Meet NCPA’s New President
Editor’s Note: Over the past two years Andy Oaks has provided valuable insights for pharmacies through his monthly Pharmacy Management column in America’s Pharmacist. However, an increasingly successful business has also increased his workload, leaving less time to fully devote to his column. As much as he enjoyed writing, Andy has decided it’s time to step aside. “It has been an honor and privilege to contribute to America’s Pharmacist,” he said. “I hope it made a positive difference for the readers.”

Andy’s previous columns are available to NCPA members in the America’s Pharmacist archive section at americaspharmacist.net. He says anybody who would like to contact him is more than welcome to do so. His phone number is 800-662-9035, and his email address is andy@rpms.us.

We wish Andy all of the best in his future endeavors and thank him for his contributions to the magazine.
Cover: Flash mobs? Dancing in the rain? Chain of chains? Dylan? Twain? Not your typical acceptance speech for an NCPA president by any stretch, but it was a comfortable fit for Lonny Wilson. (Photo by Michael DeFilippo.)

42 The State of E-Prescribing
by Lisa Fowler, PharmD
The transition hasn't always been seamless, but the technology has a demonstrated record as a powerful tool that can add to a pharmacy's success.

47 Calendar
2012 state pharmacy association meetings.

Departments

4 Up Front
by B. Douglas Hoey, Pharmacist, MBA
E-prescribing increasing across the board.

6 Newswire
Lawmakers, pharmacists rally against proposed $29 billion ESI-Medco merger at U.S. Capitol.

10 Inside Third Party
Eye on PBMs

12 Adherence—It Only Takes a Minute
Ring in the new year; ring your register.

14 Medication Safety
Pharmacy technicians: an extra layer of safety.

49 Continuing Education
by Nicole Van Hoey, PharmD
Care and treatment of ambulatory patients with diabetes: evidence-based team care initiatives.

70 Pharmacy Law
by Jeffrey S. Baird, Esq.
A physician as landlord or tenant: legal parameters.

71 Reader Resources
NCPA activities and our advertisers.

72 Notes From Capitol Hill
When the people talk, Congress listens.

Letters to the Editor—If you would like to comment on an article, email NCPA at info.ncpanet.org. Put AP in the subject line and include your phone number. Your letter may be posted on the NCPA website and edited for length and clarity.

The National Community Pharmacists Association (NCPA®) represents America’s community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health care marketplace, have more than 315,000 employees, including 62,400 pharmacists; and dispense over 41 percent of all retail prescriptions. Visit the NCPA website at www.ncpanet.org.

America’s Pharmacist annual subscription rates: $50 domestic; $70 foreign; and $15 NCPA members, deducted from annual dues.

Ask Your Family Pharmacist®
America’s Pharmacist is printed on paper that meets the SFI standards for sustainable forest management.
E-Prescribing continues to be a growing part of our business. More than half (52 percent) of all office-based physicians now actively use e-prescribing, compared with fewer than 10 percent three years ago, according to new figures from Surescripts. Some 94 percent of all retail pharmacies are receiving e-prescriptions.

The 2011 NCPA Digest, sponsored by Cardinal Health, shows that 15 percent of independent pharmacy prescriptions on average are being sent electronically. That’s nearly a 300 percent increase from two years ago.

On the plus side, electronic prescriptions should come in “clean” and require less data input. Importantly, a recent analysis by Surescripts showed up to an 800 percent return on investment to pharmacies for e-prescribing.

On the down side, more electronic prescriptions mean more transaction charges, and not all of the prescriptions are coming in clean. We know that the e-prescribing experience varies widely depending on a number of factors, including the physician application sending the e-prescription, how skilled the physician is in their use of their e-prescribing application, and the pharmacy management system receiving the e-prescription.

For most of our members, e-prescribing should be like a baseball umpire—it should perform its duties and blend into the background barely noticeable. That’s true for the majority of e-prescriptions, but when we hear complaints they generally center on the cost of the transaction and e-prescriptions with errors or that are delayed.

Most independents buy e-prescribing transactions from their pharmacy management system vendor. The pharmacy management system pays Surescripts a maximum of 16.5 cents for the transaction. An NCPA survey found that the average independent pharmacy is charged 23 cents by their pharmacy management system vendor.

When NCPA and the National Association of Chain Drug Stores created the original Surescripts in 2001, the vision was that it would be a pipeline for prescriptions between the prescriber and the pharmacy (it was also in reaction to the PBMs’ entry into the e-prescribing marketplace, RxHub). Surescripts has grown a lot in the last 10 years and it has helped further increase pharmacy’s relevance to payers increasingly looking for ways to connect the entire health care system while measuring quality and outcomes.

Over the last year we have worked with Surescripts to enhance its outreach to independent pharmacy. Surescripts recently announced that it is initiating a new hotline dedicated to independent community pharmacies to assist them in their use of e-prescribing.

The number is 877-877-3962. Call it when you need help.

E-prescribing remains a sore spot for some pharmacies because the paper-based system was working fine for them and there is a visible cost to an e-prescribing transaction. For other pharmacies, they are taking advantage of the efficiencies the system creates.

We’ll print more information from the member survey we did on e-prescribing in an upcoming issue of America’s Pharmacist. Be on the lookout for it. It will help your business.  

B. Douglas Hoey, Pharmacist, MBA NCPA Chief Executive Officer
Lawmakers, Pharmacists Rally Against Proposed $29 Billion ESI-Medco Merger at U.S. Capitol

NCPA CEO B. Douglas Hoey, Pharmacist, MBA, participated in a news conference at the U.S. Capitol organized by the Preserve Community Pharmacy Access NOW! (PC-PAN) coalition against the proposed Express Scripts Inc.-Medco Health Solutions merger. Congressional speakers included Reps. Thomas Marino (R-Pa.) and Joe Courtney (D-Conn.).

PCPAN is a broad coalition of consumers, businesses, and pharmacists chaired by former Rep. Eva M. Clayton (D-N.C.). It brought dozens of community pharmacists from around the nation to Washington, D.C., Nov. 3 to urge lawmakers and the Federal Trade Commission to reject the proposed $29 billion mega-merger that would join two of the nation’s three largest PBMs.

“Quite simply, the windfall profits of major PBMs have soared and everyone else has been paying the price,” Hoey said. “To paraphrase independent pharmacist and NCPA member Joseph Lech during a recent congressional hearing, we’ve previously heard PBM claims of reducing costs through mergers, but prescription prices keep going up, plan sponsors keep paying more, consumers are paying higher co-pays and pharmacies are being paid less, so where’s the money going?”

“The marriage of Express Scripts and Medco would give one corporation control of nearly 60 percent of the mail order pharmacy market and 52 percent of the specialty pharmacy market,” Hoey continued. “It could mean more wasteful mail order spending and higher price spikes for specialty drugs. The already limited pharmacy management options for the largest health plans, including the federal government, will grow further captive to the major PBMs. Currently 42 out of the Fortune 50 largest U.S. employers use the ‘Big Three’—Express Scripts, Medco or CVS Caremark. It is safe to say that if the merger is green-lighted, the remaining two companies would face little, if...
Q: How many refills should be transmitted for this faxback request?

A: Recently a pharmacy was audited on a faxed refill request. The prescriber indicated on the faxback that the “Total Refills Authorized—3.” The pharmacy filled as 1 + 3 refills, which was flagged as allowing 1 extra refill by the Third-Party. *It is suggested to transmit 1 + 2 refills in these cases.*

The pharmacy should transmit 1 + 3 refills when the faxed prescription reads, “I authorize this fill plus 3 additional fills.” A refill authorization of okay x3 can also subject a pharmacy to possible audit scrutiny.

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

**INDEPENDENT PHARMACY TODAY**

- 1.89—average number of pharmacies in which each independent owner has ownership
- 55—average number of hours open per week
- 6—average number of days open per week

Source: 2011 NCPA Digest, sponsored by Cardinal Health

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**Preserve Community Pharmacy Access NOW!**

Continued from page 6

any, resistance to raising costs, reducing choice and otherwise putting their own interests ahead of those of employers, patients and others.

“Another reason to oppose the merger is that PBMs have a history of getting their hand caught in the proverbial ‘cookie jar.’ PBMs have paid the states a total of $370 million for past actions, and now 28 state attorneys general are looking into the merger with a wary eye. The likelihood of further litigation will only increase in a post-merger environment.

“The unchecked, virtually unregulated growth and consolidation among PBMs also reinforces the case that Congress should pass companion bills S. 1058 / H.R. 1971, The Pharmacy Competition and Consumer Choice Act of 2011, and H.R. 1946, The Preserving Our Hometown Independent Pharmacies Act. These bills would significantly boost the patient’s choice of pharmacy while effectively curbing questionable PBM business practices that drive up health care costs.”

**APhA, NABP Plan to Develop Voluntary Community Pharmacy Accreditation Program**

The American Pharmacists Association and the National Association of Boards of Pharmacy are partnering to develop a voluntary accreditation program for community pharmacies, expected to be operational sometime this year. The standards development process will use a consensus-based approach that will involve a wide array of pharmacy and other stakeholders.

This is an issue that NCPA has been tracking for many years, and our current position is that such additional accreditation for state-licensed, retail pharmacies is duplicative and unnecessary. NCPA recognizes the individual state boards of pharmacy as exclusively responsible for governing and regulating the practice of pharmacy and as such, opposes efforts that attempt to apply burdensome accreditation requirements to community pharmacies. At this time NCPA questions the need for community pharmacy accreditation, but also wants to be prepared should marketplace trends shift with demand from payers and others. *AP*
NCPA Helps Coordinate Bipartisan House Letter On ESI-Medco Merger

Fourteen more members of the House of Representatives recently expressed their strong concerns with the proposed Express Scripts Inc.-Medco Health Solutions merger in a bipartisan letter addressed to Chairman Jon Leibowitz of the Federal Trade Commission. The letter states that a combined entity of the two giant PBMs has the potential to control an overwhelming majority of the prescription marketplace. If unregulated, the merged PBM would have unchecked ability to raise prices and limit patient access to the pharmacy of their choice, they said.

We thank Rep. Cathy McMorris-Rodgers (R-Wash.) and her staff for taking the lead in coordinating the letter. The other representatives who signed on are Robert Aderholt (R-Ala.), Spencer Bachus (R-Ala.), Jo Bonner (R-Ala.), Mo Brooks (R-Ala.), Judy Chu (D-Calif.), Maurice Hinchey (D-N.Y.), Ruben Hinojosa (D-Tex.), Martha Roby (R-Ala.), Mike Rogers (R-Ala.), Terri Sewell (D-Ala.), Peter Welch (D-Vt.), Don Young (R-Alaska), and Tom Marino (R-Pa.)

Earlier, other members of Congress, including Young and Marino, also raised reservations. Democratic Reps. Henry Waxman (Calif.), Frank Pallone (N.J.), and Diana DeGette (Colo.) wrote a joint letter. Their concerns had been preceded by those of Reps. John Conyers (D-Mich.), Joe Courtney (D-Conn.), and Jan Schakowsky (D-III.).

Additionally, Sen. Tom Harkin (D-Iowa), chairman of the powerful Health, Education, Labor and Pensions Committee, has asked the FTC for a full investigation into the proposed $29 billion merger.

Medicare Sets Minimum Monetary Recoupment Amounts for Appeals

The Centers for Medicare & Medicaid Services recently updated the minimum amount of money in controversy required to be eligible for an Administrative Law Judge hearing and judicial review within the Medicare program. As of Jan. 1, if you want to appeal any Medicare recoupment, including Part B or Part D, you must be contesting an amount of at least $130 for an ALJ hearing and $1,350 for a court case. The amount in controversy amounts will be adjusted on an annual basis.

YE ON PBMS

Email your recent example of a problem you or a patient has had with a PBM to mike.conlan@ncpanet.org, or fax it to 703-683-3619. We may edit it for length and clarity.

WE JUST WANT TO BE SURE YOU BOUGHT THE DRUGS, THAT’S ALL

“CVS Caremark required seeing my invoices from my wholesaler. For them they said it was proof that I purchased the medications. I think it was their way to see the prices I was paying for the medications. They asked for [lot numbers], which took lots of time and effort to get. My wholesaler almost did not give me the data in time, almost making me lose on the whole audit.”
Ring in the New Year; Ring Your Register

With the coverage of NCPA’s 2011 Convention in this issue, we thought we would provide a recap of some of the adherence activities that took place in Nashville. Opryland was abuzz with adherence talk, and folks who came to Meet and Learn walked away with more than a few tips to help them Succeed back at home.

The One Size Does Not Fit All education workshop was an interactive session that provided successful advice from community pharmacists on how to reach out to patients to improve their adherence. Ideas ranged from low-tech, counter-counseling techniques to quickly assess a patient’s adherence level, to technology-based solutions such as text alerts and built-in refill ratios to flag patients who are late on refills. The take-home message was clear—whatever you do, just do something. It’s not only good for your patients—it can grow your business.

A synchronized/coordinated refill program has produced such significant workload efficiencies that she has been able... [to save] $30,000 a year.

Take it from Janet Kusler. Janet owns Kusler’s Pharmacy in Snohomish, Wash., and like many, comes to the convention each year looking for at least one idea she can take back to enhance her business. Janet shared her experience of finding a game-changing idea for her pharmacy at the annual meeting two years ago in New Orleans. That one idea of a synchronized/coordinated refill program has produced such significant workload efficiencies that she has been able to reduce pharmacist hours by 10 hours a week, saving her $30,000 a year. She was even able to take more than a week off at once from the pharmacy, 16 days to be exact, and she never got a panicked phone call from the store.

The business case for adherence was made during several sessions. Pharmacy peers who have implemented coordinated refill programs similar to Janet’s shared how their bottom line has improved. Pharmacies reported cutting payroll expenses by 50 percent, tripling inventory velocity from 12 to 36 turns a year, increasing prescription volume by 30 percent and seeing a $1.87/prescription increase in gross margin. The best part is everyone wins! Patients love the convenience and knowing that everything will be ready on time, staff satisfaction increases, and the business benefits are remarkable.

Want to learn more? Then be sure to check out NCPA’s Simplify My Meds program, a new program that provides NCPA members with free tools and support to set up a coordinated refill program in their pharmacy. More than 300 pharmacies are taking advantage of this member benefit nationwide. To find out more, visit www.ncpanet.org/adherence.

Make it a New Year’s Resolution to start with one small change to improve patient adherence, and watch your business grow. All the best for a healthy and prosperous 2012!

Do you have an adherence idea, tip, or program that is working in your pharmacy? Let us know by sending an e-mail to adherence@ncpanet.org.

Editor’s Note: It’s a New Year and this column also has a new home. Since these articles debuted 18 months ago, we’ve provided members with pharmacist-focused tools and programs to improve adherence while also improving their bottom line. Thanks to our reader’s interest, we are excited to debut Adherence—It Only Takes a Minute in its new location.
Pharmacy Technicians: An Extra Layer of Safety

Pharmacy technicians play a major role in modern pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist whenever they have questions, concerns, or feel processes do not work or are unmanageable.

DROP-OFF
If technicians are stationed at the prescription drop off, consider creating a checklist of critical information the technician should obtain from each patient. The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy and medical condition (such as pregnancy) information should be updated in the patient’s profile at each patient encounter and communicated to the verification pharmacist.

ORDER ENTRY
Medication safety is enhanced when technicians know medical terminology and drug names, especially if they enter prescriptions. New drugs are a risk because technicians, and pharmacists, may not be aware of them and may instead see and select something familiar. Pharmacists and technicians should work together to determine the best method of distributing information regarding new drugs on the market.

It is also important that the technician understands the safety features of the computer system and does not create workarounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override an alert and not “bother” the pharmacist. All alerts that involve medication interactions, allergies, duplications, and other clinical warnings should be relayed to the pharmacist. Pharmacists should communicate unnecessary or superfluous alerts with managers or commercial software designers and discuss the possibility of turning off those alerts.

PRODUCTION
Many mix-ups during this production phase occur due to incorrectly reading a label. The problem is aggravated by confirmation bias, whereby one selects out what is familiar or expected on the label, rather than what is actually there. For example, a technician may choose a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf. Consequently, the wrong product may be picked. Physically separating drugs with look-alike labels and packaging can help reduce these types of errors. The

Continued on page 71
Sweet music for a megaphone

NCPA's Annual Convention showcased independent community pharmacy at Nashville's Opryland

By Michael F. Conlan
Photography by Michael DeFilippo
They call Nashville Music City so maybe it’s no surprise that the 113th Annual NCPA Convention and Trade Exposition held at the Gaylord Opryland Resort hit all the right notes. There were more pharmacists in attendance Oct. 8–12 than any time in the past four years. The trade show attracted 231 companies eager for a slice of the $93 billion independent community pharmacy marketplace. There were almost 20 hours of continuing education spanning the spectrum of clinical and business skills from adherence to compounding to technology, and another 16 CE hours offered in pre-convention programming. And woven throughout, of course, was NCPA’s attention to advocacy and government affairs.

“NCPA’s tag line is that it is ‘the voice of community pharmacy,’” noted NCPA CEO B. Douglas Hoey, Pharmacist, MBA, during his address during the Second General Session. “That’s true, but it is more accurate to say we are the megaphone for community pharmacy. You are the voice. It’s your relationships with patients and policymakers that make possible NCPA’s effectiveness in representing you.”

Convention keynoter Mike Huckabee suggested that community pharmacy’s voice would be louder if more pharmacists ran for office. “The challenge is not doing your job well or dealing with your larger competitors across town or across the street,” said the former Arkansas governor, now a TV talk show host. “The challenge is, ‘Can you survive your own government in programs like Medicaid?’”

Improving government programs such as Medicaid and implementing the many facets of the health care reform law (the Affordable Care Act) is in jeopardy because of the “partisan toxicity,” in Washington, said former Republican governor of Vermont James Douglas during the annual Government Affairs Forum. “Until the polarization in the capital ends,” he continued, “I
Agreeing with Douglas was Philip Bredesen, former Democratic governor of Tennessee, who shared the stage along with moderator John Coster, RPh, PhD, senior vice president of government affairs. “The center has become a dangerous spot to be,” observed Bredesen. “You’re subject to attack by both the right and left of your own party. That has driven the conversation to the edges.”

In his farewell address as president, Robert J. Greenwood, RPh, stressed the importance to the profession of NCPA’s adherence initiative, which was the subject of four educational sessions.

“The improper use of prescription medications is a $290 billion—that’s with a “B”—a year problem for the health care system,” Greenwood said. “And we are part of the solution. NCPA is committed to making adherence a core competency of the pharmacy profession by 2015.”

In a video message to convention attendees, Donald Berwick, MD, acting administrator of the Centers for Medicare & Medicaid Services, also said the pharmacists and well trained and well positioned to help patients take their medication as prescribed. He mentioned medication therapy management in particular, and concluded by saying there’s never been a more important time for pharmacy.

Six major awards were presented at the two general sessions honoring the recipients for their contributions to independent community pharmacy:

- Carmen A. DiCello, RPh, Altoona, Pa., the John W. Dargavel Medal
- Eddie Glover, RPh, Conway, Ark., Willard B. Simmons Independent Pharmacist of the Year
- Compliant Pharmacy Alliance Cooperative, Stoughton, Wis., Corporate Recognition Award
- Cheri Garvin, RPh, Leesburg, Va., Prescription Drug Safety Award
- David Schoech, RPh, Columbus, Kan., National Preceptor of the Year
- Kirk Hayes, Pharmacists Mutual Insurance, Algona, Iowa, Calvin J. Anthony Lifetime Achievement Award

(Pictures of the award winners are on page 25.)

Other awards went to a team of future pharmacists from Idaho State University who won the eighth annual Good Neighbor Pharmacy NCPA Pruitt-Schutte Student Business Plan Competition. They defeated teams from the University at Buffalo and the University of Oklahoma.

(For more on the competition, pictures, and other student activities, see page 27.)

On the last day of the convention, the NCPA House of Delegates met to approve policy positions proposed by members, ratify changes to the association’s governing structure, and install new leaders.

Among the new leaders are Lonny Wilson, DPh, of Oklahoma City, Okla., president for 2011–12; Donnie Calhoun, RPh, of Anniston, Ala., president elect; and Mark Riley, Little Rock, Ark., chairman of the Board of Directors, previously known as the Executive Committee. (For more on the House of Delegates, see page 26. For biographies of the NCPA leadership team, see page 23.)

Wilson, CEO of Pharmacy Providers of Oklahoma (PPOk) and owner of three pharmacies, challenged his colleagues to demonstrate their value to the health care system. “We must continue to find ways to show and quantify to payers that mail order is not a cost containment strategy,” he said. “It is not the front line calculation that saves money—it is the bottom line. Drug therapies can be complex and are best provided by face-to-face interaction of the patient and pharmacist in collaboration with the physician to optimize therapies, improve compliances, and enhance outcomes, thus reducing real costs. Payers miss the mark by using mail order and not taking advantage of pharmacist services—the real bottom line cost saving strategy.” (For more on Wilson, see page 20.)

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Flash mobs? Dancing in the rain? Chain of chains? Dylan? Twain? Not your typical acceptance speech for an NCPA president by any stretch, but it was a comfortable fit for Lonny Wilson, DPh. The association's newest leader, a veteran Oklahoma pharmacy owner and executive, Wilson took the reins for 2011–12 from Robert J. Greenwood, RPh, at the House of Delegates meeting Oct. 12.

Wilson is one of the original founders of Pharmacist Providers of Oklahoma (PPOk), a buying group, switching service, and administrator of managed care drug plans. He has been its CEO since 1989 and owns three pharmacies in the Oklahoma City area. He also is chairman of the board of directors of the medication therapy management company Mirixa, established by NCPA.

“It is time for the independent group purchasing organizations and pharmacy service administrative organization to work together...”

“For us, as independent community pharmacists, that weather, that storm, that rain, is the ever changing marketplace. We can talk about it. We can try to change it, as we are and should. [But as author/artist] Vivian Greene stated, ‘Life isn’t about waiting for the storm to pass. It’s about learning to dance in the rain.’”

“You can make a difference in our profession,” he continued, “by being engaged, making decisions and making the decision the right one, being resilient and persistent and staying positive—learning to dance in the rain.”

Michael F. Conlan is editor of America’s Pharmacist.
“The impact of medication therapy management services, delivered by the pharmacist, is being recognized in all corners of the health care marketplace as the focus on patient outcomes, quality and cost savings sharpens. Pharmacists can and will play an important role in the new care delivery models—patient centered medical homes, accountable care organizations and transition of care initiatives. “By its very definition care coordination needs to include the pharmacist, and Mirixa is helping us get there by showcasing the value of pharmacist-delivered patient care to audiences in the early stages of forming local and regional collaborative care models. “The very heart of MTM, of course, is patient adherence. As former Surgeon General C. Everett Koop famously said, ‘Prescription drugs don’t work in patients who don’t take them.’ “The improper use of prescription medications is a $290 billion—that’s with a "B"—a year problem for the health care system. And we are part of the solution. NCPA is committed to making adherence a core competency of the pharmacy profession by 2015. “Adherence represents a true opportunity for community pharmacy to demonstrate its value in improving patient health and reducing health care costs. As part of NCPA’s adherence initiative, we are pleased to announce the creation of two new awards that will be used to recognize outstanding practices in adherence. “The very heart of MTM, of course, is patient adherence. As former Surgeon General C. Everett Koop famously said, ‘Prescription drugs don’t work in patients who don’t take them.’”

“The first is the Adherence Educator of the Year award. It will showcase outstanding teachings in adherence and recognize a pharmacy educator or community pharmacist preceptor who has made a significant contribution to the education of pharmacy students in the area of medication adherence. “The second award will recognize outstanding adherence practices in community pharmacy. It will recognize an independent community pharmacist who has demonstrated a commitment to and implemented innovative pharmacy services that have resulted in measurable improvements in patient adherence. Recipients of both awards will be named at next year’s NCPA annual convention in San Diego, and nomination forms will be available in the spring. “I encourage you to look for ways in which you can bring an increased emphasis on adherence to your pharmacy practice. It’s a true win-win scenario. As pharmacists, we are in the perfect position to help make sure our patients are getting the maximum benefit from their medications.”

Above are excerpts from remarks by NCPA President 2010–11 Robert J. Greenwood.
It’s been a busy year for NCPA’s new Advocacy Center communicating the value and concerns of community pharmacists. Since we last met, NCPA has been quoted or referenced more than 235 times in newspapers and TV and countless times—occasionally accurately—on blogs and other Internet sites.

“We have sent out more than 100 news releases and posted 500 messages via the NCPA Facebook page and Twitter. NCPA’s tag line is that it is the voice of community pharmacy. That’s true, but it is more accurate to say we are the megaphone for community pharmacy.

“You are the voice. It’s your relationships with patients and policymakers that make possible NCPA’s effectiveness in representing you.

“How and what we communicate has never been more important than it is today. I submit to you that as pharmacists we are translators of proper medication use for our patients.

“And, as your advocacy organization, NCPA is your translator to policymakers.

“We communicate to them on the value and concerns of pharmacy small business owners.

“Yes, we are in challenging times, but independent community pharmacy continues to innovate and be resilient. Does that mean we are guaranteed success? Absolutely not. But does it mean that we will stand up and make sure those with the biggest influence on our business understand clearly the value we provide to the people? You bet.

“How we communicate is vital. Communicate thoughtfully. Communicating the value of what community pharmacists provide to patients and the health care system has never been more important.

“Our patients know what we do for them. They tell people like Consumer Reports, JD Power, and the Gallup Poll. We have a great story to tell. The NCPA Legislative and Legal Defense Fund and the PAC are important tools to help get our message out to legislators and in the court system.

“The LDF is key to helping us try to defeat the ESI-Medco proposed merger and with other legal cases that are either in process or are being considered.

“I believe that litigation should always be a last resort. Unfortunately, the abusive business practices of PBMs have increased. Their contracts have grown more one-sided. We’re not looking for any special favors but we are looking to be treated fairly.

“We are aware of a number of legal cases against PBMs that have originated in states. In most of those cases, NCPA has worked with those local legal teams to provide information to help them with their case. However, we believe there is a need for one central place to enable communication between plaintiffs.

“To enhance the coordination of pharmacy legal action, NCPA is forming a Pharmacy Legal Resource Center. This new asset will be a central database of sorts for legal representatives of community pharmacy groups to go where they can find legal arguments that have been tried before, some successful and some not.

“The key motivation for the NCPA Legal Resource Center is to increase effectiveness and precision. Community pharmacy has a great story to share. It’s about being a health care professional. It’s about making the community a better place to live. It’s about being a small business owner. It’s about being an entrepreneur.

“Being a successful pharmacy small business owner is not easy. As all of you know, it’s a lot of hard work. But I believe it’s important that we occasionally look up from our work and tell the story. I can assure you that if our
NCPA’s leaders are committed to the 114-year-old association’s enduring mission: to continue the growth and prosperity of independent community pharmacy by representing its professional and proprietary interests before Congress, the courts, and regulatory agencies in Washington, D.C., and in state capitals across the country. The NCPA board of directors and its officers, ratified by the House of Delegates Oct. 12, 2011 (pictured above), exemplify the spirit, determination, creativity, and dedication of independent community pharmacy today, and they passionately share a vision for its future.

As small business owners, they know that independent community pharmacy must constantly innovate and take full advantage of technology to deliver the highest quality care and service to patients. They know that independent community pharmacists must use their business, management, and clinical skills to inspire a partnerships that are a means to an end for community pharmacy owners.

“These are all questions NCPA is pursuing. As a staff, NCPA is at your service. Advocating for your business and creating an environment conducive to success is what NCPA is about.

“We are a staff of 60 people working hard to carry the voice of community pharmacy—your voice. NCPA is here with you as the megaphone for your voice.”

The above are excerpts from remarks by NCPA Chief Executive Officer B. Douglas Hoey, Pharmacist, MBA.
“The NCPA board and officers are comprised of 14 pharmacy owners—people who reflect the NCPA membership...”

**Board of Directors**

**Lonny Wilson**, NCPA president, Oklahoma City, Okla. (See story on Wilson on page 20.)

**Donnie Calhoun**, president elect, owns Golden Springs Pharmacy and Calhoun Compounding in Anniston, Ala. Calhoun is a member of the Alabama Board of Pharmacy and also serves on the Pharmacist Mutual Insurance Companies board of directors. He graduated from Samford University’s McWhorter School of Pharmacy.

**Mark Riley**, chairman, is the executive vice president of the Arkansas Pharmacists Association and an authority on pharmacy benefit managers. Riley owns East End Pharmacy in Little Rock, where he was pharmacist-in-charge for 20 years. He earned his bachelor of science in pharmacy and his doctor of pharmacy from the University of Arkansas for Medical Sciences College of Pharmacy.

**John T. Sherrer** co-owns Kenmar Pharmacy in Marietta, Ga., and is a partner in nine other Georgia pharmacies. Sherrer also owns First Aid of America, an industrial first aid and safety supply company. He graduated from the Mercer University Southern School of Pharmacy.

**Bradley J. Arthur** co-owns two full-line independent pharmacies in Buffalo, N.Y. He graduated from the University of Florida College of Pharmacy.

**Keith Hodges** owns Gloucester Pharmacy in Virginia’s historic Tidewater region and is vice president of Poquoson Pharmacy. Last November, he won election to the Virginia House of Delegates. He graduated from the Medical College of Virginia School of Pharmacy.

**DeAnn Mullins**, a certified diabetes educator, owns Mullins Pharmacy, WeCare Wellness, and the WeCare Diabetes Education Program in Lynn Haven, Fla. She is a member of the Florida Board of Pharmacy and graduated from Samford University’s McWhorter School of Pharmacy.

**Mark Riley** owns Gloucester Pharmacy in Virginia’s historic Tidewater region and is vice president of Poquoson Pharmacy. Last November, he won election to the Virginia House of Delegates. He graduated from the Medical College of Virginia School of Pharmacy.


**Officers**

**Bill Osborn**, first vice president, is president of Osborn Drugs, Inc., in Miami, Okla. He graduated from the University of Oklahoma College of Pharmacy and received his PharmD from Oklahoma University.

**Brian Caswell**, second vice president, owns Wolkar Drug in Baxter Springs, in the corner of Kansas that adjoins Oklahoma and Missouri. He graduated from the University of Kansas.

**Michele Belcher**, third vice president, owns Grants Pass Pharmacy, Inc., in Grants Pass, Ore., which offers compounding, hospice care, and compliance packaging for long-term care. She graduated from the Oregon State University College of Pharmacy.

**Hugh Chancy**, fourth vice president, co-owns Chancy Drugs of Adel, Chancy Drugs of Hahira, and Chancy Drugs of Lake Park, all in Georgia. He also co-owns C2 Medical Solutions, a sterile compounding pharmacy in Hahira. He graduated from the University of Georgia College of Pharmacy.

**Jeff Carson**, fifth vice president, owns Oakdell Pharmacy, which has four locations in the San Antonio area. He graduated from the University of Texas.
Six major awards for outstanding contributions to independent pharmacy were presented at the 113th Annual NCPA Convention and Trade Exposition in Nashville, Tenn.

**A** Corporate Recognition Award—Heckman
Bob Greenwood, (left), 2010-11 NCPA president, presents the Corporate Recognition Award to Ed Heckman, CEO of Compliant Pharmacy Alliance Cooperative.

**B** John W. Dargavel Medal—DiCello
NCPA Foundation President Sharlea Leatherwood and Rex Catton (right) of McKesson U.S. Pharmaceutical present the John W. Dargavel Medal to Carmen A. DiCello.

**C** National Preceptor of the Year Award—Schoech
NCPA Foundation President Sharlea Leatherwood presents the National Preceptor of the Year Award to David Schoech.

**D** Prescription Drug Safety Award—Garvin
Cheri Garvin receives the Prescription Drug Safety Award from Bob Greenwood, (left), 2010-11 NCPA president, and Steve Seid of Purdue Pharma.

**E** Willard B. Simmons Independent Pharmacist of the Year—Glover
Bob Greenwood, (right), 2010-11 NCPA president, and JoAnn Gaio, Upsher Smith Laboratories, present the Willard B. Simmons Independent Pharmacist of the Year Award to Eddie Glover.
Without controversy, the NCPA House of Delegates ratified the first changes to the association’s constitution and bylaws in eight years. Unveiled a year ago, the changes include allowing non-pharmacist owners to become active members, renaming the Executive Committee the Board of Directors, changing the title of the association’s day-to-day leader from Executive Vice President to Chief Executive Officer, and authorizing the Board of Directors to choose a Secretary Treasurer from its ranks.

In addition, the more than 100 delegates elected and installed new officers [see p. 23] and adopted four policy resolutions:

- **PBM Merger**—NCPA continues to oppose the proposed merger of Express Scripts, Inc. and Medco Health Solutions and calls upon the Federal Trade Commission to block it.
- **CVS Caremark Investigation**—NCPA calls upon the Federal Trade Commission to take the steps necessary to protect consumers and pharmacies from the anticompetitive and unfair, misleading and deceptive actions of CVS Caremark.
- **Pharmacy Crime**—NCPA supports federal incentives for pharmacies to purchase security technologies to deter pharmacy crime and working with federal and state law enforcement agencies on sensible solutions that will deter such crimes from happening in the first place.
- **Adherence as a Core Competency**—NCPA supports the provision of adherence services as a core competency for the profession, equally important as dispensing and counseling; working closely with schools of pharmacy to encourage the development of curricula which ensures that pharmacist graduates will be trained to embrace and carry out adherence as a consistent practice; advocating to payers, policy makers, and legislators the critical role of the community pharmacist in improving patient outcomes while reducing overall health care costs; and advocating that pharmacists are appropriately compensated for their valuable services.
A team of pharmacy students from Idaho State University College of Pharmacy was named the winner of the 2011 Good Neighbor Pharmacy National Community Pharmacists Association Pruitt-Schutte Student Business Plan Competition. A team from the University of Oklahoma College of Pharmacy came in second, and a team representing the University at Buffalo School of Pharmacy and Pharmaceutical Sciences finished third.

The three finalist teams and advisors made live presentations of their business plans before the competition judges and an audience during the annual convention after receiving complimentary registration, travel, and lodging. NCPA 2010-11 President Robert J. Greenwood announced the results of the competition during the Opening General Session of the NCPA 113th Annual Convention and Trade Exposition held Oct. 8-12 at the Gaylord Opryland Resort & Convention Center in Nashville.

The competition is supported by Good Neighbor Pharmacy, Pharmacists Mutual Companies, and the NCPA Foundation.

Team members from Idaho State University were captain Alan Pannier, and members Nick Beebe, Weston Faux and Tyler Hemsley. Kerry L. Casperson, RPh, PhD, was the team advisor. Their chapter received $3,000 and $3,000 was contributed to the school in the dean’s name to promote independent pharmacy.

The judges for this year’s live competition were Holly Henry, RPh, NCPA past president; Sharlea M. Leatherwood, PD, NCPA Foundation president; Mike Quick, national vice president, Good Neighbor Pharmacy Development; Chad Reed, Live Oak Bank; Ed Berg, MBA, CPA, CPCU, president and CEO, Pharmacists Mutual Insurance Companies; and Dan Strause, co-founder of Community Pharmacy Financial LLC.

A Chapter of the Year
The Ohio Northern University Raabe College of Pharmacy was named the 2011 NCPA Student Chapter of the Year.

B Faculty Liaison
Ed Sherman receives the 2011 NCPA Faculty Liaison of the Year Award from NCPA Foundation President Sharlea Leatherwood.

C Catalyst Grant
Steve Hiemenz (right) receives the 2011 Catalyst Grant Award for Innovative Practice from Steve Seid of Purdue Pharma.
NCPA would like to thank the following companies and organizations for their generous support of the 113th Annual NCPA Convention and Trade Exposition and their continuing support of independent community pharmacy.
Making a Connection
By most any measure

Pharmacy Creations is a thriving and well-regarded compounding pharmacy practice. The Randolph, N.J. –based business is co-owned by Scott Karolchyk, RPh, and Bernard Covalesky, RPh.

Karolchyk says the pharmacy’s specialties include a variety of quality-controlled compounded sterile injectable medications, and combined medication formulations for ophthalmic, dermatological, and urological use. It also offers patient and prescriber consultations in pain management, nutritional wellness, and women’s health.
Pharmacy Creations opened more than 12 years ago when Karolchyk and Covalesky decided they wanted to focus on compounding only.

“We both worked for other compounding pharmacies before we met,” Karolchyk says. “And we realized that you need to have a have a partner to do it right. We could do twice as much and we didn’t have to put in 100-plus hours each. That’s worked pretty well for us.”

Karolchyk says the pharmacy dispenses about 100 prescriptions daily, of which 65–70 percent are sterile. A good chunk of Pharmacy Creation’s business is with local hospitals.

“Out of the sterile segment, we’re doing probably about 20 percent [for hospitals] right now,” he says. “We do about 15–20 different [orders] a day for the hospitals. We do things like vitamin C and calcium injections, and we’re starting to get more involved in chemotherapy medications. We can basically do the whole spectrum of sterile.”
Need for Outreach

There’s a reason why Pharmacy Creations provides compounded medications for hospitals. In the last few years, commercial drug shortages have reached crisis levels. The United States saw a record high in 2010 with 178 shortages, and 2011 was worse. By fall it topped 230. Final numbers are not yet available, but shortages were on pace to reach more than 270 drugs by the end of 2011.

“Before last year, there were maybe 30–40 drugs which would go on back-order or be in short supply for a few weeks,” Karolchyk says. “They would come on the market, then go off. But it was never anything at this level. Now we have drugs that aren’t available for months at a time or may never come back on the market. It’s pretty serious. Most of these drugs are IVs, or injectables, and they affect the full scale—it’s not like a pain drug that nobody needs, or there is a substitute—these are commercial medications that are used throughout the entire health care system.”

Given those sobering realities, one would expect that compounding pharmacies would be getting recognition for the help they are providing in filling the gaps. Not exactly, says Karolchyk.

“In the all of the media coverage, there is one important aspect that is missing: they never talk about compounding pharmacy,” he says.

Karolchyk, who became president of the International Academy of Compounding Pharmacists (IACP) on Jan. 1, says a primary goal of him and for the association is to heighten awareness of the critical role compounders play.

“We’re trying to do outreach not only to the public, to hospitals, and physicians, but also to hospital pharmacists to let them know that there are alternatives, that they can outsource to qualified pharmacies. There’s a lot of theories about the shortages, but our job is to let people know that we can collaborate with our colleagues at hospitals and other institutions. [Compounding pharmacies] can provide the hospital and physicians with documentation they request—country of origin of the chemicals, quality of the chemicals, testing that was done, procedures that were followed. So there are a lot of things that community pharmacists can do to help.”

Recently IACP introduced a new assessment questionnaire to assist hospitals, practitioners, and non-compounding pharmacies identify and evaluate compounding pharmacies as they seek alternative sources for medications that currently are in limited to complete shortage status. The Compounding Pharmacy Assessment Questionnaire (CPAQ™) provides a comprehensive checklist of what to look for in a compounding pharmacy practice and is based upon United States Pharmacopeia (USP) standards, which compounding pharmacists are obligated to follow according to state board of pharmacy regulations or standards of practice. (For more on CPAQ, see sidebar on opposite page)

“The problem has been that there is not an effective way to let hospital pharmacists and doctors know that compounding can assist their patients and clinics,” Karolchyk says. “Now we’ll have at least two different tools; one for patients and one for hospitals. If a hospital pharmacist has 10 pharmacies in his immediate area, he can narrow it down to three, and using this tool find the best pharmacy for his needs.”

A Disconnect

Karolchyk can cite his own experiences as a reason to develop an assessment tool such as CPAQ. Even though
MATERIAL SUPPLIERS RESPOND TO SHORTAGES

As compounding pharmacists attempt to help pick up the slack due to a deep and prolonged drug shortage, raw material suppliers have increasingly found themselves scrambling as well. Companies which source active pharmaceutical ingredients (API) for compouders have increasingly had to seek new avenues for raw materials. It’s not uncommon for companies to go overseas to countries such as China, and any imported materials must pass inspection by the Food and Drug Administration. Reputable API suppliers will also subject all materials to meticulous testing and quality control protocols before they make product available to their clients. The following is a sampling of what a number of companies are saying about the shortages.

B&B Pharmaceuticals, Inc. (www.bandbpharmaceuticals.com), a family-owned business that started in 1997, specializes in bulk raw materials used in pharmaceutical compounding. In particular it focuses on controlled substances, hormones (HRT) and other APIs.

Matt Johnson, B&B’s senior production manager, says that there are drug shortages every year, but it’s been “running wild” lately. He also said there have been shortages of drugs such as levorphanol tartrate, an opioid medication similar to morphine which is used to treat severe pain, and succinylcholine, used medically for short-term muscle relaxation in anesthesia and intensive care.

Johnson says that Food and Drug Administration guidelines can have an effect on the supply chain if production is halted. He stresses that he’s not saying this critically as he understands the role of the agency. And he points out, “It’s not all FDA-related; increasingly manufacturers discontinue products, so we have to go abroad.”

But even that can be complicated. Sodium thiopental (known commonly as sodium pentothal), used for anesthesia, has been in short supply. Johnson said an Italian company makes the API, but because it is also used for lethal injections, would not sell it to U.S. companies because of differences between American and Italian policies on the death penalty. China is a major source of APIs, but Johnson points out that “a lot of American pharmacists and consumers don’t trust Chinese products. There are good manufacturers there, but you just have to work hard to seek out the good ones.”

B&B has strict quality controls and adheres to current good manufacturing guidelines, Johnson says. “All products are repackaged in our Class 1000 clean room and are sent to an outside laboratory for analytical, purity, and stability testing,” he says, adding that all state and federal regulations have been met or exceeded for each of its products, and certificates of analysis and material safety data sheets (MSDS) are available on every product.

Fagron (www.fagron.us) officially changed its name from Gallipot in November. Fagron purchased Gallipot, a 33-year-old company, in May 2010. The company provides specialized bulk chemicals, equipment, and supplies.

Company President Gary Schneider, RPh, recognizes the challenges that limited dosages and quantities are presenting to compouders. “We’re just trying to help fill in the gaps,” he says.

Like other companies, Fagron, which is based in Europe, is looking outside of the United States to procure materials. “We’re trying to get the [API] and to take care of as many of our clients as we can,” he says.

Schneider says that Fagron takes a case-by-case look in terms of shortages. “We try to prioritize,” he says. “If a drug is in short supply and high demand, it might get moved to the front of the line in terms of testing and preparation.”

Fagron also tries to sell to as many customers as possible, Schneider says. In other words, they won’t allow a small number of compouders to buy up stocks and hoard supplies. “Our industry has to do the right thing,” he says. “We want as many pharmacies as possible to have access to these important medications.”

As a former pharmacy owner, Schneider is impressed with the steady advances in compounding. “It’s an ancient art that was forgotten for many years,” he says. “It’s grown tremendously in the last 8–10 years. You can see that compouders are really taking pride in it.”

Freedom Pharmaceuticals (www.freedomxinc.com), describes itself as “a boutique supplier of fine compounding chemicals, excipients, bases and capsules.”

Regarding the current drug shortages, Jacob Jackson, president and CEO, says that the current drug shortages have created a unique and dire problem for hospitals and similarly situated health care entities.

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But Jackson also points out potential benefits. “This perfect storm has created unique opportunities for compounding pharmacies to fill the void through their ability to provide personalized medication solutions by mixing readily available fine chemicals and active pharmaceutical ingredients.”

For example, Jackson says intravenous 5-fluorouracil (5-FU), a key component of certain cancer treatment regimens, is at press time on national back order. Compounding pharmacies that are USP 797 compliant can provide this life-saving customized medication, through the sterile compounding of this medicine, until the commercially available product is back on the market.
“This is only one of the many examples of how pharmaceutical compounding can ease the crisis caused by drug shortages,” he says.

Letco Medical (www.letcomedical.com) is a supplier of pharmaceutical ingredients, pharmacy equipment and specialty pharmaceuticals to customers throughout the United States.

Letco is doing its best to meet customer demand, but the shortages “have had an impact,” says Erik Tosh, director of Pharmacy Business Development. “As chemical suppliers, I think we’re all basically running into the same challenges.”

Tosh notes that raw chemicals aren’t sterile, and that’s what hospitals need. When Letco obtains materials, it follows a strict testing protocol, but he says “there’s still a lot of work for compounding pharmacists to do when they receive it.”

Tosh also referenced the shortages of chemotherapy drugs, and says the complexities and risks associated with those medications present their own set of challenges. “For the amount of effort required for workplace safety [when handling chemotherapy drugs], we’re not likely to bring in those agents at all,” he says. “Safety comes first, and right now there’s not a safe way to do it cost effectively.”

As someone who was a working compounding pharmacist for more than a decade, Tosh recognizes the positives that it brings, and wants to see that segment of the profession stay up to speed.

“There’s such a burden on compounding pharmacists to meet all the requirements,” he says. “They need to know and understand so much. We need to make sure that we are teaching sterile compounding and understand that it is more than putting an IV bag together.”

Through it all, Tosh says Letco’s objective is to do whatever it can to assist compounders. “Our goal is to meet the challenges and demands of the compounding and specialty pharmacy markets, while maintaining the focus on our customers.”

Medisca (www.medisca.com) is a supplier of chemicals, including active pharmaceutical ingredients, excipients in the form of bases, oils, colors, and flavors, and reusable and disposable devices for compounding pharmacists.

Darian Zaccardo, Medisca’s vice president of development and sales, says that the company “is committed to bringing our clients the highest quality fine chemicals, compounding supplies, compounding solutions, and training that we can offer. Obviously the drug shortages have presented challenges to compounding pharmacists, so we are doing all we can to provide them with the materials they need to ensure they can provide their patients with vital medications.”

Zaccardo emphasizes the work of the company’s quality assurance department and its implementation of, and adherence to, current good manufacturing practices (cGMP). He says Medisca regularly performs in-house and independent laboratory quality assurance-related analytical testing in accordance with USP/NF, BP and EP regulatory guidelines.

“Our active pharmaceutical ingredients (API) are only purchased from FDA-registered manufacturers with an NDC number,” he says. “The chemical manufacturer also needs to provide Medisca with chemicals that meet the current monograph specifications [i.e., USP or EP]. If there is no monograph standard available, the chemical manufacturer must provide their in-house test methods.”

Ultimately, Zaccardo says, Medisca “recognizes the responsibilities of the compounding pharmacist to the medical and patient community. We are committed to ensuring we do our part in maintaining the security and integrity of our customers” through its products and services.

The Professional Compounding Centers of America (www.pccarx.com), founded in 1981, provides chemicals, equipment, devices, flavors, training and education, pharmacy software, marketing, and business and pharmacy consulting assistance.

Jim Smith, PCCA president, says the organization is trying to stay on top of any new developments. “We’ve been hearing a lot from our members,” he says. “We’re keeping track of what the FDA is saying and trying to inform our members.”

Gus Bassani, PCCA vice president of consulting, R&D and formulations, says some of the shortages appear to be regional and “spotty.” He says PCCA’s consulting department has been receiving about 500 calls per day with formula-related questions. Bassani says a typical call might be, “I just found out that [drug] is off the market, do you have any suggestions?”

As another example, he references Armour Thyroid, a drug used for thyroid conditions that was off the market for a period of time. Bassani says PCCA typically receives calls asking, “Can you walk me through ways to make thyroid injections?”

Along with its quality control and testing regimen, Smith says PCCA has access, through an extensive network of contacts, to 750 active ingredients and has 9,000 different formulations in its database.

“There seems to be a common opinion that chemicals are all the same, and they aren’t,” Bassani says. “It’s an exhaustive quality process. Once a formulation is in the database, we can talk to members about various options.”

Even though the shortages have created challenges, Smith says it provides the profession with a chance to shine.

“It creates a huge opportunity for pharmacy to be a problem solver and make a difference,” he says.
Pharmacy Creations has a solid relationship with local hospitals, he has seen firsthand a kind of disconnect between hospital pharmacists and their counterparts in the outside compounding community.

“With all of the hospitals that I deal with, my pharmacy has been vetted, our references have been checked, we’ve had site visits, and we show our testing methods for potency and sterility,” he says. “They don’t ask for all of this when they buy a commercial product. But for some reason, they ask for it when it’s a compounded product.”

But Karolchyk points out, “There are a lot of qualified pharmacies out there. There are a lot of pharmacies like ours, that have high-tech labs, that have clean rooms, that follow the standards, that do everything right—they test, test, and test. And they have something called CQI—continual total quality improvement programs.”

When asked if he thinks there is a lack of insight by hospital pharmacists about services compounders provide, Karolchyk replies, “Yes I do. I don’t mean this in a bad way, but it is ignorance. We can address this with education and increasing awareness.”

He mentions the changes that he says have continuously raised the bar in compounding in the last decade, including enhanced quality assurance, USP 797 standards, and the Pharmacy Compounding Accreditation Board’s comprehensive accreditation program. (See the December 2011 America’s Pharmacist [www.americaspharmacist.net] for more information on PCAB’s accreditation program.)

Karolchyk also senses a hesitancy to get outside of a comfort zone. For example, he says some hospital pharmacists whom he’s known for years will tell him that a product (in this case calcium) is unavailable, and they have no way of getting it.

“Then I remind them that we are currently doing something [else] for them right now, and that we can help them with the calcium. I think they [hospitals] are afraid of liability. These hospital pharmacists have to protect their institution and their patients. It’s easier for them to say to their doctors that calcium injections are unavailable, that there’s nothing available, that we have to find a substitute. Even if that isn’t best answer for patient care, it’s the best answer for the institution for liability and whatever else they are worried about.

Even though qualified pharmacists like myself and many others can help make the calcium, and it would be the most appropriate drug for their patients, and their clinics, there’s that risk of ‘what if?’”

Karolchyk also says he hears stories about pharmacists working with seriously ill patients, and suggesting alternative treatment options, only to be told “no” by a physician.

It doesn’t seem to matter even if the patient wants to try something different. “Everything conventional has failed, but that doctor still says no. And the doctors who say ‘no’ are oncologists.

“One of my friends is an oncologist in Morristown [N.J.]. We were talking about patients in dire situations, and I asked him once, ‘Why won’t you do it? If the patient is willing to sign liability releases, not holding the hospital or you at fault, and they want to do it. Why won’t you help these patients?’”

And once again, Karolchyk says the answer is liability with insurance and standards of practice. In his opinion, thinking out of the box is not encouraged.

“That’s a problem with the hospital structure sometimes, and awareness and accreditation will address these issues.”
Knowing Limits
Still, proceeding with caution is prudent. Karolchyk says compounding pharmacists can enhance their stature by promoting safe practice standards and not promising what they can’t deliver. He referenced a meeting with a hospital director who asked if he could compound a certain medication.

“I looked at it, and within 10 seconds I said no,” Karolchyk. “You have to know your limits of what you can do and what you can’t do. One of the ethical standards of IACP is that you will not compound out of your own scope of expertise, or you will refer that to someone else who can do it. The key is to do no harm to the patient. There are certain things that compounders can’t do.”

Propofol (for anesthesia) and Doxil® (chemotherapy) are examples of drugs that can’t be compounded without high-tech, specialized equipment, Karolchyk says. “The reason is because the technology is outside the scope of most compounding pharmacies. These are particle-sized, based injections. I can make the injection, but you know that certain drugs aren’t bio-equivalent, meaning that if I make it, and then my colleague Joe makes it, we’ll both have a drug that might be 100 percent potent, but it won’t work the same way in the body. And these drugs have to work identically to the commercial product. Physicians must know what to expect, the length of duration, and how long a patient will have the desired dosage.”

Karolchyk says having strong ethical standards not only elevates the profession’s image, but can pay off in the long run.

“When I speak on compounding to pharmacy students and pharmacists, I stress that the patient comes first and the money follows,” he says. “If you are good at what you do, if you help your patients, and you put them first—it’s always the patient, physician, and pharmacist. You put yourself last. Yes the money is nice, but the money is last. If you help your patients, then it’s just word of mouth, and then you get referrals. If you help one hospital, then it starts to spread.”

Karolchyk stresses the need “to let these hospitals know. They can make their own minds up. It doesn’t matter who they use. But they need to know that this option of therapy is available. Every pharmacist has compounded at one time. We were all taught it to varying degrees when we are in school. Personally, I wouldn’t feel right if I didn’t let my patients know that there are options. Even if it wasn’t beneficial to me, why wouldn’t I let my patient know that there was another option out there? If my pharmacy can’t do it, there might be 20 others that can.”

And teaming up to enhance patient care is never a bad thing in Karolchyk’s mind.

“Sometimes when we compound it might not work as expected, but it won’t hurt the patient,” he says. “Maybe it’s the wrong medication, or maybe the patient just didn’t respond to it. It happens routinely with regular medications as well. That’s what we’re trying to prove to the hospitals and doctors. The medication is here, and we can make it exactly the way it was from the manufacturer. We have access to the same technology. Collaboration is the big thing. Our mentality [in compounding] is to raise the bar and set a higher standard. Let’s be better at what we do, and let’s prove that we can do these things correctly. It increases awareness, and more patients are helped. So that’s what we believe.”

Chris Linville is managing editor of America’s Pharmacist.
How to find the most valuable apps for your portable information devices

By Bill G. Felkey
I have just returned from a national pharmacy meeting where I showed my audience an Android tablet I had brought with me. I then asked the question, “Is this a tool or a toy?” I was surprised by the number of votes indicating this 10-inch information appliance was considered to be a toy. When iPad owners were also asked if they thought their device was a toy, many voted in the affirmative about their own devices.

What this tells me is that pharmacists have not acquired an adequate suite of professional applications that make them perceive the device as being firmly in the tool category. Granted, technology can easily be rated as both a tool and a toy if we use them for both work and play, but we quickly tend to discard devices whose utility is lacking when we want to do serious work. Deciding that we value something enough to always have it with us, or that we feel not fully dressed if we have left our technology behind, is an important consideration for pharmacists.

All Day, Every Day Use
Personally, I use my information appliance array almost all day, every day. Communicating professionally with all of the important people in my life throughout the world can be done easily, and they usually can be
reached in a matter of seconds. When pondering a decision, location is typically not an issue as I can access content regardless of where I might be at a particular moment. Technology can be used to purchase goods and services whenever the desire strikes me. I also do social networking activities with my family, friends, and colleagues. Some of my favorite hobbies are bicycling, tennis, wine tasting, and online video games. I can network with friends who share some of these interests.

The best appliances in my array help accomplish whatever task I have chosen. For multitasking, a 37-inch display for my desktop computer in my office works well. On the monitor, several windows can be opened simultaneously when I am writing. It helps me combine thoughts that are generated from several sources. A desktop replacer laptop has a large screen for doing website work with a group when I’m away from home. My 13-inch travel laptop computer is ideal for giving presentations. It is light yet powerful, so it works well on the road. My Android smart phone and tablet were both made by Motorola, and by using Gmail, I am able to synchronize everything I need between all of my information appliance array devices. I also purchased a netbook computer but quickly abandoned it when it became evident that the processor was not powerful enough for my work requirements.

The application categories available on my information appliances start with my Personal Information Management suite, which includes my contacts, calendar, task lists, and technical notes. I have a complete suite of clinical references and a set of calculation and conversion tools available to me. My professional document management suite includes word processing, spreadsheets, presentation tools, and a relational database application. I also use documentation tools for clinical events, patient record-keeping and billing databases, and have an Internet browser always available for looking up additional information and accessing online applications and tools. Email is used as my professional to-do list, and I will frequently ask my colleagues to email me if they want me to do anything.

**Search and Evaluation**

I have downloaded patient education materials and multimedia formats and store them on the internal memory of the devices I carry. Keeping up with news, sports, the stock market, online shopping, and travel activities is easy using these devices. I have specialized patient education applications at my fingertips and can access information in multiple languages whenever needed. For anything else, I have a suggested method for identifying and evaluating other specialized applications. My search and evaluation strategy is as follows.

First, I open a search engine and use the search terms:

a. Download
b. Operating system (such as Android, Windows mobile, Apple)
c. Application focus (such as drug information, long-term care, cardiology)
d. Free (This gets me free applications as well as free trials of application to use for my evaluation phase of the work.)

I did a trial search using [download Android "drug information" free] without the brackets but including the quotation marks to require the search to find the exact phrase “drug information” specifically. The search resulted in more than two million hits, but the first 20 websites listed contained a great professional array of reputable drug information resources. Next, I changed the application focus to cardiology with similar results.

**Evaluating the Application**

Now I need to evaluate the application. I make sure that the application is compatible with my device(s) on which I will run it. Some of the best publishers are capable of having their products run on all of the devices in use.
Then I look at the quality and quantity of the information in the application. Many producers of these applications are respected for their print products, and all I need to decide is how well their electronic version is made accessible for my needs. I look at the coverage of the application to make sure that the information I expect to be in the application is present. I want to know if the information in a monograph is presented in such a way that the nugget of information (such as geriatric dosing) can be quickly acquired without excessive reading. Also, I want to test products using actual cases from patients to make sure that the layout of the application is compatible with my problem-solving strategy. Finally, I make sure that the navigation, updating capabilities, and integration into my personal workflow can be supported by the application working on my device.

Cross Validation

Sometimes I place more than one application in a category on my devices so that I can cross validate the information from one application with another. This is especially valuable when a patient critical decision needs to be made. The good news is that there are several reputable publishers from which to choose. As I said earlier, using a free trial will get me the kind of practical exposure to an application before a purchase decision is required.

I find it personally and professionally exciting that information can be communicated in any form, to anyone, anywhere, on any device, at any time. Health care is rapidly becoming a digital field, and digital information convergence that yields greater situational awareness for pharmacists is now a reality. I welcome your comments and questions regarding this and any pharmacy technology topic. I can be reached by email at felkebg@auburn.edu.

Bill G. Felkey is professor emeritus of pharmacy care systems at Auburn University's Harrison School of Pharmacy.
The transition hasn’t always been seamless, but the technology has a demonstrated record as a powerful tool that can add to a pharmacy’s success.

By Lisa Fowler, PharmD
Several programs in the past few years have rapidly increased the number of prescribers capable of transmitting an e-prescription and subsequently expanded the volume of e-prescriptions transmitted. On average, this is now 15 percent of an independent community pharmacy’s prescription volume; a 300 percent increase from two years ago as reported in the *NCPA Digest, sponsored by Cardinal Health*. In remarks from the Surescripts SafeRx Awards, more than half of office-based physicians now e-prescribe. This increase in activity is reflected in NCPA member feedback on the cost and workflow challenges associated with implementing e-prescribing.

Nearly 500 NCPA members completed the survey, representing about 45 pharmacy software vendors. Companies with 10 or more respondents were Cerner, Computer Rx, HBS, HCC, McKesson, New Tech, Opus, PDX, QS/1, RX30 and Speed Script. (See Table 1.)

**Troubleshooting Issues**

Troubleshooting with e-prescribing is a common headache reported by the survey respondents. Most e-prescriptions require minimal processing, reducing transcription errors and enhancing pharmacy operations. A recent analysis by Surescripts showed up to an 800 percent return on investment to pharmacies for e-prescribing. However, the benefit gained by a majority of seamless e-prescriptions can be offset by even one exception requiring extra time to communicate with the prescriber or the software vendor. Slightly more than 75 percent of pharmacies report their vendor has a dedicated support line for e-prescribing; of those with access to a vendor support line, 76 percent have contacted support. Contacting your vendor support line should always be your first move. If you don’t have vendor support or do not receive a satisfactory resolution, you have access to a support line dedicated to independent pharmacies at Surescripts. This toll-free number is 1-877-877-3962, or independent-assistance@surescripts.com. Surescripts has the ability to determine if your complaint is a result of prescriber vendor issues, pharmacy vendor issues, or user error.

For most NCPA members, e-prescribing should be like a baseball umpire—it should perform its duties and blend into the background barely noticeable. That’s true for the majority of e-prescriptions, but when we hear complaints they generally center on the cost of the transaction and e-prescriptions with errors or that are delayed.

Of particular interest to NCPA were the findings concerning the pharmacy transaction costs, one of the most frequently voiced complaints. Most independents buy e-prescribing transactions from their pharmacy management system vendor. As the volume of e-prescription transactions continues to rise, the cost of these transactions will become increasingly important to pharmacy owners. The average fee for a new e-prescription transaction is 23 cents. Surescripts lowered the price to pharmacy software vendors in 2010 from 21 cents to 16.5 cents. While there isn’t comparable data for an average fee prior to 2010, survey respondents reported that not all pharmacies benefited from this price drop. In fact, over half of pharmacies did not see a fee decrease in

Table 1
January 2010 when the vendor price was lowered. (See Table 2 and Table 3.)

Another surprise on the pricing side is that only one-third of pharmacists who responded to the survey receive an itemized statement of e-prescription transactions, while three-quarters want this information. It seems reasonable to periodically reconcile e-prescription transactions, monitoring for duplicate or erroneous fees and other costs currently invoiced together. At the request of a pharmacy, Surescripts will refund a duplicate transaction fee to the software vendor. However, without an itemized statement, auditing for duplicates and verifying the refund is credited isn’t practical.

Regarding the other major complaint from members, errors and delays, respondents commented that the system would be more valuable if these were greatly reduced or eliminated. An overwhelming majority, 86 percent, reported that at least one out of 10 e-prescriptions is not a “clean” prescription and requires follow-up with the prescriber before it can be dispensed. This may include dosing directions in the comments field which conflict with the SIG, selecting the wrong drug (such as active ingredient, formulation, dose, route of administration), selecting the wrong patient, prescribing a controlled substance, or prescribing the wrong quantity. Compounding frustration at the pharmacy is the lack of a mechanism for flagging these prescriptions or refusing them and sending an explanation to the prescriber. An error that is cleared up over the phone or by fax is often not rectified in the patient’s medical record and may happen again. (See Table 4.)

‘Mailboxing’

Many of the survey respondents wrote comments describing the trouble they experience with e-prescription “mailboxing.” Mail boxing describes the experience of significant delays in receiving e-prescriptions after the prescriber has transmitted and the pharmacy subsequently receives a number of transmissions all at once. Depending on the situation, this may be due to the prescriber’s workflow, their e-prescribing platform, the pharmacy’s e-prescribing platform, or intermediary processes. For example, some electronic medical record or practice management software allows an office staff member to enter or respond to, with limited permissions, the e-prescriptions that then go into a workflow queue for the prescriber to electronically sign and transmit. An office staff member creates an unrealistic expectation of prescription ready time when informing a patient that a prescription or refill authorization will be sent immediately to the pharmacy when, in fact, one more step is involved.

Many of the findings of the NCPA e-Prescribing member survey were confirmed recently by a study published in the Journal of the American Medical Informatics Association. Released in November, and available free online, “Transmitting and processing electronic prescriptions: experiences of physician practices and pharmacies” concludes that while the system has improved, prescriber offices and pharmacies both fall short of optimal use. For instance, both need to consistently and correctly use all features of the e-prescribing system, including refill requests and refill authorizations. The study found that a number
of pharmacies do not use a system that automatically populates the fields of their dispensing screen requiring manual entry, or in pharmacies that do, prescribers use abbreviations that need to be typed out for the prescription label. However, as structured and codified sigs have not yet been implemented, it’s likely that the pharmacist will continue to need to interpret and retype the sig.

When NCPA and NACDS created the original Surescripts in 2001, the vision was that it would be a pipeline for prescriptions between the prescriber and the pharmacy (it was also in reaction to the PBM industry’s entry into the e-prescribing marketplace, RxHub). Surescripts has grown a lot in the last 10 years and it has helped further increase pharmacy’s relevance to payers increasingly looking for ways to connect the entire health care system while measuring quality and outcomes.

Over the course of the next year or so, electronic prescriptions for controlled substances (EPCS) will begin to be sent electronically. In our survey, four out of five pharmacy owners responded that their pharmacy management system vendor has notified them that they are making preparations to accept EPCS as the industry moves forward with this latest addition to e-prescribing.

E-prescribing is a sore spot for some pharmacies because the paper-based system was working fine for them and there is a visible cost to an e-prescribing transaction. For other pharmacies, they are taking advantage of the efficiencies the system creates.

One thing we know is that e-prescribing use will continue to grow. When its workflow, safety, and cost efficiencies are being realized, it is a powerful tool that can add to the success of your business. 

Lisa Fowler, PharmD, is NCPA director of Management Affairs.

Table 4

<table>
<thead>
<tr>
<th>Percentage</th>
<th>96–100% Clean e-Rx</th>
<th>91–95% Clean e-Rx</th>
<th>90–96% Clean e-Rx</th>
<th>86–90% Clean e-Rx</th>
<th>81–85% Clean e-Rx</th>
<th>80% or fewer Clean e-Rx</th>
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<tr>
<td>30.41%</td>
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<td>13.66%</td>
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<td>12.63%</td>
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<td>24.74%</td>
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</tr>
</tbody>
</table>

Lisa Fowler, PharmD, is NCPA director of Management Affairs.
<table>
<thead>
<tr>
<th>Association</th>
<th>Dates</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama Pharmacy Association</td>
<td>June 24–27</td>
<td>Sandestin Golf &amp; Beach Resort :: Sandestin, Fla.</td>
</tr>
<tr>
<td>Alaska Pharmacists Association</td>
<td>Feb. 17–19</td>
<td>Anchorage Downtown Marriott :: Anchorage, Alaska</td>
</tr>
<tr>
<td>Arizona Pharmacy Alliance</td>
<td>June 27–July 1</td>
<td>The Wigwam Resort :: Litchfield Park, Ariz.</td>
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<td>Arkansas Pharmacists Association</td>
<td>June 21–23</td>
<td>Embassy Suites :: Rogers, Ark.</td>
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<td>Feb. 2–5</td>
<td>Hyatt Regency :: Sacramento, Calif.</td>
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<tr>
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<td>Sept. 27–28</td>
<td>MGM Grand at Foxwoods Mashantucket, Conn. :: New England Pharmacists Convention (with Massachusetts)</td>
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<tr>
<td>Delaware Pharmacists Society</td>
<td>May 15–17</td>
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<tr>
<td>Florida Pharmacy Association</td>
<td>July 4–8</td>
<td>Marriott Marco Island Resort Golf Club and Spa :: Marco Island, Fla.</td>
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<tr>
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<td>June 7–11</td>
<td>Marriott Hilton Head Resort and Spa :: Hilton Head Island, S.C.</td>
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<td>April 28–29</td>
<td>NA</td>
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<tr>
<td>Illinois Pharmacists Association</td>
<td>Sept. 20–23</td>
<td>Hilton Lisle, Ill.</td>
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<tr>
<td>Indiana Pharmacists Alliance</td>
<td>Sept. 21–22</td>
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<td>Sept. 27–30</td>
<td>Oread Hotel :: Lawrence, Kan.</td>
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<td>Kentucky Pharmacists Association</td>
<td>June 13–16</td>
<td>Marriott Griffin Gate :: Lexington, Ky.</td>
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<td>Louisiana Pharmacists Association</td>
<td>July 12–14</td>
<td>Hilton Lafayette :: Lafayette, La.</td>
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<td>Maine Pharmacy Association</td>
<td>April 27–29</td>
<td>Hilton Garden Inn :: Freeport, Maine</td>
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<td>Ocean City, Md.</td>
</tr>
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<td>MGM Grand at Foxwoods Mashantucket, Conn. :: New England Pharmacists Convention (with Connecticut)</td>
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<td>Feb. 24–26</td>
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<td>Association</td>
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<td>Location</td>
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<td>Mississippi Pharmacists Association</td>
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<td>June 13–17</td>
<td>St. Charles Convention Center :: St. Charles, Mo.</td>
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<td>May 31–June 2</td>
<td>Northwest Pharmacy Convention :: Coeur d’Alene, Idaho</td>
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<td>New Jersey Pharmacists Association</td>
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<td>New Mexico Pharmacists Association</td>
<td>June 23–24</td>
<td>Sheraton Albuquerque Airport Hotel :: Albuquerque, N.M.</td>
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<td>New York Pharmacists Society</td>
<td>April 3</td>
<td>Swyer Theater at The Egg—Capitol Concourse area :: Albany, N.Y.</td>
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<td>(Annual Pharmacy Day 2012)</td>
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<td>North Carolina Pharmacists Association</td>
<td>Oct. 28–30</td>
<td>Raleigh, N.C.</td>
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<td>Oklahoma Pharmacists Association</td>
<td>June 28–July 1</td>
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<td>Oregon State Pharmacy Association</td>
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<td>NA :: (OSPA Lane County Mid-Winter CE Seminar)</td>
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<td>June 22–24</td>
<td>Crowne Plaza :: Hilton Head, S.C.</td>
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<tr>
<td>South Dakota Pharmacy Association</td>
<td>Sept. 21–22</td>
<td>Deadwood Mountain Grand :: Deadwood, S.D.</td>
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<td>Tennessee Pharmacists Association</td>
<td>July 16–19</td>
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<td>Texas Pharmacy Association</td>
<td>July 26–28</td>
<td>Woodlands, Texas</td>
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<td>Utah Pharmacists Association</td>
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<td>St. George Dixie Center :: St. George, Utah</td>
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<td>Virginia Pharmacists Association</td>
<td>Aug. 5–8</td>
<td>Wyndham Virginia Beach Oceanfront :: Virginia Beach, Va.</td>
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<td>Washington State Pharmacy Association</td>
<td>May 31–June 3</td>
<td>Northwest Pharmacy Convention :: Coeur d’Alene Idaho</td>
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<td>Pharmacy Society of Wisconsin</td>
<td>Aug. 23–25</td>
<td>PSW Annual Meeting :: Kalahari Resort &amp; Convention Center :: Wisconsin Dells, Wis.</td>
</tr>
<tr>
<td>Wyoming Pharmacy Association</td>
<td>June 22–23</td>
<td>NA</td>
</tr>
</tbody>
</table>

Information current as of Dec. 2, 2011
Upon successful completion of this program, the reader should be able to perform the following:

1. Discuss the prevalence, pathogenesis, secondary complications, and prevention of type 2 diabetes mellitus with a focus on new populations, early identification of warning signs, and modifiable risk factors at prevention and treatment stages.
3. Identify physical and clinical requirements involved in establishing a pharmacy-based foot care clinic.
4. Compare currently available professional and site certification or credentialing programs.
5. Describe best practice methods of instituting and maintaining a community pharmacy clinic within a collaborative team setting.

INTRODUCTION AND OVERVIEW

Diabetes as a Health Crisis

Type 2 diabetes mellitus (T2DM), previously known as non–insulin-dependent diabetes, has become a major health crisis in the United States, as diagnoses reach epidemic numbers and as complications nearly double the mortality risk of the diabetic population compared with healthy individuals.

Nearly 8 percent of the U.S. population (26 million adults) has diabetes, primarily T2DM, and approximately two million more are diagnosed each year. In addition, an estimated seven million Americans likely have undiagnosed diabetes. The total cost burden of diabetes is estimated at $174 billion annually, and the severe health impact reduces life expectancy of patients with diabetes by up to 14 years.

T2DM occurs more frequently in people of specific minority ethnicities: African Americans are at 77 percent increased risk and Hispanics are at 66 percent increased risk. Asian, American Indian, and Pacific Islander populations also have greater risks than that of Caucasians. Family history, low physical activity, obesity, and history of gestational diabetes are additional risk factors.

Although elderly adults traditionally have a greater risk of diabetes development, and diagnosis after age 45 years was once the most common demographic for disease onset, the diagnosis of T2DM in younger populations is rapidly increasing in the United States—considered by some clinicians as the first response to the obesity epidemic developing in American youth. Childhood T2DM has become so prevalent that nearly half of new-onset diabetes diagnoses in children are T2DM rather than Type 1 diabetes mellitus (formerly, insulin-dependent), the more traditional childhood diagnosis.

In response to the growing epidemic, the American Diabetes Association (ADA) has reissued its recommended standards of care for patients with T2DM, and Healthy People 2020 identified top objectives for curbing the disease course at—or even before—its onset, in efforts to improve the overall health of the aging adult U.S. population. The ADA guidelines for care include emphasis on improving patient understanding of diabetes and on implementing nutritional and physical activity changes that are considered required for effective disease control. Standards of medication management,
reduction of complications, and individualization of treat-
ment plans with health care providers remain essential.
Healthy People 2020 recognizes the importance of halt-
ing T2DM progression in the United States and includes
the ADA-designed prevention goals in its health care
planning initiative. Some key Healthy People 2020 objec-
tives to meet these goals are increasing the number of
patients who have formal diabetes self-management
training and education (DSMT/E), and increasing the
number of patients who self-monitor daily, take aspirin
daily at least 15 times per month, receive annual special-
ist examinations for secondary complications, and have
glycosylated hemoglobin (Hb A1C, A1C) levels checked
at least twice yearly.

Meeting these Healthy People 2020 objectives and
the ADA standards ensures that greater numbers of pa-
tients with diabetes achieve important clinical endpoints,
including lower blood pressure, stable glucose levels,
and lipid health. During the 1999–2007 National Health
Examination Survey, only 12 percent of patients with dia-
abetes achieved these three clinical endpoints, and only
half of patients with diabetes achieved just one endpoint.
Addressing patient knowledge and self-motivated action
must be encouraged by a participatory health care team
to increase treatment adherence and improve historically
fragmented care.

Team care by health professionals and pharmacist-
driven community clinics both have been shown to
significantly improve treatment adherence, frequency of
regular blood sugar evaluations and follow-up care, con-
trol of secondary complications, and likelihood of patient-
implemented lifestyle changes. As certification programs
for health professionals develop, reimbursement options
improve, and professional guidance standards expand,
health care professionals—particularly pharmacists—
have increased capabilities and resources on hand to
minimize the health toll of T2DM.

**Disease Pathophysiology**
The primary cause of T2DM is unclear and likely multi-
factorial; an underlying dysfunction of pancreatic B cells
is one likely component. B cells, which release insulin
in response to plasma glucose concentrations, can
malfuction and stop producing insulin for unknown rea-
sons. Another, perhaps larger, component is the devel-
oment of insulin resistance, by which insulin is present
but is used incorrectly by peripheral cells. As a
result, glucose is not broken down for use
and instead continues to build in the blood
and organs. As plasma glucose levels rise and
insulin needs increase, the pancreas becomes
desensitized to the presence of glucose and
eventually loses the ability to respond to the
need for insulin. As the disease progresses,
the pancreas stops making insulin at all, caus-
ing uncontrolled and damaging hyperglyce-
mia. Thus, insulin levels may be high initially
in the disease, when peripheral resistance is
only beginning, but become low when insulin
secretion slows.

Although a single cause of insulin resist-
ance is not defined, its development is strongly
linked to obesity and weight gain, because
fatty acids in adipose tissue impair glucose use
and because the fat tissue releases damag-
ing cytokines, such as tumor necrosis factor
and interleukins, which alter glucose transport
throughout the body. The development of in-
sulin resistance coupled with pancreatic B cell
impairment and rampant hyperglycemia is tra-
ditionally slow, with insidious symptom onset.

**Underlying Metabolic Syndrome**
A complicating factor of insulin resistance
and T2DM is a disorder known as metabolic
syndrome. At its simplest, metabolic syndrome
is a cluster of risk factors—high glucose, high
blood pressure, dyslipidemia, and middle-body
obesity—for diabetes and cardiovascular dis-
ease. More complex, though, is its connection
to the progressive dysfunction of insulin activity.
At its first identification in 1998 by the World
Health Organization (WHO), insulin resistance
was considered an initial cause and a required
component of metabolic syndrome. More
recently, WHO has eased the insulin resistance
requirement while still acknowledging a link
among metabolic changes, insulin ineffective-
ness, and T2DM.

The National Cholesterol Educa-
tion Program (NCEP) Adult Treatment Panel III (ATP III)
defines metabolic syndrome today as a group
of five body changes: increased blood pressure, increased triglycerides, low high-density lipoprotein (HDL), increased plasma glucose, and central obesity. The presence of three of these five markers supports a diagnosis of metabolic syndrome by international standards. The diagnosis of metabolic syndrome is associated with a five-fold increased risk of diabetes development within five to 10 years and a doubled risk of cardiovascular disease in the same time span. Indeed, metabolic syndrome is considered a definite cause of both diabetes and cardiovascular disease. Risks for development of metabolic syndrome include genetic predisposition, environmental factors, low physical activity, increased carbohydrate intake, and obesity, especially viscerally. After meals, glucose is retained longer in fat, especially in abdominal fat, than in muscle, thus prolonging the effect of hyperglycemia on the body of an obese patient.

Despite what seems a straightforward clinical picture, T2DM diagnosis, treatment, and control are complicated by its inextricable link to insulin resistance and the metabolic syndrome. The identification of metabolic syndrome as a precursor to diabetes has broadened the understanding of underlying physical changes occurring before and during diabetes development, but the circular nature of glucose control and metabolic changes in the body precludes a direct cause and effect relationship. Because metabolic syndrome plays such an important role in insulin resistance and T2DM development, early assessment can halt disease progression. Waist circumference, when increased, is an anthropomorphic measure of central obesity and is considered an important preliminary tool to identify the need to evaluate a patient for metabolic syndrome. A particular benefit of this measurement is that waist circumference impact remains standard among men and women of any height. Waist measurement should be taken just after exhalation while the patient is standing and not contracting abdominal muscles (such as when in conversation with the clinician). The tape measure should ideally be placed halfway between the bottom of the lowest rib and the top of the iliac crest on the hip area. Three measurements should be taken, and the average of the closest two measurements should be representative for screening purposes. However, the precise cutoff waist measure to indicate metabolic syndrome risk is still nonstandardized. For example, the International Diabetes Foundation guidelines suggest that waist measure alone is indicative of metabolic syndrome, and they recommend low cutoffs of 94 cm (37 inches) and 80 cm (31 inches) for men and women, respectively. Conversely, ATP III guidance set in 2001 identifies metabolic syndrome risk at 40 inches (102 cm) and 35 inches (88 cm) for men and women, respectively. WHO identifies 37 inches as a risk indicator for any person as an easy guideline. Recent research suggests that lower cutoffs tend to increase the frequency of correct identification of metabolic syndrome, so clearer standards worldwide are certainly needed for optimal care.

**T2DM Signs and Symptoms**

Early observed symptoms of hyperglycemia are non-descript and primarily result from osmosis (changing fluid concentrations across cells and vessels) to adapt to the high plasma glucose concentrations. Polydipsia, polyuria, and some polyphagia occur and cause secondary weakness, hypotension, dehydration, and fatigue. Blurred vision, nausea and vomiting, and fungal infections result from excessive glucose, and weight loss can be a sign of extreme hyperglycemia. However, even these symptoms fluctuate as glucose and insulin levels change over time, so the disease can remain undiagnosed for extended periods, even until cardiovascular complications develop as the presenting concern.

**Secondary Vascular Complications**

Poorly controlled glucose levels and inadequate antidiabetes treatment result in serious vascular damages that have striking morbidity in the diabetic population. The aggressive treatments necessary once these complications develop increase health care costs to patients, providers, and employers or other payers. Additionally, complications drastically reduce quality of life for patients and increase the risk of death. T2DM is the seventh-high-
est cause of death in the United States, most often as a result of secondary complications. Preventing the onset of these complications by stopping T2DM development at early stages, such as when insulin resistance or metabolic syndrome are identified, and by improving early disease control are essential to saving lives of patients with diabetes.

**Evaluation Methods**

Evaluation of plasma glucose levels is the primary diagnostic and monitoring method. There are three tools available to clinicians for this purpose: fasting plasma glucose (FPG), oral glucose tolerance testing (OGTT, or two-hour plasma glucose), and the A1C. In practice, random plasma glucose without glucose loading or fasting is often measured and is used to support diagnosis if it is >200 ng/mL.

The two-hour plasma glucose test, or OGTT, is administered to adults as a 75-gram glucose drink after a fasting period of eight to 12 hours, typically in the morning, to observe blood level changes in response to the concentrated glucose intake. Normal results are plasma glucose levels <140 ng/mL, and diabetes is diagnosed with results >200 ng/mL (11.1 mmol/L). The OGTT is sensitive but inconvenient and is not the preferred diagnostic method by the ADA.

FPG, unlike random checks or the OGTT, measures glucose concentrations without any caloric stimuli. The FPG test is the ADA-recommended diagnostic method, because it is easy, cheap, convenient, fast, and patient accepted. Glucose levels for FPG testing are drawn, most often in the morning, after eight to 12 hours of fasting; levels greater than 126 mg/dL (7.0 mmol/L) are diagnostic for diabetes, and normal levels are less than 100 ng/mL. In practice, an abnormal FPG can be followed by a two-hour OGTT to potentially confirm a diagnosis.

A1C represents an indirect reflection of glucose in the blood by measuring the percentage of hemoglobin in the blood that has been glycosylated, or has been bonded with glucose molecules. A1C differs from direct glucose measures because it reflects past glucose changes in the body—glucose levels in the body during the eight to 12 weeks prior to testing. Although useful as a diagnostic tool, A1C is even more useful as a predictor of diabetic complications. An A1C of 5.6 percent to as low as 4 percent is considered normal; an A1C greater than 6.5 percent supports a diabetes diagnosis according to 2009 international guidance and should be measured twice a year in healthy, at-risk people. Higher A1C proportionally indicates uncontrolled disease and its vascular morbidities. A1C less than 7 percent is the primary treatment goal and should be measured up to four times annually in patients with diabetes that is poorly controlled. Increasing A1C also reflects medical costs: each 1 percent increase of the A1C over 7 percent significantly increases not only the likelihood of microvascular or nerve damage, but also increasing medication costs.

To involve patients more easily in controlling their A1C and, thus, glucose levels for longer durations, researchers on the A1c-Derived Average Glucose (ADAG) study have recently developed a conversion tool to report A1C percentages to patients as estimated average glucose (eAG) in mg/dL—the same units used for glucose monitor self-care checks. The conversion is recommended by the ADA to simplify information presented to patients. For example, an A1C of 7 percent entered into the equation converts to an eAG of 169 mg/dL, which clearly represents uncontrolled glucose levels to the patient.

All three tests are diagnostic and can be interchanged if necessary for confirmatory testing. One abnormal measure of any test supported by a second abnormal measurement of the same or different test on a separate day warrants a diagnosis of diabetes. Although diagnosis of T2DM is easily made by laboratory glucose evaluations, guidelines for when to check and in whom have become more defined in recent years. Improving the use of lab tools to determine and monitor those at risk of diabetes development will identify patients with T2DM and with risks of DM at early stages, potentially before the onset of symptoms from high glucose levels or complications.

**Prediabetes**

The importance of being proactive at T2DM detection has already been determined. A
growing population is being identified as having prediabetes, an occurrence of subacute glucose control problems. This is in addition to existing risk factors for diabetes—obesity, family history, gestational diabetes history, low physical activity levels, and certain ethnicities. In 2008, 35 percent of all adults in the United States, and 50 percent of those older than 65 had prediabetes according to random A1C measurements. Prediabetes was initially described in 1997 and was further defined in 2003 as impaired glucose control, a transitory state between normal glucose function and full-blown diabetes. Impaired glucose control is quantified as an FPG of 100 to 125 ng/mL (also, impaired fasting glucose; or as 110 to 125 ng/mL by WHO) or two-hour OGTT results of 140 to 199 ng/dL (also, impaired glucose tolerance). Prediabetes can be identified as an A1C of 5.7 percent to 6.4 percent as well. Prediabetes itself is a risk factor for not only diabetes but also cardiovascular disease, including hypertension and dyslipidemia, and it is likely present in 79 million U.S. adults. Regular screening for prediabetes has no supporting evidence of benefit in clinical trials. Yet early intervention of increased physical activity alone has been documented to decrease the risk of diabetes for long durations by 34 percent in a population of patients with prediabetes. This supports the consideration of more frequent glucose screening in obese patients or those with other specific risk factors for diabetes.

**Whom to Test?**

Who should be the focus of testing for glucose evaluation? Definitive risk factors for the development of diabetes or prediabetes include the following: a primary relative with T2DM, low physical activity, hypertension of 140/90 mmHg, gestational diabetes history, at-risk ethnicity, high-density lipoprotein (HDL) less than 35 mg/dL, triglycerides greater than 250 mg/dL, history of delivering an infant weighing 9 pounds or greater, insulin resistance diagnosis, or a history of cardiovascular disease, or a prior A1C of 5.7 percent or greater.

Testing should be performed in anyone with a body mass index (BMI) of 25 mg/m² or greater (overweight status) and one of the above risk factors. Any adult age 45 or older with an overweight BMI, even without additional risk factors, should be tested as well. Testing should be repeated every three years after normal results. Abnormal results should trigger both a repeat test to confirm a diagnosis of prediabetes or T2DM and immediate interventions. (See Table 1.)

In addition to these regularly scheduled tests, additional glucose measurements and more intensive care are warranted at some clinical breakpoints. These are times of greater complication risk or of excessively poor control. Some common breakpoints include the new onset of secondary complications; new pregnancy in a patient with established diabetes; frequent hypoglycemic episodes; and continually high A1C (e.g., >8 percent on separate occasions).

**Primary Lifestyle Interventions**

Whether a patient is identified with metabolic syndrome, prediabetes, or T2DM with or without cardiovascular disease, immediate and ongoing intervention is essential. “Intensive control” is a new term used to reflect an A1C goal of less than 7 percent for all patients. It involves required lifestyle interventions and consideration of additional early oral treatment—such as metformin—as needed. Encouraging patients with any metabolic dysfunction to change habits significantly improves health and reduces the disease toll. The Diabetes Prevention

<table>
<thead>
<tr>
<th>Table 1. Breakpoints for Evaluating At-Risk Patients</th>
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<tr>
<td><strong>When to Test</strong></td>
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<tr>
<td><strong>Undiagnosed At-Risk</strong></td>
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<tr>
<td>45 years of age or older with BMI ≥25 mg/m²</td>
</tr>
<tr>
<td>Any age with BMI ≥25 mg/m² and one additional risk factor*</td>
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<tr>
<td><strong>Patients With Diabetes At Greater Morbidity Risk</strong></td>
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<tr>
<td>New onset secondary complications</td>
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<tr>
<td>New onset pregnancy</td>
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<tr>
<td>Frequent hypoglycemia</td>
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<td>Continually high A1C results</td>
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</tbody>
</table>

*Additional risk factors include a primary relative with diabetes, low physical activity, hypertension, history of gestational diabetes or infant weighing ≥9 pounds at birth, at-risk ethnicity, dyslipidemia, history of cardiovascular disease, or an A1C ≥5.7%.
A program, for example, showed a 58 percent reduction of T2DM diagnoses over three years in people of all ethnicities at risk of diabetes. In the study, weight reduction and increased physical activity together were more successful than metformin alone, which resulted in a 31 percent reduction in a similar patient group. Results from these two behavior changes were especially pronounced in younger populations (between the ages of 25 to 44) and in people with morbid obesity (a BMI 35 mg/m² or greater), and the preventive effects lasted as long as 10 years—a sufficient duration to reduce cardiovascular morbidity as well.

Clinician guidance for intensive control is highlighted in the ADA and European Association for the Study of Diabetes (EASD) consensus for management, which indicates that, upon diagnosis, exercise and possibly metformin should be started immediately. Behavior changes should be augmented as necessary by oral treatments to maintain an A1C less than 7 percent. If the A1C targets are continually unmet, more aggressive therapy with combinations of oral agents from different drug classes, as well as insulin administration as an option for patients with severe hyperglycemia, should be used to maintain glycemic control. Revising combination therapies according to synergistic benefits and cost-effectiveness must be individualized and ongoing according to the A1C. The actual drug selection is less important than the critical need to maintain a low A1C.

Diabetes self-management education (DSME), a national evidence-based educational standard helps to reduce the stress of diagnosis and management for patients with diabetes and their clinicians. DSME can increase quality of life and reduce costs to patients and payers. DSME is unique in that the program emphasizes psychosocial awareness of the diabetic patient and identifies the need to associate well-being with positive self-management outcomes to ensure success.

Therefore, the best teaching practices for DSME are interactive, not didactic. DSME is not only important at diagnosis for initial coping and for establishing interventions that can incorporate into the patient’s life; it is also important throughout care for ongoing support of the disease challenges and newly introduced treatments. Ideally, DSME optimizes ongoing disease control in a trusted partnership and prevents complications to continuously improve quality of life.

**COLLABORATIVE MANAGEMENT**

**Self-Management Requirements for T2DM Control**

Patient lifestyle plays a large role in diabetes treatment by maximizing quality of life and minimizing organ system dysfunction from excessive glucose. Simply walking 30 minutes per day and reducing body weight by 7 percent can reduce the risk of developing diabetes by 50 percent or more in people at high risk of T2DM (those with prediabetes). For patients already diagnosed with diabetes, the American Association of Diabetes Educators (AADE) has identified seven self-care behaviors to help patients manage their disease on a daily basis (the AADE7). They are:

1. Healthy eating
2. Being active
3. Monitoring glucose
4. Taking medications
5. Problem solving
6. Reducing risks
7. Healthy coping

The successful T2DM intervention is a triad of self management, lifestyle changes, and proactive medical care involving a collaborative team. AADE7 provides self-care behaviors, and the successful approach to AADE living involves adequate DSME. Implementing DSME in the community pharmacy involves the patient and the pharmacist to reduce costs, improve quality of life, reduce adverse events, and increase adherence. For patients and professionals using AADE7 as a model, DSME education programs can be initiated with a team on five steps: assessment, setting goals, planning programs, implementing programs, and evaluating outcomes, including reduction of A1C, blood pressure, and lipids as well as improvement of adherence.

Patients with diabetes are responsible for 99 percent of their own care, unique among chronic diseases. Therefore, patients with diabetes require maximum amount of skills and information available. Stress the importance
of individual treatment regimens to reduce adverse events. Reinforce medical adherence for blood glucose testing, blood pressure monitoring, and daily aspirin as well as regular foot, eye, and dental care exams. A simple mnemonic for reducing long-term microvascular or macrovascular risks is called the ABCs: A1c goal less than 7 percent, Blood pressure goal less than 130/80 mmHg, and Cholesterol goal LDL less than 100 mg/dL. DSME programs can use pharmacists as coaches to provide explanations of ABCs for cardiovascular risk protection, to explain lifestyle changes and why they are important, and to emphasize the importance of medical adherence, regular preventive care, and pharmacy communication for individualization of treatment regimens.

With these steps and other healthy living choices, patients themselves hold the key to reducing morbidity and mortality associated with T2DM and, indeed, T2DM onset itself. Despite prevalent knowledge of this, much of the population is disinclined to make lifestyle changes in an effort to improve health and reduce risk. In fact, people considered at high risk for diabetes are half as likely to change their behaviors as people without risk. Instead, nearly one fifth of people at high risk for developing T2DM in 2011 survey results expressed a preference to taking medications rather than initiating beneficial physical activity and weight loss programs.

If risk awareness is commonplace, what is the reason for rapidly increasing rates of diabetes and the lack of patient self care? Inadequate or inaccessible guided health programs and lack of direct provider care are two possible reasons. Insufficient or lack of knowledge about the large benefits of small change and about the gruesome statistics of T2DM complications also are key factors. Patient initiative must be spurred on by health care providers who have the knowledge to persistently provide easily understood and easily incorporated behavior changes, and these professionals also must ensure that patients understand the reasons for and the positive results of any change.

**Intensive Professional Care**

Usual care consists of preventive services with a doctor, medication management with pharmacist communication, and patient education from a nurse. Pharmacists educate, optimize therapy, and increase adherence. Pharmacists can help patients meet AADE7 goals by acting beyond the usual pharmacy care expectations of today. The unique role of pharmacists in providing diabetes care is the teaching of behavior skills combined with the monitoring of patient ability—all while including patients in treatment decisions and lifestyle planning.

At a minimum, pharmacists can teach meter usage, measure ABCs, and review medication use. However, community pharmacists in collaboration with a physician can also implement real-time medication therapy management changes on the basis of a patient’s current A1C, blood pressure, and cholesterol measurements directly and with autonomy. Chart reviews and reminder letters to physicians are significantly less effective than pharmacist face-time with the patient for recommendations, medication changes, and test recommendations; similarly, automated clinician reminders are less effective than face-to-face interactions for improving adherence. To institute expanded services, pharmacists must set a goal, communicate regularly with the physician, evaluate end points, and recommend drug changes for continuing control.

In a meta-analysis of such intensive care pharmacist interventions, patient education alone reduced A1C by 0.5 percent. Direct involvement with patients has been associated with blood pressure reductions of 5 mm Hg each and decreases of LDL by 12.9 mg/dL, and direct pharmacist interaction decreases A1C by at least 1 percent; every 1 percent A1C decrease reduced microvascular complications by 35 percent and death by 25 percent. Pharmacist involvement also prevents disease-related hospitalizations and reduces total disease costs by 10 percent to 20 percent. The return on investment for such involvement appears as risk protection within two years, a rapid effect compared with the 10- to 14-year time frame observed to the development of secondary complications.

A successful example of a significant pharmacy-based team intervention for self management is the 1997
Asheville Project, the first documented pharmacy community care program with the pharmacists in addition to a physician or diabetes educator to provide disease management services for 46 patients in North Carolina. In one year, A1C decreased more than 1 percent and costs to patients were reduced by $150/month. Cost savings lasted from 14 months to five years after the intervention was complete. Subsequent diabetes programs continue to build upon the success of the North Carolina project; for example, in the 21st century, when face-to-face drug management was combined with pharmacist-directed preventive care for 30 minutes at least twice a year, more Healthy People 2020 objectives were met than with physician-pharmacist communication alone.

Community Interventions
Team services for T2DM can extend even beyond a nurse, dietician, and pharmacist as medication manager or intensive collaborator. The pharmacist can combine efforts with a podiatrist, optometrist, and dentist to comprise an allied health team that provides a comprehensive self-support care package for diabetes control. Team practices can offer a range of services to the public according to needs; together, the health care professionals must engage patients to reduce information gaps. To support this team care, the pharmacist can verbally encourage daily self foot care, brushing teeth twice daily, monthly oral self exams, and rapid reporting of eye or vision problems. Community programs for individuals; social support for change, especially initiation of physical activity within a group; and campaigns in the community for disease prevention and for obesity control should also be encouraged. Pharmacists with diabetes care services or clinics can bridge the gap and engage otherwise healthy community members to start screenings and referrals for early control.

CONTROLLING VASCULAR COMPLICATIONS IN THE PHARMACY
Secondary complications not only cause the greatest number of deaths attributed to diabetes, but also are the predominant reasons for low quality of life in patients living with the disease. Small-vessel complications in the eye and kidney as well as damage to the peripheral nervous system result in kidney disease, blindness, and nerve and circulatory problems that lead to more than 82,000 lower-limb amputations in the United States each year. Macrovascular (in large blood vessels) damage leads to cardiovascular disease, the cause of death in two thirds of all patients with diabetes as a result of myocardial infarction or stroke.

The mechanism of vascular disease in diabetes is likely two fold, at least. First, oxidative stress from high glucose concentrations causes cell dysfunction via increased amounts of toxic breakdown molecules in cells and tissues and causes glycosylation of proteins to impede functions. Second, small blood vessel leaks from the damaging sugar presence can begin inflammatory cell responses that cause fibrous tissue buildup in vessels and that introduce inflammatory factors like cytokines, which cause continual damage.

Aggressive Prevention of Cardiovascular Morbidity
Rates and Mechanisms of Macrovascular Damage. A profound cause of morbidity of T2DM in the United States, cardiovascular disease is a huge health care burden and causes more than 50 percent of the total diabetes management costs. General risk factors for cardiovascular disease include genetic predisposition, obesity and the resultant inflammatory cytokines released from excessive weight, and the presence of metabolic dysfunction, including T2DM, insulin resistance, or metabolic syndrome. Serious cardiovascular events, such as myocardial infarct or stroke, are predated in patients with diabetes by blood pressure and lipid changes that can be seen as warning signs, requiring aggressive treatment and control to avoid more serious damage.

Cardiovascular Control Goals. Patients and clinicians do not need to wait for a cardiovascular event to initiate prevention strategies. A1C greater than 7 percent is directly proportional to the number of coronary events. Blood pressure control is documented to reduce the risk of serious cardiovascular disease by 50 percent and
the risk of microvascular disease by one third.

A blood pressure goal of 130/80 mmHg in patients with T2DM is supported by studies, because morbidity is associated with hypertension as low as 140/90 mmHg. Reduction of diastolic pressure from 90 to 80 mmHg alone reduces cardiovascular risk by 50 percent. For every 10 mmHg of overall blood pressure (systolic or diastolic), the risk of any type of complication is reduced by 12 percent. Upon evaluation, blood pressure of 130/80 to 139/89 mmHg warrants lifestyle changes for three months and then re-evaluation; blood pressure of 140/90 mmHg or greater, though, warrants lifestyle changes as well as medication of as a primary intervention, and blood pressure at first evaluation of 150/90 mmHg warrants combination drug therapy from the start.

Best Practice Lifestyle Efforts and First-Line Medications. Specific behavioral treatments that should be initiated at the first sign of hypertension include weight loss, increased physical activity, and a healthful diet. Specifically, nutritive efforts include DASH: dietary approaches to stop hypertension (DASH). A DASH-based diet emphasizes lowered sodium intake to 1,500 mg/day, lowered potassium intake, and moderate alcohol intake as means to prevent increasing blood pressure.

Antihypertensive Drug Treatments. Antihypertensive agents are cardioprotective by decreasing blood pressure and by directly reducing heart attack and stroke risk. First-line monotherapy should be an inhibitor of the renin angiotensin system (RAS). Inhibitors of RAS are considered renoprotective antihypertensive therapy and include angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). Both drug classes similarly reduce microalbuminuria and proteinuria (the latter up to 35 percent) that reflect kidney dysfunction; delay the onset of macroalbuminuria and creatinine impairment; and slow the progression of kidney disease to end-stage renal disease.

ACE inhibitors work by preventing the formation of vasoconstricting angiotensin II. ACE inhibitors have documented protective benefits of reducing heart attack events, decreasing hospitalization rates, and reducing the likelihood of revascularization surgeries. ACE inhibitors save 1 percent of all adults from heart attack mortality and are broadly preventive of cardiovascular mortality in patients with T2DM. In fact, ACE inhibitors, especially at high doses, reduce mortality and decrease cardiovascular disease even without the presence of hypertension or renal complications from diabetes.

Use of ACE inhibitors is specifically linked to reduced mortality from individual cardiovascular events, such as ischemia, heart attack, and stroke, and to reduced occurrences of nonfatal heart attacks. ARBs, which work by preventing the actions of angiotensin II at the receptor itself, significantly reduce blood pressure at least as well as ACE inhibitors when both drugs are compared with placebo. However, ARBs do not yet have the same extensive study support for prevention of individual mortality risks. Currently, ARBs have proven success at reducing composite cardiovascular complications rather than for prevention of a particular mortality risk.

Side effects of both classes of antihypertensives that work in the RAS are typically mild, although ACE inhibitors are associated with a greater number of bothersome side effects than ARBs. Cough, fainting, and high potassium levels are most frequent with ACE inhibitors, and angioedema is possible; high potassium levels and, rarely, angioedema, can occur with ARBs as well. ACE inhibitors remain worthwhile first-line choices because of their proven benefits and because they are more widely available as lower-cost generics, which can increase adherence for some patients. ARBs, though more costly and mostly available only as brand name products, should be considered in patients who experience difficulty with the ACE inhibitor side effects that interfere with adherence. Treatment with drugs from either class requires ongoing monitoring of potassium levels and kidney function.

Antihypertensive treatment can be suboptimal because of inadequate medication review, but evaluating and adjusting antihypertensive medicines regularly each month can reduce cardiovascular accidents and congestive heart failure by 10 percent each in patients with T2DM, and blood pressure control is more cost effective.
than treating cardiovascular complications of diabetes. Two drugs are often necessary to maintain blood pressure control over the long term. When initial treatment with an ACE inhibitor or ARB is unsuccessful at maintaining blood pressure goals, combination therapy that still includes an ACE inhibitor or an ARB is warranted. The combination of drugs from both the ACE inhibitor and ARB classes together is not currently indicated and is not recommended on product labeling, in part to prevent additive side effects, such as hypotension, fainting, and kidney problems. Some off-label use of an ACE inhibitor and an ARB has been observed. Most often, a diuretic is a logical second agent instead. A thiazide or loop diuretic should be added according to microalbuminuria presence, glomerular filtration rate (GFR; loop diuretics work better than thiazides at low GFR), and side effect profile tolerance. Alternatively, a calcium channel blocker can be combined with an ACE inhibitor for successful blood pressure control in patients with severe hypertension; this combination effectively controls hypertension and reduces cardiovascular risks but is not as effective as adding a diuretic to prevent kidney dysfunction, because calcium channel blockers do not affect fluid volumes or the RAS. In severe cases, three- or four-drug regimens that include a RAS agent, a diuretic, and additional drugs, such as calcium channel blockers, beta-blockers, or spironolactone, can be prescribed for adequate control.

**Aspirin Best Practice Use.** In addition to blood pressure control, overall cardiac health should be encouraged. Aspirin, along with other cardiac and diabetic agents like ARBs, ACE inhibitors, fibrates, and thiazolidinediones, reduces inflammatory cytokines from adipose tissue, particularly interleukin 6 and C-reactive protein, to decrease insulin resistance and cardiovascular events. Specifically, using aspirin appears most beneficial at reducing cardiovascular risk in patients with T2DM and concomitant hypertension. Increasing the frequency of aspirin use is one of the newest ADA standards of care that pharmacists can implement, particularly in patients older than 40 or older than 30 and with other risk factors for cardiovascular disease (such as hypertension and obesity). Low-dose aspirin (81 mg) up to 162 mg daily protects the heart and is an important component of cardiac care in patients with diabetes.

**Community Pharmacist Clinical Roles.** Pharmacists already capably provide consultation to measure glycemic control and blood pressure and to discuss medications. Intensive care agreements allow pharmacists to check blood pressure, evaluate medication efficacy, and adjust the treatment regimen in real time to accommodate uncontrolled hypertension, identify and eliminate medicine adverse effects, and problem solve for patient-voiced concerns about nutrition or supplements that can impact blood pressure levels and drugs. This face-to-face interaction—more a discussion than a directive—will improve adherence to medication regimens, increases disease control as measured by the ABCs, and reduces secondary complications from uncontrolled vascular disease. For example, these pharmacist services can nearly double compliance to initial ACE inhibitor or ARB treatment, thereby delaying the need for additional medication and reducing cardiac risks. The constant presence of a regular pharmacy clinical service provides these benefits to patients not on occasion but on a frequent and recurring basis.

**Evaluating Microvascular and Neuropathic Damage in Lower Extremities**

**The Importance of Proper Foot Self Care.** Although foot care by patients with diabetes and their pharmacy providers might not seem intuitive or of great importance when compared with life-threatening cardiovascular risks, lower-limb problems are a frequent complication of diabetes and directly reflect poorly controlled primary disease. Symptoms in lower extremities can occur as an early sign of the onset of T2DM as well, so awareness of foot health by every health professional is essential to total care of patients with or at risk of developing diabetes.

Foot problems resulting from diabetes occur not only from infection that develops in small cuts or cracks in the skin—wounds that do not typically pose problems in healthy populations—but also from small blood vessel
and peripheral nerve damage, when circulation that supplies nerve endings in the limbs becomes impaired from high glucose concentrations. In addition, the poor microvascular circulation increases the risk of lower-limb clotting and compounds the loss of sensation and infection risk in the feet. At least 60 percent of patients with diabetes have some degree of nerve damage that impairs pain sensation, and the greatest at-risk population is patients older than 40 years of age. The circuitous combination of sensory inhibition and vascular inefficiency often results in complicated foot ulcers, or “diabetic foot.”

Nearly one-fifth of all patients with diabetes develop foot ulcers, and at least 14 percent of these patients later undergo amputation of a lower extremity—a serious and life-altering morbidity of uncontrolled T2DM. Foot care for all patients with diabetes should be encouraged, but some populations are at even greater risk of foot ulcers and amputations. Any patient with structural foot deformities (bunions), sensation loss, or a history of foot problems should be referred to a podiatrist for ongoing and lifelong preventive care to reduce the likelihood of amputation. Smokers have four times greater risk of lower-extremity problems as a result of microvascular damage, and diabetic patients with a family history of cardiovascular disease or cerebrovascular accidents (strokes) likewise have a greater risk of lower-extremity complications. Additional patients at particular risk of ulcers and amputations include those with diagnosed peripheral neuropathy or peripheral vascular disease (PVD) from any cause and patients with visual impairment or nephropathy requiring dialysis, both of which reflect existing microvascular disease. Patients with uncontrolled disease according to A1C testing results (frequent A1C >8 percent), those with reduced mobility, and those who experience frequent bouts of hyperglycemia are also at great risk of amputation without adequate follow-up care.

Despite the potential severity of microvascular and neurologic foot damage, diabetic foot can be prevented or identified at much earlier stages with aggressive health professional intervention and encouragement of lifestyle modifications. Comprehensive foot care programs that assess risk, educate patients, perform preventive treatment services, and promote rapid specialist referrals have reduced amputations by 45 percent to 85 percent in established community settings.

Baseline Community-Provided Foot Care. The ADA standards of care recommend an annual foot exam for every patient with diabetes, preferably performed by a physician or podiatrist, and they encourage daily foot checks by the patient. A multidisciplinary approach for all patients, particularly patients at high risk of secondary complications, should involve frequent community-based care opportunities. In-person care provides an ideal setting to explain the importance of foot care to patients, to demonstrate what a daily check comprises, and to ensure early identification of potential problems, including early sensation loss or lingering wounds.

Why Pharmacists? Although community pharmacy has focused in the past on guiding orthotic decision making and ordering wound-care supplies, the community pharmacy clinic is perhaps the best location for intensive promotion of foot care regimens to patients with diabetes, especially if a preliminary diabetes clinic is already in effect. Pharmacists are approached by patients seven times more often than physicians and are comfortable translating technical guidelines and directives into usable patient-education language—precisely what patients with diabetes need for improve self care of feet.

Pharmacist-Encouraged Self Care. At a minimum, pharmacists can actively promote self care for diabetic foot prevention by stressing to patients the importance of toenail trimming, foot powder to reduce moisture and prevent fungal infection, and lubricant creams to minimize dry skin and cracking. Counseling about risk aversion includes encouragement of physical activity and good nutrition to ensure adequate circulation in the lower limbs and of smoking cessation. Physical recommendations by a pharmacist include frequent sock changes; avoidance of constricting footwear or stockings; and avoidance of
bare feet to decrease the likelihood of cuts and scrapes. A quick look at the soles of feet each day can identify wounds or sores that result from ill-fitting shoes or stockings before infections or ulcers become established.

Talking points for patient education link early foot damage to serious complications: cramping as a warning sign of clots; calluses and corns as predecessors of more complex blisters and ulcers; and irritated or cracked skin on soles or between the toes as infection risks. Patients should avoid using pads or coverings on blisters, corns, or calluses. Instead, these minor foot problems should trigger an appointment with a podiatrist to evaluate ulcer risk and assess footwear.

**Pharmacy Foot Clinics.** To introduce pharmacist-guided foot checks in the community setting, pharmacists require a well-lit and private space to discuss self care, to directly observe skin, and to test for vascular or neuropathic abnormalities. Pharmacist examination of the diabetic foot should begin with a visual check of skin integrity to identify dry or moist skin, cuts, and wounds. Some clinics may choose to provide cleansing foot soaks before inspections. Visual identification of foot deformities alone is an indication for specialist referral and fitting for proper footwear. Dry or cracked skin requires counseling about frequent lubrication incorporated into daily self checks. Visual identification of ingrown nails can lead to a nail trimming demonstration: cutting straight across the nail avoids infections, and heat applications can reduce swelling of already ingrown nails to reduce infection risk.

The most efficient method of assessing lower-limb circulation is an examination of pulses in the feet, known as pedal pulses. Absent pedal pulses indicate a problem with circulation that could support a diagnosis of peripheral vascular disease or that could cause nerve damage in the extremities. Reduced sensations in the feet reflect peripheral neuropathy and indicate a loss of the protective detection of pain or irritation from foot wounds. Absent foot sensations provide an opportunity for serious ulcers to develop unnoticed after minor foot damage, which severely increases the likelihood of amputation in a patient with diabetes.

Pharmacist evaluation options for neuropathic foot checks range from simple tool-free tests, such as ankle reflex exams or direct pin prick testing on the feet, to evaluations that use a tuning fork for vibratory perception or a monofilament thread for sensation identification. All testing options are considered reliable and convenient alternatives to invasive nerve examination. However, the monofilament test is especially preferred, in part because of its ease of use. To perform a monofilament test, a clinician applies pressure with a nylon thread filament (most often a 5.07/10-gauge size) to up to 10 points on the foot sole until the tip of the filament begins to bend. If 10 sites are tested and a patient does not identify the sensation at four or more of the 10 points, peripheral neuropathy should be suspected and subsequently confirmed. Additional testing standards of monofilament use are continually being developed and evaluated for accuracy as well.

The monofilament test alone, similar to other noninvasive nerve examinations, is subject to varied sensitivity and administrator bias; therefore, the ADA recommends performing two tests to improve the accuracy of a neuropathy diagnosis. Any one failed test is a specific indication for an immediate second testing method to confirm loss of sensation; failure on two or more tests indicates peripheral damage and the need for a diagnosis and referral. Conversely, two or more normal results at a single visit indicate peripheral nerve health.

Taken together, the visual exam, pulse evaluation, and nerve testing present a thorough picture of foot health and, by proxy, of diabetes control via the level of observed vascular and nerve complications. All exams should conclude with specific product and action recommendations and a summary of patient-directed regular care behaviors, with a scheduled follow-up time recommended or set.

**ACHIEVING CERTIFICATION AND DEVELOPING A CARE PROGRAM**

Intensive care beyond usual medication counseling or chart review is of acknowledged importance to care of patients with diabetes. DSME involves health care professionals first as a means of educating patients about self
care. DSME requires a needs assessment, goal identification, patient and clinician education, and evaluation of progress toward goals. The ADA acknowledges the growing and important role of pharmacists in the provision of this expanded care. Their pharmacist standards of practice provide directives for pharmacy diabetes specialists to organize and guide care continuity and to expand upon basic DSME requirements. Pharmacist diabetes educators are encouraged to complete the following procedures:
1. Assessment of lifestyle, current lab and exam results, medications, and patient self-care ability
2. Identification of DSME outcome goals
3. Planning with the patient and team
4. Implementation of the plan with the patient
5. Evaluation of outcomes with lab testing, self care, medication review, and measurable goals
6. Documentation of a full record of care.

Individual Certification. The pharmacist scope of care at minimum includes knowledge of the disease state and comorbidities, maintenance of that knowledge, and involvement in lifestyle counseling and educational strategies. Any pharmacist can extend beyond the basic counseling to become a certified diabetes specialist. Numerous widely available program options that have varied time and financial commitments provide a working knowledge base required for credentialed or certified optimal care and clinic maintenance.

Diabetes specialization offers whole-person, all-encompassing patient care beyond medication therapy management and opens the door for collaborative professional engagement. In addition to existing site-specific professional education programs with Indian Health Services and Veterans Affairs, pharmacists can enroll in residencies and university-based post-secondary structured education on site or online at pharmacy programs such as the University of Texas, University of South Indiana, and Purdue, for example. Board-certified advanced practice specialty in diabetes (BC-ADM) with or without a residency or other certification is available as well from the AADE for registered pharmacists with a graduate degree (such as a PharmD). The exam is offered twice yearly and enables knowledgeable decision making and whole-patient care on both psychosocial and metabolic issue. BC-ADM credentialing emphasizes clinician mentoring, research, and continuous professional development in addition to the comprehensive disease state focus. Certification requires a fee of $900 for non-AADE members and requires 1,000 practical hours in addition to completion of two of five provided continuing education programs. To recertify, clinicians must repeat the fee and educational requirements, and the majority of the completed continuing education performed in the certification interim must relate to advanced disease management.

Options for practicing community pharmacists with any degree (BSPharm or PharmD) include a diabetes specialty continuing education program from APhA that awards a certificate of achievement after completion and a multidisciplinary certified diabetes educator (CDE) credentialing program available from the National Certification Board of Diabetes Educators. (See Table 2.) The APhA certificate program, titled Pharmaceutical Care for Patients With Diabetes, details the role of the pharmacist beyond medication dispensing and into management and patient education, including DSME. The program is recognized nationally as a promoter of pharmacist interventions as part of a health care team. The program cost varies according to grant subsidies and program hosts, ranging from $99 to $350. The standard certificate program is offered directly through APhA as well as through some state pharmacy associations. The material focuses on thorough clinical education about pathophysiology, medication management, and nutrition, and it touches on the roles of pharmacist educators, open communication, and psychosocial patient concerns. Pharmacists who enroll in the program complete a self-study workbook and exam, as well as online activities and case studies, which are followed by a registration-only live-training seminar and a final, post-seminar exam. Any pharmacist completing the ACPE program and scoring at least 70 percent on the exams is awarded a certificate.

The APhA program is an acknowledged introduc-
tory program to the more comprehensive and distinct CDE program administered by the National Certification Board of Diabetes Educators (NCBDE), which focuses on DSME more heavily than on medication management alone. CDE credentialing is available to allied health care professionals who complete the prerequisites and examination. To be eligible for certification, a pharmacist must hold an active license, must have at least two years of professional pharmacy experience, must have completed a minimum of 1,000 hours of DSME-based efforts (40 percent of these within the year directly before examination), and must have completed at least 15 continuing education hours in the two years prior to examination. The CDE exam is offered twice yearly, and applicants must preregister with a $350 fee. Certification, when awarded, is valid for five years; recertification requires an examination or completion of 1,000 documented practical experience hours and 75 hours of diabetes continuing education to demonstrate current disease state awareness and knowledge. Renewal by either method costs $250. For clinicians interested in becoming a CDE, the AADE offers Guidelines for the Practice of Diabetes Education for Practitioners as well as a supplemental companion, Competencies for Diabetes Educators, which identify objectives and skill goals for all ranges of diabetes specialists, from beginners to experts. These knowledge goals encompass the disease state, physiology, and treatments of diabetes; long-term supportive care; teaching skills that enhance self care and behavior change; and business aspects of diabetes specialization.

Pharmacist diabetes educators from any program must maintain knowledge about the disease and comor-bidities through initial training and continuing education, and they must provide care that includes DSME with lifestyle counseling and educational strategies. Accreditation of a diabetes education program is the gateway for allowing community pharmacies to provide DSME and for receiving reimbursement for these valuable services.

Pharmacy Accreditation. Medicare Part B reimbursement for diabetes training by the pharmacist is limited but expanding. Status as a pharmacist is not enough to establish a community care business model and receive reimbursement by Centers for Medicare and Medicaid Services or many pay-for-performance private insurers, however. To qualify for payment of DSME/T services (Medicare pays for a diabetes educator to provide training) by a pharmacist, the services must be performed as part of an accredited program billed by the pharmacy. In addition to reimbursement benefits, site accreditation validates the role of the pharmacist as a formal educator. AADE, in addition to providing educational tools for professionals and patients, is one of two organizations that awards accreditation or recognition to pharmacies for clinical care validity and reimbursement. The National Community Pharmacists Association (NCPA) has partnered with AADE to develop DASPA, a program to educate community pharma-

<table>
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<td><strong>Education Program</strong></td>
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cists about how to implement an accredited diabetes program in their pharmacies. DASPA (Diabetes Accreditation Standards–Practical Applications), is a combined online and live program that introduces program accreditation in combination with introductory management and business aspects of a diabetes clinic. Six online self-directed modules provide and test on essential knowledge about diabetes practices, DSME/T, lifestyle modification recommendations, medications, and common complications. The two-day live program is offered at intervals throughout the year to present the topics of team building, service implementation, billing 101, program establishment, and business marketing.

The DASPA program is designed to equip community pharmacists with the clinical components of providing diabetes education, the business aspects of program management, and the expertise to provide an accredited DSME/T program that meets professional standards. Through DASPA, pharmacists obtain 25 continuing pharmacy education contact hours; upon completion of the program, pharmacists will have the skills needed to implement a successful diabetes education program and pursue individual accreditation.

Importance of Building Community Partnerships. Even before personal certification or site accreditation or recognition occurs and formal clinic planning or needs assessments are underway, community outreach is crucial to establishing a flourishing and vibrant clinic. In fact, the AADE describes an appropriate community care team as containing a credentialed allied health educator and receiving community support to sustain DSME/T in addition to identifying treatment outcome goals. Early interaction with an established patient base and with participatory community leaders will promote the developing pharmacy services; expand the patient base, encourage regular communication and involvement by the pharmacist in the community; and support the needs assessments and formal steps required to build and maintain a collaborative clinic. The National Diabetes Education Program (NDEP) supports pharmacists and their clinics in these educational and community-building goals by providing clinicians with brochures about diabetes and with activities for patients to complete within their communities.

Steps to Build and Maintain a Clinic Effectively.

Establishing a T2DM practice setting requires broad integration of all aspects: experts, patients, community, certification agencies, suppliers, business and reimbursement organizations, and more. Although programs can be fully developed in private before collaborators are approached, establishing a clinic with the support of an existing partnership is likely more timesaving and cost effective as well as more teambuilding.

First, early support from businesses and the patient base can promote interest in collaboration with a primary care physician or practice to establish a pharmacy partnership by demonstrating the need in the area and the positive health and cost benefits to patients, pharmacies, and physicians alike. Fostering trust and communication early in a collaboration sets the stage for success both with nursing and clinical staff and between clerical or administrative professionals, who will inevitably be involved through delegatory roles.

Once a patient base and collaboration are set, identification of possible useful services and the capacities of the existing framework must be defined. For example, identification of guideline goals that are unmet in the current population and the possible methods to engage and treat that population should be delineated. Focusing these needs assessments and the available expert roles will provide patients with the best possible care from the start.

Business plan development, which should be shared with collaborators, early community supporters, and other individuals involved with logistics, identifies the key points succinctly: the clinic purpose, with the ADA standards of care background to support the pharmacist role; applicable collaborative agreements in writing; the physical structure and time allotments, and other physical and temporal expectations; as well as the endpoints, tracking methods, and planned follow-up and billing structures that should be implemented. Finally, the pro-
posed costs and revenue to the clinic and involved professionals, the estimated patient costs spent and saved, and the time commitment and time saved by patients and clinicians alike should be addressed, in particular to accommodate hiring needs, space issues, and the defined scope of all participants.

After the development is thus concluded, the team should market the new clinic to patients and local providers via media, office brochures, physician inservices, and community partnerships. Completing this planning integration fulfills the AADE 2010 standards suggested as the minimum required components of a sustainable diabetes education program. These are: a multi-level team with a credentialed educator and a key coordinator, community support, and identified outcome goals.

To supplement these minimum components, the NDEP suggests and justifies six steps to build a working clinic framework from the business plan: ensure a core leadership for stability and guidance; identify team members and their specific roles; identify the patient population and assess needs; assess resources and clinic needs; develop continuous care systems with a standards of scope, structure, and payment; and evaluate outcomes to adjust care accordingly.

Once a clinic and its team are established, its successful continuation is supported by regular maintenance. Regular promotion of patient quality of life benefits and ease of self care ensures a continuing patient base. Frequent encouragement of community supporters (such as networking partners and suppliers) provides a vital connection to publicity as well as up-to-date supplies and resources. Ongoing, healthy, and structured team communication ensures unfragmented care, prevents any patient from slipping through cracks, and keeps clinician knowledge current through information sharing. Some opportunities include algorithm use, shared real-time e-records, cohesive scheduled meetings, and monthly case rounds.

Aggressive but tactful follow-up for patient preventive care retains existing patients for ongoing care. Examples include prescheduled annual exams, as needed screenings and foot/sugar/hypertension checks, and scheduled phone call reminders.

For professional and lay communication alike, implementation of technology, when available, should be maximized to increase the time available for face-to-face interactions. Automatic reminders as follow-ups to personal phone calls, shared e-records, and electronic reporting tools can keep all team members—including the patients themselves—up to date on patient care.

CONCLUSION
Diabetes is not static, and patients with the disease rely on pharmacists and collaborating health professionals to provide continual care to accommodate their fluctuating needs. Pharmacists caring for people with T2DM must stay at the forefront of knowledge about diabetes care, its treatment goals, and its complications, and they should reach out to related professionals in an attempt to reduce fragmented patient care. By working together to monitor glucose control and morbidities, and by including patients and caregivers as active participants in self-management education and training, pharmacists can not only help patients with diabetes reach outcome goals but also prevent the progression of early metabolic changes into active disease. With the latter, pharmacists can help temper the spreading diabetes epidemic.

Nicole Van Hoey, PharmD, is a freelance medical writer and editor in Arlington, Va.
ESSENTIAL RESOURCES BY ORGANIZATION
Every pharmacy diabetes specialist should utilize these important resources to maintain current practice standards and knowledge as well as to provide patients with the most useful tools for and reminders of the importance of self care.

1. American Academy of Diabetes Educators (AADE): Professional resource center
   • Main site: www.diabeteseducator.org
   • AADE7 handouts: www.diabeteseducator.org/DiabetesEducation/Patient_Resources
   • Accrediting and DSME tools: www.diabeteseducator.org/ProfessionalResources/accred/
   • Patient-based Web site hub: www.diabetesselfcare.org/self-care-behaviors/overview/

2. National Diabetes Education Program (NDEP): Policies for systems change
   • Main site: www.betterdiabetescare.nih.gov
   • Patient care and specialist toolbox: www.betterdiabetescare.nih.gov/maintoolbox.htm

3. Preventive Care Guidelines
   • Task Force screening guidelines: www.uspreventiveservicestaskforce.org/uspsf/uspsdiab.htm
   • AHRQ comparative effective review 18 (cardiac) for professionals: www.ncbi.nlm.nih.gov/books/NBK36476/ and for patients: www.ncbi.nlm.nih.gov/pubmed/21919264

4. American Diabetes Association: Estimated average glucose tools
   • Interactive converter: http://professional.diabetes.org/GlucoseCalculator.aspx
   • Pharmacy flyer: http://professional.diabetes.org/content/pdf/vnzqcAverage%20Glucose%20flyer.pdf

5. Diabetes Accreditation Standards–Practical Application (DASPA): for site accreditation/educator instruction
   • Main site overview: www.ncpanet.org/index.php/daspa

Podiatry Pearls for the Pharmacist

What to Check: sensation (with monofilament or similar test), circulation (with pedal pulses), and physical foot changes (with visual exam for deformities or open wounds/fissures)

Who is at Risk: patients who smoke or who have limited mobility; patients with structural foot deformities, a history of peripheral vascular disease, or a family history of cardiovascular disease or cerebrovascular accident; patients with existing microvascular complications (retinopathy, nephropathy); and patients with highly uncontrolled glucose levels (frequent hyperglycemia, A1C regularly >8 percent)

When to Refer: any foot deformity (eg, bunions, persistent calluses) that requires professional footwear evaluation; any active ulcer or open wound, which might require anti-infective care; any documented sensation loss, which could indicate microvascular damage


Global Outcome and Preventive Care Goals for Patients

ABCs: A1C <7 percent; Blood pressure <130/80 mmHg; and cholesterol goals of HDL >35 mg/dL, LDL <100 mg/dL, and TG <250 mg/dL

Podiatry: Daily foot self checks, frequent as needed professional foot checks, and annual podiatry visits

Glucose control: Twice-daily blood glucose self checks

Allied health: Annual optometry visits and twice-annual dental visits

Lifestyle changes to implement and maintain: Physical activity (walking) 15 min/d; improved nutrition (DASH diet, lower carbs)
CASE 1
G.W. presents at your pharmacy during open hours of a regular diabetes care clinic at your community pharmacy. G.W. is bringing her mother, who is being treated for T2DM, to see you for a regular medication and blood pressure check. During the counseling and education session with her mother, G.W. comments that she had gestational diabetes during her second pregnancy, in her mid-30s, and that her children are now 10 and 12 years old. Given this basic information, how should you respond to G.W. after caring for her mother?

Response 1
Because G.W. has a history of poor glucose control, has a first-degree relative with active T2DM, and is likely near or older than 45 years old, you should recommend that she undergo testing for T2DM. Options for proceeding with an education program for G.W. include the following: weight check to evaluate BMI as a factor in metabolic syndrome; blood pressure measurement to identify possible cardiovascular complications or primary hypertension; waist measurement to identify the need for full evaluation of metabolic syndrome; and an order for a measure of blood glucose (such as a fasting plasma glucose or two-hour tolerance test, or A1C to identify longstanding dysfunction). In addition to these tests, an interactive discussion about the importance of physical activity and nutrition in curbing T2DM onset and progression is warranted in G.W. because of her family and personal history. Emphasis on the profound benefits of walking and reducing salt and carbohydrate intake in particular is beneficial, and awareness of poor foot health as an early sign of uncontrolled diabetes is similarly important. Pending the results of testing, you refer G.W. to a physician for initiation of diabetes team care and/or request a follow-up visit by G.W. to the pharmacy for repeated screening of her metabolic health status.

CASE 2
H.H. is a regular patient at your pharmacy and has been treated for T2DM with oral medications for the past two years. You have recently become a certified diabetes educator, have entered a collaborative practice agreement with a local primary care physician group, and have opened an AADE-accredited diabetes wellness program in your community pharmacy. Today, you are conducting your regular clinical services with foot exam services, and you see H.H. approach. At his physician’s suggestion, he agreed to a consultation about medications as well as a blood pressure and glucose check in your clinic. Although his measurements are stable at today’s visit, you are aware after reviewing his electronic record from the primary care provider that his A1C is 8 percent. How do you proceed with an education program and foot check?

Response 2
H.H. should be encouraged to participate in DSME, with particular encouragement about long-term glucose control and the prevention of vascular morbidities. By working together with H.H., you can maximize adherence and make rapid adjustments to his current medications as necessary. After H.H. agrees to your offered foot check, you visually examine skin for cracking (and suggestion lubrication as necessary), demonstrate proper toenail trimming (straight across), and check pulses for vascular health/clotting concerns. Finally, you perform a monofilament test to determine nerve sensations in the foot.
CONTINUING EDUCATION QUIZ

Select the correct answer.

1. The prevalence of type 2 diabetes is disproportionately increased in which population(s)?
   a. Non-Caucasian ethnicities
   b. Moderate alcohol drinkers
   c. People with genetic mutations
   d. All of the above

2. Healthy People 2020 objectives for managing diabetes in the 21st century include which of the following?
   a. Take daily aspirin at least 20 days per month
   b. Check A1C at diagnosis
   c. Self-monitor daily
   d. Two of the above

3. How is type 2 diabetes etiologically linked to insulin resistance?
   a. Insulin is used poorly by the peripheral cells to initiate plasma glucose build up.
   b. Insulin resistance is highly linked to obesity, especially central obesity.
   c. Insulin resistance leads to a net increased insulin production over the long term.
   d. B and C

4. Metabolic syndrome is defined as __________.
   a. A cluster of risk factors that include overall obesity, increased blood pressure, and increased LDL
   b. A cluster of risk factors that include waist obesity, increased blood pressure, and increased TGs
   c. A cluster of risk factors that include waist obesity, increased blood pressure, and increased HDL
   d. A cluster of risk factors that include overall obesity, increased blood pressure, and decreased LDL

5. Metabolic syndrome was first identified by _________ in _________ and was believed to be the _________ of insulin resistance.
   a. WHO, 2000, primary cause
   b. WHO, 1998, primary cause
   c. WHO, 2000, primary result
   d. WHO, 1998, primary result

6. Microvascular complications of diabetes include __________.
   a. Stroke
   b. Hypertension
   c. Diabetic foot
   d. All of the above

7. True or false: Microvascular disease causes more mortality than macrovascular disease in patients with type 2 diabetes.
   a. True
   b. False

8. According to existing research, diabetes often can be prevented in patients with prediabetes by including _________ as a behavior change.
   a. Increased physical activity by 15 minutes per day
   b. Minimized salt intake entirely
   c. Adjustment of the diet to eat more frequent meals
   d. Two of the above

9. AADE7 provides guidance strategies for _________.
   a. Directives for pharmacist educators
   b. Self-care behaviors by patients
   c. Daily clinician visits
   d. Monthly disease management

10. Intensive care differs from usual care by _________.
    a. Collaborating with the community to increase work incentives
    b. Collaborating to attend a patient at once as a health care team
    c. Involving the pharmacist as a face-to-face health care professional for the patient
    d. Involving the pharmacist as a nurse partner
11. Cardiovascular mortality from stroke increases directly in proportion to ________.
a. Increased blood pressure greater than 150/90 mmHg
b. Increased A1C > 7 percent
c. Increased retinopathy
d. Two of the above

12. Best practices for vascular care of the diabetic patient include which of the following?
a. Encouraging aspirin use daily to reduce risk of a cardiovascular event
b. Providing foot checks in the clinic to reduce amputation risks
c. Identifying and evaluating outcome goals for optimal glucose control as part of a health care team
d. All of the above

13. Related mechanisms of lower extremity damage include ________.
a. Peripheral nerve impairment from lack of adequate blood flow to the lower limbs
b. Diabetic nephropathy that increases fluid and electrolyte imbalance in the body
c. Poor circulation that increases clotting and impairs wound healing
d. A and C

14. Patients with ________ are at risk of foot ulcers.
a. A1C < 6.5 percent
b. Diabetic retinopathy
c. Blood pressure > 140/90 mmHg
d. All of the above

15. Pharmacy foot checks involve which of the following?
a. Pin prick test and two other sensory checks
b. Foot massage with acupressure
c. Toenail scrubbing and filing
d. Pedal pulse checks

16. Monofilament foot sensation tests
a. Use nylon thread to check circulation
b. Check sensation at 18 spots on the foot
c. Detect poor sensation in response to filament tip bending with pressure
d. Two of the above

17. DSME represents
a. A method of intensive care for patients alone
b. An educational model for clinician and patient knowledge
c. An educational model for only clinician knowledge
d. A well-rounded program of patient self-instruction

18. ADA standards and scopes for pharmacists include ________.
a. Providing patient training to implement self-care behaviors successfully
b. Providing medication chart reviews monthly
c. Communicating with a prescribing physician every day
d. Providing physical tools to clinic patients for home care

19. DASPA benefits include ________.
a. Medicaid certificate of approval for a clinic
b. Education about program accreditation which is required for reimbursement of services
c. Pharmacist continuing education hours toward program accreditation
d. B and C

20. Maintaining communication for effective clinic continuity of care can be achieved with which of the following?
a. Shared phone lines
b. Shared email announcements
c. Shared paper records that travel with the patient
d. Regular round table meetings focused on active case studies
FREE ONLINE C.E. Pharmacists now have online access to NCPA’s C.E. programs through Powered by CECity. By taking this test online—go to the Continuing Education section of the NCPA Web site (www.ncpanet.org) by clicking on “Professional Development” under the Education heading you will receive immediate online test results and certificates of completion at no charge.

To earn continuing education credit: ACPE Program 207-000-12-001-H04-P  
A score of 70 percent is required to successfully complete the C.E. quiz. If a passing score is not achieved, one free reexamination is permitted. Statements of credit for mail-in exams will be mailed to you approximately four weeks after the completed program quiz and evaluation has been received by NCPA.

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

- NCPA Member License
  - NCPA Member No. ____________________ State __________ No. ________________
- Nonmember State __________ No. _____________________

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

Last 4 digits of SSN  MM/DD of birth
Name
Pharmacy name
Address
City       State   ZIP
Phone number (store or home)
Store e-mail (if avail.)   Date quiz taken

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<th>Quiz: Circle your choice</th>
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<td>21. Is this program used to meet your mandatory C.E. requirements?</td>
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<td>a. yes  b. no</td>
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<td>22. Type of pharmacist: a. owner  b. manager  c. employee</td>
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<td>23. Age group: a. 21–30  b. 31–40  c. 41–50  d. 51–60  e. Over 60</td>
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<tr>
<td>24. Did this article achieve its stated objectives? a. yes  b. no</td>
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<tr>
<td>25. How much of this program can you apply in practice? a. all  b. some  c. very little  d. none</td>
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How long did it take you to complete both the reading and the quiz? ______ minutes

NCPA® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. NCPA has assigned two contact hours (0.2 CEU) of continuing education credit to this article. Eligibility to receive continuing education credit for this article expires three years from the month published.
A Physician as Landlord or Tenant: Legal Parameters

By Jeffrey S. Baird, Esq.

IN THE REAL WORLD, IT is common for businesses to have arrangements/relationships with other businesses (or persons) that are in the position to generate business. Unfortunately, pharmacists are not in the real world—they are in the health care world. The health care world is akin to Alice in Wonderland: what is up is down, what is down is up, and every day we go through the proverbial rabbit hole. A physician is a referral source to the pharmacy. Can a pharmacy lease space to or from the physician? Sure, but as is the case with everything else in health care, be careful: “the devil is in the details.”

The Medicare anti-kickback statute, 42 U.S.C. Sec. 1320a-7b(b), provides for criminal penalties for any person/entity that solicits, receives, offers or pays any remuneration to a person/entity to induce that person/entity to refer an individual for Medicare-covered items or services, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any Medicare-covered item or service, subject to certain specified exceptions. There are no technical loopholes to the anti-kickback statute. It is substance over form. If it looks like a duck, walks like a duck, and sounds like a duck, then it is a duck. There are a number of “safe harbors” to the anti-kickback statute, one of which is the “Space Rental” safe harbor. Among other requirements, there must be a written lease with a term of at least one year, the rent must be fixed one year in advance (it can be paid out monthly), and the rent must be fair market value.

If the pharmacy rents space from a referring physician, then the amount of the rent cannot be construed to be rewarding the physician for the referrals. The rent must be fixed one year in advance and it must be fair market value. The pharmacy cannot pay percentage rent because the amount of the rent will be affected by the number of referrals from the physician to the pharmacy. The rent cannot be greater than fair market value because the “excess rent” will be construed by the government to be rewarding the physician for his referrals. If the pharmacy rents space to a referring physician, then the amount of the rent cannot be construed to be rewarding the physician for the referrals. The rent must be fixed one year in advance and it must be fair market value. The rent cannot be less than fair market value because the “lesser rent” will be construed by the government to be a “sweetheart deal” for the physician. The below-fair market value rent will be construed as rewarding the physician for his referrals.

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use of bar-code technology, viewing scanned images of products and prescriptions by pharmacists, and other technology for verification in the production process will help catch errors in this step.

POINT-OF-SALE
Errors occur when a correctly filled prescription is dispensed to a patient for whom it is not intended. This can be avoided by consistent use of a second patient identifier at the point-of-sale. The person picking up the prescription should be asked to provide the patient’s address or date of birth. The technician should then check this against the information on the prescription receipt and vial. Reviewing each medication with the patient or caregiver at the point-of-sale provides the best final check. Implement a process for technicians to refer dispensing of high-alert medications to pharmacists at the point-of-sale. Use notations on bags for patients that may be new, have had major changes in medications or dosages, and other established internal protocols to direct technicians to refer the patient to the pharmacist for counseling. 

This article is from the Institute for Safe Medication Practices (ISMP). The reports described were received through the USP-ISMP Medication Errors Reporting Program. Errors, near misses, or hazardous conditions may be reported on the ISMP (www.ismp.org) website. ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.
M
ost New Year’s resolutions are made with the hope, despite past evidence, of improving one’s self. Losing weight, eating healthier, exercising more, and getting organized are a few that are sure to be on many lists. But here’s a resolution to keep that has the potential to help you, your profession, your business, your patients, and your community: personally communicate with your members of Congress.

That government is community pharmacy’s biggest business partner is a matter of record. Medicare Part D, implemented six years ago this month, covers about 30 percent of the prescriptions filled by the average independent pharmacy, according to the 2011 NCPA Digest, sponsored by Cardinal Health. Medicaid, the federal-state program, accounts for another 16 percent. Add in TRICARE, the Federal Employees Health Benefits Program, and 340B, and many independents find half of the prescriptions they fill are for government programs.

And who oversees federal programs? Who decides how much money they get; has a strong voice in their policies; and who can cut through red tape—or add to it—if they want? It is the 435 U.S. Representatives (all of whom are up for re-election in November) and 100 U.S. Senators (33 seats are up for grabs).

Citizens have more power than they realize, according to the Congressional Management Foundation, a nonpartisan, nonprofit 34-year-old think tank. “The most influential advocacy strategies for swaying an undecided member of Congress depend on personal communication from constituents,” said the Foundation after surveying more than 250 congressional staff, many of them senior managers. “Whether individuals make contact face-to-face, by phone, or through personalized email or postal mail, senators and representatives are influenced by their constituents’ own views about the public policy issues before them.” Here are some of the survey’s other findings:

• Constituent visits to the Washington office (97 percent) and the district/state office (94 percent) have “some or a lot of influence on an undecided member.” Nearly half (46 percent) said the visits had “a lot of positive influence.”

• Questions at a town hall meeting (87 percent) and letters to the editor (80 percent) have “some or a lot of influence.”

• “ Constituents who make the effort to personally communicate with their senators and representatives—except via fax—are more influential than lobbyists and news editors.”

There’s a great way to communicate personally with your members of Congress coming up in May—register for the 44th Annual NCPA Conference on National Legislation and Government Affairs. It will be held May 6–9 (Sunday to Wednesday) at the Hyatt Capitol Hill Hotel—and in the offices of your representatives and senators if you come.

More details, such as the all-star lineup of speakers and a registration link will be on our website soon. Also on our website is the Advocacy Center with all the information on our issues you’ll need for those personalized communications you’ve vowed to undertake this New Year.  

Michael F. Conlan is editor of America’s Pharmacist.