and remit to the appropriate revenue department.

Another interesting requirement for business owners centers on naming the organization. If the business name is different than that of the personal owner, or names of the partners or the officially registered name of the LLC or corporation, then the business is operating under a fictitious name. Many jurisdictions will require organizations operating under a fictitious name, also known as “Doing Business As” or DBA, to register with the local county clerk’s office. The county clerk will often conduct a complimentary name search for the intended business name to make sure it’s not already taken. Some states may require placing a fictitious name notice in the local newspaper for a specific period of time. For the majority of states, corporations are not required to file fictitious business names unless they do business under names other than their own. Generally, a business operating with a fictitious name will not be able to enforce any contracts unless the name is registered with the appropriate authority.

Facility Acquisition
There are many considerations when selecting a business location, including potential legal issues. Regardless of whether one leases or purchases a commercial property, either transaction will involve legal concerns. Both transactions typically involve a contract. Contracts are binding agreements that impose requirements on the parties even if one or both of the parties did not understand the stated obligations. Few pharmacists will have the expertise necessary to adequately represent themselves in negotiations with savvy real estate brokers or leasing agents.

Leases
Once it has been determined that a lease is the preferred method of facility acquisition, numerous legal issues should be addressed prior to signing any lease. To address these issues, lease documents may be extensive and cover topics that may be unfamiliar to the pharmacist. Legal counsel should be engaged before signing any lease. An excellent resource regarding leases for pharmacy owners can be found at www.ncpnet.org/ownership/buyers/index.php.

Lease Payments
A pharmacy tenant should ensure in advance what the lease is going to cost in order to avoid surprise liabilities that can be fatal to a small business. Maintenance of the premises is always an ongoing necessity. The tenant should ensure that the landlord will carry the burden as much as possible. At a minimum, the pharmacy tenant should ensure that the landlord has a duty to maintain the building structure, exterior, common areas, and any shared building systems such as HVAC and plumbing. Tenants should determine if the cost of utilities such as electric, natural gas, water, sewer and waste control is included in the lease agreement.

The pharmacy tenant should be aware of any restrictions or costs associated with any structural changes that may need to be made prior to occupancy or even during occupancy. For example, if it is determined that the facility is not compliant with the ADA, who will be obli-
gated to meet the code requirement? Likewise, in occupying the building for use, which party will be responsible for the elements of the buildout—the landlord or the pharmacy?

While many leases may be based on a fixed cost to the tenant, other pharmacy leases may be based on a percentage of gross sales. Along with this type of agreement can be the right of the landlord to review accounting records, tax receipts, or third-party transactions. Entering into this type of agreement may cause marginally profitable products to actually be sold at a loss to the pharmacy.

**LEASE TERMINATION CLAUSE**

Terms of the length of a lease should be clearly spelled out in lease agreements. Unfortunately, events may happen which will require early withdrawal by the tenant, such as in the event of a disruption in services or casualty damage. If the landlord does not make certain corrections, the pharmacy tenant’s business will suffer and ultimately fail unless the problem is remedied quickly. While any pharmacy tenant will want to negotiate for the right to terminate the lease in the event certain circumstances occur, the landlord is typically unwilling to consider such a provision. In addition, the landlord’s lender may not allow the landlord to consent to an early termination clause without the lender’s prior approval.

The pharmacy tenant should carefully review the lease provisions related to casualty or disruption of services and plan ahead for what it can do for such a disruption. To protect against the failure of the tenant’s business during a disruption or casualty, many landlords require that the tenant carry business interruption insurance.

**LIQUIDATED DAMAGES CLAUSE**

Failure to fulfill the obligation of the lease agreement may trigger a provision contained within the lease known as a liquidated damages clause. Liquidated damages refers to a specific sum of money that has been expressly stipulated by the parties to an agreement as an amount of damages to be recovered by either party for a breach of the agreement by the other (*Black’s Law Dictionary, 9th ed.* West 2009). The pharmacy tenant should try to negotiate a maximum amount of damages in the event of tenant default, such as three months base rent. In addition, the tenant should attempt to include a provision that the landlord has a duty to mitigate damages, such as by re-leasing, in the event of the tenant’s default. Preferred for the tenant would be the right to assign the lease or sublet the premises as part of an overall exit strategy of the lease. Typically, the landlord’s lease form will prohibit assignments of the lease without the landlord’s prior written consent.

**LEASE USE**

While a pharmacy tenant would expect to be able to use leased premises for pharmacy purposes, the lease should clearly identify the use to be allowed. The pharmacy tenant should also consider the extended nature of its business and the potential impact on its revenue stream if a nearby tenant is allowed to operate a competing business. For example, in a shopping center any number of tenants may sell health and beauty aids. In the case of *Rite Aid of Ohio, Inc. v. Marc’s Variety Store, Inc.*, the court ruled that even though the lease provided Rite Aid the right to operate a “retail drug and variety store” and granted an “exclusive privilege for the operation of a Drug Store in the shopping center,” Marc’s Variety was not considered to be operating a drug store because it did not have a pharmacy. Rite Aid attempted to restrict Marc’s Variety, as a new tenant to the shopping center, from selling product categories that competed with those of Rite Aid even though other tenants in the same shopping center had sold similar products for many years. Rite Aid’s acquiescence to the other tenants’ sales of such products was viewed as evidence that it did not view the exclusive provision as protection against competition in the sale of non-pharmacy items. (*Rite Aid of Ohio, Inc. v. Marc’s Variety Store, Inc.*, 638 N.E. 2nd 1056 [Ohio Ct. App. 1994])

**PROPERTY PURCHASE AND CONTRACTS**

A real estate contract is a contract for the purchase and sale, exchange, or other conveyance of real estate between parties. Components of the contract will include the identity of the parties, legal description, purchase...
price, and signatures. Pharmacists who decide to purchase commercial real estate will encounter some issues not found in leasing.

CLEAN TITLE
When purchasing real estate, one must be sure instruments that can affect the continuing use of the property do not cloud that title to the property. Liens, judgments, covenants, easements and other documents can prevent the owner from using the property as planned. Typically, these types of instruments are filed on record and can be found during the title examination process by an attorney. Even then, a lien or other document could be filed from the time that the record was searched until the property actually transfers to the new owner by way of a deed. To protect from such defects and other title defects that may not be uncovered during the title examination process, title insurance has become a common tool to provide protection. These types of insurance policies require a single payment at the time of purchase and provide the new owner with extended title assurance.

ZONING
Zoning is a device of land use planning used by local governments, such as counties or municipalities. Zoning may be use-based, such as whether a pharmacy may operate a business, or it may regulate building height, lot coverage, parking or similar characteristics. When purchasing either a current structure or undeveloped land, the pharmacist must be sure that the purpose for the intended use is allowed. If it is determined that the intended use is currently not permitted, the contract may be drafted in such a manner as to provide for a contingency which allows the contract to be voided if proper zoning cannot be obtained prior to closing.

COVENANT NOT TO COMPETE
When a pharmacist purchases an existing pharmacy, a “covenant not to compete” provision should be considered. The purpose of such a contract is to prevent the previous owner from working for a competitor or starting up another pharmacy. For a covenant not to compete to be valid, the terms of the agreement must be reasonable. Reasonableness is typically based on two factors: 1) The distance from the pharmacy sold that the selling pharmacist may work, and 2) the time after the sale that the selling pharmacist may become a competitor. For example, if a pharmacist who sells his pharmacy is restricted from working in a competitive fashion with the pharmacy purchaser within a 50-mile radius for a period of 10 years, such provisions would probably be viewed as excessive and the restrictions voided by a court. However, what is reasonable will vary with the circumstances (Allen v. Rose Park Pharmacy, 237 P2d 823 [Utah 1951]). Many states have enacted legislation legitimizing covenants not to compete and courts have also found in many jurisdictions that such restrictions are valid if reasonable.

PAYROLL ISSUES
Whether starting a new business or merely continuing an existing business, it is important to consider the legal issues involving payroll and the ensuing regulatory requirements of the employer. While some requirements are universal in that they are federal provisions, some mandates are state-specific. It is incumbent on the employer to determine what local liabilities exist and meet those in a timely fashion. Multiple websites are available to provide employers with payroll requirements. (See Table 3.)

EMPLOYER IDENTIFICATION NUMBERS
Before hiring an employee, the employer needs to obtain an employment identification number (EIN). To do this, the employer must obtain and complete Form SS-4. To obtain an EIN, an individual can apply online or contact the Internal Revenue Service (IRS) directly. The EIN is necessary for reporting taxes to the IRS. The same EIN will be necessary when reporting taxes to state tax agencies.

REQUIREMENTS FOR WITHHOLDING TAXES
A business’ payroll tax liability consists of not only the taxes required to be withheld from employees’ wages (Social Security tax, Medicare tax, and federal income tax), but also the
employer’s matching share of Social Security and Medicare taxes. For the majority of small businesses, there are two deposit schedules. These schedules will be either monthly or semi-weekly and will be reported on either IRS Form 941 on a quarterly basis or Form 944 annually.

There are specific guidelines when taxes must be paid depending on which schedule is used. Under the monthly deposit schedule, taxes paid on wages earned during a calendar month must be deposited by the 15th day of the following month. If the 15th day of the month falls on a day that is not a banking day, the deposit will be considered timely made if it is deposited by the close of the next banking day. Federal and state holidays, as well as Saturdays and Sundays, are treated as non-banking days. Under the semi-weekly deposit schedule, taxes on wages paid on Wednesday, Thursday and/or Friday are required to be deposited by the following Wednesday. Taxes on wages paid on Saturday, Sunday, Monday and/or Tuesday are required to be deposited by the following Friday.

The deposit schedule for a business is determined annually by review of the total taxes reported on either Form 944 or Form 941 in a four quarter look back period beginning on July 1 of the prior year and ending on June 30 of the current year. If the tax liability reported by the business was $50,000 or less during the time period, the business must follow the monthly depositor schedule. However, if the tax liability was greater than $50,000 during the same time frame, the semi-weekly depositor schedule would apply.

Generally, payment of federal taxes is made by the employer by mailing or taking a check, cash, or money order to an authorized financial institution on or before the date required by the deposit schedule or by using the Electronic Federal Tax Payment System (EFTPS). Significant penalties may apply if required deposits are not made in a timely manner. In the case of a business that has not remitted its payroll taxes, the IRS can extend penalties to certain individuals (e.g., a “responsible” person, such as a corporate officer).

New businesses will be eligible to make deposits with a financial institution and will be notified by the IRS when required to change to electronic funds transfer. Making deposits at an authorized financial institution will require the use of Form 8109, otherwise known as a Federal Tax DepositCoupon. These coupons will typically not arrive until five weeks after the business has been assigned an EIN. Additional coupons are automatically sent to the employer. If the business needs to make a deposit before receiving its EIN, the deposit must be made by mail and mailed directly to the IRS along with an explanation. If the EIN has been obtained but the coupons have not been received, Form 8109-B can be used to make the deposit. These forms, and questions in general for the IRS, should be directed to 800-829-1040.

**EMPLOYEE ELIGIBILITY VERIFICATION**

Under federal law, employers are required to verify an employee’s eligibility to work in the United States. An Employment Eligibility Verification Form, known as an I-9 form,
must be completed within three days of hiring a new employee. In addition, the employee must supply acceptable forms of documentation and the employer must confirm the employee’s citizenship or eligibility to work in the United States. Employers may only request documentation specified on the I-9 form as additional requests for information may subject the employer to a discrimination lawsuit. Once completed, the employer has the option to verify electronically the eligibility of newly hired employees through the U.S. Citizenship and Immigration Services E-Verify (www.uscis.gov/portal/site/uscis/, currently only available in select states) using the information on the I-9 form.

**RECORDKEEPING REQUIREMENTS**

There are multiple records that employers must complete, process and maintain. Different forms have different time requirements. For example, employers must keep accurate records of employment taxes for a minimum of four years after the later of the due date of the return or the date the tax is paid. In another example, employers must retain completed Form I-9 for three years after the date of hire or one year after the date employment ends, whichever is later. According to the U.S. Department of Labor, there are 12 records an employer must maintain on each employee for length of their employment. (Hiring your first employee. Entrepreneur. Found at www.entrepreneur.com/humanresources/hiring/article83774-2.html, accessed July 2, 2010.) (See Table 4.)

<table>
<thead>
<tr>
<th>Table 4. Employee Records Required to Be Maintained During Employment</th>
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<tbody>
<tr>
<td>1. Employee’s full name and social security number</td>
</tr>
<tr>
<td>2. Mailing address, including ZIP code</td>
</tr>
<tr>
<td>3. Birth date, if the employee is younger than 19</td>
</tr>
<tr>
<td>4. Sex and occupation</td>
</tr>
<tr>
<td>5. Time of day and day of the week when employee’s workweek begins, hours worked each day, and total hours worked each workweek</td>
</tr>
<tr>
<td>6. Basis on which employee’s wages are paid (weekly, bi-monthly, and so on)</td>
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<tr>
<td>7. Regular hourly pay rate</td>
</tr>
<tr>
<td>8. Total daily or weekly “straight time” earnings for each workweek</td>
</tr>
<tr>
<td>9. Total overtime earnings for each workweek</td>
</tr>
<tr>
<td>10. All additions to or deductions taken from employee’s wages</td>
</tr>
<tr>
<td>11. Total wages paid each pay period</td>
</tr>
<tr>
<td>12. Date of payment and the pay period covered by each payment</td>
</tr>
</tbody>
</table>

**MISCELLANEOUS PAYROLL REQUIREMENTS**

- Employers are required to report newly hired and re-hired employees to a state directory within 20 days of hire or re-hire. This requirement is based on the Personal Responsibility and Work Opportunity Act of 1996. (Personal Responsibility and Work Opportunity Reconciliation Act of 1996 [PRWORA, Pub.L. 104-193, 110 Stat. 2105, enacted Aug. 22, 1996])
- Businesses with employees are required to carry workers’ compensation insurance coverage through a commercial carrier, on a self-insured basis, or through the state workers’ compensation insurance program. Self-insuring may be limited by the state if the organization cannot show adequate financial resources to handle claims.
- Unemployment insurance is generally also a requirement if the business has employees.
- A few states, such as California, Hawaii, and New Jersey, require employers to provide partial wage replacement insurance coverage, commonly known as disability insurance, to eligible employees for non-work related illnesses or injury.
- Employers are also required by state and federal laws to display certain posters in the workplace if the organization is subject to the state or federal law. These posters inform employees of their rights and employer responsibilities under labor laws. Areas covered by these posters may include polygraph provisions, disability concerns, and minimum wage requirements.

**POLICIES AND PROCEDURES**

A policy and procedure manual is a vital component of all organizations, regardless of size. Policies are business statements that reflect the organization’s objectives whereas procedures are guidelines for how a certain activity is to be performed. One of the primary goals of policies and procedures is to minimize the risk of patient harm.

Enforcement of policies and procedures
depends on the organizational manager’s perceived need to assure compliance. In some cases, enforcement may be delegated to dependable subordinates. If these subordinates fail to comply with the policies and procedures that eventually cause patient harm or an employee event, the pharmacy and pharmacist in charge could be held responsible.

When a policy or procedure is adopted by a pharmacy, several actions should follow. The new policy and/or procedure should be conveyed to all subordinate employees. All employees should be advised of the importance of the policy or procedure. Time should be allowed for the policy to be implemented, if necessary.

All employees should also observe procedural requirements. Failure to follow new or changed procedures may be construed as negligence. For instance, not double checking a blood thinner or an insulin product dose prior to dispensing by two pharmacists or a pharmacist and a technician may result in patient harm. This may be viewed by a jury as gross negligence, which may lead to punitive damages. These types of damages are not based on actual harm but instead on intent to punish the activity, or lack thereof, based on reckless behavior. If a pharmacy has implemented a policy and procedure and that policy and procedure is not followed resulting in patient harm, punitive damages are a real possibility.

Policies and procedures should be clearly drafted and responsibility assigned for monitoring compliance. These documents need to be written, creating a formal document, and periodically reviewed for accuracy. It is preferred that new employees be required to read all policies and procedures and sign a document indicating that the manual has been read and understood. The importance of compliance by each employee needs to be stressed because of legal concerns and patient safety.

**MISCELLANEOUS ISSUES**

This section will attempt to address two other important issues pharmacy owners must address to be successful. These areas include evaluating third-party prescription drug contracts and total quality management (TQM), also known as continuous quality improvement (CQI). The final section will examine some of the most frequently asked questions addressed by the SBA.

As more patients are enrolled in third-party plans, it is important for pharmacists to become financially savvy when evaluating third-party prescription contracts. Desselle and Zgarrick (*Pharmacy Management, Second Edition: Essentials for All Practice Settings, Second Edition*; 2008) suggest evaluating several factors when evaluating a third-party prescription contract. First, determine the net profit per prescription. This requires the pharmacist to calculate the cost to dispense a prescription and may include a variety of items, including but not limited to, labor, equipment, supplies, and overhead costs in addition to the cost of the prescription medication itself.

The second factor to consider is the potential impact on the pharmacy’s patients. By this, it is important to determine whether refusing a particular contract will impact significant numbers of patients. Though the contract may not provide the best reimbursement, if reimbursement is adequate to support operations it may be worth accepting the contract to retain valuable patients, patients who make other purchases and patients who pay for services at the pharmacy.

Third, the pharmacy’s image may play a role in whether or not to accept a contract. If the pharmacy is perceived as refusing many third-party plans, patients may view the pharmacy as providing necessary services to only cash paying patients. The fourth factor is whether a low reimbursement rate will ultimately be shifted to these cash paying patients. If so, accepting a third-party contract may in turn, make the pharmacy less competitive with this patient segment. Finally, accepting a very low reimbursement rate may cause a “slippery slope” effect in that other third-party plans may subsequently require a reduction in their reimbursement plans. This effect could severely damage the pharmacy’s bottom line.

Quality is a critical component of any business, and pharmacy is no exception. The concept of TQM rests largely on five principles:

1. Produce quality work the first time.
2. Focus on the customer.
3. Have a strategic approach to improvement.
4. Improve continuously.

TQM refers to the application of quality principles to all functions and processes which, in the pharmacy, range from medication dispensing and shelf stocking to patient care services and laboratory testing. When examining quality, it is essential to examine the pharmacy from a 360-degree perspective. Furthermore, TQM involves all the pharmacy’s staff members. There are a variety of ways with which to measure quality. One method for assessing areas of improvement includes the use of patient satisfaction surveys. Another method involves soliciting feedback from employees. This can be accomplished by conducting regular staff meetings. During these meetings, staff members should be encouraged to discuss areas of concern they have identified. The environment must be open and receptive in order to fully foster discussion. Furthermore, it is important to include the staff’s opinions as to ways to resolve the identified areas of concern. In so doing, there will be greater buy-in, thus improving the quality of service patients receive.

FREQUENTLY ASKED QUESTIONS

How do I get a small business loan?
An individual should prepare a business plan, including the loan proposal, and submit it to a local lender. Generally, the individual requesting a loan has 10 percent or more equity; a lender may require more than 10 percent but it is the minimum for an SBA loan. If the lender is unable to approve the loan, one may request that the application be submitted, by the lender, to the SBA. The SBA can guarantee up to 80 percent of a small business loan; however, the lender must agree to loan the money with the SBA guarantee. The lender will then forward the loan application and a credit analysis to the nearest SBA district office. If the lender needs SBA applications and/or guidance, it may contact the nearest SBA district office by going to SBA. Upon SBA approval, the lending institution closes the loan and disburses the funds.

How do I write a business plan?
Information and a business plan template can be found at SBA’s home page (sba.gov). Select “Writing a Business Plan” under “Small Business Planner.” There is information there on starting a business and writing a business plan. Under “SBA local resources” there are local contacts such as SCORE (formerly known as the Service Corps of Retired Executives) and the Small Business Development Center that provide FREE one-on-one counseling in the area of starting and expanding a small business. They can assist individuals by critiquing business plans and business ideas. Individuals can locate a center by selecting “Local Resources” under sba.gov as well.

What type of collateral do I need for a loan?
Repayment ability from the cash flow of the business is a primary consideration in the SBA loan decision process but good character, management capability, collateral, and owner’s equity contribution are also important considerations. All owners of 20 percent or more of the business are required to personally guarantee SBA loans. The SBA does not deny approval for a SBA Guarantee Loan solely due to lack of collateral; however, it can be used as a reason in addition to other credit factors. For more information on requirements for a SBA Guarantee Loan as well as guarantee loan programs available, please visit the SBA website.

How do I know if I qualify as a small business so that I can receive SBA assistance?
Approximately 95 percent of all businesses are eligible for SBA assistance. Size standards vary widely depending upon the industry; however, as a general rule, the business is within SBA size limits if it is in retailing or service with annual sales under $5 million or in manufacturing or wholesaling with fewer than 100 employees. To find out more about size standards, call the SBA Office of Size Standards at 202-205-6618.
Do I have to be declined by a bank to be eligible for an SBA guaranteed loan?
No, individuals do not have to be turned down by a lender to qualify for a loan guaranteed by the SBA.

What are the SBA’s loan limits?
The SBA does not have loan minimums. Many lenders may prefer to process loans for under $100,000 under SBA’s LowDoc program. The maximum amount the SBA can guarantee is generally $1.5 million.

How much money do I need to have to qualify for an SBA loan?
While the minimum for a SBA loan is 10 percent, the borrower’s capital contribution generally must be one-fifth (20 percent) to one-third (33 percent) of the total project cost.

How long will it take to get my loan?
A credit decision on a complete loan package is usually made within 10 working days after the SBA, not including bank-processing time, receives it. This assumes that the borrower and lender have provided all the information necessary to process the loan.

Where can I get an SBA loan application?
SBA loan forms are available from a participating lender, who will also be able to provide information about both the bank and SBA documentation required.

(above FAQ section is taken from Small Business Resource Guides published for individual SBA District Offices in co-sponsorship with RENI Publishing of Winter Haven, Fla., 33880-3052. SBA’s participation in this publication is not an endorsement of the views, opinions, products, or services of the publisher or any advertiser or other participant appearing herein. All SBA programs or co-sponsored programs are extended to the public on a nondiscriminatory basis. Individual District Office editions are copyrighted. SBA Auth. No. 97-7110-64.)

WHAT ARE ADVANTAGES AND DISADVANTAGES OF BUYING A BUSINESS?
Advantages: Among the many favorable aspects to buying an existing business is the drastic reduction in startup costs. In addition, cash flow may be immediate because of existing inventory and receivables. Other positive effects include existing goodwill and easier financing opportunities, assuming the business has a positive track record.

Disadvantages: Among the biggest downsides to buying a small business is the initial purchasing cost. Since developing the business concept, customer base, brands, and other fundamental work has already been done, the costs of acquiring an existing business may be greater then starting a new business. Other possible disadvantages include hidden problems associated with the business and receivables that are valued at the time of purchase, but later turn out to be noncollectable.

WHAT IS WORKERS’ COMPENSATION INSURANCE?
Workers’ compensation insurance provides coverage for an employee who has suffered an injury or illness resulting from job-related duties. Coverage includes medical and rehabilitation costs and lost wages for employees injured on the job. This insurance can be obtained from a licensed insurance company. The law in most states requires some form of workers’ compensation insurance. Refer to the workers’ compensation authority in your particular state.

WHAT IS A SURETY BOND?
A surety bond provides a form of guarantee that individuals will complete the work that they have committed to perform. Often referred to as a performance bond, the surety bond guarantees that individuals have the financial resources to complete the job from start to finish. Through its Surety Bond Program, the SBA can guarantee bid, performance, and payment bonds for contracts up to $2 million for small businesses that cannot obtain bonds through regular commercial channels.

WHAT OTHER LICENSES DOES A SMALL BUSINESS NEED?
The following are just some of the business licenses/permits that a small business might need: doing business as (DBA) registration (usually filed at the county level), city
and/or county business license, fire department permit, sign permit, health department license, and liquor, wine, and beer licenses.

**WHAT LEGAL ASPECTS DO I NEED TO CONSIDER?**

Licenses required, zoning laws, and other regulations vary from business to business and from state to state. Your local SBA office can provide general information, but individuals will need to consult an attorney for advice specific to particular areas. Individuals also must decide about the form of organization (corporation, partnership, or sole proprietorship) and tax status (such as, should you opt for a Subchapter S status?).

**MY BUSINESS IS UNDER MY PERSONAL NAME. DO I NEED TO REGISTER IT?**

In most states individuals do not need to register their own names if using it as the business name. To determine what the requirements are in your particular state, go to BusinessLaw.gov and find the specific laws related to registering a business under the State and Local Information section.

**HOW DO I INCORPORATE MY BUSINESS?**

Once the decision to incorporate a business has been made, the legal process begins with the preparation of a certificate of incorporation. Whereas in the past three or more legally qualified individuals prepared this, today only a single incorporator is needed. The incorporator may or may not be a person who will own stock. The state is likely to have a standard form for incorporating a small business. The three typical pieces of information requested are: corporate name, purpose, and corporate life span. The corporate name is usually required to be a business name dissimilar from any other firm incorporated within the state. In addition, the name must not be deceptive or misleading. The state charter office can tell whether the name desired is available. The purpose of the business must be stated. It is a good practice to use a specific object clause that spells out the specific purpose for which the corporation is being formed. While most corporations are formed for an indefinite period, it is possible to set up a specific limited life. Often the reason for creating a corporation is because the life span of the business is unlimited.

Incorporation documents will require the names and address of incorporators, location of the registered corporate office in the state, the maximum amount and type capital stock to be issued at the time of incorporation, a provision for preemptive rights, a provision for regulation of internal affairs of the corporation, names and addresses of corporate directors until the first stockholders’ meeting, and the right to amend or repeal provisions within the certificate of incorporation.

The above requirements cover incorporating as either a C Corporation or Subchapter S Corporation. However, the Subchapter S Corporation has several additional incorporation requirements. It must be an independent group not affiliated with any other, it may have only a single class of stock, no more than 35 stockholders (only individuals or estates may qualify as stockholders), and it must be a domestic corporation. Before signing any legally binding documents, consult an attorney for legal advice. (Contributed by the Delaware SCORE Office.)

**WHAT IS THE ADVANTAGE OF FORMING AN S-CORPORATION?**

The structure of an S-Corporation is identical to the C Corporation in many ways, but offers avoidance of double taxation. If a corporation qualifies for S status with the IRS, it is taxed like a partnership; the corporation is not taxed, but the income flows through to shareholders that report the income on their individual returns.

**ARE PARTNERS CONSIDERED EMPLOYEES OF A PARTNERSHIP?**

Partners are considered to be self-employed. If an individual is a member of a partnership that carries on a trade or business, the distributive share of its income or loss from that trade or business is net earnings from self-employment. Limited partners are subject to self-employment tax only on guaranteed payments, such as salary and professional fees for services rendered.
CONCLUSION
There are many challenges to becoming a business owner. However, with those challenges come great opportunities. With the guidance and assistance of mentors, financial and legal experts, these potential barriers can be overcome. This is an exciting time for the pharmacy profession as advances in health care and medication therapy management have afforded pharmacists greater ability to improve patients’ health and well-being. As a result, the future is unlimited for pharmacy owners.

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CONTINUING EDUCATION QUIZ
Select the correct answer.

1. According to the SBA, a small business is an independent business having fewer than _____ employees.
   a. 100
   b. 250
   c. 500
   d. 1,000

2. Which of the following is not included in a typical business plan?
   a. Current balance sheet
   b. Resume of owner or all principals
   c. Income statement
   d. Five-year pro forma cash flow analysis

3. Which of the following business structures affords the owner personal liability for all the business debt?
   a. LLC
   b. S-Corporation
   c. General partnership
   d. Sole proprietorship

4. Title VII of the Civil Rights Act of 1964 prohibits discrimination on the basis of:
   a. National origin
   b. Sex
   c. Age
   d. Both a and b

5. Which of the following federal laws requires employers to provide “reasonable accommodations,” assuming certain criteria are met?
   a. Title VII
   b. The ADA
   c. The ADEA
   d. GINA

Editor’s Note: For the list of references used in this article, please contact America’s Pharmacist Managing Editor Chris Linville at 703-838-2680, or at chris.linville@ncpanet.org.
6. If a pharmacist requests an employment waiver for a new hire with a felony conviction related to controlled substances (such as a pharmacy technician), which of the following agencies may provide the waiver?
   a. FDA  
   b. OSHA  
   c. DEA  
   d. State board of pharmacy

7. Which of the following states recently enacted a law requiring background checks to be conducted for all pharmacy technicians?
   a. Ohio  
   b. New Jersey  
   c. Delaware  
   d. California

8. DEA registration as a pharmacy:
   a. Currently costs $745 per year  
   b. Only allows pharmacies to handle C-III, C-IV, and C-V controlled substances  
   c. May cover multiple pharmacies under common ownership  
   d. Typically extends for a period of three years

9. Pharmacy technician registration in a state is generally mandated by:
   a. The board of pharmacy  
   b. The Pharmacy Technician Certification Board  
   c. The Institute for the Certification of Pharmacy Technicians  
   d. Both B and C

10. Pharmacy owners would most likely be required to possess which of the following business permits?
    a. Hazardous waste disposal  
    b. Environmental  
    c. Signage  
    d. Agrarian

11. If a pharmacy business is operating under a fictitious name:
    a. The pharmacist has likely changed its legal name  
    b. The pharmacy will likely need to register with the local county clerk’s office  
    c. Criminal charges will be brought by the district attorney’s office  
    d. The business structure must be that of a partnership

12. Pharmacy tenants should ensure in lease agreements that landlords maintain:
    a. Telephone lines  
    b. Common areas  
    c. Pharmacy computer files  
    d. Cash registers

13. To protect against the failure of the tenant’s business during a disruption or casualty, landlords may require a tenant to acquire:
    a. Interruption insurance  
    b. Catastrophic insurance  
    c. Loss prevention insurance  
    d. Title insurance

14. A liquidated damages clause in a lease agreement will provide that:
    a. An arbitrator determine any damages to either party in the breach of a lease agreement  
    b. The judicial system is the sole source of relief in event of a breach of the lease agreement by either party  
    c. A specific sum of money that has been expressly stipulated will serve as the amount of damages that can be recovered by either party in the event of lease breach  
    d. The sum that can be collected in a breach of a lease agreement by either party is fluid, not fixed and subject to mediation by both parties
15. Clear title to real estate may be clouded by all of the following EXCEPT:
   a. Liens
   b. Easements
   c. Judgments
   d. Pharmacy regulations

16. For a covenant not to compete to be valid it must be reasonable regarding:
   a. Purchase price
   b. Non-discrimination based on race and nationality by sellers
   c. Work restriction after the time of the sale
   d. Tax record compliance audit

17. Before a new employer can hire any employees the employer must obtain a(n):
   a. Employment identification number
   b. Federal tax deposit coupon
   c. IRS authorization for employment
   d. Tax record compliance audit

18. Federal taxes required to be withheld from all employees include:
   a. Disability
   b. Workers’ compensation
   c. Health care
   d. Social security

19. Employers are required to verify an employee’s eligibility to work in the United States by:
   a. Performing a background check by using a national search agency
   b. Completing an employment eligibility verification form
   c. Testing for drug and alcohol use
   d. Contacting the National Security Agency for clearance

20. TQM is also known as:
   a. Total Quantity Management
   b. Total Quality Management
   c. Top Quantity Management
   d. Top Quality Management

21. TQM is also known as:
   a. Total Quantity Management
   b. Total Quality Management
   c. Top Quantity Management
   d. Top Quality Management

22. Top Quality Management

23. contacting the national security agency for

24. completing an employment eligibility verification form

25. employees the employer must obtain a(n):

26. All fields below are required. Mail this form and $7 for manual processing to: NCPS,
   Attn: Jane Davey; 100 Daingerfield Road Alexandria, VA 22314.

27. Last 4 digits of SSN    MM-DD of birth

28. Phone number (store or home)

29. city       state   ZIP

30. Pharmacy name

31. Name

32. Last 4 digits of SSN    MM-DD of birth

33. Record your quiz answers and the following information on this form.

34. NCPA Member License

35. NCPA Member No.    State    No.

36. Nonmember License

37. State    No.

38. All fields below are required. Mail this form and $7 for manual processing to: NCPS,
   Attn: Jane Davey; 100 Daingerfield Road Alexandria, VA 22314. Make check payable to NCPS.

39. Last 4 digits of SSN    MM-DD of birth

40. Name

41. Pharmacy name

42. Address

43. City       State   ZIP

44. Phone number (store or home)

45. Store e-mail (if available)

46. Date quiz taken

47. Quiz: Shade in your choice

48. 1. a b c d e

49. 2. a b c d e

50. 3. a b c d e

51. 4. a b c d e

52. 5. a b c d e

53. 6. a b c d e

54. 7. a b c d e

55. 8. a b c d e

56. 9. a b c d e

57. 10. a b c d e

58. Quiz: Circle your choice

59. 26. Is this program used to meet your mandatory C.E. requirements?
   a. yes, b. no

60. 27. Type of pharmacist: a. owner b. manager c. employee

61. 28. Age group: a. 21–30 b. 31–40 c. 41–50 d. 51–60 e. Over 60

62. 29. Did this article achieve its stated objectives?
   a. yes, b. no

63. 30. How much of this program can you apply in practice?
   a. all, b. some c. very little d. none

64. How long did it take you to complete both the reading and the quiz? ______ minutes
The Power of Monthly Newsletters

by Dan Benamoz, RPh

A MONTHLY NEWSLETTER IS AN easy and inexpensive way of keep- ing in constant contact with your customers. Every month you don’t contact a customer you lose 10 percent of the value of your relationship. So if you don’t contact your customer for 10 months, it’s all over.

Then you shift from your marketing being focused on keeping a relationship with a customer intact, to having to go back and try to win over customers because they have forgotten about you. That’s why so many businesses lose customers—they forget to nurture the relationships they worked so hard to get in the first place.

Why is a monthly newsletter so powerful? Here are a few reasons.

• It develops a relationship between you and your customers.
• It keeps you and your company at the top of your customers’ consciousness.
• It gives you a chance to sell some more things. A monthly newsletter is a great way to introduce new products, or to feature specific products such as supplements.
• It gives you a chance to continually educate your customers so that they can make more informed buying decisions.
• It’s a place where you can acknowledge customers who have referred others to you. This will increase the number of referrals you get. Since one customer sees that others refer you, she will too.

A newsletter is a marketing must. It is an essential ingredient to keeping customers and generating new ones. It’s the No. 1 tool our best clients use for fostering repeat business and encouraging referrals.

Some pharmacies take the time to write a new issue every month for their customers. However, this can take hours to do, and if you’re in the midst of a busy season you may be too tired for that. There are numerous sources of newsletters that take you or your staff a small amount of time to customize and send off regularly each and every month. I recommend that issues don’t focus on boring scientific articles, or other technical information that your customers won’t be interested in reading. I use and recommend a collection of tips, stories and other fun information on a whole series of topics, with direct response mechanisms within it to get them involved in reading it and contacting you.

Each month the issue can have a special insert that you can include in the mailing to create sales, with a postcard version of that insert so you can contact them again.

Our most savvy pharmacy owners list the newsletter as their most effective sales-generating strategy out of everything they use. And those who create the most sales results from each issue tend to implement the following contact sequence with their customer list:
1. Send a short voice broadcast message (follow current FCC regulations)—or send an email—to mention that the newsletter is about to hit the mail, and to be sure to look for this month’s special. (They send this two to three days before the issues mail out to them.)
2. Send the newsletter out.
3. Ten days after the newsletter is mailed, follow up with a postcard about the same special to their customers, reminding them that the expiration date is coming.

Dan Benamoz is CEO of Pharmacy Development Services, a pharmacy specific business development and coaching company serving independents nationwide since 1998. They can be found at www.pharmacy-owners.com.
Are You Ready to Consider Dispensing Automation?

By Bill G. Felkey

As our nation’s baby boomers continue to age, our country is experiencing record prescription volumes. If you have ever attended one of my technology seminars, you’ve probably heard me tell you that technology enhances the work of human beings or can completely replace that work, especially when it is repetitive and tedious. Perhaps the best example of work that can be replaced in the pharmacy by automation and robotic hardware is focused on your end-to-end dispensing operations.

There is certainly a wide variety of automation from which to choose that is currently available in today’s pharmacy technology market. Much of this technology is designed for in-store application to assist with the dispensing of oral solids, unit of use packaging, and for specialty practices automation is available for liquids and syringe preparation. Some of these same technologies can be used in central fulfillment operations that allow for custom packaging of up to 40 percent of the prescription volume in an average community pharmacy. Other automation addresses intake and workflow issues and can assist with “will call” management and after hours dispensing kiosks.

Depending on the pharmacy practice, automation can be justified solely on the basis of the safety that it provides for patients, even at the initial startup of the new practice. Barcode interfaces used with non-robotic scales or counting devices yield some measure of peace of mind as pharmacists increasingly delegate dispensing duties to technicians. Having the right drug, strength, and form verified by technology is always a good idea in the early stages of the dispensing process, even though the pharmacist will ultimately be the final quality control manager before any medication is dispensed. Ask any vendor you are considering what research data they have on their product’s impact on patient safety.

Aesthetically, you may want to consider placing your technology so that patients can observe your robotic device in operation. You will find that some patients are absolutely fascinated with robotics that are functioning to keep them safe and make you more effective in your operations.

Choose Wisely

Volume is, of course, another driver for the adoption of automation and robotics in the pharmacy. It used to be that 200 prescriptions per day was the number at which an investment in robotic automation started to make financial sense. Many companies have begun offering a scalable product that can be cost justified at volumes starting around 100 prescriptions per day. I recommend that you find out how any technology solution you consider will deliver high-speed capacity to match your operations. Like every technology, human labor will be required for the upkeep of your system and this labor may vary from vendor company to company. If you experience really high volume, you’ll also want to know what the technology’s capability is for uninterrupted throughout during your peak operating periods.

I recommend that you consider revamping your

Continued on next page
overall workflow when you implement automation into your process. Of course, the footprint of the device you finally choose and available square footage of your prescription department will heavily impact your redesign. Aesthetically, you may want to consider placing your technology so that patients can observe your robotic device in operation. You will find that some patients are absolutely fascinated with robotics that are functioning to keep them safe and make you more effective in your operations.

Some automation is designed to eliminate cross-contamination between medications in its design. Others allow for on-demand dispensing cell calibration and refill procedures that differ from its competitors. You will probably want to do a site visit with someone who is using the technology that makes it to your shortlist of consideration. Due diligence in the selection process requires that you determine the meantime between failures (where unscheduled downtime can impact your operation) as well as the accuracy of the counting technology are all part of your due diligence before purchasing. Remember to check on whether your vendor can remotely access your automation to assist you with service and what kind of response time for repairs you can expect given your proximity to a service technician.

After you have decided to **invest in automation and robotics**, I also recommend that you consider how you can redeploy any labor savings attained by your use of automation into other revenue-generating activities.

**COST CONSIDERATIONS**

Make sure you calculate the total operating costs for the automation and determine the customer service reputation of any vendor you are considering. You should get some idea of labor savings that you can expect as well as supply savings and waste reduction estimates. Try to determine the impact on your inventory and any carrying cost reduction associated with the adoption of the automation.

Determine how operator training will take place in your pharmacy and how the interface or integration to your pharmacy practice management system will operate. Optimizing your investment after a purchase can be done through tracking and reporting software for your device. Reports will indicate when cell assignment can be optimized for seasonal changes and to maximize the percent of your total prescription mix being managed by the automation.

Some automation companies provide dose images to assist with verification and can automatically add auxiliary labels to multiple vial sizes in the system. Other companies produce automation that supports long-term care packaging of medication. Still others produce medication regimen compliance packaging in the form of pouches that contain all of the doses that patients are to ingest on a given day at a given time. You may be surprised how many products will surface to assist you in becoming more efficient and effective in your operations once you start your search.

After you have decided to invest in automation and robotics, I also recommend that you consider how you can redeploy any labor savings attained by your use of automation into other revenue-generating activities. For example, can you reassign personnel to work on medication adherence issues in your practice through a refill reminder program? Consider if your new technology will allow you some additional time to add immunizations as a new service to your practice. For a listing of vendors to start with, visit http://rxtecnologyresource.com. I try to keep up with the automation and robotic market for pharmacy and would welcome your questions and comments. You can reach me by email at felkebg@auburn.edu.

Bill G. Felkey is professor emeritus of health care informatics at the Harrison School of Pharmacy at Auburn University, Auburn, Ala.
A client contacted me recently with concerns regarding his prescription volume for the past month that was in decline from the same month previous year. He had hired a part-time pharmacist a few months prior to the call to work for him a couple days a week and he wanted to make sure the business was sustaining bottom line goals consistent with his objectives. The report of a recent decline in prescription volume made him wonder if he had made a mistake.

Instead of speculating, we did the math using accurate information from historical data and compared year to date volume for the current year to the same time period of the previous year. This comparison alone provided much relief to my client, as the decline of volume year to date was at a much lower percentage than the decline of the previous month. Reviewing performance over a longer period of time provided a more indicative picture of the state of the operation.

However, prescription volume was still down year to date, causing concern to my client. The decline in volume also equated to declines in prescription sales and gross profit dollars. What was he to do moving forward considering these key performance metrics recently unveiled?

The answer was to identify the cause of the decline and to take as many corrective actions as possible to maintain optimal operating efficiencies needed to achieve his bottom line goals.

There were a number of contributing factors to the decline in volume, sales, and gross profit dollars. The sluggish economy, stagnate trade area, and the aging and subsequent passing of his patient base were deemed to be the most significant. We reviewed marketing plans and the effectiveness of those efforts and believed there were some things that could be done differently that might bring in new business to offset the declines.

Marketing efforts take time to develop, get implemented, and produce results. Profits were down and corrective actions needed to be taken at once. We calculated the decline to be attributed to the loss of approximately three prescriptions per day. With an average fee of $12 per prescription, the daily loss was $36. This figure multiplied times the number of days open in a month, 26 on average, and the decline in gross profit dollars to be anticipated if the trend in lost volume continued equated to $936. When annualized, this amount results in $11,232 in lost gross profit dollars. This amount was worthy of taking corrective actions.

The anticipated decline in gross profit dollars was equal to the wages my client paid for a relief pharmacist for two days work per month. He decided to cut those days back until marketing efforts had taken place and more time had passed to see if the trending decline changed course. Bottom line profits would not be sacrificed in the face of challenging times.

Challenging times are those still filled with opportunities. The key is to use accurate and pertinent information in a timely and meaningful way to keep your business headed in your desired direction. Have a plan in place and visit the actual performance on a regular basis. Ask questions and get answers needed from a perspective that allows you to take an array of actions that when applied correctly will lead to better results. Retail pharmacy is a “make it happen business” with elements that remain in management’s control. Take control and lead your business. Eliminate speculation and rely on THE POWER OF INFORMATION.

Andy Oaks is the president of Retail Pharmacy Management Services, Inc. For information, visit www.rpms.biz. Contact Oaks at 800–662–9035, or andy@rpms.us.
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Oppose the Merger of PBM Giants Express Scripts and Medco

By Michael F. Conlan

Actions requested of Congress:
• Ask the Federal Trade Commission to block this merger; stand up for patient choice.
• Oppose higher drug costs and protect small business owners.
  • Support legislation to curb PBM audit abuses (S.1058/H.R.1971).
  • Support legislation to level the playing field and give small pharmacies an anti-trust exemption (H.R.1946).
  • For more details, go to www.ncpanet.org.

MERGER WOULD RESULT IN UNPARALLELED MARKET CONCENTRATION
The pharmacy benefit management marketplace is already extremely concentrated and dominated by “the big three”—Express Scripts, Medco, and CVS Caremark. The proposed merger of two of the three biggest PBMs would result in unparalleled market concentration. Analysts have already predicted that the combined entity will dominate the PBM market with control over 30 percent of annual prescriptions processed—both at retail and mail (see Figure 1 below)—and about 80 percent in the private sector market. Additional points:
• Extreme market concentration will result in reduced choices for both third party and federal/state payers.
• Merged entity would likely corner the market on specialty drugs.
• Greater cost savings in the market? Where’s the proof?
• Proposed merger will have negative affect on all retail pharmacies—particularly on independent community pharmacies.
• The PBM industry is virtually unregulated at federal or state level and has a long track record of enforcement actions alleging fraudulent and deceptive conduct.

Figure 1. PBM Market Concentration