Since our industry launch in 2010, we have become the largest lender to independent pharmacies nationwide. We have committed almost Half a Billion Dollars to over 500 stores in 46 states and 2 U.S. territories.

Our primary goal is to provide financing to independent pharmacists to help their businesses thrive. Contact one of our Senior Loan Officers for more information.

Jimmy Neil
910.212.4951

Whitney Bouknight
910.798.1205

Mike Bollinger
910.212.4953

liveoakbank.com/pharmacy • 877.890.5867

©2014 Live Oak Banking Company. All rights reserved. Member FDIC
When you go from four locations to 20 in 10 years, it takes far more than computer software. QS/1 has been a very valuable strategic partner in Long’s expansion. Working together the various QS/1 products give us the information we need to make decisions for individual stores or all locations. QS/1 has made us more efficient and given us the ability to give our customers the attention they deserve.

“QS/1 is more than a vendor. They are a strategic partner.”

– Marshall Frost, PharmD

Learn how QS/1’s strategic solutions can help you, too. Call 866.234.6965 or visit www.qs1.com today.
INNOVATION IS HERE™

COMPLIANCETrack
powered by: PRS

One Program
One Source

Total Compliance—All Online.

Serving Pharmacy Since 1982

Selected the EXCLUSIVE Program for NCPA, Federation of Pharmacy Networks, 50+ Buying Groups & Wholesalers.
Which would your patients prefer?

**THIS SMELLS.**

**THIS DOESN’T.**

**NASACORT®. RIGHT ON SHELF. RIGHT NOW.**

Remind your patients to double check their medicine labels so they don’t double up on medicines that contain acetaminophen.

Acetaminophen is found in more than 600 different prescription and over-the-counter medicines, including many for cold and flu. It is safe and effective when used as directed, but taking more than directed is an overdose and can lead to liver damage.

Visit KnowYourDose.org to order free patient education materials to display and distribute in your pharmacy.

National Community Pharmacists Association is a founding member of the Acetaminophen Awareness Coalition.
**FEATURES**

**SPECIAL CONVENTION REVIEW**

**Here, Now, Around the Corner** .................................................. 20
*by Michael F. Conlan*
NCPA preps for the issues of today and tomorrow at Annual Convention.

**House of Delegates** ................................................................. 23
Elects leadership team, adopts policies.

**Leadership Team** ................................................................. 24
Your association leaders: meet the board of directors and officers.

**Award Winners** ................................................................. 26
Eight honored.

**University of Oklahoma at Tulsa Wins** .......................... 27
Student business plan competition.

**THIS MONTH’S cover FEATURE**

**Meet NCPA’s New President** .................................................. 28
John Sherrer, RPh, was enjoying a successful pharmacy career when it was interrupted by a major stroke in 2009. He remembers how his “entire life changed in the blink of an eye.” He was in the hospital for eight weeks, and spent two years in outpatient rehabilitation and therapy. Never one to give up or be easily deterred, Sherrer worked hard to get himself healthy again and it paid off. In October, Sherrer was sworn in as NCPA president, where he began his leadership path 14 years ago. In his presidential acceptance speech to the NCPA House of Delegates he said, “I stand before you as a survivor. I also stand before you as a stronger and more compassionate leader.”

**Special Thanks** ................................................................. 29
Convention sponsors.

**Pharmacy Quality Measures** .................................................. 32
*by Natalie Bari*
An FAQ explaining the use of benzodiazepine sedative hypnotic medications in the elderly.

**Mobile Health: It’s Simply Undeniable** .......................... 34
*by Bill G. Felkey*
And it can be a huge opportunity for your practice.

**Profit Pearls** ................................................................. 37
*by Charlie Hinton*
Middleport Family Health Center.
In a recent survey by Hammacher of independent pharmacy stores, 73% of pharmacists surveyed said their front-end business is either growing or holding steady. 

Are you a part of that 73%? Here is how we can help.

- Full line BOGO, at least 4x a year, with marketing support.

- FREE monthly full color consumer circular program.

- FREE consumer educational booklet, English and Spanish. PLUS coupon inside for customer appreciation.

- In/Out displays, with highly competitive retails to encourage front-end shopping. (100% return guaranteed)

- Private label community service loyalty-building programs.

- New and unique items, that can account for as much as 35% of category sales.

Call For Details: 1-800-327-6005  
E-Mail: Sales@masonvitamins.com  
Visit Us: www.masonvitamins.com
DEPARTMENTS

Up Front ................................................................. 8
by B. Douglas Hoey, Pharmacist, MBA
New year, same resolve to open all preferred networks.

Newswire ..............................................................10
NCPA gets congressional action on generic drug price spikes.

Adherence—It Only Takes A Minute ..................................14
by Bri Morris, PharmD
2015: The year to adhere.

Medication Safety ......................................................16
Evaluate safety of liquid dosing devices for patients.

Pharmacy Law ............................................................18
by Jeffrey S. Batirl, Esq.
Know the laws covering pharmacy-physician business relationships.

Continuing Education ..................................................39
by Nicole Van Hoey, PharmD, and Taifa Peaks, MS

Reader Resources .......................................................55
NCPA activities and our advertisers.

Front-End Overhaul .....................................................56
by Gabe Traban
Rack up the extra sale.

AMERICA’S PHARMACIST VOLUME 137, NO. 1 (ISSN 1093-5401, USPS 515-4190) is published monthly by the National Community Pharmacists Association, 100 Daingerfield Road, Alexandria, VA 22314, © 2015 NCPA. All rights reserved.

Ask Your Family Pharmacist®

POSTMASTER—Send address changes to: America’s Pharmacist, Circulation Dept., 100 Daingerfield Road, Alexandria, VA 22314, 703-683-8200; info@ncpanet.org. Periodical postage paid at Alexandria, VA, and other mailing offices. Printed in the USA.

FOR MEMBERSHIP INFORMATION, email ncpamembership@ncpanet.org. For other information go to www.ncpanet.org.

AMERICA’S PHARMACIST ONLINE
Read the dynamic edition of America’s Pharmacist and search its archive of past issues online or on mobile devices at www.americaspharmacist.net. “Go green” and decide not to receive a mailed copy of America’s Pharmacist. You’ll still have access to all the editorial content of the printed edition at your fingertips wherever you are.

The National Community Pharmacists Association (NCPA®) represents the interests of America’s community pharmacists, including the owners of nearly 23,000 independent community pharmacies. Together they represent an $88.8 billion health care marketplace, dispense nearly 40% of all retail prescriptions, and employ more than 300,000 individuals, including over 62,000 pharmacists. To learn more, go to www.ncpanet.org, visit Facebook, or follow NCPA on Twitter.

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


www.americaspharmacist.net

AMERICA’S PHARMACIST®
Certified Sourcing

America’s Pharmacist is printed on paper that meets the SF standards for Certified Sourcing.
Now that the 2015 Medicare Part D plans are in effect, I hope that you aren’t having too many of those beginning-of-the-year glitches. (If you are, contact us. We’ll do our best to help.) This plan year more independent pharmacies and regional chains are being allowed to participate in preferred networks. While more progress is needed, the regulatory and political impact of community pharmacy’s coordinated efforts has paid off. More patients will be able to go to the pharmacy of their choice without financial penalty in 2015 than in 2014. (If this isn’t working as advertised, please let us know.)

The battle to allow any willing pharmacy to participate at the same terms and conditions has been going on for several years. NCPA has had multiple meetings with the Centers for Medicare & Medicaid Services and countless interactions with members of Congress to express the concerns of NCPA members.

While progress has been made, it would be incredibly premature to proclaim “mission accomplished.” Several large Part D plans, including the biggest, the AARP MedicareRx plan insured through UnitedHealthcare, still continue to lock out independents and regional chain pharmacies from having the opportunity to participate in their preferred networks. NCPA will not rest until every community pharmacy at least has the opportunity to participate in all Medicare drug plans.

I want to say “thank you” to all of the groups in NCPA’s Any Willing Pharmacy Coalition that have coordinated with us to help unify the influence of community pharmacy. There truly is strength in having one coordinated voice. I also want to thank the hundreds of NCPA members and their patients who have contacted their members of Congress to let them know about the challenges that preferred networks have created.

I emphasize, though, that while some progress has been made for 2015, it could be taken away next year. Legislation is still needed to make sure that beneficiaries have the ability to get the same copay from any willing pharmacy that wishes to participate in a Medicare Part D plan preferred network.

In the last Congress, H.R. 4577, the Ensuring Seniors Access to Local Pharmacies Act, was introduced and garnered more than 80 cosponsors across the political spectrum and across the country. Unfortunately, time and circumstances worked against the bill and it died when the 113th Congress finally adjourned. The new Congress is in town this month, and we are working to get similar legislation introduced quickly.

While the job’s not done, community pharmacy stepped up with a unified and coordinated message—and we got results. With many new faces in Congress and long-time pharmacy champions defeated or retired, it is imperative for community pharmacists to reach out to their elected officials. NCPA members can make a compelling case on how community pharmacists improve health care quality and lower costs, if they get the opportunity.

Lawmakers will listen to you. But you have to seek them out.

Best,

B. Douglas Hoey, Pharmacist, MBA
NCPA Chief Executive Officer
Download “NCPA Mobile” Today!

Don’t be left out of the latest news affecting community pharmacy—download our new app, NCPA Mobile!

Receive real-time updates, join the conversation on Twitter with a built-in feed, and never miss out on breaking news affecting community pharmacy. Keep the app on your phone year-round for updates, news, alerts, and more from NCPA.

To get the free NCPA Mobile app:

**iPhone and iPad users**—search “NCPA Mobile” on the Apple App Store.

**Android users**—search “NCPA Mobile” on the Google Play Store.

**BlackBerry, Windows Phone, laptop users**—visit www.ncpanet.org/app

Or simply scan the QR code above.
When member reports of usually steep price increases for a number of common generic drugs moved from a trickle to a steady stream, NCPA knew it had to move from anecdote to action. NCPA CEO B. Douglas Hoey, Pharmacist, MBA, ordered up a member survey, and more than 1,100 pharmacists responded. Among the key findings:

- 77 percent said there had been 26 or more large upswings in acquisition prices in the past six months.
- 86 percent said it took the PBM or other third party payer between two and six months to update its reimbursement rate (but not retroactively).
- 84 percent said the acquisition price spike/lagging reimbursement trend is having a “very significant” impact on their ability to remain in business to continue serving patients.

Armed with this information, Hoey wrote key congressional committees asking for an oversight hearing. That request paid off with an investigation and a public hearing by the Senate subcommittee on primary health and aging. One pharmacy association was invited to testify: NCPA.

Pennsylvania pharmacy owner Robert Frankil, RPh, told Congress that steep generic drug price increases are “wreaking havoc on patients, pharmacists, and health care payers alike.”

Pennsylvania pharmacy owner Robert Frankil, RPh, told the panel in November that steep generic drug price increases “are wreaking havoc on patients, pharmacists, and health care payers alike. In addition, the associated payment lags on these medications are jeopardizing the abil—

"Lost' Copies Found Where the Auditor Left Them

“The final [audit] report showed that there were a dozen or so missing hard copies from the files. If the hard copies cannot be found, then the entire amount of the pay, including all refills, is deducted from the pharmacy payments. I personally handled the audit a few months earlier, and I did not recall any missing hard copies. I went back to the files and I found all of them exactly where they should have been. All the Rxs even had checks and notation marks that the auditor made. I challenged this, of course, and went through the process of copying the record and submitting them again. I essentially had to do double work because the auditor ‘lost’ his copies.

“Many pharmacies do not go through the final audit results and challenge the findings, because the process is so time consuming. How much money does this represent nationally that auditors steal from pharmacies?”

Email your recent example of a problem you or a patient has had with a PBM to mike.conlan@ncpanet.org, for use in Eye on PBMs. We may edit it for length and clarity.
NEW YEAR RESOLUTION #1: BUY THE DAILY PHARMACY PLANNING GUIDE. WATCH SALES SURGE.

Sharpen your competitive edge with the Daily Pharmacy Planning Guide to boost profits and manage a better business year-round. The Guide starts in December 2014 and takes you through January 2016. A must-have item for any pharmacy owner!

Each Month Includes:
✓ Ideas for seasonal end-caps, promotional signs, and gifts.
✓ Reminders to prepare for upcoming holidays.
✓ Inventory recommendations and tips for more efficient front-end management.
✓ Theme-month highlights and special marketing opportunities.
✓ And much more!

Perfect for any size pharmacy!

ORDER YOUR COPY TODAY!

NAME:

PHARMACY NAME:

NCPA MEMBER ID (REQUIRED FOR DISCOUNTS):

SHIPPING ADDRESS:

CITY     STATE   ZIP

EMAIL     PHONE #

Credit Card Payment
✓ American Express ✓ Discover ✓ MasterCard ✓ Visa

Number of Guides: ___________

CARD NUMBER     EXP. DATE     SEC. CODE

NAME ON CARD/PRINT:

SIGNATURE     TODAY’S DATE

$34.95 each (NCPA member price)
$69.95 each (non-member price)

To order, fax form back to 703-683-3619, call NCPA at 1-800-544-7447, or mail to: NCPA, 100 Daingerfield Road, Alexandria, VA 22314. Or visit www.ncpanet.org/bookstore.

Shipping charges and tax for VA residents will be added to the price noted on this form.

If you are not completely satisfied with your purchase, simply return it for a refund. All returns will be charged a 15% re-stocking fee. Unfortunately, we cannot refund shipping/handling fees.

Thank you for your order!
Cash Discount Cards – Hidden Fees & Release of PHI

Q: Is there a cost to the pharmacy and the patient when using a “free” discount card?

A: Millions of Americans are still without true prescription drug insurance and many of these people rely on “discount cards” that promise huge savings off retail prices. While it is often true that these cards may reduce the out-of-pocket price a patient pays at the pharmacy counter (compared to usual & customary), it comes at a great cost to both the pharmacy and patient.

Many discount cards charge the pharmacy a transaction fee (often hidden) that may range anywhere from just a few dollars up to $40 or more! In many cases these fees are charged to the pharmacy even if you reverse the claim.

Additionally, when patients present these cards to your pharmacy, they are authorizing you to release their protected health information (PHI) to the discount card company. What the discount card company does with the claims data is not totally clear; however, it is probable that they use this information to market directly to your patients. Many patients are unaware of this fact and have opted not to use these cards once they know that their privacy is compromised.

It is important to distinguish between discount cards that you may be contractually obligated to accept, like those agreed to under participation in a pharmacy services administrative organization contract (such as HealthMart, EPIC, Leader) versus those cards patients print off the Internet or receive in the mail.

PAAS National encourages you to be on the lookout for these cards and contact your PSAO to determine if you are required to accept them or not.

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

Continued from page 10

ity of small business pharmacies to remain viable and continue to provide critical medications and related care to patients."

The two lawmakers who launched an investigation into the increases, which found one antibiotic whose price shot up by 8,281 percent in six months, introduced legislation they hoped would end such upward spirals.

Subcommittee chairman Sen. Bernie Sanders (I-Vt.), and Rep. Elijah Cummings (D-Md.), sponsored the Medicaid Generic Drug Price Fairness Act, which would require generic drug manufacturers to provide a rebate to Medicaid if their prices increase faster than inflation. Brand-name manufacturers currently are under such a requirement. The bill is likely to be reintroduced in the new Congress.

PAAS National encourages you to be on the lookout for these cards and contact your PSAO to determine if you are required to accept them or not.

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

Continued on page 55
These workshops are specifically designed for pharmacists who want to own and manage their own pharmacy. More than 50 percent of past workshop participants now own their pharmacy. Register now at www.ncpanet.org/owregistration.
2015: The Year to Adhere

by Bri Morris, PharmD

As pharmacists, we know the value of medications. We know what happens when patients don’t take their medication the way it was intended. So, why not make addressing adherence your pharmacy’s New Year’s resolution for 2015? Here are a few, simple ways your pharmacy can help address adherence:

**CALL PATIENTS WHEN NEW PRESCRIPTIONS AREN’T PICKED UP**
You know the drill: Two prescriptions for Ms. Smith have been prescribed electronically, neither of which she has taken before. You fill the prescriptions, and then set the bottles on the counter in front of you so you can be sure to talk with her when she comes for pick-up. Fast forward one week: Ms. Smith’s bottles have been moved to will call and there is no sign of Ms. Smith.

Believe it or not, about one-third of all new prescriptions are never picked up for the first fill at the pharmacy. Save yourself the trouble of returning the prescription to stock and give Ms. Smith a call a couple days after the pharmacy has filled the scripts. She may not even know she has anything to pick up.

**COUNSEL PATIENTS ON NEW MEDICATIONS, THEN FOLLOW UP A FEW DAYS LATER**
Whether it is stomach cramps on metformin or fatigue on atenolol, you know what experiencing side effects can mean for a patient’s long-term treatment. Make a habit of calling patients to check in 3-5 days after starting a new medication. This would be a great activity for pharmacy students.

**TARGET YOUR HIGH RISK POPULATIONS**
Sure, medication adherence is important to all disease states, but for some chronic conditions, medication adherence is essential. Take time to talk with your diabetes, transplant, and AIDS patients about their care.

**IMPLEMENT A MEDICATION SYNCHRONIZATION PROGRAM**
Aligning all of a patient’s medications to be filled on the same day just makes sense. NCPA’s Simplify My Meds® is a turnkey adherence program that gives you all the training and resources needed to start a medication synchronization program in your pharmacy. Simplify My Meds is free to all NCPA members.

**MAKE YOURSELF AVAILABLE**
According to the NCPA’s 2013 National Report Card on Medication Adherence, a person’s personal connectedness with the pharmacist is the number one predictor of medication adherence. Enough said.

Most New Year’s resolutions are abandoned before the warm weather hits. However, addressing adherence is one resolution that will stick all year. Your pharmacy is dedicated to improving patients’ lives, and adherence helps you get them there. Now, if we could all have the same resolve for our personal resolutions....

Bri Morris, PharmD, is NCPA associate director, strategic initiatives.
Non-Adherence: (noun) : Not taking medications as prescribed

$290 billion COST IN AMERICA*

Non-adherent Behaviors**
1 in 2 missed a dose
1 in 3 forgot if they took the med
1 in 4 did not get refill on time
1 in 4 didn’t start a new Rx at all

2014 National Report Card on Adherence = B.**

Medication Synchronization (Med Sync):
All Of A Patient’s Medications Refilled At Once

DAY 1
Enrollment
Patient opts-in to program

DAY 20-23
Check-in call from pharmacy (make sure there are no Rx changes)

DAY 28-29
Rx Pick Up Reminder

DAY 30
Appointment Date
Rx Pick Up and option for appt with pharmacist

Benefits to patient
☐ Never run out of medication
☐ Single trip to the pharmacy each month
☐ Improved adherence
☐ Help managing prescriptions

74% say med sync is helpful in improving their overall adherence**

83% of those in a med sync program find it helpful in managing their prescriptions**

References:

Launch Your Own Medication Synchronization Program.
Get Started with Simplify My Meds® Today.
www.ncpanet.org/smm
Consumers often receive or purchase an oral syringe along with prescription and over-the-counter (OTC) liquid medications. Oral syringes provide greater accuracy when measuring liquids, so the Institute for Safe Medication Practices promotes their use, particularly when measuring doses for infants and children. But a recent incident illustrates an unintended consequence of using an oral syringe with a commonly available bottle adapter.

A child with supraventricular tachycardia was taking Tambocor (flecainide), which had been compounded by a local pharmacy. The pharmacy properly dispensed the drug in a prescription bottle with a child-resistant cap. To facilitate removal and measurement of the suspension, they dispensed it with an oral syringe and a screw-on type bottle adapter. After using the adapter and oral syringe to measure out a dose, the family did not remove the adapter from the medicine bottle and replace it with the child-resistant cap before storing it in the refrigerator. One evening, the family noticed the child coming up the stairs with a nearly empty bottle of the medicine in his hand. Apparently, the child went into the refrigerator to get a juice bottle but picked up the medicine bottle. He was able to access the suspension and drink most of it because the child-resistant cap was not on the bottle. The child was taken to a local hospital for treatment of the overdose, transferred to another hospital, and successfully treated.

This event should serve as a warning that, in the home, external bottle adapters must be removed and replaced with the safety cap after each dose is prepared. However, labeling on some commercially available oral syringes with adapters does not say anything about removing the adapter and recapping the bottle with the child-resistant cap for storage. For example, some oral syringes (such as EZY DOSE, store brands) are packaged with an adapter called a “DOSAGE-KORC” that can easily be removed by a child to gain access to the medication. A warning appears in small font to recap the medication to prevent product instability, but no warning regarding accidental poisoning can be seen on the packages. Also, this adapter does not allow the child-resistant cap to be replaced on the bottle unless it is removed. The removed adapter is also a choking hazard to children.

Each of the adapters has a hole in the middle to allow the bottle to be turned upside down to facilitate drawing the medication into an oral syringe. The screwed-on adapters may attract young children because they often look like the top of a sippy cup or sports bottle. While medication may not easily flow via gravity from all the different forms of adapters, they are not child-resistant tops and may be removed by children, thus gaining access to the medication. However, since most often bottles containing the medication are plastic, they may be able to be ‘squeezed,’ enabling children to obtain a stream of medication from the container.

Health care professionals should be aware of the oral dispensers they stock or dispense with liquid medications. Patients and caregivers must be educated on the safe use of these devices and to always re-secure the child-resistant cap after each use. Drug and device manufacturers, pharmacists, and others should distribute or dispense medications only with an oral syringe adapter that allows the bottle’s child-resistant cap to be replaced. Manufacturers of OTC single-ingredient acetaminophen infants’ products are already doing this. Their bottles include adapters which restrict the flow of medication if not used with the included oral syringes. Hopefully, the use of these adapters will expand.

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.
Introducing the Pharmacist eLink® Career Center powered by InPharmacyJobs

InPharmacyJobs is the most comprehensive listing of current positions available in pharmacy. If you are seeking a new pharmacist or technician, you can now post your job listing on InPharmacyJobs through Pharmacist eLink. Make sure your job is being seen by more than 40,000 registered users of Pharmacist eLink.

If you’re a job seeker, you can access hundreds of timely listings for FREE. Find your dream job—or your dream employee—today on Pharmacist eLink.
A physician is a referral source to the pharmacy. If a pharmacy pays money to a physician for services, or provides meals, gifts, and entertainment to a physician, or subsidizes a trip that the physician will take, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.

The Medicare anti-kickback statute states that a health care provider cannot provide anything of value to a person or entity in exchange for referring, or arranging for the referral of, patients covered by a government health care program. The payer and the payee are equally liable under the statute. Courts have enumerated the “one purpose” test, which states that if one purpose behind a payment to a referral source is intended to induce referrals, then the anti-kickback statute is violated notwithstanding that the primary purpose of the payment is to pay for legitimate services. Because the anti-kickback statute is so broad, the Office of Inspector General has published a number of “safe harbors.” A safe harbor is a hypothetical fact situation. If the arrangement falls within the fact situation, then the compensation paid does not violate the anti-kickback statute. A relevant safe harbor is the Personal Services and Management Contracts (PSMC) safe harbor. This safe harbor contains a number of requirements, including the following:

- The pharmacy and physician will enter into a written agreement with a term of at least one year.
- The pharmacy will pay the physician for legitimate services.
- The compensation will be set one year in advance (such as $6,000 over the next 12 months).
- The compensation will be the fair market value equivalent of the physician’s services.

The Stark physician self-referral statute states that if a physician has an ownership/compensation arrangement with a provider that furnishes “designated health services,” then the physician cannot refer patients, covered by Medicare or Medicaid, to the provider. A pharmacy falls within the definition of a provider that furnishes DHS. There are a number of exceptions to Stark. Two of the exceptions are the non-cash/non-cash equivalent expenditure exception, and the personal services exception. The non-cash/non-cash equivalent expenditure exception states that a provider can expend up to $380 per year on non-cash/non-cash equivalent items for a referring physician. Non-cash/non-cash equivalent items include meals, trips, conference fees, and concert tickets, to name several. Cash, gift cards, gift certificates, and similar “cash equivalent” items do not fall within this exception. The personal services exception is similar to the PSMC safe harbor.

Most states have their own versions of the Medicare anti-kickback statute. Some state anti-kickback statutes apply only if the payer is the state’s Medicaid program. Other state anti-kickback statutes apply regardless of the payer. Some states have physician self-referral statutes that are similar to Stark. Each state has a version of a medical practices act (MPA), which is a set of statutes that are specific to physicians. Many of the MPAs have physician-specific statutes that address “fee splitting,” “kickbacks,” “referral fees,” and “patient brokering.”

The pharmacy can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined value of all of these items do not exceed $380 in a 12-month period. For example, if a pharmacy wants a physician to accompany the pharmacist on a trip to a continuing education conference, then the pharmacy can safely subsidize up to $380 of the physician’s trip expenses. The amount of the trip subsidy will be...

▶ Continued on page 55
Pharmacist e-Link.
Stay on top of your pharmacy skills in today’s competitive marketplace. Get the edge you need to succeed. Pharmacist e-Link® delivers timely business information, tools, and resources to more than 40,000 pharmacists:

- Access to FREE CE courses
- Industry news & product updates
- Access to the RxWiki widget, a comprehensive search tool for medications, conditions, news, and video

FREE MEMBERSHIP.
AUSTIN

116th Annual Convention & Trade Exposition
NCPA preps for the issues of today and tomorrow at Annual Convention

by Michael F. Conlan
Photography by Michael DeFilippo

To reach the future, you have to get through today. When you do get there, you have to be ready. That was the dual purpose of more than 20 hours of continuing education, a trade show with more than 230 industry vendors, and the message delivered by NCPA leaders at the association’s Annual Convention and Trade Exposition.

“NCPA must focus its energies on issues that are ‘here and now,’” said CEO B. Douglas Hoey, Pharmacist, MBA, at the Second General Session. “However, NCPA also has a responsibility to help pharmacies plan for the future by helping them ‘see around the corner’ to anticipate what the future holds.

“The two are interdependent,” Hoey continued. “If we don’t work on the here and now issues, there won’t be a tomorrow. And, if there is no planning for what’s around the corner, we won’t be ready to act when tomorrow’s future becomes the new here and now.”

Meeting in Austin, some 3,000 pharmacists, future pharmacists, and supporters of community pharmacy convened to network, sharpen their clinical and business skills, elect leaders, and adopt policy positions for the 116-year-old association.

In his State of the Association remarks, Hoey predicted that the current PBM business model is ending and PBMs’ “next target is controlling the specialty pharmacy marketplace and perhaps high-dollar compounds as well.” To prevent PBMs from shutting community pharmacy out of the specialty market, which in two years is projected to top $100 billion in prescription sales, Hoey declared, “There must be a universal, enforceable definition of what a specialty pharmaceutical is that pharmacists and payers agree to, and not what a PBM unilaterally decides. We must be willing to document our services. We must also be willing to participate in developing pharmacy networks that deliver the product, provide billing assistance, and capture the data.”
Outgoing president Mark Riley, PharmD, reminded the audience at the First General Session of some of partial policy successes such as the Centers for Medicare & Medicaid Services requiring Medicare Part D plans to have generic drug price updates at least weekly in 2016. He also pledged to continue to final victory.

“CMS now ‘gets it,’” Riley said. “They understand that we were and are right on several of the issues surrounding Medicare Part D. The board of directors made a commitment about four years ago to commit more resources to educating CMS on the issues, and our staff did a great job convincing them that what we had been saying was true. We will continue to work to bring about fairness in the Part D program and shine a light on the PBM practices that are a big part of the Part D problems.”

Riley was honored throughout the convention for his year of presidential service, but perhaps the biggest honor was establishing a scholarship at the University of Arkansas in his name. To endow it, $25,000 was needed. Within seven days, the contributions had hit $30,000.

Each General Session also had an awards segment (see page 26) and a keynote speaker. Guy Kawasaki, an author, entrepreneur, and former Apple “evangelist,” shared his tips on how to be more “enchanted” in your business and community. One piece of advice: be “bakers” focused on creating more opportunities rather than “eaters,” looking only at getting your share. His latest book is Enchantment: the Art of Changing Hearts, Minds, and Actions.

The second keynoter was Canadian musician Dave Carroll, literally an overnight YouTube sensation with his song and video “United Breaks Guitars.” Carroll talked about the power that social media can give just one person to share a story and connect with millions of people and the impact that has on how companies have to manage customer service expectations today.

The delegates also unanimously elected John T. Sherrer, RPh, as president for 2014–15, and Christian Tadrus, PharmD, to fill a vacancy as fifth vice president. The new chairman of the Board of Directors is DeAnn Mullins, RPh. For a full report on the NCPA leadership team, see pages 24 and 25.

The 2015 Annual Convention will be held at the Gaylord National Resort at National Harbor near Washington, D.C., Oct. 10–14.

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

To view a gallery of convention photos, visit NCPA’s Facebook page at www.facebook.com/commpharmacy
NCPA’s governing body, its House of Delegates, endorsed a leadership team for 2014–15, installed two new officers, and ratified five official policy resolutions on the final day of the 116th Annual Convention.

The delegates unanimously elected John T. Sherrer, RPh, of Marietta, Ga., as president, and Christian Tadrus, PharmD, of Moberly, Mo., as fifth vice president. Sherrer will also serve on the board of directors. The board’s new chairman is DeAnn Mullins, RPh, of Lynn Haven, Fla.

The resolutions the delegates approved state that NCPA will:

• Continue to support legislative and regulatory policies that would allow “any willing pharmacy” to participate in a Medicare Part D plan, including its preferred networks, if the pharmacy accepts the plan’s preferred cost-sharing terms and conditions.

• Oppose any decisions by third-party payers to unilaterally deny, restrict, or limit coverage for compounds that are prepared pursuant to the state-regulated practice of compounding.

• Support state and federal efforts to improve consumer access to naloxone for opioid drug overdoses and to advocate for the expanded role of the pharmacist in the wider distribution of naloxone under protocols approved by state pharmacy and medical boards.

• Engage in and support efforts that provide pharmacists with the authority (at the patient’s direction) to adjust a patient’s medication quantity or refill schedule, and to provide the patient with synchronization in order to improve adherence and manage a patient’s maintenance medication.

• Partner with the NCPA Foundation to centralize many of the resources and services available to aid community pharmacists in disaster/emergency preparedness, response, and recovery and identify strategic ways for independent community pharmacy owners to get “A-List” access to key decision makers before disaster strikes. In addition, NCPA will work in conjunction with the foundation to further support community pharmacists’ ability to prepare for and respond to natural disasters by centralizing resources available; facilitating access to key decision makers before disaster strikes; and providing them with the skills and knowledge needed to volunteer as first responders for disaster recovery and response initiatives.

“From patient choice of pharmacy to medication adherence to combating prescription drug abuse, these resolutions address some of the most pressing issues in community pharmacy today,” said NCPA CEO B. Douglas Hoey, Pharmacist, MBA. “We are grateful for the contributions and input of NCPA members leading up to and at the House of Delegates meeting. Member participation is vital for NCPA to continue as an active and effective representative for the community pharmacists it serves.”

To make it more convenient for increased participation, at next year’s convention the House of Delegates will meet Tuesday afternoon instead of Wednesday morning as has been the recent practice.
Running a business while at the same time volunteering for a national professional association requires passion and commitment—traits that NCPA’s 2014–15 leaders display in abundance. The board of directors and officers devote countless hours of their personal time to advancing NCPA’s founding mission: continuing 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 new leadership team, ratified by the House of Delegates Oct. 22, 2014 (pictured above), personify the spirit, determination, creativity, and dedication of independent community pharmacy today, and they passionately share a vision for its future.

All are small business health care providers. They know that independent community pharmacists must constantly innovate and take full advantage of their education, expertise, and technology to deliver the highest quality care, service, and outcomes to patients. They know that independent community pharmacists must use their business, management, and clinical skills not just to survive, but to thrive, in a constantly changing and challenging health care landscape. And they know NCPA must be there to help.

**BOARD OF DIRECTORS**

- **John T. Sherrer**, president, co-owns Kenmar Pharmacy in Marietta, Ga., and is a partner in three more 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. For more on the new president, see page 28.

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

- **DeAnn Mullins**, chairman, is a certified diabetes educator and owns Mullins Pharmacy, WeCare Wellness, and the WeCare Diabetes Education Program in Lynn Haven, Fla. She is a former member of the Florida Board of Pharmacy and graduated from...
Your Association Leaders: Meet the Board of Directors and Officers

Samford University’s McWhorter School of Pharmacy.

David Smith owns Means-Lauf Super Drug in Brookville, Pa. He graduated from the University of Pittsburgh School of Pharmacy.

Bill Osborn 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 is president of Wolkar Drug in Baxter Springs and co-owner of Four States Pharmacy in Gelena and Cherryvale Pharmacy in Cherryvale, all in Kansas. He graduated from the University of Kansas School of Pharmacy.

Michele Belcher co-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 co-owns five Chancy Drugs locations in south Georgia, including four retail and one closed-door pharmacy. He graduated from the University of Georgia College of Pharmacy.

Mark Riley, immediate past president, is executive vice president and CEO 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.

OFFICERS

Jeff Carson, first vice president, is part owner of Oakdell Pharmacy, which has five locations in San Antonio. He graduated from the University of Texas.

Lea Wolsoncroft, second vice president, owns KidsMeds Pharmacy in Birmingham, Ala. She graduated from Samford University’s McWhorter School of Pharmacy.

Jeff Harrell, third vice president, is co-owner of eight independent pharmacies in Washington state, consisting of six retail and two long-term care locations, three of which compound. He graduated from Washington State University.

Kristen Riddle, fourth vice president, is president and director of clinical services for U.S. Compounding Pharmacy, a PCAB™-accredited, compounding-only pharmacy located in Conway, Ark. She is also partner/owner in a community pharmacy – American Home Pharmacy.

Christian Tadrus, fifth vice president, is an owner of Sam’s Health Mart Pharmacies in central Missouri providing prescriptions, compounding, long-term care services, hearing aids, and durable medical equipment. Tadrus is the immediate past president of the Missouri Pharmacy Association, a certified asthma educator, and a leader in expanding the adoption of innovative pharmacist care models. He graduated from the St. Louis College of Pharmacy.
Eight major awards for outstanding contributions to independent pharmacy were presented at the 116th Annual NCPA Convention and Trade Exposition in Austin, Texas.

1. **Corporate Recognition Award**—Live Oak Bank
   Jimmy Neil (right), receives the Corporate Recognition Award on behalf of Live Oak Bank from Bradley J. Arthur, chairman of NCPA’s Board of Directors.

2. **John W. Dargavel Medal**—Hesterlee
   Edward Hesterlee (center), was honored with the John W. Dargavel Medal. He was presented with the award by Sharlea Leatherwood, NCPA Foundation president and past NCPA president, and Rex Catton of McKesson.

3. **National Preceptor of the Year Award**—Kreckel
   Peter Kreckel is presented with the National Preceptor of the Year Award by Sharlea Leatherwood, NCPA Foundation president and past NCPA president.

4. **Prescription Drug Safety Award**—Iannarone
   Frank Iannarone III (center), receives the Prescription Drug Safety Award from Mark Riley (left), 2013-14 NCPA president, and Michael Cullen of Purdue Pharma.

5. **Willard B. Simmons Independent Pharmacist of the Year**—Dunn
   Jack Dunn (center) receives the Willard B. Simmons Independent Pharmacist of the Year Award from Bradley J. Arthur, chairman of NCPA’s Board of Directors, and JoAnn Gaio of Upsher Smith Laboratories, Inc.

6. **Outstanding Adherence Practitioner**—Caldwell
   Max Caldwell, (right), receives the Outstanding Adherence Practitioner Award from Bradley J. Arthur, chairman of NCPA’s Board of Directors.

7. **NARD Ownership Award**—Bryant
   Barry Bryant (right) receives the NARD Ownership Award from Sharlea Leatherwood, NCPA Foundation president and past NCPA president.

8. **NCPA Lifetime Academic Achievement Award**—Hotchkiss
   Gene Hotchkiss (right), receives the NCPA Lifetime Academic Achievement Award from Mark Riley, 2013-14 NCPA president.
A team of pharmacy students from the University of Oklahoma at Tulsa College of Pharmacy was named the winner of the 11th annual Good Neighbor Pharmacy NCPA Pruitt-Schutte Student Business Plan Competition. A team from the University of Arkansas for Medical Sciences College of Pharmacy was runner-up, and a team representing the University of California, San Francisco School of Pharmacy finished as the second-runner up.

The three finalist teams made live presentations of their business plans before the competition judges and a large audience after receiving complimentary registration, travel and lodging. The results were announced at NCPA’s 116th Annual Convention and Trade Exposition in Austin, Texas.

The 2014 competition drew participants from 42 schools and colleges of pharmacy across the United States. The contest is named in honor of two great champions of independent community pharmacy, the late Neil Pruitt, Sr. and the late H. Joseph Schutte. The competition is supported by Good Neighbor Pharmacy, Pharmacists Mutual Companies, and the NCPA Foundation.

The University of Oklahoma at Tulsa College of Pharmacy team members were Latosha Zugelder, Lindsey Crane, and Lindsay Bebout. The team adviser is Katherine O’Neal and the dean is JoLaine Dragaulis. Their chapter received $3,000, and $3,000 was contributed to the school in the dean’s name to promote independent pharmacy. The team members, team advisor, and the dean will also receive complimentary registration, travel, and lodging to NCPA’s 2015 Multiple Locations Conference in St. Kitts.

The University of Arkansas for Medical Sciences College of Pharmacy chapter received received $2,000, and $2,000 was contributed to the school in the dean’s name to promote independent pharmacy.

The University of California, San Francisco School of Pharmacy chapter received $1,000, and $1,000 was contributed to the school in the dean’s name to promote independent pharmacy.
John T. Sherrer received his pharmacy degree from Mercer University Southern School of Pharmacy in Atlanta in 1977. Two years after graduation, he opened his first community pharmacy in Marietta, Ga. Since then, he has been an owner or partner in 14 other pharmacies. Currently, Sherrer and his wife own Kenmar and Poole’s Pharmacies located in Marietta, as well as the industrial and first aid supply company, First Aid of America.

Sherrer has been active in local and state pharmacy associations for more than 30 years. His affiliations with these associations have played a key role in shaping both Sherrer’s personal and professional life. He met his wife Sharon, also a pharmacist, at a Cobb County Pharmaceutical Association meeting.

“She was excited to have just received her pharmacy license the day before,” he recalls fondly, “I was excited just to get her phone number.”

Sherrer later joined the Georgia Pharmacists Association (GPhA), where he served on numerous boards and committees, as well as serving as president in 1988. Following that, he was appointed by two different governors to serve on the Georgia State Board of Pharmacy for 11 years, including a year as president. He currently is chairman of the Georgia Pharmacy Foundation, which serves as the philanthropic arm of GPhA and works to provide scholarship opportunities for pharmacy students.

Sherrer’s busy lifestyle and road to success encountered a setback in 2009 when he suffered a major stroke. He remembers how his “entire life changed in the blink of an eye.” He was in the hospital for eight weeks, and spent two years in outpatient rehabilitation and therapy. “This was a major life adjustment,” Sherrer says, “because I was used to helping others, but I found myself needing more help than ever before.”

Never one to give up or be easily deterred, Sherrer worked hard to get himself healthy again and it paid off. In October, Sherrer was sworn in as NCPA president, where he began the leadership path 14 years ago. In his presidential acceptance speech to the NCPA House of Delegates he said, “I stand before you as a survivor. I also stand before you as a stronger and more compassionate leader.” Sherrer knows that he has his work cut out for him, and he is looking forward to the upcoming year and tasks that lie ahead.

In his term as NCPA President, Sherrer would like to see NCPA continue to support state legislative initiatives to address fairness and standardization in MAC pricing methodologies. In addition, he believes that “pharmacists are uniquely qualified to have a major impact on medication adherence and to facilitate improved patient outcomes in medication therapy.” Sherrer also hopes to see progress on pharmacists gaining provider status, which would allow them to provide additional patient services if they are permitted under the law of the state where they practice, and to bill for them under Medicare Part B. “Successfully seizing this opportunity,” he says, “will have a positive impact on the future course of our profession.”

Sherrer believes the advancement of pharmacy as a profession “should be a concern for every pharmacist. Now more than ever before, it is imperative for pharmacists to be involved in pharmacy associations and to be advocates in the legislative process. It is our responsibility to educate our elected representatives concerning the issues affecting pharmacy. It is also important that we continue to support those that understand and promote our issues.”

Not only does Sherrer continue to be active in the pharmacy community, he also plays an active role in his local community. He serves on the board of directors for Kennestone Regional Hospital, as well as Good Samaritan of Cobb County. He is a member of First United Methodist Church of Marietta and enjoys spending time with his friends and family.

For John and Sharon, pharmacy is a family affair. Their daughter Lindsey manages First Aid of America and is the marketing director for Kenmar and Poole’s Pharmacies. Lindsey’s husband Mike Crooks is also a pharmacist. The Sherrer’s son, Thomas, is a 2015 PharmD candidate at Mercer University and will join the family business after graduation.
NCPA would like to thank the following companies and organizations for their generous support of the 116th NCPA Annual Convention and Trade Exposition and their continued support of independent community pharmacy.
Connect with NCPA Online!

facebook.com/commparmacy
@commparmacy
ncpanet.org/googleplus
linkedin.com/in/ncpanet
youtube.com/ncpavids
An FAQ Explaining the Use of Benzodiazepine Sedative Hypnotic Medications in the Elderly

by Natalie Bari

WHERE DOES THIS MEASURE FIT INTO THE OVERALL MEDICARE PART D STAR RATINGS?
This measure was endorsed by the Pharmacy Quality Alliance (PQA) in May 2014. But to date, it has not been adopted by the Medicare Part D Star Ratings program. The measure is often described as an extension of the PQA measure on the use of high-risk medications in the elderly (HRM), which was used in the calculation of the CMS 2015 Star Ratings using 2013 claims data. Both measures feature medications from the American Geriatrics Society’s Beers Criteria for potentially inappropriate medication use in older adults. The original HRM measure discussed the use of non-benzodiazepine sedative hypnotics, but it did not include benzodiazepines as they were listed as “avoid only for treatment of insomnia, agitation or delirium.” The additional measure was created to address the concern that an unintended consequence of the HRM measure would be increased use of benzodiazepines for the diagnoses (such as insomnia, agitation, delirium) that the Beers Criteria state should be avoided.

WHAT DOES THIS MEASURE ANALYZE?
This measure calculates the percent of patients 65 years of age and older who have received two or more prescription fills for any benzodiazepine sedative hypnotic for a cumulative period of more than 90 days. The benzodiazepine sedative hypnotic medications are defined to include estazolam,
temazepam, triazolam, flurazepam, and quazepam. A PQA pilot testing of the measure utilizing populations from Medicare Advantage Plans (MA-PD) and prescription drug plans (PDP) established baseline averages of 1.81 percent for the MA-PD populations and 1.14 percent for the PDP populations.

WHAT IMPACT CAN THIS HAVE ON MY PHARMACY?
Pharmacies have a stake in monitoring their performance against endorsed quality measures. By taking an early interest in this measure, pharmacies have time to develop a system to improve intervention strategy with patients, caregivers, and prescribers. If the time comes that the pharmacy is in a network that begins tracking this measure, the pharmacy will be in a good position to request preferred status or pay-for-performance incentives. Pharmacies can boost performance using medication review, recognizing cognitive impairment and counseling on good sleep hygiene and fall prevention.

WHAT IMPACT DOES THIS HAVE ON PATIENT SAFETY?
The use of benzodiazepine sedative hypnotic medications in the elderly is directly related to patient safety. Research has suggested that more than 25 percent of hospital ED visits are related to adverse drug events that occur in elderly patients. This measure is developed around the American Geriatrics Society’s Beers Criteria in an effort to combat this growing statistic. The Beers Criteria was developed to address the age-related physiological changes (such as decreased renal function, reduced muscle mass) that put elderly patients at an increased risk for drug-related adverse effects.

Retrospective studies revealed that benzodiazepine use may have caused up to 10 percent of drug-associated hospital admissions among the elderly, especially among patients who use them frequently over a prolonged period of time. The use of these drugs has been associated with intellectual and cognitive impairment, including diminished short-term recall and increased forgetfulness. These effects are often mistaken as part of the normal aging process or early onset dementia, but for many patients on benzodiazepine sedative hypnotics, cognitive function improves when these agents are discontinued. Benzodiazepines also contribute to psychomotor impairment, which increases the risk of falls and automobile accidents in elderly patients. Several studies have also revealed an increased incidence of hip fracture and recurrent falls among elderly patients using benzodiazepines chronically.

As such, the Beers Criteria recommends that for improved elderly patient safety all benzodiazepines be avoided for treatment of insomnia, agitation or delirium. This quality measure seeks to further improve elderly patient safety by dramatically decreasing the use of the benzodiazepine agents specifically labeled as sedative hypnotics.

WHAT CAN I DO TO IMPROVE PERFORMANCE?
Adopting this measure will help you improve patient safety in your pharmacy and prepare for its inclusion in quality measurement programs. You can manage it much in the same way you would manage the HRM measure, by analyzing your records to identify elderly patients who take these medications. Use your pharmacy software to develop reports of patients on these medications and analyze the frequency of their prescription fills. Utilize MTM services to evaluate patients’ use of these drugs and consult patients’ physicians when appropriate for therapy changes.

*See additional resources for more information.

Natalie Bari is a 2015 PharmD candidate at the University of Arkansas for Medical Sciences College of Pharmacy.

*Additional Resources:
- PQA Quality Connection bi-monthly briefing: PQA Endorses New Performance Measure...
- AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults: http://www.americangeriatrics.org/files/documents/beers/PrintableBeersPocketCard.pdf

Editor’s Note: This is another in a continuing series of articles covering treatment of various health issues and how they relate to the Medicare Part D Star Ratings program.
And it can be a huge opportunity for your practice

by Bill G. Felkey
My friend and colleague, Dr. Brent Fox, shared a terrific presentation he developed for a webinar to Veterans Administration health care providers on the topic of Mobile Health (a.k.a. mHealth). I decided to share some of the compelling data he collected and add my own perspectives in this article to help persuade you to take action on the incorporation of mobile strategies to your practice, both internally and externally. I have met so many technology-savvy pharmacists in my work with NCPA that it would be easy to put you in touch with people who are reaping benefits of these technologies. My goal is to give you a reason to start adopting mobile solutions if you are not already "all in" with the concept. Here we go.

GLOBAL REACH

First, let it sink in that there are 6.9 billion mobile device users globally. In other words, a huge percentage of the world’s population is connected in a way that could be used for your practice. So maybe you’re not going to provide medication therapy management services to Italians. If you live in a town big enough to have streetlights, have you noticed how many people are holding their ear to a mobile phone as they drive? Do you notice how every stoplight has people missing the green light because they’re checking information on their devices? Or how every restaurant is full of people sharing a meal while deleting spam from their inbox, instead of talking to each other?

I know I’m listing things that probably disturb you and in some states are illegal, but years ago, before all of this technology was available, a pharmacist attending one of my talks asked me a question about an elderly female patient who comes into his pharmacy every week and complains about something each time. I asked him if he had ever considered that sometimes we focus too much on how many times she comes into the pharmacy, and not enough on the reasons she keeps showing up. The very thing that annoys us about people and their technology use also represents an opportunity. It’s a HUGE opportunity that is sitting there waiting for you to use it for a great set of accomplishments.

QUESTIONS TO PONDER

Are you using mobile technology to support your practice? Have you ever called your family members who are wandering around the big box store somewhere after you got separated from them? Did you call them or text them? Are you using this technology with your staff in your practice? When you’re shopping personally for goods and services do you ever look up product and consumer review information? Do you promote this for your patients who patronize your practice as well? Do you ever remotely access your home computer or perhaps your car from your smartphone? Do you ever remotely access your pharmacy system from your smartphone? Have you ever looked at YouTube to tell you how to assemble something, or repair something, or maintain something? Have you ever told a patient that there is an excellent video available on YouTube to help them get the best results from the product they are purchasing from you? Have you recommended a mobile device application to a friend or family member because you think it’s so good and helpful? Have you done the same with a pharmacist colleague or a patient trying to cope with a new diagnosis?

You see, it’s all about people, data, and mobile technology coming together to support us and the patients under your care. Increasingly, this gives us the ability to apply this resource to furthering our health goals and desires in practice. Each category
Help pharmacists manage texting, and many powerful apps and programs that can benefit from it if they are motivated to figure out how to let this resource make them more efficient and effective. I’m not advocating letting your technology drive the process. I am asking that you step back, look at the problems and bottlenecks that are occurring in your practice, and see how technology can help.

**TEXT TACTICS**

Consider the simple text message. The 6.9 million mobile device subscribers mentioned previously use texting on their devices at an 81 percent level. Do you have patients who need to be doing self-care management behaviors? A text message can prompt taking medication, recording a vital sign, or measuring blood pressure, blood sugar, or asthma status. Appointment reminders can be sent to include refills by text. Texts can encourage participation in positive lifestyle changes such as diet, exercise, smoking cessation, or learning about a resource that can assist patients in being motivated to take positive action in their lives. Patients can also text back when they have accomplished a recommended behavior. There are many powerful apps and programs that help pharmacists manage texting, and many are free. Chances are that your younger employees are totally up to speed on this communication channel. If this sounds interesting, perhaps you can do a little brainstorming with them.

We don’t have to worry so much about the device part of this equation. Because the Internet is a common denominator for all devices now, we can package content in such a way that it reaches almost every end user. For example, most of the publishers of respected tertiary references for pharmacists have products that will work on every smartphone and tablet operating system. Their products bundle clinical references, calculators and converters, web resources, remote access to clinical data, and condition and practice specific apps. They can also capture images and clinical data to store or transmit to other stakeholders as needed. Have you noticed that you could take a smartphone on vacation and never miss that laptop you used to lug around with you on trips?

**CONNECTIVITY INCREASING**

Back in the 1990s when the Internet was really getting started, we used to worry about access. Studies are showing that mobile technology in the form of cell phones, tablets, and even laptops are now just as connected as wired desktop users.

Have you begun using mobile apps in place of traditional website access? My bank and investment company, pharmacy access, Amazon shopping, surfing on Craigslist, and bidding on eBay are all done with mobile apps. Many of these are big improvements on the website experience offered by each company. It is predicted that 81 billion downloads of mobile apps took place in 2014. Apple and Google Play currently offer 258 exercise-related apps and 240 apps relating to medication use. Increasingly, smartphones and smartphone sensors can help with a variety of outcome measurements and the recording of lifestyle change efforts. Several companies are offering health-focused smartphones for purchase.

**OPPORTUNITIES ABOUND**

Mobile health technologies need to be a part of your practice strategy for several reasons. These technologies end up being very personal and tunable to individual needs. Most of your staff, patients, and you either pick up a smartphone immediately or within 15 minutes of waking up every day. Does this sound like an opportunity? Most of these devices are carried by their users everywhere they go, all day long. Does this sound like an opportunity? These devices are almost always on and connected. Does this sound like an opportunity? Finally, whenever users have an impulse (either good or bad), they are available to help influence behavior change. I am ready to continue this conversation and you can reach me by email at felkebg@auburn.edu to send me comments or questions. Do you agree with my title? Are the opportunities for mobile health undeniable?

Bill G. Felkey is professor emeritus at Auburn University’s Harrison School of Pharmacy.
For more than 30 years, Steve Giroux has witnessed the evolution of the profession of community pharmacy. Giroux graduated from University at Buffalo School of Pharmacy in 1981. He began working as a staff pharmacist at independently owned Owl Drug Stores, before eventually leaving to start his own community pharmacy. In the summer of 1983, Giroux and his business partner opened Middleport Family Health Center in Middleport, N.Y., after buying out a low-volume store from a regional chain. Since that time, his business has continued to grow to the point where he is a whole or part owner of nine different locations throughout New York. In addition, he is a past NCPA president and has held a variety of positions in pharmacy organizations at both the local, state, and national level.

Despite overseeing his developing business and being heavily involved with various pharmacy organizations, Giroux is still able to regularly work as a pharmacist at his flagship store, Middleport Family Health Center. To him, patient care always comes first and was the reason that he pursued a career in pharmacy. Giroux has not run a successful business for the past 30 years by trying to maintain the status quo. Instead, he is constantly looking forward to new opportunities to improve patient care, his business model, and the profession of pharmacy.

Middleport Family Health Center is a full-service pharmacy serving nursing homes, assisted living centers, medical care facilities, and the community. It also provides compounding, immunizations, diabetes education, wellness programs, medication synchronization, and a large selection of front-end merchandise, among many other products and services. In recent years, Middleport Family Health has created an ASHP-accredited PGY1 community pharmacy residency program, and has taken part in NCPA’s Front-End Overhaul® program. Participating in innovative programs such as these has kept Giroux’s business successful while being on the forefront of community pharmacy care.

COMMUNITY PHARMACY RESIDENCY PROGRAM

During Giroux’s term as NCPA president in 2007-08, the American Pharmacist Association set forth its vision for all pharmacists to be post-graduate trained by 2020. At that time, roughly 90 percent of the residency programs were positioned in a pharmacy institution setting, and Giroux was motivated to expand opportunities for residencies in the community.

Soon, Middleport Family Health Center began the process of starting an accredited PGY1 community pharmacy residency program. The start-up of the program was made easier by his first resident, Giroux’s daughter, Rachel. She was a recent graduate from University of the Pacific and had showed a strong interest in refining her clinical and business skills in a community setting. There were some minor kinks in
Middleport Family Health Center is currently in its fifth year of the community pharmacy residency program and the program continues to grow. Two years ago, an additional resident was added to meet the increased demand for clinical pharmacy services. The residents increased the utilization of NCPA’s Simplify My Meds® program, made their immunization programs more robust, and took on a larger role in a diabetes education program. The residents began spending more time in physicians’ offices meeting face-to-face with some of the more challenging patients.

“One of the most exciting features of the residency program is its dynamic nature that changes with the goals and ambitions of each new pair of residents. The focus has shifted from diabetes education, to business management, to medication therapy management, and to medication reconciliation, all while providing a strong background in community pharmacy training. Additionally, the program is affiliated with nearby University at Buffalo, further leading to collaboration with other health care professionals and allowing for the achievement of a teaching certificate.

Giroux encourages all students with interest in community pharmacy to consider a residency with an independent pharmacy. It is a great opportunity and more programs are starting up around the country. Community pharmacy residency programs can help to open up some of the limitations within the profession, all while expanding the practice.

FRONT-END OVERHAUL

Two years ago, Giroux was evaluating his pharmacies and looking for areas to increase profitability. A key area that he identified was his front-end sales. The nine stores in which he has an ownership stake all have large front ends, with two stores measuring more than 7,000 square feet each. These stores have high foot traffic and a product mix that included many types of durable medical equipment, vitamins, and health and beauty products. Giroux and his staff have traditionally handled all of the front-end merchandising themselves, but he realized there was room for improvement.

Over the past two years, Giroux has worked with Trahan to overhaul three of his pharmacies, but the impact can be felt throughout all of his stores. In April 2014, Giroux opened Wurlitzer Family Pharmacy with his son, Zachary, as the business manager and his daughter, Rachel, as a pharmacist. Zachary, who has a degree in business from Roberts Wesleyan College, used a lot of the insight from the first three site evaluations when starting up the new store.

After the site evaluations, there have been increases in front-end sales and the customer feedback has been positive. However, for Steve and Zachary, the front-end overhaul is an ongoing process, which is constantly changing in order to maximize profits. Going forward with the improved merchandising, he hopes to continue to see change in the mindset and culture of all of his businesses’ employees. With three stores having undergone an evaluation, Giroux is hoping to eventually expand to all nine of his locations. When asked if there is anything that he would have done differently, he responds, “Yeah, I would have gotten started sooner.”

Charlie Hinton is a 2015 PharmD candidate at the University at Buffalo.
Maintaining Symptom Control and Quality of Life for Outpatients with Multiple Sclerosis: Treatment Update

by Nicole Van Hoey, PharmD; and Taifa Peaks, MS

Upon successful completion of this article, the pharmacist should be able to:
1. Discuss the neurologic and inflammatory processes of relapsing-remitting and progressive multiple sclerosis as they relate to signs and symptoms of disease exacerbations.
2. Describe the place in therapy of systemic corticosteroids and established and emerging disease-modifying therapies according to 2010 expert consensus guidelines.
3. Identify the most common adverse effects of disease-modifying therapies, and outline a plan to reduce these effects while maintaining treatment goals.
4. Evaluate treatment options for patients who wish to delay medication to control relapses (such as women with multiple sclerosis who are pregnant, nursing, or trying to conceive).
5. Design alternative, behavioral, and other non-drug interventions that can improve the quality of life in patients with relapsing-remitting multiple sclerosis.

Upon successful completion of this article, the pharmacy technician should be able to:
1. Discuss the neurologic and inflammatory processes of relapsing-remitting and progressive multiple sclerosis as they relate to signs and symptoms of disease exacerbations.
2. Identify the most common adverse effects of disease-modifying therapies.
3. Discuss alternative, behavioral, and other non-drug interventions that can improve the quality of life in patients with relapsing-remitting multiple sclerosis.

FREE ONLINE CE. To take advantage of free continuing pharmacy education (CPE) for this program, pharmacists and pharmacy technicians must achieve a passing score of 70% on the online continuing education quiz for the program. If a passing score is not achieved, one free reexamination is permitted. To take this test, go to www.pharmacisterlink.com and click on the CE tab. Click on the CE Center, which will take you to the online activities that are available. If you have not registered with Pharmacist eLink, you must do so before being able to access the CE Center. You will receive immediate online test results and credits will be posted to CPE Monitor within six weeks. To obtain your CPE Monitor e-Profile ID, please go to www.cpemonitor.com to register.
INTRODUCTION
Multiple sclerosis (MS) is the most common cause of neurologic disability in young adults in the United States today, and is the second-most common cause of disability in young adults. This neurodegenerative disorder involves immune and inflammatory components that contribute to progressive and chronic impairment of motor function and cognition. Despite the more than dozen medications approved for the most common form of MS, there remains no cure and insufficient efficacy in available treatment plans. Because MS does not increase mortality and only minimally lowers projected longevity, patients diagnosed with the disease often face multiple decades of chronic care, with inconsistent expectations about symptoms, progression, and treatment options. Current treatment goals are to reduce symptom impacts and maximize quality of life through well-rounded interventions and lifestyle adaptations. Pharmacists can become more active members of the health care team that cares for patients with MS by providing proactive medication counseling services, identifying appropriate assistance devices and behavioral improvements, and incorporating non-medication therapies into their patient interaction services.

CONTRIBUTING FACTORS AND EPIDEMIOLOGY

CAUSES AND RISKS
Like many autoimmune conditions, MS remains a chronic disease with no identifiable cause. However, multiple contributors to MS development have been identified. Genetics plays an important role, with two genes identified in 2007 by the International MS Genetic Consortium as indicators of likely MS onset. Approximately 15 percent of people with a first-degree relative who has MS are likely to receive a diagnosis; this is 20 percent greater than the likelihood in the general population. Genes alone are not enough to induce the onset of MS symptoms, however. Identical twins, for example, share only a 33 percent risk of both developing MS.

Along with family history, multiple environmental factors and behavioral choices contribute to MS development. Higher rates of MS are associated with latitudes further away from the equator, and people living in equatorial areas experience lower risk of onset. The geographic risk remains significant through puberty (15 years of age). That is, people who move to a latitude with lower MS risks before the age of 15 years will assume the new geographic risk. However, geographic clusters—in which a higher-than-expected prevalence of MS is observed in a single region—have been observed, which reflects the complicated overlapping causes and risks of the disease. These diagnostic clusters are monitored by the federal Agency for Toxic Substances and Disease Registry; cases of possible clusters can be referred to them at atsdric@cdc.gov or 888-422-8737.

Vitamin D plays an important disease-related role because it is associated with greater absorption of sunlight in equatorial regions, and as a stand-alone behavioral factor through supplemental vitamin intake, has recently been better clarified. Vitamin D is synthesized inside the body with sun exposure, and high vitamin D levels have been associated with less severe MS disability. In January 2014, a study of patients with MS quantified this association by correlating high blood vitamin D (≥50 nmol/L) with better five-year outcomes than in patients with vitamin D levels <50 nmol/L. High vitamin D levels appear protective for patients early in an MS diagnosis, and early treatment with vitamin D appears to delay progression of symptoms. Its use was associated with less CNS activity, slower progression of lesions, and development of lesion volumes, and less disability. A corollary, that low vitamin D could increase the risk of developing MS, is still unclear.

Smoking is one of the most significant behavioral effects on MS development and progression. Smoking appears to contribute to the onset of CNS damage in MS, and patients with diagnosed MS who smoke experience more MS attacks, faster rates of progression, and increased severity of attacks. Conversely, patients already diagnosed with MS experience slowed disease progression if they quit smoking at any time.

Infectious assault also might increase the risk of MS development. Epstein-Barr virus (EBV), the infection that causes mononucleosis, has been suggested as a link to MS onset, especially in patients who are infected by EBV and develop their immune responses to the virus in teen or adult ages. The connection with EBV does not appear direct but instead suggests that an immune response to the viral infection may trigger the immune system attack that develops into MS in susceptible people.

Numerous potential causes have been ruled out, including aspartame use, the presence of household pets, environmental allergies, exposure to heavy metals, and physical trauma. Connections among the existing risk factors remain poorly delineated, so identification of a single at-risk population is not possible for this challenging disease.

EPIDEMIOLOGY
Multiple sclerosis affects at least 300,000 Americans and more than 2 million individuals worldwide. Women are disproportionately affected; the most common form of MS occurs twice as often than in men. Disease onset occurs most often, in 70 percent of diagnoses, between the ages of 21 and 40 years, but anyone as young as 10 years and as old as 60 years can be diagnosed with the disease.

MS affects individuals of all ethnic backgrounds; however, MS is diagnosed more often in white populations, particularly those with Northern European ancestry, than in other ethnicities, regardless of other risk factors. Native
American and Asian populations across the globe have lower risks of MS, and diagnosis is quite rare in these groups. African Americans, though also at lower risk for development of MS, experience a more aggressive disease course when they are afflicted.

Geographic risks of MS are reflected in the epidemiologic patterns across the country. In the United States, there is a greater prevalence of multiple sclerosis in Northern states—such as Minnesota, Vermont, and Washington—than in Southern latitudes, such as Florida and Texas. This trend is also evident on a global scale: The rates of MS observed in countries such as Spain, Germany, and the United Kingdom significantly outnumber those seen in Kenya, Venezuela, or other nations with closer proximities to the equator. However, some areas of the globe appear unaffected by MS: Scandinavian and Alaskan Inuit populations experience extremely low rates of MS despite their Northern locations.

**MS DEVELOPMENT**

**Disease pathway**

Although the disease is variable both in diagnosis and progression, the mechanism of MS symptom onset is quite clear. The central nervous system, comprised of the brain, spinal cord, and optic nerve, is the only area of attack in MS development. Neural pathways within the central nervous system (CNS) are conducted within a myelin sheath, or protective covering around nerve cells, or axons. The fatty nature of the myelin sheath is responsible for the white matter’s appearance. These sheaths are essential for rapid neural transmissions that allow the CNS to control all parts of our body. Without them, the nerve signals slow or stop. The widespread damage caused by MS results initially and almost entirely from the destruction of this myelin.

The earliest myelin damage in MS is thought to result from autoimmune attack in the CNS. Typically, immune cells cannot cross the blood-brain barrier but instead patrol the peripheral nervous and other organ systems throughout the body. When they are able to enter the brain they are thought to inappropriately attack the white matter there. The resulting inflammatory response at the immune cell site then damages myelin and axons.

Adding insult to injury, as the neurons lose their myelin sheath, scar tissue builds in the damaged white matter. These plaques, or lesions, can be as small as a pin or...
as large as a golf ball. With continued demyelination, axons are destroyed and lose their ability to transmit information (called CNS gliosis because of the resulting scar tissue) and the cerebral cortex atrophies, causing irreversible physical and cognitive damage on top of the already-impaired functions from lesion damage.

Until recently, MS lesions were believed to occur only in the white matter myelin pathways, which could be directly linked to physical changes. Now, researchers believe that demyelination of grey matter also occurs and contributes to chronic impairments, particularly irreversible cognitive impairments of MS.

The location of an identified lesion in the white matter usually correlates well with physical changes of the disease, but the development of lesions throughout the CNS does not follow a predictable pattern of progression in individual patients or across the larger population. After diagnosis, symptoms can steadily worsen slowly or rapidly, or they can remain intermittent. Even intermittent attacks can range from mild to very debilitating.

**MS SUBTYPES**

MS can be divided into particular subtypes according to the CNS lesion, and corresponding physical symptom, patterns. Each subtype presents with its own symptom commonalities, progression and prognosis rates, and areas of greatest impairment.

**RELAPSING**

Most patients diagnosed with MS experience intermittent symptoms and periods of apparent health. This MS subtype, called relapsing-remitting MS, is the primary focus for research, treatment, and prevention of worsened disease. RRMS is the most common form of MS, documented in 85 percent of all diagnoses. Patients with RRMS experience the classical attack of symptoms that last days to weeks during acute inflammation in the CNS; after the attack, varying lengths of remission occur, as demyelinated lesions become inactive.

Identifying and treating patients with RRMS can be challenging because of the unpredictable symptom course. Recent research has shown, though, that CNS lesions develop in patients with RRMS even when they are in a period of so-called remission, without outward symptoms. Magnetic resonance imaging (MRI) of patients who appear to be in remission displays definite signs of inflammatory activity in the CNS. Symptoms may be not be present because the lesions are in areas of the brain that are not linked to physical movements or because the inflammation is low enough that patients do not perceive any change. In fact, clinicians estimate that only 10 percent of the active lesions in the CNS are perceived by the patients as “exacerbations,” or periods of relapse.

**PROGRESSIVE**

Patients with RRMS, without treatment, will eventually develop continually symptomatic disease, called secondary progressive MS (SPMS). Approximately 70 percent of all patients with RRMS eventually accumulate moderate disability and no longer experience times of remission; at this time, their disease is characterized as SPMS, and steady progression of disability occurs in place of acute relapses. Ongoing ambulatory impairment is especially common in SPMS and most often occurs after 10 to 30 years of living with the RRMS form.

In a small subset (15 percent) of patients with MS, progressive disease is present at diagnosis. Patients with this subtype, called primary progressive MS, or PPMS, are more likely to be diagnosed after the age of 40 years; incidence is similar in men and women. Patients with PPMS do not experience remission periods but have a slow and steady decline in function, as the CNS assault and clinical symptoms last for more than a year at a time. These patients more quickly develop chronic disability through impairment of motor functions and activities of daily living. PPMS is harder to identify on CNS imaging, because the inflammatory component appears to play a smaller role. Currently, almost no treatments exist to reduce or halt damage in patients with progressive MS.

**CLINICALLY ISOLATED SYNDROME**

In unusual instances, a single symptom, associated with a single inflammatory event in the CNS, may mimic MS, but without a second clinical or laboratory finding to confirm diagnosis of relapsing or progressive disease. When the symptom lasts for at least 24 hours and demyelination is documented, patients may be diagnosed with clinically isolated syndrome, or CIS. Patients with CIS should be monitored closely, because they are more likely to go on later to receive a diagnosis of MS, usually in its relapsing-remitting form.

**MS SYMPTOMS AND NATURAL COURSE**

MS symptoms are particularly challenging for patients, because they are often invisible to others. Patients can appear completely healthy while struggling with mobility, vision, and other aspects of daily tasks. Lingering effects between RRMS attacks are inconsistent and sometimes subtle. Symptom presentation usually relates clearly to the location of the active, or developing, plaque in the CNS. In RRMS, symptoms begin over a few days and can last for only days or for as long as weeks to months. Although attacks are highly individualized, the types of symptoms that occur in early disease do follow a broad pattern of presentation that can aid diagnosis.

**EARLY SYMPTOMS**

Initial symptoms of MS are often overlooked, because they disappear during remission. This pattern presents chal-
lenges to practitioners for diagnosis but also to patients who do not understand the ranges of symptoms that characterize MS onset.

Early symptoms that should prompt a pharmacist to encourage a patient to see a doctor are ocular symptoms and swallowing problems. Double vision, blurred vision, or pain behind the eyes can be the initial symptom that brings patients to an optometrist, ophthalmologist or primary care physician. Vision color disturbance and temporary blindness have been associated with initial MS lesions. Diagnosis may follow an ocular exam, MRI, and possibly a visual evoked potential examination. Bladder urgency and constipation may be early symptoms in young patients.

Persistent dizziness, limb or facial tingling, and muscle weakness in the hands or legs may develop. Stiffness in limb muscles can be extreme enough to affect walking or ability to stand. Half of patients with RRMS, during the natural progression of the disease, will experience ataxia. Balance and coordination are almost always impaired at some point in most patients, and clumsy and fatigue are commonly reported symptoms.

Heat intolerance is one classic symptom of MS at any stage. Overheating also is associated with worsening of other symptoms, including vision and balance. For patients who experience heat intolerance frequently, pharmacists can recommend cooling wraps or vests for immediate relief. Pharmacists can help patients identify clothing constructed from materials that wick sweat and help the body cool itself.

**LATER SYMPTOMS**

As relapses continue, damage accumulates and worsens the patient’s overall disability even during remissions. Bowel and bladder control issues become more frequent. Neurologic effects such as dizziness, balance disruption, hearing loss, problems with speech, chewing, and swallowing are common later in the disease course. Vision changes may continue as damage to the optic nerve progresses. Uhthoff’s syndrome is a sign of optic nerve demyelination in which vision begins to blur or dim when patients overheat due to weather or exercise.

Muscle weakness, tremor, and spasm may affect small or large portions of the body. Patients may report tingling and numbness in the limbs to facial pain and twitching. These contribute to problems with mobility, coordination and control of limb activity. These walking difficulties often require assistive devices and care by a physical therapist.

Fatigue remains a common and bothersome symptom during later relapsing and progressive disease forms. This subjective symptom may worsen in late afternoons and may be present regardless of other symptoms or attacks. It may worsen especially with heat or exertion. Some patients will experience constant low-level fatigue. Sleep disturbances, particularly insomnia and restless legs syndrome also become common as the disease progresses.

Cognitive impairments are more likely in later disease and are easily missed in physical evaluations. At least half of patients experience cognitive changes that include poor concentration and memory, lack of focus, and impaired judgment. Related cognitive symptoms include poor attention, reasoning, planning, and problem solving. These effects may be minor and infrequent at first and gradually become more noticeable to the patient others. Mood changes, especially depression, are quite common and are, associated with coping difficulties or as a symptom of MS itself. Depression, whether it existed before or after MS diagnosis and diagnosed alone or with anxiety, is itself associated with increased cognitive symptoms of MS. In addition, the overall MS population carries a higher risk of suicide, such that routine screening for suicidal ideation is suggested. When patients come to the pharmacy for MS medications, informal clues about their mental status can be an important observation between follow-up with their primary care physician and neurology specialists. Details about grooming, hygiene, ease of eye contact and conversation, and appropriate dress for the weather are indicators of larger mental status concerns.

A formal mental status evaluation, however, must only be conducted with permission of the patient—or it will be considered assault. A practical option for pharmacists who note disturbed mental affect during consultation is to refer the patient tactfully to a clinician for formal evaluation. For example, a member of the pharmacy staff may remark that a patient who has long worn a close-cropped haircut and been clean-shaven seems to be growing a beard and long hair. The pharmacist might ask about the patient’s change in appearance and listen for clues that he is indifferent to his appearance or has a physical barrier to usual grooming. These could be signs of depression, disease relapse or disease progression.

Patients with primary or secondary progressive disease who experience chronic mobility issues and movement disorders are most likely to require assistive devices that the pharmacy can provide. Patients can improve mobility and safety by being fitted for walkers or canes, and they can maintain independence by using a reacher, an elevated toilet seat, installing shower handles and using bath stools.

**TRIGGERS**

Despite the variety of symptoms and pathways, all types of MS share some triggers. Many patients report increased symptoms following exposure to heat or physical activity. Fever, hot baths, and sun exposure can initiate a relapse, and patients with MS may report heat intolerance as well.
Although exercise and movement play important roles in maintaining function in patients with MS, unstructured activity and overexertion can lead to increased symptoms in some patients. Infections, with or without fever, also may increase the immune and inflammatory responses that worsen CNS damage.

The symptoms of MS do not increase mortality or reduce longevity, but they do have sometimes severe impacts on patient quality of life. The focus in identifying and caring for patients with this chronic disease must involve prevention of disability and reduction of lesions to minimize symptoms. The ability to identify triggers is an important contributor to reducing relapse, with or without medication therapy, and patient-reported outcomes are a large part of disease evaluation. Patients can more easily identify their personal triggers by keeping a log or journal that associates symptoms of relapse with recorded activities, locations, and food intake on the attack days. Personalized electronic diaries can be especially useful; these tools can track symptoms and triggers as well as medication adherence and adverse effects. Specialized electronic tools are being studied in ongoing clinical trials, but mobile applications (“apps”) are also available to patients on a variety of web-enabled devices. A summary of apps for MS clinicians and patients is available on the Healthline.com website (http://www.healthline.com/health-slideshow/top-iphone-android-multiple-sclerosis-apps).

**DIAGNOSIS AND EVALUATION**

**CLINICAL EVALUATION AND TOOLS**

Diagnosing MS as early as possible is critical to establishing care—including medication therapy—that slows disease progression. However, no single tool, test, or clinical feature is yet able to definitively diagnose the condition. Even though sclerosis that is now MS was first described in the early 1800s, diagnosis today relies almost entirely on clinical evaluation, which takes into account patient history, a thorough physical evaluation, and neurologic testing. The irregularity of attack durations and frequencies, as well as the wide range of presenting symptoms, contributes to patient confusion and diagnostic delays. For example, disabilities like gait problems or poor bladder control develop during an acute relapse but can resolve almost entirely during periods of remission, making evaluation of these disappearing symptoms at a medical appointment more difficult. Often, when symptoms are recognized as a larger problem, diagnosis occurs only after elimination of overlapping conditions, including neoplasms, myelitis, small-vessel ischemia, and other challenging diseases.

When MS is suspected on the basis of persistent symptoms without a known cause, physicians have several evaluation methods available to confirm a suspected MS diagnosis. MRI with contrast is the scan of choice to visualize CNS lesions; active and past areas of inflammation appear as bright white and dark shadow areas, respectively. Contrast MRI is a safe, dye-free, and noninvasive method of visualizing MS lesions. The technique was first used in 1981 to identify plaques and, by 1988, confirmed the presence of active lesions in patients who did not exhibit symptoms. A baseline MRI at diagnosis also can be a useful comparator with later MRIs to document patient progression.

Additional tools to confirm a suspected diagnosis of MS include evoked potential and lumbar puncture testing. Evoked potentials measure the electrical response of nerves and physical movements to visual stimulation. Visual, auditory, and sensory (limb) tests are available, but only visual evoked potential (VEP) testing is considered for diagnosis because of its accuracy. In VEP testing, electrodes attached to the scalp record how fast a patient’s brain responds to visual checkerboard stimuli. Demyelination of MS slows conduction and increases reaction time to those stimuli. Evoked potentials are most often used when diagnosis is suspected but symptoms—especially early visual symptoms—are too subtle to be reported by the patient.

Lumbar puncture, or spinal tap, obtains cerebrospinal fluid (CSF) that can be analyzed for indicators of inflammation, such as abnormally high levels of immunoglobulins. These spinal taps can rule out infections or other immune disorders, but they are painful and invasive. Because they lack specificity for MS also, CSF measurements are infrequently used to confirm or evaluate an MS diagnosis.

**STANDARDIZED DIAGNOSTIC CRITERIA**

Diagnosis of MS requires dissemination of symptoms or lesions in time and space: at least two separate symptom flares (each persisting for at least 24 hours and separated by at least 30 days) and at least two different types of symptoms (reflecting different areas of CNS damage) must occur. Older criteria required at least two separate symptom flares and evidence of two separate CNS areas of attack (observed by different symptom patterns). In 2001 and 2005, the McDonald criteria incorporated MRI findings into the dissemination requires but complicated guidance. To simplify the diagnostic approach, the National MS Society Task Force in 2010 supported a revision of the McDonald criteria.

This most current guidance again requires two separate areas of damage in the CNS with symptoms separated by at least one month, but allows evidence of additional lesions on a single contrast MRI to contribute to diagnosis after the first attack. The revisions are intended to shorten the time to diagnosis and avoid treatment delays; for example, a patient with one attack but two lesions can be diagnosed with MS if an MRI shows that the lesions are disparate in space (brain location) or time (past versus active).
DISABILITY EVALUATION
After diagnosis, symptom impact can be measured with different assessment scales, including the clinically validated Kurtzke Expanded Disability Status Scale (EDSS). The EDSS quantitatively categorizes from 0 to 10 the degree of disability experienced by MS patients. A score of 0 indicates a normal neurological exam and corresponding normal functional capabilities; a score of 10 indicates death associated with MS impairments. The EDSS reflects progression over the natural or treated course of the disease and allows health care providers to establish a symptom timeline. This scale is especially useful in quantifying the residual effects of MS damage, through evaluation during periods of remission.

MS TREATMENT OPTIONS
Corticosteroids
Until the 1990s, no treatments existed to stop the course of MS by slowing or preventing the occurrence of relapses. Instead, treatment was aimed exclusively at symptom control during an attack, to minimize symptoms only as they occurred. This approach primarily involved anti-inflammatory drugs, and corticosteroids were the mainstay selection for patients with RRMS flares. Corticosteroids can reduce inflammation quickly and can increase the speed of recovery time from an attack in RRMS. In patients who experience severe disease flares, though, the American Academy of Neurology recommends plasmapheresis, which quickly removes the immune cells causing the inflammatory assault, instead of traditional corticosteroid administration.

Intravenous methylprednisolone at a high bolus dose of 1,000 mg has been administered monthly for patients with primary or secondary progressive disease; however, corticosteroids generally have little effect in patients with progressive forms of MS because of the smaller inflammatory role in this disease subtype. The same bolus dose can be administered for 3-5 days at the first indication of a flare in RRMS to control symptoms before they worsen. The IV medication can be followed by an oral corticosteroid taper to avoid common adverse effects of high-dose steroid administration.

Methylprednisolone does not contribute to long-term disease control, but only briefly reduces the inflammatory response. In addition to this lack of long-term disease control, challenges of corticosteroid use include difficulty of administration and concerns about short- and long-term adverse effects. Immediate adverse effects associated with corticosteroid injections include bleeding and injection-site reactions; long-term risks of corticosteroid use include increased susceptibility to infection and higher rates of osteoporosis.

Today, methylprednisolone is less often used by physicians as monotherapy and is instead more common as adjunctive therapy in patients who experience relapse symptoms while receiving a first-line disease-modifying therapy (DMT). This combination treatment approach may shorten the relapse duration or reduce the symptom severity. Some clinical studies have demonstrated greater efficacy of additive bolus methylprednisolone at minimizing symptoms than the maintenance regimen alone, but the true benefits remain unclear.

Standard Disease-Modulating Therapies
In 1993, treatment for MS changed drastically, with the approval of the first agent to reduce or prevent relapse in RRMS, known as a disease-modulating or -modifying therapy (DMT). Approval of interferon (IFN) beta-1b (Betaseron) was followed closely by that of IFN beta-1a (Avonex, Rebif). IFN betas as a class minimize relapse duration, frequency, and severity by tempering the number of pro-inflammatory agents produced by the body; however, these DMTs do not cure or reverse MS.

Two of three IFN beta formulations are available as single-dose pre-filled syringes or autoinjectors for patient administration. The third is supplied as a syringe prefilled with diluent for a single-dose vial. Although they have similar names, the doses, schedules, and injection sites vary (Table 1). The standard formulations available for outpatient self-injection include IFN beta-1a 30 μg weekly as an intramuscular injection (Avonex); IFN beta-1a 22 μg or 44 μg as a subcutaneous injection (Rebif); and IFN beta-1b 0.25 mg (1 mL) as a subcutaneous injection administered every other day (Betaseron). Titration options are available for all three products. Although Avonex is most often initiated at the 30-μg weekly maintenance dose, it may also be tapered upward in 7.5-μg increments with the AVOSTARTGRIP titration kit. Similarly, maintenance Rebif doses of 22 μg or 44 μg may be initiated immediately or achieved after titration; the Rebif Rebidose titration kit provides a baseline dose of 8.8 μg, or 20 percent of the maintenance goal, for a four-week upward titration. Betaseron may be administered in increments of 0.0625 mg (0.25 mL) as a subcutaneous injection every other day, with increases every two weeks, until the target goal of 1 mL is achieved.

Unless there is evidence of leukopenia or abnormal liver function tests, dosages of IFNs do not require adjustment for hepatic or renal impairment. IFNs are in FDA pregnancy category C meaning that patients who are of reproductive age are advised to consult their physicians and together weigh the risks and benefits of using these medications. Unless pregnancy is impossible, even women who are not planning a pregnancy should have this conversation.

All three available IFN DMTs provide similar efficacy for relapse reduction compared with placebo in clinical studies, making them solid first-line options for treating RRMS. However, their injection-site administration method,
varying dosage frequencies, and sometimes bothersome adverse effects contribute to poor adherence.

Common adverse effects of IFN therapy include myalgia, headache, and flu-like symptoms. Allergic reactions, including shock, hives, and dyspnea, are possible with IFN use. Some patients receiving Avonex experience heightened depression and suicidal ideation. Patients who receive IFN therapy, including Avonex, must receive a copy of the product’s medication guide with each prescription and refill. The guide explains the best methods for administering the medication as well as the possible adverse effects that can occur with IFN use.

Avonex also has been associated with increased rates of hepatic injury and with exacerbations of cardiac symptoms in cardiovascular disease. When either INF beta-1a or beta-1b is prescribed, patients should undergo baseline and periodic (at one, three, six, nine, and 12 months) liver function tests, complete blood cell counts, and cardiac evaluations. After one year of treatment, period laboratory monitoring may be performed every six months.

Injection-site reactions account for more than 75 percent of patient-reported adverse events with IFNs. Patient training for appropriate injection technique is essential before an IFN product is dispensed. Sites of injection should vary each week, and areas of the skin that are red or bruised should not be selected as injection sites. Pain, bleeding, and edema have occurred at injection sites when patients inject subcutaneous formulations into the muscle or intramuscular formulations into the fatty layers of skin. Skin tissue necrosis may occur, though rarely, with subcutaneous injections. Patients must be able to distinguish between subcutaneous and intramuscular injection sites and must rotate injection sites to minimize local adverse effects and achieve appropriate drug dosages.

Along with physical injection-site reactions, anxiety associated with self-injection is commonplace. Injection anxiety is a real barrier to patient adherence, and the National MS Society offers a patient injection anxiety tool for clinicians (along with numerous other useful tools to assist practitioners with meeting patient needs) at http://www.nationalmssociety.org/For-Professionals/Clinical-Care/Resources-for-You-and-Your-Practice/Re-

<table>
<thead>
<tr>
<th>Table 1: Standard DMTs: IFN Formulations and Glatiramer Acetate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interferon beta-1a (Avonex)</strong></td>
</tr>
<tr>
<td><strong>Interferon beta-1a (Rebif)</strong></td>
</tr>
<tr>
<td><strong>Interferon beta-1b (Betaseron)</strong></td>
</tr>
<tr>
<td><strong>Glatiramer Acetate (Copaxone)</strong></td>
</tr>
<tr>
<td><strong>Doses available</strong></td>
</tr>
<tr>
<td>30 μg maintenance and 7.5 μg tapers</td>
</tr>
<tr>
<td>22 μg or 44 μg maintenance and 8.8 μg tapers</td>
</tr>
<tr>
<td>250 μg maintenance and quarter-dose tapers</td>
</tr>
<tr>
<td>20 mg and 40 mg maintenance options; NOT interchangeable</td>
</tr>
<tr>
<td><strong>Administration</strong></td>
</tr>
<tr>
<td>Intramuscular injection</td>
</tr>
<tr>
<td>Subcutaneous injection</td>
</tr>
<tr>
<td>Subcutaneous injection</td>
</tr>
<tr>
<td>Subcutaneous injection</td>
</tr>
<tr>
<td><strong>Dosing schedules</strong></td>
</tr>
<tr>
<td>Once weekly</td>
</tr>
<tr>
<td>Three times a week, at least 48 hours apart</td>
</tr>
<tr>
<td>Three times a week, at least 48 hours apart (estimated as every other day)</td>
</tr>
<tr>
<td>Daily (20 mg) or three times a week (40 mg) according to patient preference</td>
</tr>
<tr>
<td><strong>Formulations for patient use</strong></td>
</tr>
<tr>
<td>Prefilled syringe and auto-titration prefilled kit</td>
</tr>
<tr>
<td>Prefilled syringe; Autoinjector</td>
</tr>
<tr>
<td>Single-use vial with prefilled diluent syringe</td>
</tr>
<tr>
<td>Prefilled syringes: white plunger (20 mg) and blue plunger (40 mg); must remain away from direct light and should remain refrigerated until 20 minutes before administration</td>
</tr>
<tr>
<td><strong>Common adverse effects or safety requirements</strong></td>
</tr>
<tr>
<td>Injection-site reactions, flu-like symptoms, Med Guide must be dispensed describing potential serious side effects of these medications including but not limited to: depression or suicidal ideation (particularly with Avonex); increased hepatic injury; risk to pregnancy, allergic reaction, seizure, blood problems (RBC, WBC, platelet) and exacerbated cardiovascular disease</td>
</tr>
<tr>
<td>Monitor LFTs, CBC, and cardiac function at initiation and periodically during treatment (ie, at 1, 3, 6, 9, and 12 months, and every 6 months thereafter)</td>
</tr>
<tr>
<td>Injection-site reactions, urticaria and difficulty breathing, flushing and chest pain</td>
</tr>
</tbody>
</table>
Glatiramer acetate is delivered only by injection, as a subcutaneous injection of either 20 mg/mL or 40 mg/mL from prefilled, single-dose syringes. The 20-mg/mL dosage has a white plunger and is injected daily; the 40-mg/mL formulation has a blue plunger and is injected three times per week. The syringe formulations cannot be interchanged and should be stored under refrigeration, between 36 degrees Fahrenheit and 46 degrees Fahrenheit (2 degrees Celsius and 8 degrees Celsius), both in the pharmacy and at home; all formulations should be kept away from direct light. The syringes should reach room temperature before administration. If refrigeration is not accessible, the syringes may be stored at room temperature, between 59 degrees F and 86 degrees F (15 degrees C and 30 degrees C), both in the pharmacy and at home; all formulations should be kept away from direct light. The syringes should reach room temperature before being injected by patients; to achieve the best injection-related adverse effects and anxiety. Rotation of injection sites at least once weekly reduces the risk of developing pain, redness, and swelling. Irreversible lipodystrophy and skin necrosis are rare but potential adverse injection-site reactions.

Some common adverse effects of glatiramer acetate are chest pain and flushing; urticaria and difficulty breathing also may occur. These symptoms can begin at any time during treatment but are most likely to occur at least one month after starting the medication. These symptoms typically resolve within 15 minutes, and they warrant professional medical attention if they persist for several weeks.

The decision to initiate therapy with an IFN versus with glatiramer acetate is individualized and involves an assessment of patient preferences about dosing frequencies, adverse effect risks, hepatic function, and concomitant drug therapies.

**NEW TREATMENT OPTIONS**

**MONOCLONAL ANTIBODIES**

Only in the 2000s did new drug approvals on MS treatments expand into monoclonal antibodies and other disease-modulating approaches. New additions to the MS arsenal include Tysabri, Gilenya, Aubagio, and more.

Monoclonal antibodies act against MS by modulating, or changing the actions, of the immune system. The first approved agent, natalizumab (Tysabri), works by minimizing immune cell movement across the blood brain barrier, thus blocking cell entry into the CNS. It is administered by IV injection monthly. Its efficacy is very high: the annualized relapse rate over 1-2 years is 68 percent, and natalizumab carries a significantly reduced risk of progression compared with IFN beta-1a at two years. It also reduces enhanced lesions on MRI by 92 percent, and it significantly increases quality of life as measured by the SF-36 survey, which evaluates health outcomes from a patient quality-of-life perspective. Natalizumab is indicated for patients who do not respond to IFN or glatiramer acetate. It remains second-line because of its risk for progressive multifocal leukoencephalopathy (PML), a sometimes fatal viral infection in the CNS. Symptoms of PML are similar to those of MS but do not remit; patients who receive natalizumab for more than two years are at greatest risk, as are those who have had prior immunosuppressive therapy. Other adverse effects are mild and infrequent; hypersensitivity is possible.

Recently, natalizumab has been considered as a stronger treatment option in patients with severe MS or with...
Fingolimod (Gilenya), approved in 2010, is the first oral virus before the drug is considered; patients with antibodies against JC virus have been infected with the virus in the past and therefore are at greater risk of developing PML with treatment.

Newer monoclonal antibodies in clinical trials for the treatment of MS are daclizumab (Zenapax) and alemtuzumab (Lemtrada). Alemtuzumab targets CD52 on B and T cells, and it was approved in 2013 in the EU and Canada but did not receive FDA approval for use in the United States. In some studies, alemtuzumab led to significantly lower numbers of lesions, whether new or enlarged, compared with IFN beta-1a and had less brain volume reduction after two years. Accumulated disability also was significantly reduced, and alemtuzumab appeared more effective than IFN beta-1a at reducing relapse rates in some clinical trials.

However, alemtuzumab is associated with serious infections, occurring in two-thirds of all treated patients, and with a high rate of infusion-related reactions, in which 90 percent of treated patients experience headache, rash, nausea, and fever; and additional serious adverse events. Immune thrombocytopenia occurred in 3 percent of patients, thyroid changes occur in nearly one-third of patients in studies, and possible delayed secondary autoimmune events have been noted.

Daclizumab is an anti-CD25 antibody that blocks CD25 expression on T cells to reduce inflammation. In clinical studies, daclizumab reduces relapse rate, MRI disease activity, and disability compared with placebo or with IFN beta treatment. In trials, daclizumab is being administered by subcutaneous injection once every four weeks. In patients who are refractory to IFN treatments, daclizumab has displayed improvements in EDSS scores and >75 percent reduction in the number of lesions. Monthly doses also are being studied in patients with secondary progressive disease, though results remain unclear. Daclizumab and other investigational monoclonal antibody agents, such as ocrelizumab, are promising future treatments for MS, but their approval and patient population base could be limited by their adverse effect profiles. For example, studies of ocrelizumab in patients with lupus or rheumatoid arthritis have been discontinued because of the severe adverse effect profile noted with its use, particularly the opportunistic infection rates.

**ORAL DISEASE-MODIFYING THERAPY**

In 2010, oral DMTs were introduced; these agents may increase adherence to and ease of chronic medication dosing in patients with RRMS.

Fingolimod (Gilenya), approved in 2010, is the first oral treatment for RRMS. It is a sphingosine-1-p receptor modulator that blocks autoimmune activity by inhibiting white blood cells from leaving the lymph, entering the circulation, and crossing the blood brain barrier. Fingolimod has been dosed at 0.5 mg, or 1.25 mg daily by mouth in phase 3 studies. At these doses, fingolimod reduces the annualized relapse rate approximately 60 percent versus placebo and improves MRI results, and it significantly reduces the annualized relapse rate at one year compared with IFN beta-1a treatment. Only the 0.5-mg dosage is approved in the United States.

Although most adverse effects of fingolimod are well tolerated, some screening and observation are required with administration. Mild side effects include headache, flu, dyspnea, nausea, and diarrhea. Lowered heart rate is possible within one hour after a dose; this effect is dose proportional and can result in clinical bradycardia or AV block. Patients should be observed at the infusion site for six hours after dosing. In addition, risk of infection is higher with fingolimod use because of its reductive effect on white blood cell entry into the circulation. In studies, two fatal cases of herpes infections (herpes zoster and herpes simplex encephalitis) occurred. In one death, the patient had a history of varicella zoster virus, resulting in a recommendation that patients should be screened for prior varicella zoster virus infection and receive a varicella zoster vaccination before first using fingolimod. Fingolimod might be linked to tumor activity, possible PML, and partial exacerbation of MS symptoms after use ends.

Additionally, the drug in pregnancy category C because animal studies show risk to fetus though there is no documented harm to human fetus. Patients who are considering fingolimod must stop taking the drug before any conception occurs. A large subpopulation of patients with MS is contraindicated for fingolimod use as well: patients with recent (six months) MI, TIA, angina, stroke, or heart failure, those on antiarrhythmia drugs, and possibly patients with T2DM all should not receive Gilenya therapy. Because of these serious adverse effect restrictions and contraindications, Gilenya should be reserved for a last-line treatment option. Patients who do receive fingolimod must undergo a baseline ECG, LFTs, CBC, eye exam, skin exam, and vaccination history.

Teriflunomide (Aubagio), approved in 2012 for RRMS at doses of 7.14 mg, inhibits peripheral B and T cells that lead to inflammation and reduces the movement of those cells into the CNS. Teriflunomide is administered by mouth once daily. It significantly reduces the annualized relapse rate and delays disability and improves MRI scans in patients compared with placebo at either dose, and it works well in patients who have received prior DMTs or who are treatment naive. Teriflunomide also provides significant benefits as an add-on therapy compared with standard DMT monotherapy. Adverse effects include nausea, diarrhea, increased ALTs, and hair thinning. There
Lymphopenia occurs. Be observed closely during DMF treatment, especially if patient taking DMF for psoriasis; patients with MS should be reduced by taking each dose with food. White blood cell counts can decrease during DMF use, so CBC should be measured at baseline and every six months to one year, or as needed more often. PML has been observed in a patient taking DMF for psoriasis; patients with MS should be observed closely during DMF treatment, especially if lymphopenia occurs.

DMF dosage recommendation is an initiation with seven days of 120 mg twice daily, then increased to 240 mg twice daily after seven days. Adverse effects associated with DMF are generally mild, such as flushing, pruritus, proteinuria, and gastrointestinal discomfort. Flushing may be reduced by taking each dose with food. White blood cell counts can decrease during DMF use, so CBC should be measured at baseline and every six months to one year, or as needed more often. PML has been observed in a patient taking DMF for psoriasis; patients with MS should be observed closely during DMF treatment, especially if lymphopenia occurs.

DMF has been explored for decades worldwide as a treatment for another autoimmune condition, psoriasis. In MS, DMF possibly acts by blocking inflammatory cell movement into the CNS by blocking white blood cells at receptor sites. DMF (Tecfidera) was approved by FDA in 2013 for the treatment of RRMS. DMF capsules taken twice daily are considered a first-line therapy alternative. Its efficacy is comparable to other DMTs, and DMF is especially effective at improving motor functioning. DMF also significantly increases quality of life and well being, as measured by the SF-36 survey. Overall, efficacy was significantly better than placebo at two years in clinical trials. Significant MRI improvement versus placebo have been observed with high doses, but relapse rate improvements were not always significant. Differences in benefits were not significant compared with glatiramer acetate.

DMF dosage recommendation is an initiation with seven days of 120 mg twice daily, then increased to 240 mg twice daily after seven days. Adverse effects associated with DMF are generally mild, such as flushing, pruritus, proteinuria, and gastrointestinal discomfort. Flushing may be reduced by taking each dose with food. White blood cell counts can decrease during DMF use, so CBC should be measured at baseline and every six months to one year, or as needed more often. PML has been observed in a patient taking DMF for psoriasis; patients with MS should be observed closely during DMF treatment, especially if lymphopenia occurs.

Dalfampridine (Ampyra), approved in 2010, is an amnopyridine that fills a useful role in patients with advanced RRMS or progressive disease: it is approved specifically to improve walking function and physical mobility in MS. Dalfampridine improves conduction of nerve signals in patients who experience ataxia. In clinical trials, after receiving dalfampridine, patients experienced significantly increased walking speed and leg strength compared with patients who received placebo. Dalfampridine oral tablets are taken twice daily approximately 12 hours apart. Tablets should be swallowed whole and patients should not double up or take extra doses if a dose is missed. Dalfampridine should be avoided in patients who have a history of seizure activity or who have impaired kidney function defined as creatinine clearance of less than 50 mL/min.

**OTHER PARENTERAL DRUGS**

Mitoxantrone (Novantrone) is use for patients with RRMS. It is also the only agent also indicated for patients with progressive disease. Mitoxantrone is administered by intravenous infusion over 5-15 minutes over three months. It is considered a last resort that is used for patients with rapid loss of function from the disease, because of its limited benefits and its black-box cardiotoxicity profile; it should not be used first line, even for patients with progressive or severe disease. Patients who are most likely to respond are those younger than 50 years old and without longstanding disability. Cardiac evaluation (such as left ventricular ejection fraction [LVEF] measurement) is recommended before administration and periodically if symptoms of congestive heart failure develop. Patients with LVEFs <50 percent or who reach a lifetime dose of 140 mg/m2 should not receive mitoxantrone.

The newest addition to the MS treatment arsenal, approved in Europe and in the United States in August 2014, is Plegridy, or peginterferon beta-1a. Pegylation of this IFN agent results in a longer half-life and less frequent injections. This formulation is administered subcutaneously in a 0.5-mL autoinjector pen and is dosed every two weeks. Its safety is well established, and its efficacy versus placebo at reducing relapse rate and EDSS disability is likewise well documented in clinical trial data.

Pharmacists may be approached by patients with MS about off-label or investigational treatment options, or about nondrug therapies. For example, drugs in the statin anti-hypercholesterolemia drug class have been considered off label for nerve protection in MS. Statins carry immunomodulating properties but also may be pro-inflammatory. When statins have been studied in MS, most evaluations showed no prevention of myelin sheath degeneration or plaque development and only minimal effects on brain shrinkage. Any consideration of these treatments should be discouraged. Likewise, no compelling efficacy...
Evidence from symptom measures or MRI scans supports the use of IVIG to treat any type of MS.

**SELECTING TREATMENT REGIMENS**

Today's DMT options are numerous and include the IFNs, GA, fingolimod, DMF, teriflunomide, and mitoxantrone; these are supplemented by the monoclonal antibodies and emerging therapies. DMTs have been a treatment mainstay for more than 20 years, because they reduce inflammation and regulate immune cells. After all of this time, though, there still are no consensus guidelines for starting or revising treatments, or for selecting the optimal starting course in a given patient.

DMTs are most effective in early RRMS. Traditionally, patients with MS who had little to no symptoms could logically opt to delay treatment. Because more recent research into brain lesions shows that CNS damage occurs even without outward symptoms, the argument exists to support early treatment in all diagnosed patients. The need to start treatment early must be individually balanced with the considerations of adverse effects, adherence rates associated with longer time on medications, and durability of an effective response. DMTs work best before disease progresses even to moderate disability, which can be irreversible if it remains untreated. Even patients with mild disease, when untreated, become disabled within 10 to 20 years. Today's approach is to evaluate patients after a first attack and then search the CNS for lesions on a contrast MRI. Treatment should be considered even if the first attack was potentially representative of clinically isolated syndrome. Patients should be re-evaluated at least every 6-12 months.

Treatment should be selected on the basis of the adverse effect profile, the administration route, and patient antibody profiles. Avonex or Copaxone are still considered the best first-line options in 2014 summary recomTable 2: Initial Doses for First Line Disease-Modifying Therapies access through UptoDate (http://www.uptodate.com/contents/treatment-of-relapsing-remitting-multiple-sclerosis-in-adults#H35). Initial therapy should be continued until the adverse effects become tolerable to the patient or until the disease fails to respond to therapy. Treatment adjustment for nonresponsive disease then can involve adjunct methylprednisolone or treatment switch to natalizumab or another second-line agent.

Early and sustained treatment slows the disease course and maintains higher quality of life. However, clear reasons to delay or interrupt treatment do exist, and nondrug treatment options are available in addition to medications.

**SPECIAL CONSIDERATIONS**

In a condition that persistently impairs physical and cognitive function without shortening life expectancy, maintaining a high quality of life is especially important to the patient. When prescription treatments cause undue adverse effects, are not adhered to during remission periods of apparent health, or must be avoided when risks outweigh benefits, pharmacists can guide patients through multiple nondrug options and behavioral modifications that minimize the impact of MS on daily living. Likewise, adding these quality-of-life efforts can improve patient functioning even while they receive prescription therapy.

Many clinical or personal situations may warrant treatment delay or interruption, either because risks for severe side effects outweigh potential benefits or because of patient preference or adherence concerns. For example, patients who wish to conceive, patients with early-stage MS who experience relapses infrequently and have few apparent symptoms, patients wary of any risk for side effects, and patients who are not willing to administer self-injections may present cases where treatment delay or interruption should be discussed with the patient.

Patients being treated for neuropsychiatric conditions might elect to avoid treatment with corticosteroids, because these drugs can aggravate mood, energy, and sleep levels. However, mitoxantrone, glatiramer acetate, and the IFNs have not been associated with altered affect or sleep disturbances, though the IFN products have medication guides that describe the specific risks for suicidal ideation.

Women with MS who are asymptomatic in early disease and are of childbearing age may consider delaying therapy, DMTs in general are not approved for use in pregnancy and are not recommended during nursing. Similarly, women with MS who are stable on a first-line drug may elect to interrupt treatment for a pregnancy. The natural progression of MS during pregnancy may factor into this decision: relapses are less frequent during trimesters 2 and 3, possibly because of increased maternal levels of immunosuppressants and corticosteroid levels. Pharmacists can counsel women that fertility is not altered by MS, that anesthesia during delivery is considered safe, and that rebound increases in relapse are possible after delivery, when natural corticosteroid production decreases. During pregnancy, pharmacists can reinforce safety in women with MS, who may experience aggravation of bladder problems and fatigue and who may require assistive devices to

**Table 2: Initial Doses for First Line Disease-Modifying Therapies**

- IFN beta-1a 30 mcg IM weekly
- IFN beta-1a 22 mcg or 44 mcg SQ three times weekly
- IFN beta-1b 0.25 mg/1 mL SQ every other day
- GA 20 mg SQ daily
- DMF 120 mg twice daily delayed release capsule for 1 week, then 240 mg twice daily by mouth
- Teriflunomide 7 mg or 14 mg tablet once daily by mouth

America's PHARMacist | January 2015
maintain mobility when balance and gait are affected by changing centers of gravity. Women who do experience acute relapses during pregnancy or nursing may safely receive methylprednisolone/prednisone treatment. Registries are available for physicians to report use of off-label DMTs and any associated fetal outcomes. Open registries include hotlines for Aubagio (1-800-745-4447, option 2), Gilenya (1-877-598-7237), and Tecfidera (1-800-456-2255).

Pharmacists should encourage patients without clinical reasons to avoid treatment to begin a first-line agent without delay after diagnosis, in most instances, because research shows that lesions are developing even when symptoms are not apparent. The importance of adherence to the injection schedule even during periods of remission should be emphasized as early as possible in these treatment decisions.

COPING SKILLS
Many patient advocacy organizations exist for MS to encourage primary research into disease mechanisms and treatments as well as to provide patients with answers about how to live well with the disease. The MS Association of America (http://www.mymsaa.org/) offers videos, brochures, and even children’s books that explain MS to patients and family. Their blog, MS Conversations, makes the history of and new research into MS accessible and understandable for patients and supporters.

In 1946, the National MS Society was established as a reputable source of information about coping with the disease. In addition to supporting standardized diagnostic criteria, the Society encourages the use of health journals and the involvement of a team of caregivers, including friends, family, and health care providers, to help the patient maintain independence and functionality. Nondrug therapy incorporates a range of health providers: speech therapists, occupational and physical therapists, ophthalmologists, and more.

The National MS Society also offers a navigator for patients, with a toll-free hotline, to connect people with a new MS diagnosis with a range of local practitioners to develop well-rounded, multifactorial treatment planning. Unfortunately, pharmacists are not listed in their collection of providers; however, pharmacists who are approached by patients with MS at the counseling window should actively involve themselves in the entirety of patient care and recommend the navigator when patients are in need of non-pharmaceutical care. Pharmacists can contribute beyond medication management by providing assistive devices, such as walkers, canes, and bath bars, to fit patient needs. They also can encourage routine and manageable exercise levels and avoidance of triggers as well as recommend adaptations at home that can reduce falls and encourage support groups for their patients.

Stress relief is particularly important to well being and avoidance of relapse that patients attempt many different approaches to relieve anxiety. Acupuncture, exercise, and specialty diets are just a few examples of these efforts. Acupuncture was evaluated in 1997 by the NIH for many symptoms commonly experienced by patients with MS (such as urinary control, depression, dizziness, pain, headache, and anxiety)—but not for MS itself. It is unclear whether acupuncture has an effect on the immune system contribution to MS disease progression.

Moderate levels of exercise have recognized physical and psychological benefits in MS. However, over-exertion can trigger symptom attacks, so patients should consult a physical or exercise therapist to determine their most appropriate exercise levels and durations.

Dietary changes are not recommended for patients

<table>
<thead>
<tr>
<th>Table 3: Pregnancy Risk Category of Drugs Indicated for Multiple Sclerosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy Category A</td>
</tr>
<tr>
<td>Glatiramer acetate (Copaxone)</td>
</tr>
<tr>
<td>Interferon beta-1a (Rebif)</td>
</tr>
<tr>
<td>Fingolimod (Gilenya)</td>
</tr>
</tbody>
</table>
with MS without oversight by a nutritionist or other health care provider. A well-balanced diet is essential for overall health and provides enough nutrients for patients with MS. Many people with the disease try to delay relapse by changing their diets or adding nutritional supplements. The Swank diet comprises lower daily saturated fat levels and higher polyunsaturated fat levels than typical diets; supplements like vitamin B12 and magnesium are used by some patients to reduce muscular symptoms of MS.

**COMPLEMENTARY MEDICINE**

Like diet and nutritional supplements, complementary medicine products aim to minimize disease effects without prescription therapy. Patients with any disorder may turn to complementary and alternative medicine (CAM) because they believe these treatments are more natural or safer than prescription therapies. Many CAM options are effective, but many others use impure products or carry unsafe side effects. Pharmacists must relate to patients the balance of safety and usefulness of CAM, especially in a condition that is as chronic and progressive as MS.

In 2013, American Academy of Neurology assessed the efficacy of many CAM products for MS symptoms, including gingko biloba, omega-3 fatty acid supplementation to a low-fat diet, lofepramine with phenylalanine and vitamin B12 (also known as the Cari Loder regimen), bee venom therapy, and cannabinoids.

Gingko biloba 120 mg taken twice a day was considered possibly effective for the reduction of fatigue but not effective for improving cognition. It did not cause excessive bleeding or any other significant adverse effects in patients with MS.

Omega-3 fatty acids found in fish oil or olive oil, when added to a low-fat diet, did not reduce symptoms, and the safety of this therapy was not reported. Similar conclusions were reached for lofepramine, an oral tricyclic antidepressant available throughout Europe and the United Kingdom, combined with phenylalanine and vitamin B12 as well as for bee venom therapy. If patients ask about bee venom therapy, pharmacists should counsel on the possibility of dangerous anaphylactic reactions associated with unknown (or known) allergy to bees.

The efficacy and safety of cannabinoids were reviewed by the academy on the basis of 11 studies. The safety and efficacy of smoked cannabinoids could not be established. However, oral formulations, such as cannabinoid extract and synthetic THC, were effective at reducing spasticity and pain for up to one year. An oromucosal spray formulation was classified as probably effective for reducing spasticity for up to six weeks and discomfort for up to 10 weeks. Regarding safety, the academy noted that cannabinoids can cause neurological problems, including disorientation; and gastrointestinal upset, such as nausea and vomiting. Cardiovascular and hematological changes, though rare, may develop.

**CONCLUSION**

Both relapsing-remitting and progressive MS challenge patients to maintain adherence to demanding, and sometimes ineffective, medications and to build ongoing self-care awareness for multiple decades while avoiding serious adverse effects and improving quality of life. Pharmacist guidance on drug interactions, emerging treatment options for all subtypes, and effective complementary and alternative medications substantially reduces symptoms and maintains independence for outpatients with this chronic condition.

Nicole Van Hoey, PharmD, is a freelance medical writer and editor in Arlington, Va. Taifa Peaks, MS, holistic nutrition, is a 2015 PharmD candidate at the Creighton University School of Pharmacy and Health Professions.
Continuing Education Quiz
Select the correct answer.

1. Pharmacists are already an integral part of the MS patient’s health care provider team and MS Navigator resources.
   a. True
   b. False

2. Which of the following are already identified as possible causes of MS?
   a. Puberty (age >15 years)
   b. Alcohol use (>3 times weekly)
   c. Genetic predisposition
   d. History of S. pneumoniae infection

3. Smoking is associated with which of these MS endpoints?
   a. Increased number of attacks
   b. Increased severity of attacks
   c. Faster rates of MS progression
   d. Two of the above
   e. All of the above

4. O.R.W., a 38-year-old African-American and a regular patient at your Georgia pharmacy, asks about risks of MS and places to live. He is moving to Maine and has a history of the disease on his maternal side. What facts can you share about his particular risks?
   a. His risk will be increased because of the new northern latitude.
   b. He should begin vitamin D immediately to reduce his risk.
   c. He has a lower risk of developing MS than people with the same genetic history but Asian or Native American ethnic backgrounds.
   d. His risk drops to almost nothing when he turns 41 years of age.

5. MS pathogenesis revolves around
   a. Myelin damage by immune cells in the peripheral nervous system
   b. Immune and inflammatory cell entry across a blood-brain barrier breach
   c. Axon damage that is always temporary
   d. Plaques in the CNS that are at least 4.5 cm diameter, roughly the size of a golf ball

6. Key features of RRMS include
   a. Flares, or attacks, that can last up to 24 hours
   b. Symptoms that are clearly reversible after flares end
   c. Active CNS inflammatory lesions during flares and past lesions associated with prior flares
   d. Active lesions that are always perceived by the patient as physical symptoms

7. Your 25-year-old patient, G.M., was recently diagnosed with RRMS. She worries about her risk of progression and fears using a wheelchair for the rest of her life. What statistics about the disease can you share to better inform her about her prognosis?
   a. Only 30 percent of patients with RRMS convert to progressive disease.
   b. Disability is rarely in ambulatory form.
   c. Conversion to progressive disease most often occurs after 10 to 30 years of living with RRMS.
   d. Many treatments exist for progressive disease, so a wheelchair is unlikely in her future.

8. G.M. is reassured but wants to know more about what symptoms she will experience in early disease. She has opted to wait to start disease modifying therapy because her diagnosis was made on the basis of dizziness and correlating MRI results. She received reading material and a follow-up appointment date in eight weeks. What symptoms do you describe to G.M. to watch for until her next appointment?
   a. Ocular symptoms, including blurring, double vision, pain, and color changes
   b. Fatigue, which patients report as symptoms but clinicians do not consider serious enough to monitor
   c. Heat sensitivity, which is more likely to develop after at least 10 years of living with MS
   d. Cognitive symptoms similar to Alzheimer’s disease, which can require full-time nursing assistance

9. Because symptoms are so variable, and because G.M. does not have another appointment soon, what are some behavioral techniques that you can suggest to improve her quality of life now?
   a. Daily diary use to note triggers and extent of symptoms
   b. Moderate exercise as often as possible without overdoing it
   c. Share information about MS—especially invisible symptoms—with friends and family for support
   d. All of the above
10. You also warn G.M. to especially note triggers such as ______ because it may worsen CNS damage
   a. Tanning booth use
   b. Snowy or icy weather
   c. Using a personal trainer for >one hour/day
   d. Viral infection with or without fever

11. The latest diagnostic criteria
   a. Recommend a single, gold standard test to identify MS quickly
   b. Were updated in 2014
   c. Guide diagnosis according to symptom dissemination across time and space
   d. Are called the revised Fowler criteria

12. After four months, G.M. begins disease-modifying therapy. Which pair of DMT agent and instructions is accurate?
   a. Rebif 44 μg; inject subcutaneously using the needle provided in the autoinjector or prefilled syringe three times a week.
   b. Copaxone 40 mg; remove prefilled syringe from refrigeration and immediately inject subcutaneously, once weekly.
   c. Copaxone 20 mg; remove prefilled syringe from refrigeration and immediately inject subcutaneously, three times per week.
   d. Betaseron 250 μg; reconstitute and inject 5 mL daily into the upper-outer arm.

13. Glatiramer acetate has which of the following?
   a. Greater efficacy than interferon beta-1b on all MS evaluation measures
   b. A long period of titration to avoid side effects
   c. An oral alternative formulation
   d. No liver function testing requirements

14. Mitoxantrone offers which of the following?
   a. The only approved treatment option for progressive disease
   b. The best option for patients older than 50 years of age
   c. No cardiac risks
   d. A first-line alternative when injection anxiety is high

15. Oral options for G.M. to consider when her injectable disease-modifying therapy begins to lose efficacy or adverse effects become intolerable are
   a. Fingolimod 14 mg by mouth daily
   b. Teriflunomide 14 mg by mouth daily
   c. Dalfampridine 150 mg by mouth twice daily
   d. Plegridy 125 mg by mouth daily

16. Which of the following is FALSE regarding disease-modifying therapy with dimethyl fumarate?
   a. Starting dose is 120 mg twice daily, then maintenance dose 240 mg twice daily.
   b. DMF is the only disease-modifying therapy in pregnancy class B.
   c. DMF may lower white blood cell count.
   d. Flushing caused by DMF is common and may decrease over time.
   e. None of the above are false.

17. Adverse effects associated with monoclonal antibody treatments include
   a. PML with natalizumab and possibly with DMF
   b. PML with all monoclonal antibody formulations
   c. PML regardless of JC virus antibody status
   d. Broad opportunistic infections

18. A literature review of 11 studies on the use of cannabinoids shows that they
   a. Can cause disorientation and GI upset
   b. Are commercially available as sublingual drop formulations
   c. Are clearly effective for treating CNS damage caused by MS
   d. Are clearly safe for use in patients with MS

19. A repeat visitor to your pharmacy approaches you with a question about using ginkgo supplements to treat her relapsing-remitting MS (RRMS). What can you advise about ginkgo for her?
   a. Ginkgo biloba has been associated with excessive bleeding when studied in patients with MS.
   b. Ginkgo supplements are considered very safe in patients with MS.
   c. Ginkgo is effective at reducing fatigue and improving cognition in patients with RRMS.
   d. Ginkgo biloba might reduce fatigue in some patients with MS at doses of 120 mg twice daily.

20. Assistive devices offered by pharmacists to improve quality of life and safety in patients with MS include
   a. Heating vests
   b. Compression stockings
   c. Reading glasses
   d. None of the above
co-insurance, meaning consumers will pay a percentage of the total cost of the drugs, most likely applicable to brand name products.

- Four tiers the norm—All Part D plans will have four or more tiers, a notable first since the inception of the Part D program in 2006.
- For the first time a specialty tier in all PDPs—Plans can only place a drug on the specialty tier if the total drug price negotiated between the plan and pharmacies exceeds $600 a month. Co-insurance will be limited to 25-33 percent, depending on the size of the deductible for a given plan. Unlike drugs placed on all other tiers, beneficiaries cannot appeal the cost sharing for drugs placed on the specialty tier.

MORE PBM TRANSPARENCY TO BE REQUIRED BY LABOR DEPARTMENT?

NCPA testimony to a federal advisory panel brought results when the panel recommended that greater transparency for pharmacy benefit managers be required in private health plans. The Department of Labor ERISA Advisory Council voted unanimously to urge the department to extend existing financial disclosure requirements to PBMs.

The council said PBMs should tell health plan sponsors about all forms of direct and indirect compensation received in association with providing services to each health plan. The council found that some forms of PBM compensation have the potential for creating conflicts of interest.

“We commend the ERISA Advisory Council on its action and we are also excited that U.S. Labor Secretary Thomas Perez has indicated his desire to ensure those long overdue changes are implemented,” said NCPA CEO B. Douglas Hoey, Pharmacist, MBA. Hoey noted that Perez echoed “many of the concerns expressed by NCPA. Secretary Perez said that it is important for plan sponsors to do a ‘deep dive’ on issues such as PBM compensation in order to ensure that beneficiary monies are not being ‘thrown away’ and that the plan is not leaving money ‘on the table’ that could be more wisely spent.”

NCPA was invited by the council to testify and offered specific recommendations.

“It’s clear from the testimony provided to the advisory council that payers of prescription drug plans require more data to ensure that PBMs are delivering on the value they promised,” Hoey concluded. “The council’s vote is a critical step toward ensuring that happens.”

PAYMENT FOR LEGITIMATE SERVICES

Additionally, the pharmacy can pay the physician for legitimate services. For example, if the pharmacy has a legitimate need for a medical director, then the pharmacy and physician can enter into a medical director agreement that complies with both the PSMC safe harbor to the Medicare anti-kickback statute and the personal services exception to Stark.

Another legitimate way for money to exchange hands between a pharmacy and a physician is for the physician to rent space to the pharmacy or vice versa. The rental agreement needs to comply with the space rental safe harbor to the Medicare anti-kickback statute and the space rental exception to Stark. Among other requirements, the parties must execute a written lease agreement that has a term of at least one year; the rent paid must be fixed one year in advance (such as $48,000 over the next 12 months); and the rent must be fair market value.

Jeffrey S. Baird, Esq. is chairman of the Health Care Group at Brown & Fortunato, P.C., a law firm based in Amarillo, Texas. He represents pharmacies, infusion companies, home medical equipment companies and other health care providers throughout the United States. Baird is board certified in health law by the Texas Board of Legal Specialization. He can be reached at (806) 345–6320 or jbaird@bf-law.com.
There are three types of purchases customers make: planned sales (“I need something for my cough”); companion sales (“I’ll pick up some facial tissue while I am here”); and impulse sales (“Oh, a flashlight for the car, I’ll grab one”).

With proper inventory and strategic pricing, harvesting planned sales is easy and needed to pay the bills. Companion and impulse sales are where the added revenue is waiting. Impulse sales flourish when combined with creative signage. Companion sales increase with creative and sometimes daring merchandising. I say “daring” for the reason that since the beginning of time, we have been told that racks and/or displays given or sold to us by manufacturers are the only way to display the manufacturer’s product and nothing else. That way of thinking would work if you were running a gift shop on a Carnival cruise ship or on top of a mountain in Vermont, but with today’s competition only a stone’s throw away, you have to fight for every sale, and every rack and/or display needs to entice every possible purchase.

Become a daring master merchandiser and use the displays you already have in your store to put more money in the register. Start with the greeting card racks. Yes, I know the greeting card company will not be happy, but – and this is where the daring part comes in – they would be even more unhappy if the racks looked empty or if lost revenue stopped you from paying your greeting card invoices.

When I worked for a pharmacy, we sold more 1-pound boxed candy out of our greeting card rack than we did on our candy end-cap during Valentine’s Day, Mother’s Day, and Christmas. The co-owner of Fairfax Pharmacy, Alana Hogle, has had great luck selling everything from calendars to children’s books out of greeting card racks. Community pharmacies from coast to coast have successfully dared to cross-merchandise things such as crayons, photo frames, framed art, gift bags, wrapping tissue, flat-pack gift wrap, local author’s books, maps, Easter candy, coloring books, and even candles next to birthday cards and stickers in greeting card racks.

**Tip:** It is better to place cross-merchandised items in one block of space in the greeting card rack than to scatter a sample of different types of product throughout the display. Give it a try – Valentine’s Day is coming soon.

Are you daring? Are you willing to be creative and try something new? Go ahead, rack up the extra sale – and send me pictures of your successes.

Gabe Trahan is NCPA’s senior director of store operations and marketing. Gabe uses 30 years of front-end merchandising experience to help NCPA members increase store traffic and improve profits. Visit www.ncpanet.org/feo to watch videos, read tips, and view two galleries of photo examples by Gabe. Follow him on Twitter @NCPAGabe for additional tips.
MARK YOUR CALENDAR | FEBRUARY 11–15, 2015

St. Kitts

NCPA MULTIPLE LOCATIONS PHARMACY CONFERENCE
Continuing Education, Networking, Exhibitors, and much more...
Marriott Hotel, St. Kitts | Check www.ncpanet.org for updates
GUARANTEE

If you are ever fined while following COMPLIANCETrack – PRS will pay the fine!

COMPLIANCETrack
powered by PRS

One Program
One Source

Total Compliance—All Online.

View our DEMO NOW!

www.prspharmacyServices.com/complianceTrack