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FEATURES

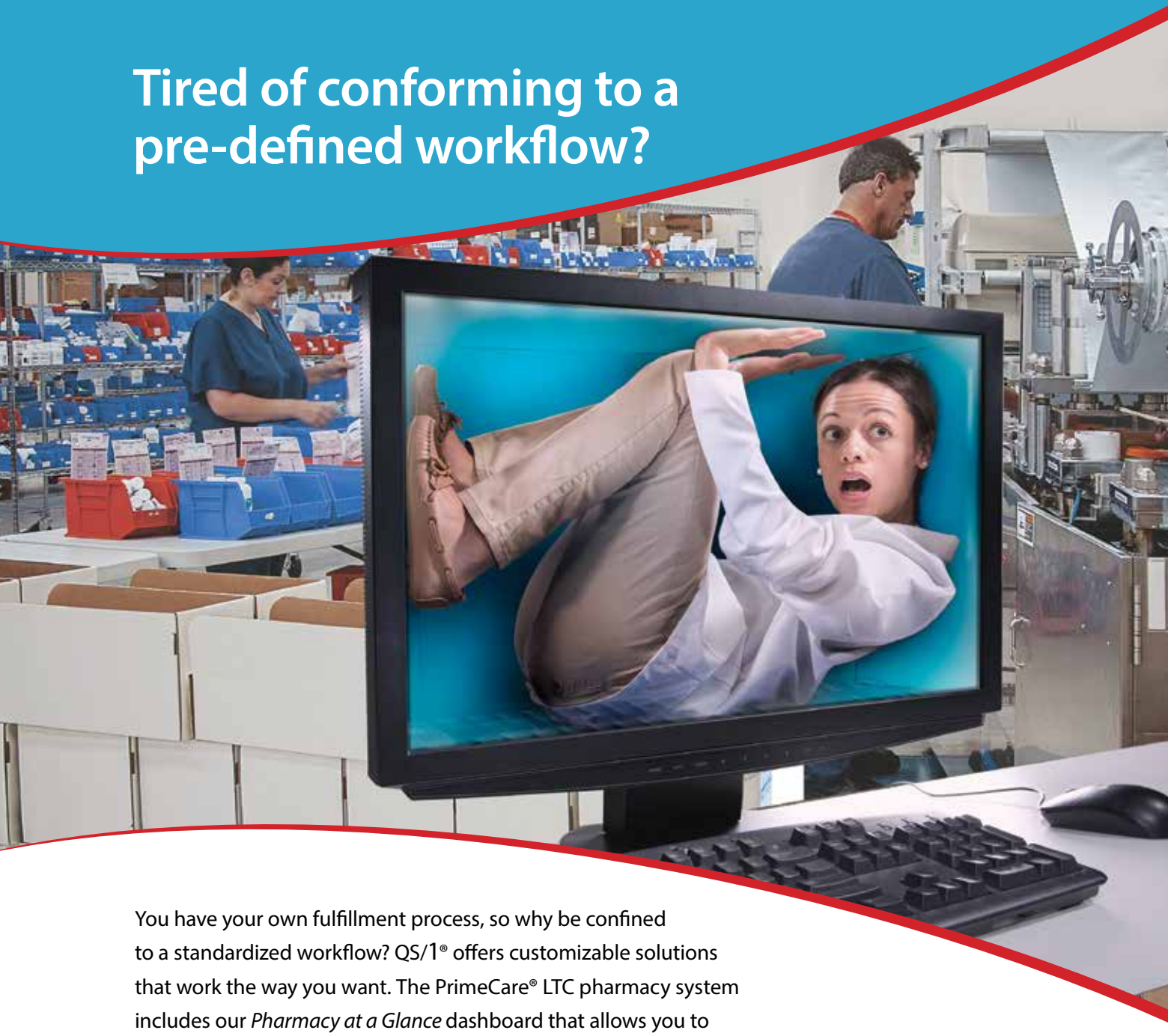
THIS MONTH'S *cover* FEATURE

Caption: Deciding to sell your pharmacy is one of the biggest decisions business owners will make in their career. The chain drug stores have dedicated teams offering themselves up as a solution.

If you ultimately make the decision to sell, there are often others who might be interested in buying your pharmacy. Maybe there's someone on your staff or maybe an employee stock option plan is a good alternative for you. Perhaps it's another independent in your town or county. A junior partnership is also a worthy choice. So tread carefully. Investigate your options to keep your legacy alive by keeping the independent business you built independent.

DEPARTMENTS

Tired of conforming to a pre-defined workflow?



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- The Hydration Pharmaceuticals Trust
- Xlear, Inc.
- RxSafe, LLC

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Ask Your Family Pharmacist®

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PBMs Always Claim to Save Money, But Someone Is Paying for Waste

Sometime last year, an older gentleman came into my pharmacy to discuss his treatment for Hepatitis C, and his experience often reminds me of what is wrong with certain aspects of our current delivery system. After receiving a prescription for the combination of the Solvadi plus Ribavirin protocol through a mail order specialty pharmacy utilized by the physician, the patient—not fully understanding what was involved—proceeded to take the Solvadi only.

This patient shared with me that during the entire course of treatment he did not receive a single telephone call to explain the therapy or follow up at any time to see if there were any side effects or questions associated with the treatment. Upon completion of the three-month course of therapy, the patient was informed that the system markers for the presence of Hepatitis C were unchanged, meaning that the therapy failed because he had not been properly managed.

The cost to the system was just under $88,000, and once discovered had to be re-instituted by a physician who reached out to us because we had the capability to ensure that this situation would not have occurred in our pharmacy.

Who ultimately is left to pay the cost of similar such examples? The patient whose life was disrupted because of the lack of care associated with his circumstances by the specialty mail order firm? Or perhaps also the system, which is determined to find what is the most appropriate manner to provide these much-needed medications?

In the big picture, this is another example of the anti-competitive effects of PBMs on the market—PBM ownership of mail order and specialty mail order pharmacies. This creates a situation in which the PBM draws up a plan design and establishes reimbursement rates for networks of retail pharmacies that are in direct competition with the mail order and specialty pharmacies owned by the PBM. And, of course, the PBM knows exactly what the reimbursement amounts are for all of the players in this equation.

So, not only do the PBMs incentivize beneficiaries to use PBM-owned mail order pharmacies, but they also may be motivated to switch patients to more costly medications on which the PBM receives additional rebate amounts from the manufacturer.

At a minimum, PBMs need stricter scrutiny when they are involved in federal prescription drug plans: Medicare Part D, Medicaid, the military's TRICARE program, and the Federal Employee Health Benefits Program. Congress should enact H.R. 244, a bipartisan bill that would require the same timely updates to MAC pricing lists in FEHBP and TRICARE as are now required in Part D, as NCPA had long advocated. Also, an any willing pharmacy law should be on the books. H.R. 793 and S. 1190 would allow any pharmacy located in a health professional shortage or medically underserved area to participate in any Part D preferred pharmacy network if they are willing to meet comparable terms and conditions. ■

At a minimum, PBMs need stricter scrutiny when they are involved in federal prescription drug plans.

Best,

Bradley J. Arthur, RPh
NCPA President 2015–16

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Consumer Ads by Rx Makers New Target on Capitol Hill

Along with congressional complaints about the high cost of drugs and lack of pricing transparency, direct-to-consumer (DTC) advertisements also are gaining the attention of lawmakers.

Sen. Al Franken (D-Minn.) has introduced legislation that would end tax breaks pharmaceutical manufacturers can take for advertising their medicines directly to consumers. Franken says his bill is designed to encourage companies to focus on developing new drugs instead of "marketing schemes."

DTC ads would be banned for the first three years a prescription drug is on the market, under a bill sponsored by Rep. Rosa DeLauro (D-Conn.). She said the moratorium would help fight the rising cost of prescription drugs and protect consumers from misleading information.

DTC ad spending soared more than 60 percent in the past four years, hitting $5.2 billion last year, reported STAT, a new digital publication affiliated with the *Boston Globe.* One-quarter of that spending went to just five drugs: Humira, Lyrica, Eliquis, Cialis, and Xeljanz.

Last year, the American Medical Association called for a total ban on drug ads directed at consumers. New Zealand is the only other country that permits them. ■

THE AUDIT ADVISOR

Affected by the ProAir HFA Shortage?

Q: I am unable to get a shipment of ProAir HFA from my wholesaler anytime soon. What are my options?

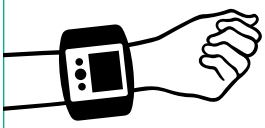
A: You have two options, both requiring you to talk to the prescriber to get a new prescription or authorization to change the drug dispensed.

Option 1: Change the patient to Ventolin HFA or Proventil HFA. These are not AB rated to ProAir HFA, so you would need to talk to the prescriber to make sure that they are fine with changing the prescription to either of these choices.
Option 2: Change the patient to ProAir Respiclick. Again, this is not AB rated to ProAir HFA and does require a new prescription or clinical documentation approving the change. The Respiclick is billed as 1 each and also contains 200 puffs like the HFA.

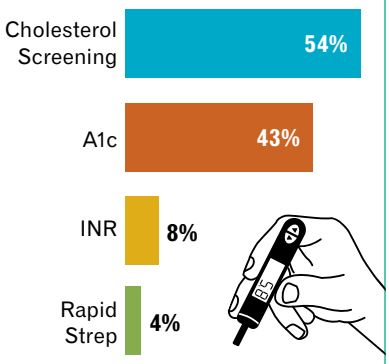
If you receive a new prescription for ProAir, without the designation of HFA or Respiclick, PAAS National recommends that you verify which form the prescriber intends for the patient.

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.

Independent Pharmacy Today



Point-of-Care Testing



Source: 2015 *NCPA Digest*, sponsored by Cardinal Health

ADVOCACY *ALERT*

- NCPA raised member concerns about **shutoffs of needed medications,** long-term care issues, and constructive transfer in recent sessions with Drug Enforcement Administration section chiefs.
- While progress is being made, there are still too many Part D plans that are outliers relating to access to preferred cost sharing and lower copays for beneficiaries, NCPA has told the Centers for Medicare & Medicaid Services (CMS). NCPA continues to encourage Medicare officials to implement an **any willing pharmacy** requirement and urge Congress to enact it legislatively, as H.R. 793 and S. 1190 would do.
- NCPA has urged CMS to thoroughly review the Part D bidding process and require more complete and accurate information related to preferred cost sharing pharmacies on its Plan Finder. In addition, preferred network **plans should incur a financial penalty** or other sanction if drugs are more expensive at preferred pharmacies after considering abusive direct and indirect remuneration fees (DIRs).

Are You Tracking LTC's Top Tech Trends for 2016?

by Bill G. Felkey

I know, I know, when some of you read my title above you can't help but ask, "Are long-term care facilities going to actually start having technology trends this year?" At a breakfast meeting with an LTC pharmacist friend recently, he hinted that he would be thrilled if the nurses in his facilities would learn how to use their fax machines properly.

Long-term care has traditionally come in last place of all health care sectors regarding the adoption of technology that would make operations more efficient and effective. This has been my personal and professional observation for the last 30 years. My mother is currently a resident in one of the lowest tech independent living facilities I have ever seen. When I call her staff office to ask how her blood pressure and sugar levels are trending, they tell me they will have to go and read them off of the paper taped to the refrigerator door in her apartment.

So you can imagine my surprise, during the last five years, when I spoke at two state Leading Age meetings in New York and Wisconsin and found that their exhibit halls each had approximately 10 LTC-specific electronic health record (EHR) vendors. Granted, I have visited six other LTC state meetings where less adoption was taking place, but the fact that owners and operators of these facilities wanted me to come and brief them on the technology they should be considering impressed me. The following are five health care trends that are impacting the LTC industry and creating pressure on the facilities you serve to get more connected. It is my hope that I will sensitize you to ways for you to use this momentum as an opportunity to improve your connectivity as well.

HEALTH SYSTEM CHANGE AND POPULATION HEALTH REQUIRE TIGHTER CONNECTIVITY

This major technology trend in 2016 is a wake-up call for both LTC and the pharmacy profession in all of its specialties. Health system pharmacists are the only ones who can rest easy within this first trend category because their practice venue is leading the way. If you attended one of my technology briefing sessions in the last several years, you have probably heard me give the warning that "if you are not at the table, you may be on the menu." LTC facilities are purchasing EHR products so they can send and receive patient-specific data when different levels of care are required for their residents.

Unfortunately, many pharmacy management systems for both community and LTC practice are not capable of processing data-sharing documents and industry-standard EHR records data without performing manual data entry. In LTC facilities, required minimum data set (MDS) information is still being collected on paper and then aggregated for manual electronic data entry. Similarly, pharmacies are routinely receiving and then printing faxes, only to have these data manually entered as well. Both of these environments experience data entry errors from this process.

LTC facility owner/operators tell me their main driver for purchasing EHRs (even without receiving any government support for these purchases) is to better manage the hand-offs between their care and acute care entities. Surveys report that 97 percent of U.S. hospitals have an operational EHR in place. Those that are preparing to offer population health are looking closely at everyone on their grassroots continuum of care to see how they

can connect and thrive with tightly connected and affiliated partners in this emerging environment. Will you and your practice be on this list?

CARE COORDINATION AND MONITORING USING MOBILE DEVICES AND APPS

Have you seen the statistic that 84 percent of U.S. physicians are using an iPad in their practices, with another 10 percent reporting they work on another similar device? I asked an audience of 700 pharmacists, from various types of practices, how many owned a smartphone. All but one person were installed users of this device. The LTC staff in the facilities that you support may not be as highly equipped, but they are probably close to having the infrastructure necessary for operating mobile apps that can support your information needs from these facilities.

Are you currently utilizing any mobile apps in your practice? Have you considered that only minor modifications of existing medication apps would be needed to turn one of the hundreds of these products into something that could improve facility communication within your operations? I have been writing on the need for a multidisciplinary app that would allow pharmacists, physicians, and nurses to better communicate and coordinate on the care of patients. The same app could aggregate monitoring data. The good news is that the interfaces that already exist in your pharmacy management system for collecting website information can be utilized to communicate to and from mobile devices using mobile apps.

QUALITY MEASURES GAINING IN EMPHASIS

The Centers for Medicare and Medicaid Services instituted a Nursing Home Compare public reporting site in 2008. All of health care is currently paying attention to these CMS star ratings. In LTC, 5-star ratings can be achieved through three domains of measurement: health inspections, staffing, and quality measures. Health inspectors record deficiencies and the number of revisits required to correct identified deficiencies. Staffing levels ascertain the numbers of registered nurses and licensed practical nurses ratios to residents. Quality measures utilized MDS reports from residents in two categories of long– and short-stay utilization.

Community pharmacists are using star ratings to increase emphasis on adherence and medication therapy management services. LTC pharma-

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▶ *Continued from page 11*

cists can use this increased quality measure emphasis to encourage facilities to adopt systems that can improve facility measures. Specific pain and antipsychotic medication implementation ratings could be the path to collaboration and cooperation.

RESIDENTS DEMANDING CONNECTIVITY FOR FAMILY AND PERSONAL INDEPENDENCE

In 2016, we can expect that new residents and their families will increase their expectations and demands for technology infrastructure to be present in LTC facilities. I recently learned that the facility my mother is using added Wi-Fi, but only to the common area near their front door. Residents frequently have their core family members spread out over several states and actual visits from their distant children and grandchildren can be infrequent.

Tech-savvy residents will also want to connect through the Internet to all of the online resources they took advantage of from their homes. The stages of LTC living should use these technologies to create a sense of personal independence desired by all of us. The same technology that allows these residents to connect can help with your LTC operational plans with staff members and your service provision to facilities. I recommend monitoring technology adoption (perhaps by creating a short survey) in the facilities that you serve.

THE CLOUD CAN MAKE TECH LESS CLOUDY

Don't forget about cloud storage supporting HIPAA protections that can assist you with data sharing between your pharmacy operations and your network of LTC facilities. Remember, HIPAA compliance in the cloud can not only allow you to work affiliations with your facilities, but can allow you to connect and interact with patients and their families directly once they have given you approval and access to their information.

As always, I welcome your comments and questions on this topic. You can reach me by email at felkebg@auburn.edu if you would like to continue the conversation. ■

Bill G. Felkey is professor emeritus at Auburn University's Harrison School of Pharmacy.

We Can Learn New Tricks

by Liz Tiefenthaler

It all started with a new website.

When Alan and Jane Lovich opened North Brunswick Pharmacy in 2000, pharmacy was a different business. Reimbursements were higher, competition was less, and the Internet, while growing in importance, was not a required part of a marketing plan. Alan Lovich recognized that he needed a website for a number of reasons. His New Jersey pharmacy attracts many of its new patients through word-of-mouth, and there was no place for these new patients to go to learn more about his pharmacy. Also, patients wanted to be able to refill prescriptions online.

Fast forward seven months, and not only had Lovich embraced his new website, but he has also started using social media, including advertising on Facebook.

"I wanted to find a new customer for my pharmacy," Lovich says. "I am tired of filling prescriptions at less than I can collect for them. It just doesn't make good sense from a business perspective. I wanted to attract an older demographic who would prefer to pay cash for their prescriptions." Lovich decided to target these patients by offering an Extended Supply Discount Program. Now, there are plenty of independents who provide similar incentives to their patients, but using this as a vehicle—in conjunction with social media—to attract new cash patients is a progressive way to market. In the first month, there were more than 600 visitors who clicked on his ad and went to the North Brunswick website. Lovich also combined doctor detailing with his Facebook advertising and is seeing new physician referrals coming in to his pharmacy. As a new and innovative marketer for his pharmacy, Lovich is proof that we can learn new tricks and should be open to trying something new.

As you look at your marketing plan for 2016, be willing to trying different avenues for reaching new patients. For example, if you have always used radio, maybe this is the time to take that money and try something new. Ryan Summers, who owns four pharmacies in Missouri, did just that. He has switched his marketing budget from radio and billboards to boosting ads on Facebook. Summers is able to measure his return on investment by the number of people who click on his ads and go to his website. "On Facebook, you can see clicks and comments. As pharmacists, we are trained to look for results, and I can see what I am paying for," he says. Summers uses Facebook to promote his Kid's Free Vitamins, compounding, and most recently, his $4/$10 program.

"I really like to use Facebook to promote not just new programs, but also our $4/10 list," Summers says. "When I did that, it went over really well. I wanted to let people know about a program that we have done from the very beginning. It is important to keep educating patients on current programs and remind them of offerings they may have heard about but have forgotten."

We can learn new tricks if we are open to change. Not all of it is guaranteed to be a success, but if you aren't willing to try different marketing tactics, then you are hurting your chances of finding new ways to grow your business. Lovich and Summers threw out preconceived ideas and are embracing new ways to market their pharmacies. We can all learn a lesson from them. ■

Liz Tiefenthaler is the president of Pharm Fresh Media, a full-service marketing company focused on helping independent pharmacies gain new customers and build loyalty with their current customers. She can be reached at liz@pharmfreshmedia.com.

Double Check Changed NDCs

Anytime a change is made to a prescription after it is entered into the pharmacy computer system, particularly if your workflow includes a verification of the order entry prior to the production phase, an independent check of the revised order entry against the original prescription should be conducted. If this is not done, you increase the risk that an error introduced with the change can reach a patient.

The Institute for Safe Medication Practices has received a number of reports describing events in which the wrong medication was dispensed after a technician or pharmacist changed a national drug code number after the original order entry and corresponding verification had been completed. The NDC number was changed to match a product selected from stock which, in each case, was the wrong product or dosage strength. For example, a pharmacist incorrectly retrieved morphine 30 mg instead of morphine extended release 30 mg, and changed the NDC in the computer system to that of the immediate release product. In another case, a pharmacy technician retrieved cyclobenzaprine 10 mg instead of 5 mg; the technician then changed the NDC in the computer system to the 10 mg product and relabeled the prescription. Each of the reports we received indicate that an independent check of the change in NDC was not conducted prior to the production phase. In each case, the wrong product was dispensed but the error was fortunately caught before the drug was administered to the patient.

Examine your processes for reviewing changes made after entering a prescription. If not already present, build in an independent double-check using the original prescription anytime a change is made to a prescription that has already undergone some sort of verification. This verification step should occur before the prescription can proceed to the next step in your pharmacy workflow.

RISKS WHEN COPYING OLD PRESCRIPTIONS

ISMP has received a number of reports describing dispensing errors that occurred when a patient's previous prescription was copied and edited in the pharmacy computer system. The latest example involves a patient with a new prescription for oxy**CODONE** 5 mg. A few months earlier, this same patient had received a prescription for oxy**CODONE** 30 mg. To expedite the dispensing process for the new prescription, the pharmacist chose to copy the previous oxy**CODONE** 30 mg prescription but failed to edit and select the correct dosage strength. The patient received oxy**CODONE** 30 mg and used this strength for a month. The pharmacy's analysis of the event found that the final prescription verification was conducted by the pharmacist immediately after he completed the order entry and filling of the prescription; this limited the effectiveness of the check process.

Care must be taken when copying and editing old prescriptions when entering a new prescription. Whenever possible, have a pharmacist not involved in the order entry and production of the prescription conduct the final verification. Pharmacy computer system vendors also have a role to play in preventing this error. When copying an old prescription, the computer system should not allow the user to proceed unless critical elements of the prescription, including drug name, drug strength, suffix, quantity, directions, and refills, are confirmed. This will result in more checks and may slow the process but is necessary to reduce the risk of medication errors. Even if your computer system can't incorporate this change, your manual process used to verify prescriptions should include these additional steps. Providing patient counseling and opening the bag of filled prescriptions at the point-of-sale to verify that the medications are correct and for the right patient are some of the most effective strategies to catch dispensing errors. ■

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 website at www.ismp.org. ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.

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Pharmacy Services Agreement: Key Provisions

by Jeffrey S. Baird, Esq.

Once they sang about being "forever young," but the Baby Boomers now need the services pharmacists have to offer. Those 78 million post-World War II babies, now aged 52 to 70, are retiring at the rate of 10,000 per day. Thanks to improvements in health care, they'll have longer lives than previous generations. But, they'll need to be cared for longer, too.

The term "long-term care" includes the following: skilled nursing facilities (SNFs) in which a patient receives rehabilitation care and then goes home; independent living facilities, in which residents live independently in their apartments but have access to a number of services; assisted living facilities, in which residents live in their own rooms/apartments and receive day-to-day services; and custodial care facilities, in which residents receive 24-hour care. Each one of these patients/residents has a need for the pharmacy's products and services.

It is common for an LTC facility to enter into a pharmacy services agreement (PSA) with a pharmacy. Under the PSA, the pharmacy will provide a number of services to the facility. Because the facility is a referral source to the pharmacy, to avoid problems under the Medicare anti-kickback statute (AKS) and many state anti-kickback statutes, it is important for the facility to pay fair market value compensation to the pharmacy for its services.

With this backdrop in mind, a properly-drafted PSA should contain the following provisions:

OBLIGATIONS OF THE FACILITY

- Ensure that the pharmacy has access to the residents' medical records.
- Provide the pharmacy with any statement of deficiencies submitted by a government agency.

SERVICES PROVIDED BY THE PHARMACY

The services provided by the pharmacy can include all or some of the following:

- Develop procedures for the provision of pharmacy products and services (collectively referred to as 'services').
- Coordinate services when they are provided by multiple pharmacies.
- Develop IV therapy procedures.
- Resolve medication-related problems by working with the facility's interdisciplinary team.
- Establish procedures for conducting the monthly medication review (MRR) for each resident, addressing expected time frames for conducting MRR and reporting findings, addressing irregularities, and documenting and reporting results of the MRR.
- Establish procedures that address the conduct of MRRs for residents who are anticipated to stay less than 30 days, and residents who experience an acute change of condition that may be medication-related.
- Establish a system of records of receipts and disposition of controlled drugs to enable a reconciliation.
- Develop procedures to address the acquisition, receipt, dispensation, administration, disposition, labeling, and storage of medications and personnel authorized to access and/or administer medications.
- Participate in quarterly quality assurance committee meetings.
- Conduct inspections of nursing stations, their drug storage areas, and emergency medication kits.
- Develop policies that identify who is responsible for identifying and prescribing indications for use of medications, providing and administering medications, and monitoring residents for the effects and potential adverse consequences of the resident's medication regiment.

- Assist the facility in assessing each resident to ascertain the causes of the condition requiring treatment, including determining if the resident's condition reflects an adverse medication consequence.
- Conduct an MRR for each resident at least once a month. In conducting MRRs, the pharmacy will identify irregularities such as syndromes potentially related to medication therapy, emerging or existing adverse medication consequences, and the potential for adverse drug reactions and medication errors.
- For residents anticipated to stay less than 30 days or with an acute change of condition, the pharmacy will provide, upon the facility's request, interim medication regimen review (iMRR) reports.
- Within 48 hours of conducting an MRR, the pharmacy will provide a summary report to the attending physician and the facility's director of nursing documenting that no irregularity was identified or reporting any irregularities.
- Work with the facility to ensure that medications are labeled in accordance with federal and state labeling requirements, and that the safe and secure storage of medications in locked compartments under proper temperature controls is in accordance with manufacturers' specifications.

COMPENSATION BY FACILITY TO THE PHARMACY

The following is sample language for compensation to the pharmacy:

"The Facility will pay a retainer of $_____ ("Retainer") within 10 days of the effective date of the PSA. The Retainer will be applied to the balance of the first invoice issued to the Facility. In the event that the Retainer exceeds the amount of the first invoice, the remaining amount will be applied to subsequent invoices. The Facility will pay the pharmacy $_____ per hour. The Facility will reimburse the pharmacy for reasonable pre-approved expenses incurred by the pharmacy." ■

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.


COMMUNITY
Rx

Don't **Sell** **to** *a* *Chain*

Let NCPA help you make the best decision

by B. Douglas Hoey, Pharmacist, MBA

A few weeks ago I got a call from a pharmacist that I've known for a long time. I had heard that he had decided to sell his pharmacy to a chain drugstore a couple of years ago.

He told me his rationale at the time. Prescription reimbursements were going down. Hassles were going up and so were the uncertainties as it seemed like the big guys just kept getting bigger. They made him an offer. He decided he couldn't refuse it. It's not necessarily a bad storyline. Small business owner starts business, pours heart and soul into business to make it successful, then eventually sells business and lives happily ever after, right?

Wrong. Once the business was sold he missed the personal fulfilment of building something that was his. Ironically, he missed the satisfaction of solving the problems that had been dragging him down. He missed being his own boss. And, most of all, even though he was still working, he missed taking care of patients his way versus taking care of them following someone else's directions.

Deciding to sell his or her pharmacy is one of the biggest decisions a business owner will make. The chain drugstores have dedicated teams offering themselves up as a solution. In fact, chances are that sometime in the last few weeks you received correspon-

Planning Makes Perfect

Selling a pharmacy is something that many owners do just once in a lifetime. Although you can't practice for that one-time event, you can—and should—prepare well in advance for it. The junior partnership route, described on page 22, is one approach. (We have a whole book about it in our bookstore.) But most owners, regardless of what option they choose—to a recent graduate, a colleague, or a chain store refugee—working with a broker or not, have questions galore about what to expect in a sale.

NCPA's many resources are housed in the Pharmacy Solutions section of our website under "Ownership." The tools are invaluable for sellers and buyers, students and managers.

For sellers, there are financial ratio calculators to evaluate business performance and potential value; webinars and videos; online advertising for pharmacy transactions at www.pharmacymatching.com; and business considerations for pharmacy transition, including six "Seller's White Papers" from attorney and NCPA contributor to *America's Pharmacist* Jeffrey S. Baird, Esq., to name a few.

But every seller needs a buyer, right? So, NCPA has a number of resources for potential buyers, too. Our business partner Live Oak Bank of Wilmington, N.C., has invested $600 million in community pharmacy loans of up to $5 million, and has an expedited process for those of under $350,000. First Financial Bank of Cincinnati and Bankers Healthcare Group of Davie, Fla., also are NCPA corporate members.

Sign up on www.pharmacymatching.com for free and answer seller listings online. Buyers can also advertise. Post a pharmacy buyer's listing for 180 days at $50; NCPA members get half off.

And don't forget about NCPA's Ownership Workshops, sponsored by McKesson. The next one is June 3-5 in Memphis and one will be part of the Annual Convention's pre-convention program Oct. 13-15 in New Orleans.

–Michael F. Conlan, editor, America's Pharmacist

dence from one of them professing to empathize with community pharmacy's problems, like DIR clawbacks and slow and low MAC payments; sympathizing with the challenges that comes with owning a small business, like long hours and managing people. They offer to do you a favor by taking your pharmacy off of your hands!

PROCEED WITH CAUTION

Take a deep breath. Count to 10. Find your happy place. Yoga people, assume your favorite pose. Do what you need to do to have a clear head as you consider the professional and personal impact selling your pharmacy will have on your life. After all, selling your pharmacy is not only selling your business, it's selling a part of yourself.

INVESTIGATE OTHER POTENTIAL BUYERS

If you ultimately make the decision to sell, there are often others who might be interested in buying your pharmacy. Maybe there's someone on your staff or maybe an employee stock option plan is a good alternative for you. Perhaps it's another independent in your town or county. A junior partnership is a worthy option, as the article on page 22 illustrates.

Only a few years ago, finding financing used to be an almost insurmountable problem. Traditional lenders back then had a hard time understanding that the value of a pharmacy was not limited to asset (mostly inventory) based loans. Not anymore. Pharmacy lenders like Live Oak Bank and others have made financing much more accessible.

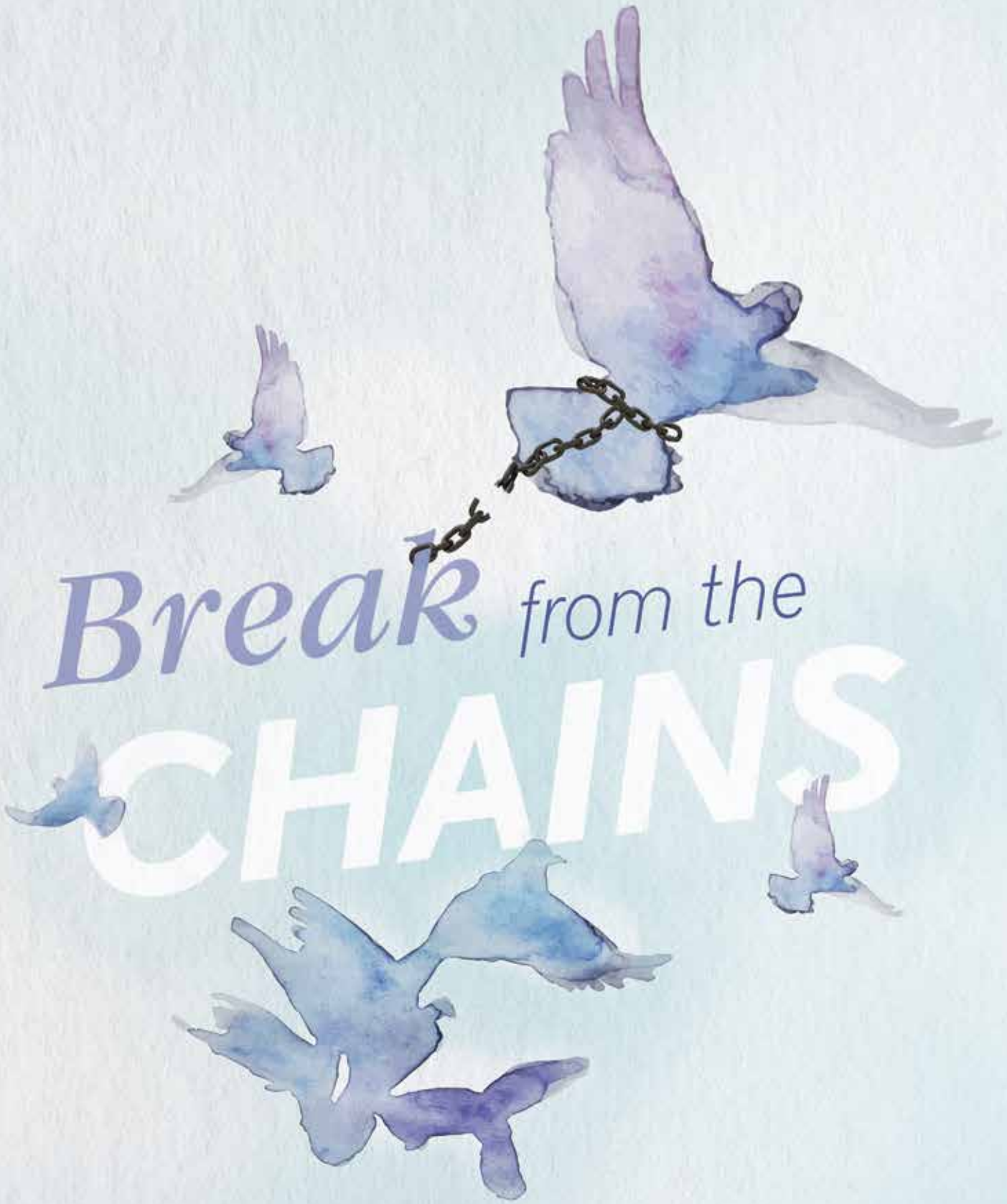
Your wholesaler is highly motivated to help connect you with someone else. They want to keep you as a customer. But if they can't have that, they for sure want to keep your business. NCPA offers a pharmacy matching service that can help current owners connect with buyers.

CAVEAT VENDITOR—LET THE SELLER BEWARE

If you decide that selling to a chain is your best option, go into the transaction with eyes wide open. Remember, chains buy other pharmacies as their day job. They know how to make the transaction most favorable to their corporation and they know the psychology of the deal. Get everything in writing. Parse every word. Have a lawyer familiar with transfers of ownership help you. You may decide to hire a broker. Likewise, make sure the broker's incentives align with protecting your interests. Getting extra help will cost a few dollars, but for some this will be the biggest transaction of your life. Don't be penny-wise and pound foolish.

The member who called me had seller's remorse. For everyone, it's an intensely personal decision. When you feel like you're ready to make the decision to sell, NCPA is here to help you. Check out your options. Tread carefully. Investigate your options to keep your legacy alive by keeping the independent business you built independent. ■

B. Douglas Hoey, Pharmacist, MBA, is chief executive officer of NCPA.


Break from the
CHAINS

Selling to a junior partner can help independent pharmacies stay independent

by Richard Jackson

The establishment of a partnership or a "junior partnership" is an alternative to a direct and immediate sale. In this scenario, the sale of the pharmacy occurs over several years, with the new owner acquiring a gradually increasing total percentage of ownership in the pharmacy while increasing his or her share of the management.

For many owners, the transfer of ownership to an individual instead of a chain is difficult because the prospective buyer may lack the necessary capital to make the purchase. It is this problem that causes many independent owners to sell to a chain instead of an individual. The junior partnership in this description provides the owner and potential buyer with a practical guide of how the transfer of ownership of a community pharmacy may be accomplished in a situation wherein the buyer has little or no capital. Adjustments in the factors in the example, such as the timing of initial purchase, total time frame, percentage of purchase per year, and amount paid, may be adjusted to meet special needs of the owner or buyer.

In this description, the first 50 percent of the pharmacy is purchased over a six-year period at approximately 10 percent per year. After the sixth year, the junior partner could purchase the remaining 50 percent using a bank loan, owner financing, or the same procedure as for the first 50 percent. The junior partner pays for and receives the first 10 percent of the pharmacy after the second year of the agreement, which gives him two years to become familiar with the business and save for the purchase of the initial 10 percent. After years three, four, five, and six of the agreement, an additional 10 percent is purchased per year based on the valuation of the pharmacy at that time.

AGREEMENT ON PROVISIONS IMPORTANT

All provisions of the junior partnership should be agreed upon in writing by both the owner and junior partner. This agreement should be drawn up or at least reviewed by an attorney. Particular attention should be given to provisions that would allow the owner or the junior partner to terminate the agreement should particular situations develop. In the event a portion of the pharmacy had been purchased by the junior partner at the time of termination, provisions should be delineated to describe the disposition of the junior partner's share; in other words, whether the shares are bought back by the seller, or the buyer has the right to complete the buyout and the method for valuing the portion of the business to be sold.

This junior partner will receive a reasonable salary plus a bonus of approximately 15 percent of the annual salary. This bonus is used as an incentive for the junior partner to remain with the pharmacy and continue to participate in the junior partnership. Salary increases would be provided each year as allowed for in the junior partnership agreement.

Ten percent of the ownership in the pharmacy will be transferred to the junior partner beginning at the end of the second year and continuing through the end of year six. Therefore, the junior partner will obtain 50 percent of the ownership of the pharmacy in six years. In this particular example, the junior partner will actually pay for only 5 percent of the pharmacy at the end of each year in which a payment is due. An additional 5 percent will be

Special Considerations to Tailor a Junior Partnership

1. Percent purchased each year
2. Number of years
3. Bonus to buyer
4. Ownership share target
5. Discounting share price or gifting

Alternate A) 10 percent per year for three years and then conventional financing with 30 percent collateral.

Alternate B) 5 percent per year for five years and then conventional financing with 25 percent collateral.

Alternate C) Owner finances a five-year loan to buy 20–50 percent and then convention financing for the balance with acquired percent collateral. Consider growth rate of value of pharmacy versus interest rate on owner-financed loan.

Figure 1. Pharmacy Yearly Value in a Junior Partnership

Line		End Y1	End Y2	End Y3	End Y4	End Y5	End Y6	Total
1	Pharmacy Value	$882,762.00	$909,244.86	$936,522.21	$964,617.87	$993,556.41	$1,023,363.10	
2	Percentage Purchased End Of Year	0%	10%	10%	10%	10%	10%	50%
3	Junior Partner % During Year	0%	0%	10%	20%	30%	40%	
4	Junior Partner $ Share of NP	$ –	$ –	$18,730.44	$38,584.71	$59,613.38	$81,869.05	
5	$ to Seller	$ –	$45,462.24	$46,826.11	$48,230.89	$49,677.82	$51,168.16	$241,365.22
6	Net Profit	$176,552.40	$181,848.97	$187,304.44	$192,923.57	$198,711.28	$204,672.62	
7	Seller % Owned During Year	100%	100%	90%	80%	70%	60%	
8	Seller NP $	$176,552.40	$181,848.97	$168,574.00	$154,338.86	$139,097.90	$122,803.57	$943,215.70
9	Total to Seller	$176,552.40	$227,311.22	$215,400.11	$202,569.75	$188,775.72	$173,971.73	$1,184,580.92

provided by the owner at no charge as an extra incentive for the junior partner. In essence, the junior partner would receive 50 percent ownership in the business in years 1–6 of the agreement, but would only pay for 25 percent. It is important for the seller and buyer to seek advice from a qualified advisor to understand the tax ramifications of stock incentives or discounting stock price.

During the first six years of the junior partnership agreement, wherein the junior partner purchases 50 percent of the pharmacy, the owner receives compensation in the form of his or her share of the net profit of the pharmacy and payment from the junior partner for the incremental 10 percent of the business beginning at the end of year two. During years one and two the owner owns 100 percent of the business and is entitled to 100 percent of the profits.

At the end of the second year, the junior partner purchases the first 10 percent of the business; therefore, during year three he receives 10 percent of the net profit and the owner 90 percent. At the end of the six-year agreement, the junior partner will have purchased 50 percent of the business. He may then choose to go to a lending institution and obtain a loan to purchase the remaining 50 percent at full value. He would then have 50 percent of the pharmacy to use as collateral. The seller may consider offering owner financing for the remaining 50 percent.

FIGURE 1 BREAKDOWN

Line 1: The value of the pharmacy is estimated to increase 3 percent per year in this example. The actual value of the pharmacy would be determined at the end of each year after normalization of the financial data and according to selected formulas agreed upon by the seller and junior partner. The value of the pharmacy as of 2013 was $882,762.

Line 2: Percentage of the pharmacy purchased at the end of each year in the six-year agreement. Ten percent is purchased at the end of years two through six. At the end of six years the junior partner owns 50 percent of the business and can borrow the funds to purchase the remaining 50 percent. The value of the pharmacy at the end of six years in this example is projected to be $1,023,363. Half of that value would be $511,682, which would be paid to the seller.

Line 3: These percentages represent the percent of the pharmacy owned by the junior partner during each year. It is this percentage that is used to determine the amount of the net profit which the junior partner is entitled to and is listed in Line 4.

Line 4: Multiplying the junior partner share of the business by the net profit provides the amounts listed in Line 4. The estimated net profit each year is provided in Line 6 and described below.

Line 5: The amount paid at the end of each year by the junior partner to the

Figure 2. Income from Bonus and Profits and Projected Payments of Junior Partner

Year of Transfer Agreement	Income From Net Profit	Income From Annual Bonus	Net Profit and Annual Bonus of Junior Partner	End-of-Year Payment To Current Owner	Cumulative Surplus
1	$0	$25,000	$25,000	$0	$25,000
2	$0	$25,000	$25,000	$45,462	($20,462)
3	$18,730	$25,000	$43,730	$46,826	($3,096)
4	$38,584	$25,000	$63,584	$48,230	$15,354
5	$59,613	$25,000	$84,613	$49,677	$34,936
6	$81,869	$25,000	$106,869	$51,168	$55,701

seller in this example is determined by taking one half of the value of the percentage of the pharmacy transferred. For example, at the end of year one, the junior partner acquires 10 percent of the business. Ten percent of the value of the pharmacy at the end of year two is estimated to be $90,924. The junior partner pays one half of that or $45,462 (5 percent of the value of the pharmacy). The junior partner is responsible for the tax liability of the amount of the pharmacy that is "gifted" by the seller to the junior partner.

Line 6: The net profit of the business is estimated to increase each year by 3 percent in this example. Each year the financial data would be normalized and actually determined.

Line 7: The percentage of the business owned by the seller during each year of the junior partnership agreement is provided in Line 7. This is used to determine the amount of the net profit to which the seller is entitled at the end of each year. In the event a cash withdrawal is not made or is not possible to be made, a payable would be established by the pharmacy to the seller.

Line 8: The amount of the net profit to which the seller is entitled appears in Line 8. This is determined by multiplying the percentage in Line 7 by the net profit in Line 6.

Line 9: The total amount received by the seller each year is determined by adding his share of the net profit in Line 8 and the payment of the junior partner in Line 5. The total amount received during the six years of the junior partnership agreement is $241,365 for the first 50 percent of the business ($48,273 if stock sold at full price). Adding this to the $943,216 collected from net profits provides the total amount received by the seller to be $1,184,581. The selling price of the remaining 50 percent of the business is estimated to be $511,682 (50 percent of the value of $1,023,363 at the end of year six).

In this agreement, the junior partner would have to save personal funds to make the first three payments to the seller because payments are made primarily from the junior partner's share of the net profit and the bonus which, combined, don't exceed the stock purchase price until after year four. However, by the time the junior partner in this example makes the first payment, he or she would have received two annual bonus payments. Using these bonus payments, plus saving diligently from salary in the first four years, the junior partner could make the stock purchase payments. Beyond year four, the payments could be made totally from the junior partner's bonus and share of the net profit.

FIGURE 2 BREAKDOWN

Figure 2 provides a breakdown of the junior partner's income from his or her share of the business and the annual bonus compared to the end of year payment to the seller. The total of the bonus and junior partner share of the net profit covers the end-of-year payment to the seller beginning in the fourth year. For the second and third years, there is a deficit ($20,462 in year two and $3,096 in year three).

This procedure provides for the establishment of a junior partnership for an independent owner to transfer ownership to a prospective buyer who may not have the necessary capital to purchase the pharmacy outright. The procedure is financially beneficial for both the owner and the junior partner. Most importantly for many independent owners, it provides a mechanism to transfer the ownership of the pharmacy and keep independent pharmacy independent. ■

Richard Jackson, PhD, is president of Community Pharmacy Consulting, Sarasota, Fla.

Value Added

Use your pharmacy's valuation as a management tool

by Ed Webman, RPh

Pharmacists and pharmacy owners are resourceful and entrepreneurial professionals. Despite the many challenges that independent owners have faced over the years—such as increased chain competition, mail order, preferred networks, and manufacturer limited distribution networks—independent pharmacy has thrived. The approximately 23,000 existing independent pharmacies have been successful in finding opportunities to provide products and services to their communities and have built valuable businesses. These owners have accumulated assets: home(s), investments, and retirement accounts, and most have a good idea of their personal net worth. Yet many owners struggle in valuing what is generally the largest asset in their portfolio, their business.

Of course, every owner wants to understand the value of his or her pharmacy when it comes time to sell, but the value of the business should be used as a tool to manage the business as well. A business valuation helps an owner plan for the future and prepare for emergencies. In addition to selling, there are many reasons to calculate the value of an on-going business, including:

- Understanding the business' value will help your family deal with the sale or disposition of the business in the case of an emergency such as death or disability.
- You may need to separate from partners and/or shareholders (death, disability, divorce, partnership breakup), and you need a valuation to divide up the business.
- A business valuation can assist owners in calculating and working toward their retirement goals.
- A business valuation can assist an owner with estate planning.
- The existing business' cash flow and collateral may be used to finance expansion or an acquisition.
- A business valuation is a crucial first step in creating an exit strategy. Planning should occur 3-5 years before the owner intends on exiting the business.

The independent pharmacy industry is a varied marketplace including a number of business models. Today's independent pharmacists provide a broad spectrum of services, including retail, long-term care (LTC), compounding, specialty, infusion, clinical education and management services, and durable medical equipment. All of these pharmacy services have varied gross margins and operating expenses. For example, $1 million of gross revenues in specialty pharmacy and $1 million of gross revenues in compounding pharmacy have very different cost of goods sold, very different operating expense structures, and contribute very differently to earnings. To understand and compare the profitability of various pharmacy business models, we will use earnings before interest, taxes, depreciation, and amortization (EBITDA) and net operating income (NOI).

To calculate EBITDA, take the net income of the business from the income statement, sometimes called the profit and loss statement (P&L), and add-back the interest, taxes, depreciation, and amortization expenses (EBITDA= net income + interest + taxes + depreciation + amortization). Additionally, when evaluating privately held businesses, it is important to normalize the expenses and also add-back to EBITDA any personal, non-business related, or above market expenses that may be run through the business. Common examples are an owner paying themselves an above market salary, unnecessary payroll such as family or friends, or possibly paying themselves above market rent if they own the building. This normalized EBITDA is one of the metrics used to compare and value pharmacies. Next, net operating income (NOI) is also used. In this case, NOI is EBITDA plus the owner's compensation. Again, NOI needs to be normalized for the amount of time the owner staffs the pharmacy. For example, if an owner works as a staff pharmacist half time, his normalized salary would be reduced by half. Half of his salary is as a dispensing pharmacist and half as an owner. A new owner would have to replace the hours that the owner works as a dispensing pharmacist, so that would be an expense. The normalized NOI reflects the cash an owner has available after reasonable or normalized expenses, to pay themselves, service any debt, and receive a dividend or distribution from the business.

PHARMACY ASSETS

A pharmacy's value is the sum of its tangible and intangible assets. Tangible assets are those which you can see and measure, such as inventory, furniture, fixtures, and equipment (FF&E), and accounts receivable (A/R). The tangible assets are counted and totaled when valuing a business. The intangible assets are those which cannot be seen and include goodwill, prescription files, customer lists, and non-competition

Bill's Retail Pharmacy		
Gross Revenues	$3,900,000	
Cost of Goods Sold (COGS)	$2,983,500	
Gross Profit (GP)	$916,500	23.50%
*Owner's Compensation (OC)	$120,000	3.08%
Interest Expense	$20,000	0.51%
Depreciation	$20,000	0.51%
Amortization	$30,000	0.77%
Selling & Gen. Admin. Exp.	$546,000	14.00%
Total Expense (TE)	$736,000	18.87%
Net Income (GP – TE)	$180,500	4.63%
EBITDA	$250,500	6.42%
NOI	$370,500	9.50%
Inventory	$245,000	
Annual Rxs filled	63,500	

*Owner is working half time as a filling pharmacist; see #6 normalized example.

agreements. For valuation, these intangible assets are generally combined and collectively referred to as goodwill. The value of the intangible assets may be calculated, often using the formulas and methods described in this article. Each formula provides the owner or buyer a different lens to view a pharmacy's value.

We will consider valuing the three most common types of independent pharmacy services: retail, compounding, and LTC. For these examples, we will assume that the FF&E is fully depreciated and has no residual value. The working capital assets (cash, accounts receivable, accounts payable, and all liabilities) are not included. We are simply valuing the goodwill and inventory.

RETAIL PHARMACY VALUATION

Most of the formulas commonly used in pharmacy valuations are related to retail pharmacy. To best understand the use of pharmacy valuation formulas, let's consider the income statement of the well-run Bill's Retail Pharmacy at left.

Along with profitability, the efficiency of a pharmacy must be considered. As the largest asset in a retail pharmacy is generally inventory, its carrying cost must be factored in. Inventory turnover is the metric to measure efficiency; 12 inventory turns is often used as the benchmark for a well-run pharmacy. This can be calculated by dividing the total cost of goods for the year by average inventory value. The multipliers used above are for a well-run retail store. If the business is not as profitable or efficient, the multiplier would be less; likewise, if the business were exceptional, they may be higher.

COMPOUNDING PHARMACY VALUATION

Compounding has become the most prevalent pharmacy specialty among independents. Approximately 65

Retail Pharmacy Formulas

1. Percentage of Sales + Inventory: Multiply the pharmacy's gross revenues by a percentage, in this case, 15 percent, and then add inventory:

   $3,900,000 x 15 percent = $585,000 + $245,000 = **$830,000**

2. Net Income: Multiply the pharmacy's net income by a multiplier, in this case 5x (this assumes the buyer will get a 20 percent return on sales):

   $180,500 x 5 = **$902,500**

3. Gross Profit: Simply take one year's gross profit:

   $916,500

4. Price per Prescription Filled + Inventory: In the example, we'll use $12 per prescription. Chains commonly utilize this method when acquiring an independent pharmacy.

   63,500 x $12 = $762,000 + $245,000 = **$1,007,000**

5. Net Income + Inventory: This is similar to formula 2, except we use a multiplier of 4 and add inventory.

   $180,500 x 4 = $722,000 + $245,000 = **$967,000**

6. *Normalized* NOI + Inventory: The net operating income (NOI) is normalized to reflect the amount of time the owner is working as a filling pharmacist, as they would need to be replaced or at least their salary would be; in this case, half time. This normalized NOI is then multiplied by a factor. With a net income above 3 percent, this is a well-performing pharmacy; we'll use 3.5x:

   Normalized NOI = one-half owner salary of $120,000 + EBITDA $250,500 = $310,500

   $310,500 x 3.5 = $1,086,750 + $245,000 = **$1,331,750**

percent of the nation's independent pharmacies provide compounding services. In the past 10 years, the number of compounding-only pharmacies has grown dramatically and the valuation of these pharmacies is somewhat different.

According to Creighton Maynard of Healthcare Business Solutions, a consultant for compounding pharmacies and an expert in their valuation, "The valuation multipliers use 20 percent EBITDA as a benchmark. The multipliers increase with EBITDA above 20 percent; likewise, they decrease below 20 percent."

Consider the income statement of Will's Compounding Pharmacy (at right) and the formulas that follow:

The multipliers and factors used in valuing a compounding pharmacy are somewhat higher than those used in retail pharmacies. Compounding pharmacies have greater gross margins, higher labor costs, and very low inventory compared to retail pharmacies. The value-add in compounding decommoditizes the business, contributing to the increased valuation.

Will's Compounding Pharmacy		
Gross Revenues	$995,500	
Cost of Goods Sold (COGS)	$155,000	
Gross Profit	$840,500	84.43%
*Owner's Compensation (OC)	$120,000	12.05%
Interest Expense	$0	0.00%
Depreciation & Amortization	$25,000	2.51%
Selling & Gen. Admin. Exp.	$456,000	45.81%
Total Expense	$601,000	60.37%
Total Expense (TE)	$736,000	18.87%
Net Income	$239,500	24.06%
EBITDA	EBITDA	26.57%
NOI (EBITDA + OC)	NOI (EBITDA + OC)	38.62%
Inventory	$35,000	
Annual Rx's filled	16,500	

LONG-TERM CARE PHARMACY VALUATION

The long-term care pharmacy business is divided into three major categories: skilled nursing facilities (SNF) commonly referred to as nursing homes, assisted living facilities (ALF), and intermediate care facilities (ICF) commonly referred to as group homes. The SNF business has become highly specialized and is largely reimbursed on per-diem rates with carve-outs. Though many independent pharmacies still service SNFs, independent pharmacy owners have increasingly focused on ALFs and ICFs. With the advent of Medicare Part D, most ALF and ICF patients are covered through Medicaid or Medicare and they may be dual-eligible. This expansion of coverage and demographic changes have created a growth opportunity for LTC pharmacy.

According to Michael Cammeyer of Harbor Healthcare Consultants, a pharmacy M&A firm specializing in LTC, "The days of pricing solely on a price per bed are gone. Buyers of LTC pharmacies, large and small, strategic or financial, use a financial model. The larger and more profitable the pharmacy, the higher the multiple; the range is from 5 to 6x EBITDA." With that in mind, consider the income statement of William's LTC Pharmacy on page 32.

As with compounding pharmacy, valuations in long-term pharmacy are somewhat higher than those seen in retail pharmacies. LTC pharmacies generally have greater gross margins, higher inventory turns, and increased labor costs compared to retail pharmacies. The value-add services in LTC pharmacies (such as packing, consulting, and delivering) decommoditizes the business. Also, LTC clients tend to be sticky and recurring revenue is more predictable.

CONSIDERING VALUATIONS

In years past, many pharmacy owners relied on relatively simple back-of-

Compounding Pharmacy Formulas

1. Percentage of Sales: Multiply the gross sales by a factor; in this case, we'll use 135 percent, as the pharmacy's EBITDA is approximately 35 percent greater than the benchmark EBITDA of 20 percent. The multiplier is increased 5 percent for every 1 percent greater than 20 percent; in this case, there is a difference of approximately seven percentage points.

   $995,500 x 135 percent = **$1,343,925**

2. Percentage of Sales plus Inventory: Multiply the gross sales by a factor and add inventory. In this case, we used 127 percent; 20 percent would be 100 percent, 27 percent is 127 percent.

   $995,500 x 127 percent = $1,264,285 + $35,000 = **$1,299,285**

3. Net Income (EBITDA): Multiply the EBITDA by 5x; this is the same as #2 in the retail example, except we use EBITDA:

   $264,500 x 5 = **$1,322,500**

4. *normalized* NOI + Inventory: The NOI is normalized; in this case, the owner is not working as a filling pharmacy, so their entire compensation is included in NOI. A multiple of 3.5x is used as before.

   Normalized NOI = $120,000 + EBITDA $264,500 = **$384,500**

   $384,500 x 3.5 = $1,345,750 + $35,000 = **$1,380,750**

the-envelope formulas to value their business. At the time, the pharmacy business model was much simpler and the gross revenues far less. Pharmacy is now a sophisticated business, with the average independent pharmacy generating approximately $4 million in gross revenue, and earnings of approximately $250,000. The value of a business is tied to the expectation of future earnings and cash flow. A financial model focused on the earnings, EBITDA and NOI, with a multiplier most fairly values the business. A financial model rewards owners for the historical cash flows they have built. Banks utilize a financial model focused on cash flow when considering a loan request from a buyer. Additionally, most independent pharmacies are not monoline businesses, but have diversified revenue streams, and earnings need to be valued, not simply on revenue and prescription counts.

When utilizing a financial model to value a pharmacy, it is most important to thoroughly normalize and recast the financial statements and cash flow. Along with normalizing the expenses as was discussed earlier, normalizing also includes ensuring the financials accurately represent the revenues, cost-of-goods-sold (COGS), gross profit, and ultimately the net income. In pharmacies, common concerns are: Is the P&L done on a cash or an accrual basis? Does it accurately reflect COGS rather than purchases? Are all rebates included? Are the inventory figures accurate? Are the accounts receivable (A/R) figures accurate? Are the accounts payable figures (A/P) accurate?

You need to fully understand a business' income statement or P&L, and balance sheet, to comprehend its value and earning potential. When financial statements have to be significantly recast and normalized, there is often a discount to the valuation of the business. Clear and accurate financial statements will help ensure that pharmacy owners will get the highest possible valuation for their business.

Other Things to Consider

- How are the pharmacy revenues and profits trending? A pharmacy that is increasing in profitability should command a higher multiplier than one that is level or declining.
- How are the prospects for growth in revenues and profits?
- How is the competition? Are there other independent pharmacies in the market?
- Is there a concentration risk? Is the pharmacy reliant on one customer such as an LTC facility, a large employer, one product (such as pain creams), one prescriber, or one payer such as Medicaid or an insurance company?
- What is the transition risk? How involved is the owner? The less the owner is involved in day-to-day activities, the fewer the changes in transition, and the more a buyer may be willing to pay.
- How are the facilities? Will the new owner need to remodel?
- How is the technology? Will the owner need to invest in new equipment and change workflows?
- How are the inventory levels? Has the seller let the inventory levels run down, requiring the new owner to beef up and invest in additional inventory?
- How is the staff? Are they professional? Will the new owner be able to utilize the existing staff or will they need to build a new team?

William's LTC Pharmacy		
Gross Revenues	$5,675,000	
Cost of Goods Sold (COGS)	$3,975,050	
Gross Profit	$1,699,950	29.96%
*Owner's Compensation (OC)	$120,000	2.11%
Interest Expense	$85,000	1.50%
Depreciation & Amortization	$84,500	1.49%
Selling & Gen. Admin. Exp.	$1,258,050	22.17%
Total Expense	$1,547,550	27.27%
Net Income (GP – TE)	$152,400	2.69%
EBITDA	$321,900	5.67%
NOI (EBITDA + OC)	$441,900	7.79%
Inventory	$235,000	
Number of beds serviced	940	
Annual Rxs filled	107,000	

*The owner is not working as a filling pharmacist.

LTC Pharmacy Formulas

1. Net Income (EBITDA): The pharmacy above falls into the 5x EBITDA range.

$321,900 x 5 = $1,609,500

2. *Normalized* NOI + inventory: As with the example in the compounding pharmacy, the owner is not working as a pharmacist but running the business. The entire owner's compensation is added back. A multiple of 3.5x is used as before.

$120,000 + $321,900 = $441,900

$441,900 x 3.5 = $1,546,650 + $235,000 = $1,781,650

FOR BUYERS

When evaluating a pharmacy acquisition, the buyer must consider not only the acquisition price of the pharmacy, but the project cost. The project cost includes the pharmacy acquisition and the working capital needed to fund the A/R and operate the business. Buyers should always pay for historical financial performance, not the potential. Buyers need to fully understand how the prospective pharmacy will impact them financially. The cash flow of the new pharmacy must be able to support the debt, the normalized expenses, and provide a salary and/or a return to the buyer.

The same pharmacy is not worth the same price to all buyers. Are they an associate in the pharmacy? How will things transition? Buyers may be willing to pay a bit more when they fully understand the business and the market. If buyers already own an existing store, are there synergies? Is their pharmacy in same market? Will they possibly combine the stores? When a buyer combines stores, many of the existing store's expenses will not recur, creating more value to the new owner. Is the seller willing to finance a large portion of the acquisition? The structure and the terms of a deal are important, and the price is often dependent upon on the terms.

When valuing a pharmacy, formulas should be used as a guide, as they provide a starting point and a range for the negotiations between the buyer and the seller. Of course, individual situations vary, and it is prudent to consult professionals such as an accountant and/or an attorney. However, a business is ultimately worth what a buyer is willing to pay and the seller is willing to accept. ■

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Geriatric Formulary Strategies

The right drug list can differentiate your LTC pharmacy

by McKesson Alternate Site Pharmacy

Aging Baby Boomers are living longer and receiving increasing quantities and combinations of medication, contributing to an estimated drug spend of $6.4 billion for long-term care (LTC) pharmacies in 2015—$1.2 billion more than was reported in 2014. In this highly regulated class of trade, pharmacies are on the hook to help skilled nursing facilities (SNFs) reduce F-tags—federal regulations that can result in costly penalties. Additionally, they are expected to dispense the best drugs possible and manage clinical outcomes amid reimbursement pressures and demands to contain costs.

Forced to do more with less, many LTC pharmacies are seeking new ways to standardize processes, increase efficiency, and minimize inventory costs. Introducing a geriatric formulary can help your LTC pharmacy become a stronger, differentiated partner to the SNFs that you serve. And with evidence-based recommendations, you can ultimately help your pharmacy and the SNFs you serve reduce costs and improve clinical outcomes.

WHAT IS A GERIATRIC FORMULARY?

A geriatric formulary is an optimized list of the most commonly used drugs, developed specifically to guide LTC pharmacies in dispensing the best medications possible for the geriatric population. Formulary development should take into account the physiological changes of aging. It should also evaluate drug interactions and side effect profiles. Each drug must be thoroughly reviewed and researched, using a variety of sources such as the Beers Criteria Medication List, which identifies potentially inappropriate medications for geriatric patients.

HOW TO HELP DEVELOP AND MAXIMIZE YOUR GERIATRIC FORMULARY

You can empower consultant pharmacists and staff to dispense the best drugs possible for geriatric patients by making your formulary meaningful, credible, and consistent. When developing your geriatric formulary, make sure to conduct a thorough clinical evaluation using standard criteria so the list is carefully vetted and appropriate for the target population.

To make your formulary meaningful, be sure it includes drugs, sorted by therapeutic category, that are most frequently dispensed in the LTC setting (such as 85–90 percent of the commonly used generic drugs). To make it credible, ensure your formulary is truly vetted by a reputable source, such as a pharmacy and therapeutic (P&T) committee or an independent third party. Having an independent third party clinically vet the formulary

enhances the credibility and consistency of therapeutic recommendations made by consultant pharmacists for the facilities served.

By providing documentation to support your preferred drugs, your customers will begin to understand the clinical lens that was applied when determining which drugs to dispense. Finally, for consistency, be sure to update the formulary regularly to reflect any Food and Drug Administration or industry changes, such as new drugs that have come off patent, changes to side effect profiles, and so on.

WORKING WITH CUSTOMERS TO IMPROVE OUTCOMES

If your pharmacy serves multiple facilities, you can start to standardize which drugs are dispensed across multiple therapeutic classes. This can help improve clinical outcomes by minimizing drug-related complications while also helping to reduce inventory costs. Your formulary can also give your customers confidence and clarity, thus helping to improve your existing partnerships and business objectives. Last, building and leveraging a strong geriatric formulary can help differentiate your pharmacy in a competitive marketplace, allowing for future growth and retention.

ADVANTAGES OF A GERIATRIC FORMULARY

Your LTC pharmacy can improve clinical and financial outcomes by using a geriatric formulary to do the following:

- Help comply with nursing home (F-tag) regulations—Patients frequently enter the nursing facility from an acute care environment on a host of medications that may not be necessary or optimal. Work closely with the facilities you serve to maximize their compliance with unique regulations that govern this class of trade, and help them avoid costly penalties.
- Enhance Medicare A to Medicare D continuity—Minimize costs to the facility by avoiding non-covered drugs as patients transition from Med A to Med D and as the facility becomes responsible for all non-covered drugs. By starting patients on optimal therapies under Med A that are most likely to be covered under Med D, your pharmacy can help increase continuity for the patient and reduce non-covered costs for the facility.
- Promote consistency across consultant pharmacists—Establish credibility and confidence through a preferred drug list that takes the guesswork out of medication review and interchanges. With a credible preferred drug list developed specifically for geriatric patients, consultant pharmacists are in a better position to standardize drugs across facilities, which helps pharmacies with inventory forecasting and cost reduction.
- Facilitate cost containment through therapeutic interchange—Utilize the preferred drug list to develop and provide a roadmap for alternatives to higher-cost branded drugs and those less appropriate for a geriatric population.
- Lower operating costs through minimized on-hand inventory—Easily standardize medications across facilities to reduce inventory on the shelf.
- Support business decisions—Elevate your clinical program by making recommendations that are clinically superior and consistent.
- Serve as a key differentiator—Become a more strategic partner, better equipped to win and retain nursing facilities' business and compete in the LTC market.
- Reduce acute care readmissions—Help improve patient care and maximize clinical outcomes by providing safe, effective medications. ■

McKesson Alternate Site Pharmacy is part of McKesson Corp.

Women's Weight Loss Wellness: Effective and Safe Diet Techniques

by Nicole Van Hoey, PharmD

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Upon successful completion of this article, the pharmacist should be able to:

1. Identify time periods when women are most at risk of weight gain and negative body image, then discuss how this impacts dieting choices.
2. Describe fad and other popular diet techniques in the context of long-term efficacy and safety.
3. Compare macronutrient diet components, focusing on their importance for bodily functions as well as their primary food sources.
4. Discuss components of and barriers to pharmacist-promoted weight management strategies that foster long-term nutrition.

Upon successful completion of this article, the pharmacy technician should be able to:

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INTRODUCTION

The U.S. obesity epidemic hits women hard, and the most efficacious weight control options are still unclear. Diet and weight loss industries have boomed as a result, but health safety remains a concern associated with many diet options. Pharmacists are poised to contribute to women's weight loss efforts by providing positive reinforcement and safe, effective approaches to diet and nutrition.

Case Presentation

D.G., a 49-year-old woman, is in your pharmacy perusing the aisle of diet supplements, protein bars, and meal-replacement shakes. She approaches the counter and purchases a prescription for an antihypertensive and a caffeine-based weight loss product. As the pharmacist on duty, you request private counseling and invite her to attend your new weight management clinic on the coming Saturday. She is reticent but accepts your brochure and appears on Saturday morning. She weighs in at 152 pounds and is 5'3" tall, which equates to a BMI of 27 kg/m^2 on your Centers for Disease Control and Prevention-provided chart. Her waist circumference is 31 inches, within normal limits for women. D.G. reports a typical calorie intake of 2,100 kcals/d, and her hypertension was diagnosed two years ago (well controlled at 128/72 mmHg with an ACE inhibitor). She comments about struggling with weight gain after her first child was born and again recently. Describe your clinical efforts at evaluation and counseling for D.G., making sure to qualitatively and quantitatively address short- and long-term goals as well as behavior change counseling and follow-up.

INTRODUCTION TO WEIGHT MANAGEMENT

The United States is in the midst of an obesity epidemic: Americans are among the world's heaviest people, and obesity is the most preventable cause of chronic disease in this country. Excess weight is more common in affluent countries, and more than two-thirds of all U.S. adults are considered overweight or obese. Middle-aged urban women comprise one of the largest demographic groups that struggle with weight gain. Women particularly connect weight fluctuations and body fat with self-image. Weight loss in the United States, subsequently, is a big business. According to a 2013 Gallup Poll, more than 50 percent of women in the United States want to lose weight, regardless of their current weight status. More than 17 million women use over-the-counter products for weight loss, and educated women older than 35 years of age are the primary users. In 2008, approximately 34 percent of people on prescription weight loss agents use additional OTC products without health professional guidance.

Up to 90 percent of women worry about weight, despite evidence that weight changes across decades are normal. Rhythmic cycles of a woman's life are associated with expected weight fluctuations, which are especially connected to hormonal changes, such as menstrual cycles, pregnancy and nursing, and menopause. During menopause in particular, a natural weight gain of 8–12 pounds occurs when the body's metabolic, energy-burning processes slow. Weight gain at this stage results in great anxiety and negative body image in women. In fact, although young adulthood is characteristically plagued by eating disorders, middle-aged perimenopausal women are at risk of developing them as well. Body weight has continued to top female concerns into the 60- to 90-year-old decades, despite evidence that moderate weight increases alone are not linked to mortality in the older ages.

Body image is crucial to well-being; body dissatisfaction in women has doubled, to 56 percent of women, from 1972 to 1997, as women believe that they should be in better control of their weight changes. Excess weight accumulation at middle age is disempowering and leads to weight re-gain and yo-yo (that is, rapidly repeated) dieting. Drastic changes of eating patterns at this stage of life, in attempts to keep weight off, often warrant health professional intervention, because body image problems in midlife are potential precursors to clinical eating disorders.

Obesity develops as a result of genetic factors, behaviors or lifestyle choices, and some diseases or medications. The true interplay of factors is difficult to characterize, though. Behavioral risks for weight gain can be identified by evaluating eating patterns, food choices, and daily activity levels. Family history, medical conditions like thyroid or adrenal disorders, and medication use (such as corticosteroids, anti-depressants and atypical antipsychotics) are identifiable contributing factors toward obesity. An individual's natural metabolism is also a factor. Metabolism slows with age and is generally slower in women than in men. Metabolism reflects the body's ability to convert foods into energy needs; it is typically unaffected by food choices, although excessive dieting can impede a healthy metabolic response to foods. Because weight is directly related to the balance of energy taken in through food calories and energy expended through physical activity, behaviors can counter genetics and play a primary role in the likelihood of weight gain or loss. If caloric intake exceeds output by physical activity, weight and fat accumulate in the body.

Clinically measured weight gain and fat storage at particular body areas have been linked directly to chronic diseases. Obesity and overweight status are the primary causes of at least one quarter of hypertension diagnoses, according to the 44-year Framingham Heart Study. Heart disease, high cholesterol, myocardial infarction, diabetes mellitus,

and other preventable diseases result in part from uncontrolled obesity and high fat intake. To identify an individual's true body fat and associated obesity diagnosis, body mass index (BMI) calculations and waist circumference measurements are used to indirectly reflect the proportion of excess weight overall and around the abdomen, respectively. The National Institutes of Health Weight-Control Information Network suggests that women should have a waist circumference under 35 inches to prevent morbidity. BMI accounts for height and weight to define acceptable parameters of body fat. Measurements of 18.5–24.9 kg/m^2 reflect normal weight; 25–29.9, overweight; and 30–39.9, obese. According to the NIH, approximately one fourth of adults age 20 years or older in the United States are obese by BMI calculations. Disease prevalence is proportional to increasing BMI, and diabetes and cardiovascular disease risks increase as abdominal fat increases, particularly with BMIs higher than 35 kg/m^2 in women. Modest weight loss of 10 to 20 pounds in an obese adult improves blood pressure, total cholesterol, triglycerides, and lowers diabetes risk and blood glucose; even within a BMI category, this small loss improves health. However, in 2008, fewer than half of physicians measured BMI regularly in adult patients, making increased regular BMI evaluation one of the Healthy People 2020 objectives.

Despite the rampant health concerns resulting from excess weight and body fat, the obesity epidemic continues to grow. However, reversing disease risks is possible through weight reduction and better nutrition management. Proper education about regular eating habits is essential. Approximately 43 million women in the United States reportedly diet for weight loss, and an additional 26 million diet for maintenance. Only 20 percent of women eat instinctively when hungry; 40 percent of women either restrict or overeat; and at least 50 percent of women reportedly feel guilt after eating. An education plan about nutrition, disease risks, and behavior change benefits, supplemented by Healthy People 2020 goals, must be emphasized. The practitioner challenge is in approaching patients about weight and chronic disease risks. Pharmacists and other health professionals are positioned to encourage patients in community settings toward weight loss, weight maintenance, and nutrition education that constructively evaluates weight in terms of disease risks while recommending useful tools to promote healthier lifestyles for women of any age and BMI.

POPULAR WEIGHT LOSS PRODUCTS AND PROGRAMS

A Dieting Strategies Overview

Losing weight can seem like an unreachable goal, especially as women age. It is unsurprising that women turn to diet products or programs that promise easy and fast results, regardless of cost or safety. However, yo-yo dieting behaviors can stall weight loss, inhibit healthy habits, and teach the body to guard fat and lower its metabolic rate in preparation for starvation conditions. As women repeatedly diet, their metabolism responds protectively to store nutrients and not burn energy efficiently. As a result, weight often becomes harder to shed and plateaus before a long-term weight goal is achieved.

Few popular dieting options encourage a nutritionally sound approach or support long-term, maintained weight loss that may prevent disease. Some fad diets, plans, and products can cause bothersome or dangerous adverse effects, including nutritional deficiencies, when used alone or in combination.

FAD DIETS DEFINED AND CHARACTERIZED

Spotting the Dangers

The simplest definition of a fad diet is a weight loss method that gains—and subsequently loses—popularity quickly. Numerous fad diets are available and can be interspersed with more traditional diet products in store aisles. All fads share special characteristics that distinguish them from nutritionally sound options. These diets incorporate extreme food elimination or restriction; they include regimented diets like the lemon detox or grapefruit diets that promise drastic, rapid weight loss. Such diets eliminate meals in favor of a single food or type, claim to stimulate fat burning for energy, and do not involve meal planning or variety, resulting in boredom and lack of enjoyment from eating. These diets are ultimately not maintainable.

Fads seem too good to be true, and they usually are. Cleanses, like the acai berry diet, rely on testimonials instead of science. Fads can be effective for immediate weight loss, because they drastically reduce caloric intake to 800 kcal/d or less, not because they reset metabolism to burn fat faster. Very-low-calorie diets do not provide calories and nutrients sufficient to sustain health. Consumers can identify fads by these additional distinguishing factors: they rarely emphasize physical activity or encourage long-term management after a drastic weight loss; they are costly and lack any health data or warnings; and they blame weight gain on unchangeable factors such as personality.

Why Are Fads a Danger?

The severe restriction fad encourages an unhealthy approach to eating and violates the first principle of good nutrition: to follow a balanced and varied diet and activity plan. These very-low-calorie diets lack crucial nutrients found in balanced meals. People frequently overlap fads or observe the diets in rapid sequence, and these restrictions ultimately threaten health by withholding nutrition and

draining the body of energy needed to function. Malnutrition that results from eliminations or cleanses can cause serious damage to the nervous, renal, and cardiovascular systems. Acidosis, kidney stones, anemia, ketosis, and more can develop from vitamin and mineral restriction; lethargy and poor digestive health also are common.

The most recent fad diets—the paleo and gluten-free diets—continue the trend of elimination in favor of balance. For example, the paleo diet, which assumes that digestive capabilities of humans have not evolved over millions of years, and which was the most Googled diet of 2013, prohibits all grains or farmed products, avoids processed foods, and encourages fresh fruits and vegetables; however, the diet does not prohibit foods with high saturated fats, such as bacon and other fatty red meats, as protein sources. This type of diet, without cooked grains that contribute feelings of fullness and fortified vitamin sources, is difficult to sustain, and many followers trend toward intake of foods that are high in unhealthy fats. Because of this, the *2016 US News and World Report* Diet Rankings lists the paleo diet as 35 (the last) on its list of diets for safety, adequate nutrition, weight loss, health preventiveness, and ease of use.

Gluten-free diets (such as the "Wheat belly" program) exist on the mistaken premise that calories from wheats and grains collect predominantly around the abdomen. Although gluten-free diets are touted as energy and weight loss boosters, no evidence supports these claims for people who are not sensitive to gluten. Less than 1 percent of the U.S. population is diagnosed with the autoimmune gluten sensitivity or celiac disease, which requires strict gluten avoidance, but 21 percent of Americans in a 2015 Gallup poll reportedly observed gluten-free diets. Consumers appear to confuse gluten (and its most common source, wheat) with fat instead of recognizing gluten products such as whole-grain breads or oats as sources of essential nutrients. Instead of avoiding carbohydrates from processed foods only, people on gluten-free diets remove almost all grain sources of carbohydrates. As a result, consumers lose a dominant source of B vitamins and an important fiber source (such as fortified whole-grain or bran cereals). Whole grains also contribute iron and a significant number of antioxidants to a person's diet, so anemia from low iron intake and oxidative damage to heart muscle and cells throughout the body can develop without the antioxidants found in healthful grains.

The risk of eliminating gluten products entirely is compounded by the replacement choices made by many people who choose this diet. Instead of replacing wheat, oats, or barley with higher-protein, gluten-free grains such as farro or quinoa, many of these dieters rely on products such as white rice, tapioca, or potato starch or—more often—on processed gluten-free products that are heavily marketed to this dieting population. The U.S. gluten-free industry (aimed at dieters more than at people with celiac disease) in 2014 was a $9 billion market. Reliance on these prepared gluten-free products can actually increase weight gain because of the added fats and sugars in these foods and frequently becomes a cost burden, as prices for gluten-free products reach double the costs of whole-grain competitors in grocery stores.

If patients insist on trying either popular diet, pharmacists can guide them, directly or through a dietician, toward incorporation of healthy food options like ancient grains (such as quinoa) instead of wheat or nuts and beans instead of red meat for protein.

Macronutrient Restriction Plans

Coexisting with elimination fads are more tempered options for weight loss that are based on quantities of nutrients in specific foods. Programs that require altered proportions of carbohydrate, fat, and protein macronutrients, such as the South Beach Diet and the Atkins diet, are advertised on the premise that eating proportionally smaller amounts of fats or carbohydrates will result in successful and maintainable weight loss.

These diets programs hold appeal largely because they advocate a guided eating method with modest education but without extreme deprivation. Programs like the Atkins diet, the 17-day diet, and others appear medically sound, may be developed or promoted by physicians, and often endorse some physical activity and maintenance efforts. These diets typically allow a variety of foods, might suggest food types that should be avoided or limited, and can involve costly prepared food products to meet nutrient specifications.

Low-carb, low-fat, and moderately low-calorie diets are more persistent in their consumer availability than severe restriction fads. For example, the Atkins diet was first introduced in 1970, and its use peaked again in the early 2000s. Low-fat diets, advocated by groups like the American Heart Association (AHA), peaked in popularity during the late 20th century as models for weight loss and cardiovascular health. These diets are primarily aimed to prevent heart disease through the avoidance of fats, which increase cholesterol levels, while promoting weight loss. Fats have approximately twice the calories per gram of carbohydrate or protein food sources. However, traditional low-fat diets do not necessarily promote quality of fats, and carbohydrate intake can remain unchecked, which can increase diabetes and cardiovascular disease as well.

Conversely, low-carb diets approach health and weight loss from the perspective of insulin and glucose control. Since 2007, multiple versions of low-carb diets have been favored over low-fat options, as diabetes, cardiovascular disease, and insulin resistance have become intertwined. Carbohydrates such as starches, fibers, and simple sugars are present in fruits, vegetables, grains, and dairy as well as in processed foods and alcohols. The body absorbs carbohydrates and converts them to glucose, which triggers the release and production of insulin. Refined carbohydrates such as sugars and starches more rapidly increase glucose and insulin concentrations than complex, unrefined carbohydrates such as grains and fibers. One goal of low-carb programs such as Atkins, Zone Diet, or the South Beach Diet is to encourage moderate and gradual insulin release after meals instead of dramatic, rapid peaks that can foster insulin resistance and chronic disease.

Low-carb diets are not all the same, though. Some, like Atkins, greatly restrict carbohydrates but place no limits on fat and protein intake each day. Others, like the Zone diet, specify the types of carbohydrates allowed by their effects on blood glucose levels. The South Beach Diet was developed by a nutritionist and a cardiologist to counter an exclusively low-fat diet approach. These low-carb programs have been clinically studied and compared with each other and with low-fat diets to determine their true effects on weight loss, nutrition, and chronic disease. Consumers and health professionals both require this additional knowledge to determine which diet plans are most effective.

The Atkins diet, as one of the most enduringly popular low-carb programs, promotes insulin control through avoidance of refined carbohydrates. Unfortunately, the Atkins diet allows up to 60 percent of a day's calories from fat—25 percent of which can be unhealthy, saturated fat. The Atkins program is designed for very-low-carbohydrate intake during weight loss, with fewer than 20 grams per day of carbohydrates, and low carbohydrate intake during maintenance, with fewer than 50 g/day. Total calories per day are not necessarily restricted, and multivitamin use is encouraged.

The Zone diet allows up to 40 percent of calories as carbohydrates at every meal, with even distribution between fat and protein intake. The Zone diet, instead of overall limitation, emphasizes the type of carbohydrate on the premise that slower carbohydrates and higher protein intake minimize insulin changes and promote satiety, respectively. Unrefined carbohydrate sources such as grains, and fats from nuts and olive oils, are recommended. The Zone diet also encourages moderate caloric restriction by 500 calories per meal, and it allows two 100-calorie snacks each day, for a goal of 1,200 calories per day total.

The South Beach Diet, developed in the late 1990s, has retained popularity by countering restrictive, low-fat diets with a program focused on a rebalanced approach to complex carbohydrates from grains, vegetables, and fruits. This program begins with an early-phase washout period that bans refined and high-sugar carbohydrate foods, including alcohol. In the following two phases, healthy carbohydrates are reintroduced, and the diet is maintained by eating only low-processed carbohydrates of any quantity and by eating only healthy fats. Rather than restricting intake in the latter phases, the South Beach Diet encourages snacks that fall within approved food choices.

Low-carb diets, if not observed carefully for nutrition, can cause an imbalance of protein, carbohydrates, and fat in the body that results in vitamin deficiencies and poor digestive health. Efficacy remains unproven for many programs, especially for long-term use. Crucially, with restriction to fewer than 100 g/day of carbohydrates, the body burns muscle, not fat, for fuel (glucose); gastrointestinal and neurologic symptoms result. According to the Institute of Medicine, 130 g/day of carbohydrates is necessary for optimal brain function.

The Atkins and Zone low-carb diets have been compared with simple caloric restriction of 1,200 kcal/day and with a low-fat (such as 10 percent to 30 percent fat) diet. When more than 300 overweight, premenopausal women observed these diets for one year, weight loss and improved disease risk metrics resulted, with non-significant differences, in all groups. More important, though, was what diet comparison revealed about vitamin and mineral deficiency risks. Deficiencies were most pronounced in caloric restriction and in Atkins dieters: both were lower in thiamine and magnesium. Additionally, Atkins program dieters experienced pronounced inadequacies of folate, iron, and vitamin C after only eight weeks of observing the diet. Zone dieters were observed to have had lower risks of nutrient inadequacy. They reported especially adequate levels of fat-soluble vitamins A, E, and K, and of vitamin C. The Zone diet also had adequate levels of vitamin B6 and niacin despite caloric restriction and no multivitamin supplementation. Although these popular diets are safer nutritionally than fad options, they do not prepare consumers for long-term weight control. In addition, there remains little scientific support and guidance for health professional counseling on appropriate use.

Meal Plan Popularity

Like macronutrient-based diets, meal plans encourage moderate weight loss, and they often include physical activity recommendations as well as positive reinforcement through group meetings and outreach. Meal plans enhance weight

loss likelihood by restricting caloric intake to only 1,000–1,500 calories per day, with arranged foods or liquid shakes.

Meal-replacement shakes emphasize rapid weight loss, but calorie intake from liquids is often insufficient for continued daily needs. For example, shake diets that promote liquid replacements for breakfast and lunch can provide fewer than 450 calories, not enough to sustain energy until the evening, and can lead to overeating at dinner. A responsible approach to weight loss with diet shakes is to maintain the two-shake-per-day period for only three months and then continue with only one liquid meal replacement daily for the rest of the year. Small, low-calorie after-meal snacks of solid food should be encouraged, especially during a two-shake-per-day period, to maintain energy.

Prepared meals are touted as well-balanced foods of sufficient nutritional value. Programs such as Weight Watchers and Medifast embody support group accountability which often provides positive feedback toward interim and long-term weight-management goals. The programs are highly directed and easy to follow, in part because they do not require participants to explicitly count calories or make ingredient choices on their own each day. Instead, the plan measures the portion sizes, designs healthful and balanced meal options, and tracks calories for the consumer. Snacks and other supplementary foods are often provided in prepackaged, calorie-limited options like shakes and protein bars.

Unlike fad diets, these programs vary food choices to improve eating enjoyment and diet adherence. Meal plans appear to be positive, well-rounded approaches to weight loss, and they can be effective for many women, especially those who respond well to group accountability and reinforcement. In fact, in a 2011 study that compared one year of physician-supervised private weight loss efforts with one year of physician-encouraged Weight Watchers participation, women on the meal plan program lost substantially more weight and more body fat, and maintained the diet more successfully, than the private dieters. However, meal plans are extremely costly at the outset and as the program continues because of the specialty food purchases. These programs are not always successful for maintenance after completion because they do not require consumers to determine their own portion sizes and healthy food choices. Therefore, although weight loss is proven for programs like Weight Watchers, durable success depends more on an individual's ability to maintain the lifestyle changes independently.

Diet Supplements: No Quick Fix

When weight loss attempts fail, or when they become less effective after years of yo-yo dieting, women may turn to supplements for a quick fix. Diet pills promise rapid results without prolonged effort. Herbal, homeopathic or vitamin products claim to shed excess pounds, often by burning fat or boosting the metabolism, and they are often viewed by consumers as replacements for nutrition and physical activity. Although these supplements appeal as an easy solution, their safety and effectiveness are questionable at best. Documented cardiac dangers from stimulant drugs such as fen-phen (fenfluramine and pheniramine) or phenylpropanolamine have resulted in these and similar stimulant products being removed from the market. Available products today continue to pose great risks to consumers, in part because weight loss supplements are obtained easily, without consulting health professionals, in stores or online. Also, according to the Federal Trade Commission, these types of supplements are commonly tainted because of the lack of pre-market oversight, and the label or even active ingredients may be inaccurate. Women frequently combine supplements, even during diet and food restriction attempts, to achieve even more weight loss. Just as patients are unlikely to disclose supplement use to their physicians, doctors infrequently question patients about weight loss drug use because of the lack of safe and effective recommendations available.

Diet supplements often fall into two categories: stimulants and diuretics. Purported diuretics, such as celery seed, ginger, aloe, parsley, or green tea, reduce weight by removing water from the body. Although the loss appears significant, it is not connected to fat stores and cannot be sustained. Water imbalance affects essential minerals like sodium and potassium; dehydration, acidosis, and hypotension are potential adverse effects of excessive diuretic use.

Stimulant products, including Metabolife, Hydroxycut, and Dexatrim, claim to reduce appetite and to burn fat. Instead, their stimulatory effects on the nervous system can result in headaches, hypertension, dizziness, nausea, and increased heart rate. These pills frequently contain ephedrine derivatives alone or in combination with caffeine to enhance stimulatory effects. Although coffee, green tea, yerbamate, and other caffeine-containing supplements might suppress hunger, increase fluid weight loss, and enhance the body's use of fat for energy, these responses are minimal at best. According to the Mayo Clinic and numerous clinical studies, caffeine's effect on weight loss is questionable, but its adverse effects when used as a drug can be dangerous. Overlapping use of stimulants in particular can cause hypertension as well as heart palpitations and arrhythmias that increase mortality. Diet pills are most frequently used by obese young women, who neglect short- and long-term nutrition with these weight loss attempts. These supplements are expensive alternatives to a well-balanced long-term diet and lifestyle change.

BETTER WEIGHT LOSS CONSIDERATIONS

Understanding Successful Diet Methods

Fad and restriction diets, then, are primarily used for short-term weight loss, and meal plans are often too costly to continue as a weight maintenance option. Safe, effective, and maintainable weight loss strategies exist, but they require long-term attention to quality of food intake. By learning how to choose foods with fibers, vitamins, minerals, and appropriate macronutrients, consumers obtain the knowledge and ability to persevere through normal weight fluctuations over time while minimizing the negative impact on body image. For providers and other health care professionals, background knowledge about the importance of macronutrients and their proportions guide individualized discussions about weight control. Understanding the basics of nutrition for weight management relies on explanations of how the body uses different types of foods, how different foods relate to disease risks, and how to evaluate fat effects on the body.

Healthful Macronutrient Proportions

All foods contain macronutrients that provide essential vitamins and minerals required by the body. (See Table 1.) These macronutrients—fats, proteins, and carbohydrates—are the backbones of healthful eating and should not be eliminated from the diet, even for weight loss. However, all three macronutrients have more and less healthful food choices that impact weight management and disease risk.

Fats

Fats in the diet receive particular criticism as unnecessary components of a healthy diet, especially while attempting weight loss. Fats do increase the likelihood of weight gain more than other macronutrients, though the fat source is an important distinction for proper nutrition. When not being used, fats are stored and carried in the body by different lipoproteins. Low-density lipoprotein (LDL) forms occlusive fatty plaques by attaching to blood vessels; conversely, high-density lipoprotein (HDL) more often transports fats to the liver. The right fats contribute to wellness by providing energy, maintaining cell and muscle health, insulating the body, and fostering absorption of important vitamins like A, D, E, and K. Data from the Nurses' Health Study supports the concept that the percentage of unhealthy fats, not total fats, affects disease. Unhealthy fats increase the risk for cardiac diseases by increasing total cholesterol, especially

Table 1. Vital Macronutrient Descriptions and Selection

Macronutrient	Benefits	Risks	Sources		U.S. Dietary Guidelines 2010 Recommended Amounts	U.S. Dietary Guidelines 2015 Suggestions
			Healthful	Unhealthful		
Fats	Cell production, energy storage, vitamin absorption	Cholesterol plaques, excess abdominal girth, low satiety	Unsaturated options such as olive and canola oils, flax, salmon	Saturated and trans (i.e., solid) fats such as processed meats, full-fat cream, butter	<10% (especially for saturated and trans fats)	<10% of daily calories from saturated or trans fats
Carbs	Energy provision	Insulin resistance and glucose imbalance	Slow carbs, low glycemic index foods that promote even insulin release, including bran	Simple or fast carbs, high glycemic index foods that cause glucose and insulin spikes; alcohol	45%–65%	<10% of daily calories from added sugars; 50% of daily grains from whole grains (not refined products)
Proteins	High satiety, iron source, bone and muscle health	Often fatty food sources, can be high calorie	Lean meats, soy, lentils, hummus, beans	Red meats, eggs or full-fat dairy in excess	Up to 35%	A variety of sources, especially nutrient-dense, low-fat sources (non-red lean meats, pulses, nuts)

LDL. Although cholesterol is important for hormone and cellular production, it is made within the body and is not required from dietary sources like egg yolks or salmon. The best diets limit unhealthy saturated fats and trans fats and have higher percentages of healthy unsaturated fats instead. People at high risk of cardiac disease, including those who are overweight or obese, should aim for intake that lowers their LDL to under 70 mg/dl.

Saturated fats, which increase LDL to a 1:2 ratio, are concentrated in animal products such as whole fat dairy, meats with skins and any processed meats, and lard. Highly processed oils like palm or coconut oil are also high in saturated fat. Trans fats are at least as unhealthy and are typically man-made solid fats, such as stick margarines or partially hydrogenated shortenings useful for baking. They are frequently used to make pastries and fried foods and are substantial ingredients in packaged cookies and crackers. In fact, many diet products, such as gluten-free crackers or packaged foods, may be high in undesirable ingredients, like sodium or saturated fat. Trans fats increase LDL and reduce HDL over time, especially when they are the primary fat source in a diet.

Plant sterols and unsaturated fats are alternatives to unhealthy fats. Plant sterols are increasingly common additives in oils, margarines, and some dairy products. They block cholesterol absorption after digestion, which results in lower LDL concentrations, particularly when 2 grams per day or more of sterols are ingested regularly. Replacement of saturated fat products with unsaturated alternatives improves LDL and total cholesterol levels even if the day's total fat percentage remains steady, because unsaturated fats are comparatively less likely to accumulate as LDL in the bloodstream.

Two unsaturated fats, omega 3 and omega 6 essential fatty acids, contribute to proper functioning of the heart, brain, eyes, and more. Also known as monounsaturated and polyunsaturated fats, they moderate insulin use and lower cholesterol and heart disease risks. Natural sources of monounsaturated fats include olive and canola oils, nuts, seeds, and select fish. Omega-3 fatty acids are polyunsaturated fats found in soy, flaxseed, walnuts, salmon, tuna, and mackerel; other nuts and seeds like sunflower (as well as their oils) are common sources of omega 6 fatty acids. Eating unsaturated fats in place of unhealthy ones, rather than eliminating fat entirely from the diet, is a proven way to support cardiovascular and metabolic health while dieting.

U.S. Dietary Guidelines in 2010 and 2015 recommend fewer than 10 percent of total calories per day from saturated fats; acceptable cholesterol intake according to the 2010 guidelines and American Heart Association remains under 300 mg/day for anyone older than 2 years of age. These guidelines especially emphasize minimal trans fat intake even if total fat, when combined with unsaturated sources, approaches 20-30 percent of the day's calories. Contrasting with the 2010 guidelines, American diets in 2011 contained up to 35 percent of daily calories from solid (trans) fats and added sugars (not naturally occurring sugars, like in fruits). People who already experience adverse cardiovascular health as a result of high saturated and trans fat intake can still counter long-term disease risks by changing their diets to fewer than 7 percent saturated and trans fats each day and to under 200 mg/day of cholesterol intake, according to the American Heart Association. Detrimental fats are best reduced by replacing them with monounsaturated and polyunsaturated fats as well as with plant sterol options.

Carbohydrates

Food sources of carbohydrates include starches, sugars, and fibers, but carbohydrate health distinctions are not as simple. Traditional labels of simple or monosaccharide (such as sucrose-containing products like candies) and complex or polysaccharide (such as starches like potatoes, corn, and rice) carbohydrates do not account for variance in the quality of carbohydrates found in fruits, vegetables, grains, and legumes. AHA basic nutritional guidelines recommend less than 100 kcal/day from added simple sugars for women. Other carbohydrates, however, are nutrition essentials, such as fibers and whole wheat, and cannot be eliminated from a diet. In fact, U.S. Dietary Guidelines in 2010 suggest up to 45–65 percent of daily calories should be from healthful carbohydrate foods, and the 2015 guidelines specifically focus on added sugars instead of total carbohydrates, with a recommendation of under 10 percent of daily calories from added sugars.

Fiber in particular is crucial to digestive and overall health. Fiber remains in the digestive tract, where it blocks fat and cholesterol absorption, encourages intestinal motility, and reduces hunger. Soluble fibers modulate insulin use by preventing excessive glucose absorption; common examples include apples, oats, kidney beans, citrus fruits, and barley; pulses such as lentils and chickpeas also contribute high amounts of fiber. Insoluble fibers act as roughage and pass through the tract with other undigested materials. Whole wheat, popcorn, broccoli, bran, carrots, and green beans are examples of insoluble fibers that maintain bowel health. The U.S. Dietary Guidelines, for the first time in 2010, set a recommended daily fiber allowance for everyone ages 4 years or older of 25 g/day, with a range of 22-28 g/day emphasized for women; most get half that with existing diets. According to the 2015 guidelines, only 13 percent of women achieve or exceed the recommended daily fiber intake. In

2016, the United Nations declared a "year of pulses" (pulses being another name for grain legumes) to encourage increased intake of these low-fat fiber sources worldwide.

To identify the most healthful carbohydrates, today's research focuses on the importance of carbohydrate effects on glucose and insulin in the body, especially because excessive insulin production is associated with increased rates of obesity, cardiac diseases, and diabetes mellitus as well as the metabolic syndrome, which connects all three morbidities with each other and with increased mortality.

Proponents of qualitative carbohydrate evaluation rely on a food's glycemic index (sometimes abbreviated "GI") to select the healthiest food sources for weight loss and disease prevention. The glycemic index of a food describes the carbohydrate's effect on glucose response; a higher glycemic index food causes greater amounts and rates of glucose absorption, which triggers a similarly spiked insulin release. Oral glucose is assigned an arbitrary glycemic index of 100, and other foods are measured against it on specialized charts, which differ slightly according to ingredients tested for inclusion by each research institution. For example, a starch like white bread has a glycemic index of 73, whereas bran cereal is 55, on a chart designed by Oregon State University (available at http://extension.oregonstate.edu/coos/sites/default/files/Fcd/documents/glycemic _ index.pdf). Low glycemic index foods, such as green vegetables and legumes, are sometimes called slow carbs, because they are absorbed more slowly into the bloodstream. These foods also trigger glucose absorption but provide a low, sustained source of energy that encourages more subtle, less damaging insulin fluctuations and that delays hunger. Distinct problems come into play, though, when evaluating entire meals for glycemic index content and when quantities of other nutrients, such as saturated fats, are not taken into account along with the glycemic effects.

Weight loss could be enhanced by selecting low glycemic index foods, which are typically healthful and unprocessed options. These foods have the potential to reduce hunger, and thus food intake, and optimize the body's energy use because of the slower glucose absorption rates and more appropriate insulin use. Although the true effects of the glycemic index and carbohydrate intake on weight loss and disease risks are still being studied, the choice to replace refined sugars from candies and alcohols with slowly absorbed, complex grains and fruit sources is nutritionally sound and should be encouraged.

Proteins

The importance of proteins on weight loss, disease risk, and diet adherence has emerged in a new role in the 21st century. Proteins are found in animal products, particularly meats, eggs, and dairy, and some vegetable sources; they contribute to muscle strength and bone growth and are also important sources of iron.

The 2010 U.S. Dietary Guidelines suggested that up to 35 percent of daily calories should be obtained from proteins. The 2015 guidelines emphasize an increased variety of proteins in the diet, particularly nutrient-dense options like salmon, nuts, and legumes (as well as bananas, peanut butter, and spinach) instead of fatty red meats. (Specific nutrient-dense meal and snack options are described for consumers at www.CNPP.USDA.gov and at the USDA Choose My Plate website). Due to their saturated fat content, proteins from animal sources such as red meats increase heart disease risks and should be eschewed in favor of more healthful plant alternatives; specific examples include lower-fat nuts like almonds, hummus, lentils, beans, and soy products.

Higher lean protein is frequently balanced by lower amounts of carbohydrate and fat intake, which may lower cholesterol, blood pressure, and blood glucose. Small protein-heavy snacks, such as hummus and whole-grain pita or carrots, in midmorning and midafternoon, can reduce lunch and dinner portion sizes better than many processed snack options that contain saturated fat. Energy-promoting cereal bars are increasingly prevalent as alternatives to processed foods such as crackers or cookies. Such snack bars can provide a healthful protein boost along with high fiber in one low-calorie option, and they can be tucked into a purse or briefcase for busy days. However, some protein-rich pre-packaged bars remain surprisingly high in fats, so even these products require careful selection for the best weight loss and health benefits.

Although the quantities of proteins that impact disease and health are still uncertain, their effect on diet and weight loss is decidedly positive. In a 2010 crossover study by Larsen et al. of glycemic index and protein variances on a diet intended to maintain weight lost with caloric restriction diets, the high-protein/low-glycemic index diet best supported weight maintenance in 773 patients for 26 weeks. Higher protein prevented weight re-gain over time. Proteins require longer digestion and thus delay gastric emptying more than most carbohydrates, and more than any fats. Therefore, protein in the diet has the largest effect on satiety: proteins are the most filling foods. Diets with increased daily percentages of healthy proteins reduce hunger and lower food intake and calories; similarly, they improve the likelihood of diet adherence, because they avoid the feeling of deprivation. Protein helps maintain weight after diet goals are met through similar mechanisms.

A WELL-ROUNDED APPROACH: DIET PRINCIPLES AND EXAMPLES

Principles

Optimal percentages of fats, carbohydrates, and proteins are highly debated regarding their effects on nutrition, weight management, and disease. Guidelines set forth by individual organizations, such as the AHA and the American Diabetes Association (ADA), vary on recommended macronutrient ranges. The U.S. Dietary Guidelines are updated every five years to incorporate the latest research about food intake. The 2010 guidelines suggested a wide carbohydrate range of 45–65 percent with greater fiber intake, high lean protein content of 35 percent for satiety, and a relatively narrow fat range of 20–35 percent from mostly unsaturated sources for any diet. In 2015, when the guidelines report focused on the quality of these nutrients, recommendations were to increase whole-grain intake to 50 percent of daily grain intake and to lower the percentage of nutrients obtained from refined wheat or processed foods.

Age-specific suggestions by the NIH for women over 50 focuses on enhancing heart health and protecting bones: in addition to increasing whole-grain intake, twice-weekly seafood and increased water intake regardless of thirst are encouraged. Specific daily quantities for this demographic include two cups of fruit, three cups of vegetables, 5-10 ounces of grain, 5-7 ounces of protein, three cups of low/no-fat milk, 5-8 teaspoons of olive or canola oils, and low intake of solid fats or added sugars.

By incorporating balanced, healthful choices within each nutrient type, such as by consuming more grains and fewer sugars or refined foods, effective weight control can be reached regardless of the exact percentage intake of micronutrients each day. The CDC reiterates the concept that focusing on one macronutrient does not help lower calories overall and can increase the risk of nutrient deficiencies. For example, in a *New England Journal of Medicine* report that compared four diets touting cardiovascular health with varying percentages of macronutrients, persistence and mental outlook were positively correlated with diet success. Carbohydrate intake ranged from 35–65 percent; fats, from 20–40 percent; and proteins, from 15–25 percent. After two years, weight loss and personal satisfaction were similar among all four diets in more than 800 people with BMIs of 25 kg/m^2 or greater who completed the programs. Higher protein diets were more often associated with positivity and adherence, and the converse was true for higher fat diets. All diets, regardless of macronutrient composition, shared qualities identified as beneficial aspects to a weight loss approach: 8 percent or fewer calories from saturated fats; 20 grams of fiber each day; a caloric deficit of 750 calories from baseline that fostered weight loss; and group participation.

To encourage weight loss in people who are overweight or obese, the National Heart, Lung, and Blood Institute (NHLBI) provides realistic, guided goals for any diet. Initial goals of 5–10 percent weight reduction over six months are considered sufficient for most people. Weight loss at this rate holds a multitude of benefits toward reduced disease risk without deficiencies or unhealthy habits. Weight Watchers reports that a small, 10 percent body weight loss from any baseline instills confidence to continue. Additionally, slow weight loss allows the body time to adjust, so the pounds are kept off more easily. According to one-year observational data on the Look AHEAD study, metrics of cardiovascular disease risk in people with BMIs of 25 or greater and existing diabetes all improved with only a 5–10 percent weight loss. Positive results included A1c reduction by 0.5 percent points, blood pressure reduction by 5 mmHg, HDL increases by 5 mg/dL, and triglyceride reduction by 40 mg/dL. Changes were even greater with 10–15 percent weight loss, and benefits were noted from any weight baseline.

The NHLBI recommends that additional weight loss be considered for obese people only after the initial 10 percent body weight reduction has been maintained for six months. This approach both ensures safety and reinforces positive assessments of body image and long-term goals. Continued, slow weight loss not only allows time for new habits to develop, it also is the most likely method to avoid yo-yo dieting. Calories represent energy from food, and approximately 3,500 kcal equals one pound of body fat. To achieve a 5–10 percent weight loss in the recommended six months initially or as a continual effort, just 1–2 pounds per week is usually necessary. Loss of just one pound per week is attainable by reducing calories by 500 kcal/day. For women who prefer to count calories, a maximum of 1,200 per day is recommended by the CDC for steady weekly weight loss, and up to 1,600 kcal/day is acceptable for women who weigh more than 165 pounds or for athletes who expend more energy. On a 2,000-kcal/d diet, high-calorie foods are considered those with at least 400 kcal; moderate, 100 kcal; and low, 40 kcal per U.S. Dietary Guidelines. Regardless of total caloric intake, nutritionists advise a daily fluctuation of 100 to 200 calories to avoid rigidity and negative feedback.

Examples: Mediterranean

Although no single diet works for everyone, the Mediterranean diet approaches the current AHA-recommended diet program and has research-backed efficacy at minimizing the onset of diabetes in at-risk populations; in studies, observation of the Mediterranean diet also has been linked to improvements in coronary heart disease, macular degeneration, and even survival, with documented two-year increases in lifespan. The diet is based on traditional

lifestyles in countries near the Mediterranean Sea, which incorporate large amounts of moderate exercise throughout the day.

All variants of the diet rely on fresh foods, cereals, and oils and share the following healthy eating characteristics: large quantities of vegetables and fruits (such as 7–10 servings/day) and of legumes, grains, and cereals; moderate dairy intake as cheese, not cream; low to moderate animal proteins, primarily from lean fish instead of fatty red meats; high amounts of unsaturated fats (such as olive oil) compared with saturated fats (such as butter); and modest amounts of red wine (such as one 4-ounce glass for women) each day. The total fat typically does not exceed 30 percent, and the saturated fat component always remains at or below 8 percent.

Extra protein comes from nuts and seeds. Beans and potato products round out carbohydrates and egg intake (as a cholesterol source) is fewer than four per week. Compared with U.S. diets, the Mediterranean diet is substantially lower in saturated fats that increase cholesterol and, ultimately, mortality, despite high total fat intake. When the Mediterranean diet was compared with a low-fat diet in people with cardiovascular risk factors, the number of new diabetes diagnoses was halved in the Mediterranean diet group because of its extremely low saturated fat intake.

Examples: TLC

Understandably, choosing and observing a diet is complex for patients, especially because recommendations continually change. The Institute of Medicine Food and Nutrition Board suggests that consumers experience high levels of confusion about terms used to describe foods, such as "trans-fat free," "low glycemic index/low GI," or "all natural." By focusing consumer education on grains and fresh foods that are nutrient filled instead of calorie heavy, organizations such as the ADA hope to encourage durable habits, not just weight loss diets. An example of such a durable program put forth jointly by the AHA and ADA through the CDX is the Therapeutic Lifestyle Changes (TLC) plan. The TLC is part of the NCEP Adult Treatment Panel initiative on diet, weight, and physical activity for heart disease prevention. A component of TLC targets reduced LDL as a primary goal; secondary end points of TLC are lower triglycerides, increased HDL, lower blood glucose, lower blood pressure, and weight loss.

TLC as a diet plan appears quite similar to the Mediterranean diet by favoring unprocessed carbohydrates, unsaturated fats, and fish for lean protein. TLC identifies fat intakes by type of fat and emphasizes a goal of less than 7 percent of the dietary fat per day from saturated or trans sources. Within a 25–35 percent fat range, polyunsaturated fats should account for up to 10 percent, while monounsaturated fats can contribute 20 percent. An additional 2 g/day of plant sterols is suggested.

Proteins in the TLC diet comprise 15–25 percent of a day's calories, and carbohydrates can reach up to 50–60 percent of daily calories. However, whole grains, fresh fruits and vegetables, and cereals are the largest recommended, non-refined carbohydrates. TLC also quantifies a fiber goal, unlike many diet programs or recommendations. Fiber intake of 20–30 g/d matches the 2010 U.S. Dietary Guidelines recommendation and likely contributes extensively to weight management and digestive health. The latest NIH suggestion for followers of the TLC diet includes addition of 5-10 grams of fiber daily to reduce LDL by 3-5 percent.

As with other successful weight loss programs, TLC requires some calorie restriction, to 1,200 calories per day, to achieve energy balance. However, the program acknowledges that people typically ingest consistent amounts of food each day, regardless of caloric content. In addition to terminology concerns, consumers struggle to maintain diets that require strict calculation efforts. The TLC diet program outlines an alternate approach that uses energy density, or kcal/g, to make appropriate food choices. Energy density can be calculated and precisely adapted to a diet, but it often can be estimated with practice. Energy density is defined as calories per given weight of food. Low-density foods are low in calories, so larger portions are allowed in the diet. Foods with low energy density add fewer calories, despite maintaining the same quantity of daily food intake, which promotes eating without large weight gain. Diets such as TLC that incorporate low-calorie foods, or those with low energy density, are easy to follow because they do not restrict eating; thus, they provide positive reinforcement to continue a diet until it becomes a lifestyle.

Substituting lower-density foods for higher-density options is mentally easier than eliminating a food type or group entirely; replacement without explicit calorie counting encourages eating instinctively, until sated. Low-energy-density foods as first courses can lower consumption of higher-calorie main courses, and mixing low-density foods such as broths or vegetables into high-energy-dense foods like casseroles also stretches the food intake and ultimately lowers the energy density of the entire meal.

Low-energy-dense foods often are healthful food choices that are high in fiber, vitamin A, vitamin C, and folate. Conversely, high-energy-dense foods include crackers, cookies, chips, bacon, and margarines—all of which contain saturated or trans fats and are over-consumed easily because they

do not assuage hunger. More specific examples of low-energy-dense foods include zucchini, celery, carrots, and spinach. Fiber is quite low in density, at 1.5 to 2.5 kcal/g. Carbohydrates and proteins, at approximately 4 kcals/g, are moderately dense; fats have the highest energy density, at 9 kcal/g. Density of any food can be calculated by dividing calories per serving by the grams per serving size.

Weight Management After Loss

A weight maintenance strategy differs from a weight loss program in its goals, methods, and durations, although both rely on lifestyle change, variety, and incorporation of physical activity for the best results. Unfortunately, lifestyle changes and moderation are challenging to initiate and sustain, especially alone. Behavioral interventions that support the consumer along a pathway of goals increase the likelihood of success for weight loss, weight maintenance, and disease prevention. Dieters and maintainers need distinctly different reminders, habits, approaches, and guidance.

BEHAVIOR CHANGE TIPS FOR DIETERS AND MAINTAINERS

For Dieters

Dieters depend upon regimented efforts toward one large goal, even with multiple interim goals. Steady, confidence-boosting weight loss is even more likely to succeed when dieters plan for stressors or diet setbacks. In the 21st century, this confidence boost frequently comes in the form of social media encouragement, whether in partnerships or in online groups.

The AHA encourages dieters to anticipate difficult periods and pre-plan accordingly, ideally addressing barriers to healthy habits with professional guidance and support. They suggest small steps toward early change: begin with a one-week food diary to document hidden calories, identify behaviors that foster overeating, and prepare for barriers against change. The AHA suggests reassessment every six weeks, not sooner, to identify what changes worked and to incorporate variety. A food diary can also expand into a lifestyle journal that reveals more than just food intake. Such a journal can document three steps crucial to lifestyle change: eating triggers (such as time, place, actions that are associated with foods); eating surroundings (such as areas associated with food intake, number of chews taken and speed of meals); and why a person eats and how they react to food (treating food as a reward).

Techniques to support a diet without requiring measurements or scales and to support incremental changes ease the dieting experience as well. Evaluating weight once weekly instead of daily while actively trying to change food habits will more reliably reflect the effects of eating patterns maintained over seven days and is more likely to reflect successes toward a weight-loss goal. Increasing intake of zero-calorie drinks such as water or unsweetened iced tea increase feelings of fullness between meals, maintain optimal hydration, and do not contribute to daily sugar or sodium intake.

During any diet, estimating appropriate portion sizes helps prepare the dieter for long-term weight maintenance. The website My Plate helps dieters identify normal portions and healthy foods without associating these choices with specific numbers on the scale. With practice, women can learn to identify healthy portion sizes of different foods instead of restricting or avoiding them entirely. AHA recommendations to foster this approach include keeping portions generally smaller than fist size to reduce overeating and keeping meat portions at ½ fist size to limit fat intake.

For Maintainers

Maintenance of a healthy weight, unlike dieting, is a way of life, not a one-time goal. Weight maintenance is quite frequently omitted from diet programs, but it is often the greater challenge. Avoiding the issue of how to maintain weight loss and habits learned often leads to weight rebound, repeat dieting, and the yo-yo effect. Weight loss programs should not be sustained indefinitely, though; instead, solid nutrition principles and a physical activity plan can maintain success without reaching for more loss and risking nutrient deficits.

Weight maintenance requires new goals: the ability to not regain 6-7 pounds over two years after a successful weight loss of 10 percent; and maintenance of a waist circumference two inches smaller than the original baseline circumference, for example. One key component of weight maintenance is implementation of a nutrition plan that does not restrict calories extensively but that does retain healthy habits from dieting (such as portion control, meal and snack preparation). Instead of focusing on calorie counting or food avoidance, maintenance eaters need to establish and continue habits; these are most likely to become lifelong changes if they include variety, accountability, and positive feedback from families or support groups.

As with dieting, maintenance eating should be enjoyable and not repetitive. Maintenance eaters who falter should reassess and consider their well-being, not the numbers on a scale, to instill positive habits and goals. AHA recommendations for maintenance eaters include continued avoidance of high-fat food options (such as full-fat dairy), increased low-energy-dense vegetable intake to lessen hunger without additional calories, and routinely high fiber intake to slow digestion.

Planning for stressors or social excursions continues beyond avoidance associated with popular diets and involves freezing smaller meals and treats, carrying healthful snacks while away from home, and selecting restaurant appetizers instead of entrees to reduce portion sizes. Maintenance relies heavily on self-imposed nutrition choices, including more whole fruits and veggies, grains, legumes, and greens; less fat and sugar; and smaller portions.

Numerous barriers exist to prolonged behavior change, including the extra time, effort, and cost required to continue healthy habits. Involving peers, family, or community groups greatly minimizes these barriers. Goals are better achieved and maintained when families eat well together and when everyone is involved in meal planning, writing shopping lists, and recipe development, to lessen the burden of weight loss on one individual.

Maintenance of weight loss also depends on continued incorporation of physical activity working toward a long-term goal of 30-60 minutes per day. However, even 10 minutes of exercise can be effective; short bursts of activity burn more fat than prolonged activity. Physical activity does not have to be fancy or expensive, either; walking is one of the easiest ways to improve cardiovascular health and encourage long-term weight maintenance. The popular goal of 10,000 steps per day, whether tracked by a simple pedometer, a smartphone app, or a wearable device, can translate to nearly 3-5 miles of walking for a person with an average stride. According to an analysis of 26 studies of pedometer use in 2007, pedometer walkers add an average of 2,000 steps/day above non–pedometer users (an activity increase of 27 percent). Health benefits of walking are maintained whether 3,000 steps are walked in 30 minutes or whether those steps are achieved in three 10-minute increments. For patients who aim to maintain weight loss but do not achieve 10,000 steps/d, a reasonable program is to increase by 500 steps/day (approximately one-quarter mile).

Activities or workouts with a partner help to avoid procrastination or skipping sessions, and exercise variety and periodic reassessments are beneficial. By choosing active options within an individual's lifestyle (such as stairs in place of elevators), physical activity goals are better achieved. In fact, the mental approach to physical activity plays a large role in its continuation: "Being active" instead of "working out" is a mental switch that encourages frequent, fit-in-existing-schedule physical actions.

Encouraging Behavior Change

People tend to overestimate calorie requirements and underestimate calorie intake, and only 200 extra calories per day regularly can contribute more than 20 pounds of body weight. Because inappropriate portion sizes and mindless, on-the-go snacks are dominant sources of these extra calories, daily food diaries and journals associated with food choices contribute to successful weight management. Writing daily intake on a throw-away napkin is better than not tracking food habits at all, but many structured programs also exist to help patients document their choices. Along with online professionally endorsed programs like the American Heart Association DASH diet for hypertension or the NIH Weight control Information Network (WIN), new online sites target subpopulations at risk for weight gain: Sisters Together is a booklet-based NIH program to help African American women ages 20 or older who are overweight or obese change their habits. Similarly, the teen webpage Bodyworks—a toolkit—emphasizes healthy eating options for teenagers.

In 2009, Canadian researchers took the concept further and demonstrated the efficacy of cognitive behavior therapy (CBT) for weight maintenance by using a workbook to improve healthy outlook and minimize obsession with weight on a scale. CBT is a psychological treatment process used to improve coping skills through better comprehension of a situation and work toward interim and long-term behavior change goals. For example, cognitive behavior programs that aim to reduce overeating as an ultimate goal will provide short-term supports to identify and avoid eating triggers, replace foods with healthful options, and educate the patient about choices and results.

In the Canadian study, a cognitive behavior workbook for weight management was developed to encompass all aspects of sound dieting and maintenance principles. Study participants used worksheets for individual food planning and exercise ideas. They received encouragement of new habits, and positive rewards for spotting and avoiding food triggers. More important, though, the workbook educates dieters in plain language about the combined roles of genes, activity, and lifestyle choices in the development and dangers of obesity—both to reduce negativity and to explain why a small change in activity and food selection both have great benefits toward disease prevention.

The workbook also stresses the importance of weekly, not daily, check-ins with groups or health providers to monitor permanent changes and periodically assess and adjust goals. The book—which was published in the United States in 2009 as "The Cognitive Behavioral Workbook for Weight Management: A Step-By-Step Program" by Michele Laliberte, Randi E. McCabe, and Valerie Taylor—discusses when and for whom more drastic weight loss efforts, like medication, are warranted. Although the book is best used with professional guidance, individual use is acceptable and can be successful with self-motivation.

Technology Roles

As smartphones and tablets become ubiquitous across age and socioeconomic demographics, the apps and online groups spill into all areas of daily living, including physical activity and dieting. Benefits of using electronics to document diet and exercise include "virtual dispersion," or the ability to input and check personal progress (such as calorie intake or cardiovascular measures during exercise) multiple times daily, wherever a person is at the time. Online programs or apps for individuals offer structured lessons and scheduled podcasts that support personal goals, too—often with minimal or no cost.

Social media groups also play an important role in maintaining diet and exercise efforts over the long term. Online diet groups, friend interactions on any of the numerous social media platforms, and chat rooms encourage progress toward a stated goal and offer immediate support to bolster willpower. A 2015 psychology study of social media effects on the physical activity of 217 graduate students noted that one-time promotional messages in a social network wore off quickly, but pairing of buddies (even relative strangers) online provided continual motivation for physical activity across the 13-week study period.

An unplanned benefit of increased technologic use for weight loss and activity is the potential contribution to available preventive care data. New Precision Medicine and NIH efforts aim to enroll 1 million volunteer users of technology, like wearable devices, social media, and smartphone apps, to gather data related to their health outcomes, especially smoking effects and cardiac disease contributors. Likewise, an NIH grant to Notre Dame will give students wearable devices to track activity, sleep, and health measures to look for patterns among technology use, health actions, and health outcomes.

PHARMACY PROGRAMMING: PERCEPTIONS AND SUCCESSES

Americans are gaining weight and developing chronic diseases rapidly without acknowledging these conditions in themselves. Health professionals have a duty to encourage open discussion about obesity and its link to diseases such as hypercholesterolemia and diabetes. However, only 20 percent of physicians counseled patients with existing cardiovascular disease, high cholesterol, or diabetes about their diet or nutrition in 2007, according to Healthy People 2020. Obesity directly correlates with cardiovascular disease and stroke: 22 pounds of extra weight can increase cardiovascular disease risk 12 percent. High cholesterol increases proportionally with increasing BMI as well, starting at only 25 kg/m^2, and the NHANES III study reports a greater likelihood of this morbidity in women than in men.

Only 3–5 minutes of conversation with a patient can motivate him or her toward weight loss and nutrition changes. Education about the numerous food labels, as well as patient-friendly language like "extra weight" instead of "morbid obesity" or "body fat" provide positive associations about food discussions and health care among patients and their health providers.

As medication therapy management (MTM) programs expand and reimbursable activity through accountable care organizations become more common, the public perception of pharmacists as purveyors of health information and wellness can likewise grow and improve public health outreach. Consumer interest and pharmacist confidence, followed by program development and subsequent compensation for professional services, are vital components but also current barriers to community weight loss programs.

Basic Metrics

Pharmacists should first evaluate whether a person requires weight loss by evaluating BMI, weight in pounds, and waist circumference as well as comorbid diseases and potential primary causes of obesity (such as thyroid disease). BMI is most accurately measured by weighing a person with minimal clothing and measuring height to the nearest quarter inch. Results can be referenced against BMI tables provided by the CDC and other health organizations that have completed the calculations already. BMI, though an indirect correlate of body fat composition, has become the gold standard for obesity care and is an independent marker for stroke, heart disease, diabetes, and high cholesterol. Fat collects around the waist, so its circumference, as an efficient indirect measure of abdominal fat, is particularly recommended to identify cardiovascular risks. Using a flexible tape measure, the pharmacist can measure around the waist just over the navel. An initial goal waist circumference per the AHA is less than 35 inches in overweight or obese women.

For patients with BMI or waist circumference greater than normal, nutrition evaluation and goal setting are good first steps toward healthy habits. If a patient has a baseline BMI of 25 kg/m^2 or greater, a starter weight loss goal of 10 percent can be attempted with diet and exercise. Especially patients with morbid obesity (such as BMI of 40 kg/m^2 or greater), or with obesity and chronic diseases after failure of concerted lifestyle and diet efforts, should be referred to physicians for OTC prescription treatments or surgery.

Medication Considerations

Medications are infrequently indicated for weight loss. Their use should be guided by BMI and should supplement diet and exercise when these have not succeeded alone.

People with BMI greater than 27 kg/m^2 and a high risk of (or at least one existing) cardiovascular or metabolic disease (such as diabetes), or anyone with BMI of 30 kg/m^2 or greater, are candidates for adjunct medication treatment. Medication goals must be as realistic as the weight loss program goals. For example, because medication use often involves chronic disease prevention, small goals include reducing risk markers for these diseases (such as LDL or blood pressure) instead of reaching an ideal weight. All approved medications for weight loss use are approved only in addition to behavior modifications, specifically low-calorie diets and increased physical activity.

Approved medication options are limited, in part because their high rates of safety concerns discourage companies from sustaining research into new treatments. Many approved weight loss medications are identified through off-label use of serotonergic or antiepileptic medications that cause weight loss during clinical or postmarketing studies for an indicated use. Although some of these off-label treatments have been evaluated for obesity indications in recent years, they still carry cardiovascular, neurologic, and other risks as monotherapy treatments of obesity. Three currently available new prescription weight-loss options (lorcaserin, naltrexone/bupropion, and liraglutide) were approved only after prior safety rejections or combined with boxed warning or post-marketing risk assessments.

Lorcaserin hydrochloride (Belviq) is a selective serotonin 2C receptor agonist in the hypothalamus with an unknown mechanism of action for weight loss. It appears to promote satiety and reduce appetite. Although it was rejected by the European Medicines Agency, it was approved by the FDA in 2012 at a dosage of 10 mg twice daily with or without food. Some patients in clinical trials experienced up to 5 percent weight loss, although rebound weight gain also occurred. If patients who are prescribed Belviq fail to achieve 5 percent weight loss by 12 weeks of use, they should discontinue the drug. Belviq is a C-IV controlled substance that carries a risk of abuse or dependence. High doses or combined use with other serotonin-active or dopamine-antagonist drugs can lead to mental status changes, hallucinations, and euphoria. More common side effects that led to discontinuation in clinical trials were headache and dizziness. Belviq is metabolized by the liver and inhibits the CYP2D6 enzyme, so it can increase concentrations of drugs like dextromethorphan. In part because of a risk of lower heart rate and increased valve disease that are being evaluated in postmarketing studies, Belviq carries a boxed warning; Belviq also was associated with increased rates of tumors in earlier animal studies.

A non-serotonergic monotherapy option as a behavioral adjunct treatment approved in September 2014 is the naltrexone 8 mg/bupropion hydrochloride 90 mg tablet (Contrave). Naltrexone, an opioid antagonist, and bupropion, a weak dopamine/norepinephrine inhibitor, appear to regulate hypothalamic appetite regulatory center and dopamine reward system actions, although the exact weight loss mechanism again is unclear. Contrave is tapered up from one tablet once daily for one week to a maintenance maximum of two tablets twice daily, and it must not be taken with high-fat meals (which increase the systemic concentration). Like Belviq, a 5 percent weight loss by week 12 is expected, and the drug should be discontinued if this is not achieved. Contrave should not be used in patients who take opioids, because of an overdose risk, or in patients who take sedatives or other bupropion drugs, in patients with histories of seizures or eating disorders, or in patients with uncontrolled hypertension. Because of its bupropion content, Contrave has a boxed warning of suicidal thoughts and actions, especially in younger patients, and of neuropsychological changes, such as manic episodes or seizures; also, Contrave is associated with dangerous blood pressure increases.

In 2014, another crossover prescription weight loss option evolved from an approved medication for type 2 diabetes mellitus, liraglutide, a GLP-1 analog agonist. Liraglutide for weight loss (Saxenda) is a subcutaneous injectable formulation (6 mg/ml) administered to the stomach, thigh, or upper arm at a maintenance dosage of 3 mg daily (increased weekly from a starting dose of 0.6 mg daily). However, this option remains costly and difficult to use, with many adverse effects. Low blood sugar, dizziness, headache, bloating, gas, nausea/vomiting/diarrhea, and dry mouth are common. Saxenda also carries a boxed warning, which highlights the increased risk of medullary thyroid (C-cell tumor) carcinomas. Sandexa was approved in conjunction with a risk evaluation and mitigation system (REMS) program (saxendarems.com) because of this association. Despite the addition of these three agents to the weight loss arsenal, the great need for safe, practical prescription medications to treat excess weight with comorbidities remains unmet.

The only approved OTC option for weight control is orlistat, a drug that blocks fat absorption from the gastrointestinal tract to induce weight loss of up to 5-10 pounds within six months of use. The drug's fat-purging effect teaches fat avoidance, especially with more than 30 percent of fat intake per meal. However, fat soluble vitamins A, D, E, and K are also blocked, and oily stools are a serious concern for patients. Orlistat 60 mg over the counter or 120 mg as a prescription, taken up to three times daily with a fatty meal, can lower blood pressure, glucose, and cholesterol as well as induce significant weight loss of

8-10 percent at one year. However, many people cannot tolerate orlistat because of its 10-15 percent rate of gastrointestinal side effects.

Changing Perceptions

Weight loss programs in the pharmacy are slow to take hold, despite recent successes in select community settings. A significant reason is that consumers in the United States and worldwide expect to receive drug information, not lifestyle or nutrition advice, from their pharmacists. They also view behavioral interventions as potential distractions from traditional dispensing efforts. However, consumer confidence about medication-related interventions by pharmacists, such as nicotine replacement counseling, approaches confidence in physicians.

Public health interactions are not expected but are rated highly when they are provided, regardless of the topic (such as osteoporosis, diabetes). Positive interactions after participation in a clinic approach rated 80–98 percent for a wide range of services. Performing interventions increases the likelihood of support; for example, opinions of pharmacists as disease management experts and confidence in the pharmacist ability increased 24 percent after polled consumers attended a diabetes clinic. Consumers are generally positive about pharmacists and pharmacies for health efforts, and satisfaction with established programs is quite high. The broader demand, though, appears quite low, because consumers do not expect new efforts or realize their usefulness.

Community pharmacy settings are potentially ideal for weight management initiatives, because they are open and accessible to all ranges of people. The latest partnership efforts, ACOs, emphasize proactive efforts to maintain patient health through collaboration and are primed to prevent metabolic and cardiac chronic diseases through weight management. Although the pharmacist role in ACOs has been slow to take off, pharmacists must remain invested and confident about the programs. In an evaluation of nearly 70 papers, successes and peer attitudes about pharmacist involvement in public health incorporation identified professional reticence when medications are not the focus. Many pharmacists did not think they were adequately trained to have or to use knowledge about behavioral interventions for smoking, weight, or contraception. Pharmacists, when polled, agreed upon several barriers to establishing and continuing a weight loss clinic in their community settings. Practical concerns, as anticipated, included a lack of private space for discussions or evaluations as well as insufficient staffing, time with patients, and insurance reimbursement. More professional concerns center on a lack of training and knowledge foundation about weight loss programs and popular products. Pharmacists appear well-versed in the effects of excess weight and fat on chronic disease and health; however, education on particular weight loss regimens or specific optimal programs is lacking both for pharmacists and for public health care providers in general.

Documented successes at weight loss intervention efforts are expanding, though. One example, as demonstrated in a college community in 2007, is the Healthy Habits Program, which enrolled nearly 300 student patients on a college campus. BMI, percentage of body fat, and diseases related to obesity were measured. Nearly one-third of patients reduced their BMI category (such as from obese to overweight), more than one-quarter lowered their disease risk statuses, and the mean weight loss from baseline reached the 10 percent benchmark. The program not only improved health, it also increased public awareness of the pharmacy as a resource and attracted more patients to the pharmacy as a business. Similarly, in 2014, a six-month weight loss program for urban patients with obesity was led by community pharmacists in Arizona. Significant reductions in BMI, weight loss, waist circumference, and visceral fat percentage were documented, and patients were highly satisfied with the program.

Behavioral modification programs in the community setting, like the Take Charge program, utilize education and encouragement to motivate patients. Pharmacists meet with and educate patients on a variety of obesity-related topics over the course of 13 weeks to provide patients with direction during the weight loss process.

Implementation of new weight management services is a sound long-term business strategy, and examples such as this should be used as a backbone for introducing new programs. Pharmacist self-confidence can be improved with training to encourage a positive outlook that is crucial to the likelihood of clinic and patient success. As Michael Pollan has emphasized, cooking (and eating) should be a pleasure, not a burden.

CONCLUSION

In their continual attempts to achieve or maintain weight loss, women consistently rotate through advertised programs, supplements, and fads—often without professional guidance. This repeated flux in weight and nutrient intake, instead of establishing long-term healthy habits, only encourages the difficulty of weight loss as women age and negatively reinforces body image while contributing to the development of chronic diseases.

Weight loss programs that moderately restrict calories without eliminating or severely restricting a specific food group are generally the safest diets and most effective means of shedding pounds. Maintaining new habits, allowing small calorie fluctuations, and including high-protein snacks to curb hunger are successful approaches to maintain a healthy weight and avoid habits like binge or social eating.

Pharmacists must be able to counsel patients, when approached, about diet and weight loss products. More than that, though, pharmacists should increase their own knowledge of nutritionally sound alternatives so as to proactively engage consumers about the best weight loss and weight maintenance goals and products for them. Ultimately, pharmacists can promote health with a multifaceted clinic approach or simply through the counseling window when physical and mental barriers to weight management and business practices are addressed and limited.

The ultimate goal of providing trusted health resources to the public to prevent chronic disease goes hand-in-hand with improving pharmacist confidence and public perceptions of the pharmacist as a health professional, not just a dispenser. Much like diabetes care clinics, weight loss interventions can introduce a new standard for public health care in the United States and become a door to optimal care of chronic cardiovascular and metabolic diseases.

CASE RESOLUTION

Because this is D.G.'s initial weight management consultation, you should begin with a needs assessment: does she require weight loss or weight maintenance? Her BMI reflects an overweight, but not yet obese, status. Her hypertension, but not her waist circumference, indicates potential long-term cardiovascular risks that could increase morbidity and mortality together with her increased weight. She is a candidate for weight loss counseling, but not for medication or surgery at this time. Her recent attempts at fad diets also suggest the need for a conversation about essential nutrients and their sources.

On the basis of her current weight, a 10 percent weight loss goal of approximately 15 pounds over six months (to a goal of 137 pounds and a BMI of approximately 24 kg/m2) is reasonable and approaches normal weight status on the CDC chart. D.G. can be referred to a dietician for full nutritional evaluation and counseling, but you are aware of the U.S. Dietary Guidelines from 2010 and 2015 and can start her on a nutritional path toward weight loss and eventual maintenance.

By reducing her daily calorie intake to 1,600 kcals (a reduction of 500 kcals), D.G. can lose one pound a week and meet NIH safe weight loss recommendations without extreme restriction. You can provide D.G. a food diary on paper or as an app to track types of food, portion sizes, and eating habits each day and can refer her to the My Plate website. Similarly, your nutritional instruction will outline means of increasing protein for midmorning and midafternoon snacks, increasing fiber to at least 22 grams per day, and minimizing saturated and trans fats to at least under 10 percent of total daily calories (and ideally to under 7 percent because of her existing hypertension). If D.G. continues to worry about the effect of carbohydrates on her current weight, a discussion about the glycemic index, "slow carb" choices, and whole-grain options is warranted, and incorporation of low-energy-dense foods and increased water intake can reduce hunger between meals.

D.G. should revisit your clinic regularly to assess improvements in weight, BMI, waist circumference, and blood pressure during this initial six-month weight loss period. After this time, a full re-evaluation can identify future weight loss or weight management needs and can introduce additional long-term strategies to continue nutritionally sound diet plans. ■

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Editor's Note: For the list of references used in this article, please contact *America's Pharmacist* Managing Editor Chris Linville at 703-838-2680, or at chris.linville@ncpanet.org.

Continuing Education Quiz

Select the correct answer.

1. Observers of the fad paleo diet:
a. Avoid all ancient grains because today's body cannot digest them.
b. Risk deficiencies in B and other vitamins through loss of fortified grain foods.
c. Are encouraged to eat fatty red meat like our Paleolithic ancestors.
d. All of the above.

2. Body mass index and waist circumference are best described how?
a. Direct measures of excessive fat intake
b. Direct measures of overall weight
c. Indirect measures of excessive fat intake overall and around the abdomen, respectively
d. Indirect measures of excess weight overall and around the abdomen, respectively

3. Why is yo-yo dieting ultimately detrimental to weight loss attempts?
a. Repeated weight loss can lead to malnutrition.
b. Excessive fat burning followed by weight gain can confuse the body.
c. Metabolism slows over time as the body adapts to repeat dieting by storing extra nutrients and fat.
d. Metabolism can be sped up only for incremental benefits.

4. How many obese and overweight adults in the United States have hypertension and/or high cholesterol?
a. Nearly 25 percent
b. Nearly 40 percent
c. Nearly 60 percent
d. Nearly 70 percent

5. Which type of eating behavior is most common?
a. Restrictive eating
b. Over eating
c. Instinctive eating
d. Both A and B

6. Which of the following statements about the gluten-free is true?
a. Approximately 21 percent of Americans have autoimmune reactions to gluten.
b. The gluten-free market is a small niche that caters to the 1 percent of people with celiac disease or gluten sensitivity.
c. No clear evidence exists that avoidance of gluten will reduce fat storage around the waist in women.
d. Gluten-free diets are easy to observe because of the myriad healthful options now available in grocery stores.

7. Which of the following vitamins and minerals can become deficient with long-term observation of the Atkins diet?
a. Thiamin
b. Potassium
c. Iron
d. Both A and B
e. Both A and C

8. Benefits of technologic advances for personal diet and exercise goals include which of the following?
a. Personal counseling offered by certified professionals with minimal to no cost.
b. Encouragement solely from strangers who won't know if you miss your target goals.
c. Access anywhere, anytime to encouragement, exercise programs, and diet journals.
d. All of the above.

9. Which of the following statements about the most recent prescription weight loss medications is accurate?
a. Contrave, Belviq, and Saxenda all contain one active ingredient to increase weight loss through reduced fat absorption.
b. The combination of separate prescriptions of naltrexone and the established smoking cessation agent bupropion can achieve the same weight loss goal as use of the combination approved as Contrave, because the doses are identical.
c. Saxenda use is complicated by its injectable formulation and its lack of step-up dosing that results in high rates of adverse events immediately after the first dose is administered.
d. Belviq appears to promote satiety and reduce appetite, but it inhibits the liver enzyme CYP2D6 and should be used with caution with dextromethorphan and other drugs that are metabolized by this enzyme.

10. Women who use over-the-counter supplements for weight loss can experience which of the following?
a. Reduced appetite from fat-burning stimulants
b. Hunger suppression from yerba mate
c. Heart palpitations from stimulation by ephedra derivatives and/or caffeine
d. Longstanding weight loss from diuretics like celery seed

11. How do insoluble and soluble fibers differ?
a. Insolubles remain in the tract, while solubles absorb into the bloodstream.
b. Both fibers act as roughage, but insoluble fibers require water for activity.
c. Soluble fibers prevent glucose absorption, while insoluble fibers contribute to motility.
d. Soluble fibers include popcorn and carrots, while insoluble fibers are in oats and citrus fruits.

12. Which products contain healthful fat choices?
a. Tuna
b. Canola oil
c. Margarine made primarily from plant sterols
d. All of the above

13. In what ways does protein intake contribute to weight control?
a. Slows gastric emptying and reduces hunger
b. Provides the most calories to reduce hunger
c. Is the easiest snack option
d. All of the above

14. Despite 2010 recommendations of ____ to ____ g/d of fiber for women, only ____ percent of women in 2015 met or achieved that goal.
a. 22 to 28; 13
b. 30; 25
c. 13 to 15; 25
d. 22 to 25; 10

15. Why is the Mediterranean diet likely beneficial to heart health?
a. It eliminates unsaturated fats.
b. It incorporates the greatest levels of physical activity of any diet.
c. It relies heavily on olive oil instead of solid butter.
d. It emphasizes high intake of fresh meats instead of processed meats.

16. Energy density is useful for weight loss in what ways?
a. It reports another interpretation of standardized calorie intake.
b. It identifies foods that can be eaten in large quantities without exceeding the day's caloric intake.
c. It provides ways to lose weight by restriction intake of every macronutrient equally.
d. Both B and C.

17. In 2014, another medicine received second approval a weight loss agent after a prior approval for ____; the ____ formulation of Sandexa (liraglutide) is only one of its barriers to use in obese patients.
a. Hypertension; injectable
b. Type 2 diabetes mellitus; injectable
c. Type 2 diabetes mellitus; sublingual
d. Type 1 diabetes mellitus; injectable

18. Which patient qualifies for prescription medication to treat obesity?
a. BMI of 22 kg/m2 and high cholesterol
b. BMI of 35 kg/m2 and family history of hypertension
c. BMI of 35 kg/m2 and waist circumference of 36 inches
d. BMI of 42 kg/m2 and no history of cardiovascular disease

19. Orlistat's gastrointestinal effects are known for which of the following?
a. Occurring especially with meals that contain more than 30 percent fats
b. Causing diarrhea
c. Lowering digestive gas
d. Blocking fiber effects

20. Health benefits of protein include:
a. Extra energy, especially when protein is the largest portion of the dinner meal.
b. Extra energy, which is especially important earlier in the day to avoid overeating less healthful options.
c. A feeling of fullness, particularly when lean sources like nuts are ingested instead of fatty sources like red meat.
d. Both B and C.

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The Two Different Types of Sale Circular Programs

by Gabe Trahan

There are two types of sale circular programs. One is an in-store event where circulars are placed throughout the store and supported by window signage and in-store signs. In-store sale events are not designed or expected to draw new customers, but instead delight loyal customers with the surprise of extra savings on different types of merchandise. These include discounts on private label, "buy one, get one" offers, bonus sizes, seasonal items, and, almost always, vitamins. The attractive aspect of in-store circular programs is that they have no distribution cost. In-store programs should be considered as another form of a reward program.

OUT-OF-STORE/PUBLICITY EVENTS

The other sale circular program is a publicity event, where circulars are not only placed throughout the store and supported by signage, but are distributed throughout the local community and among the store's customer base. Common distribution methods (ranked from most effective to least effective) are direct mail to the customer's home (most costly), shared mail (circular distributed with other ads), and newspaper insertion.

The success of a newspaper insert hinges on the popularity of the paper and the day the insert is to be delivered. Avoid Mondays and be cautious of the popular weekend edition—weekends mean that your circular will most likely be one of many, and it will most definitely be nestled next to your competition, begging for comparison. Instead, consider placing your ad on Wednesdays.

Out-of-store distribution (publicity event) programs will offer easily recognizable savings on popular seasonal items, brand OTC items, some private label, household commodities, deep discounts on food and drinks, and something for all age groups. The purpose of out-of-store distribution programs is to attract new customers and entice loyal customers to make an additional visit to the store.

What these two types of events have in common: both should be treated as sales events inviting customers to shop and become more familiar with what the store has to offer.

GET YOUR STORE READY FOR THE EVENT

You need to have sufficient inventory and sales staff to support the sales event. Prior to the event, use a copy of the flier as an inventory sheet to confirm that you have enough product to meet the expected needs of your customers. You can also use the flier to check the promotional sale retail prices to confirm that they coincide with your marked sale retails.

Purchase a package of inexpensive shower curtain rings and clip the rings in a hole through the top left-hand side of the flyer. Hang the promotional material throughout the store, starting on each side of your end-caps.

Finally, get the mop and bucket out. Much like inviting people to your home for a party, the store, like your home, should sparkle and look inviting.

A FEW WORDS OF CAUTION

Very few sales events, if any, should run for longer than 10 days, especially if the sale involves discounting some of the store's best-sellers. Giving up the profit margin on popular items for a month at a time will hurt your net profits in the end.

Hosting a sales event and not having sufficient inventory to back up the sale can be disastrous. Do not invite people to shop your store and then let them down. The only way to judge the success of your sales event is by knowing how many people you have made happy and how many new customers you have gained. Do not judge a sale by what is left over on your shelves, but instead by the number of happy consumers leaving your store. Good luck! ■

Gabe Trahan is NCPA's senior director of store operations and marketing. Gabe uses 30-plus 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 galleries of photo examples by Gabe. Follow him on Twitter @NCPAGabe for additional tips.

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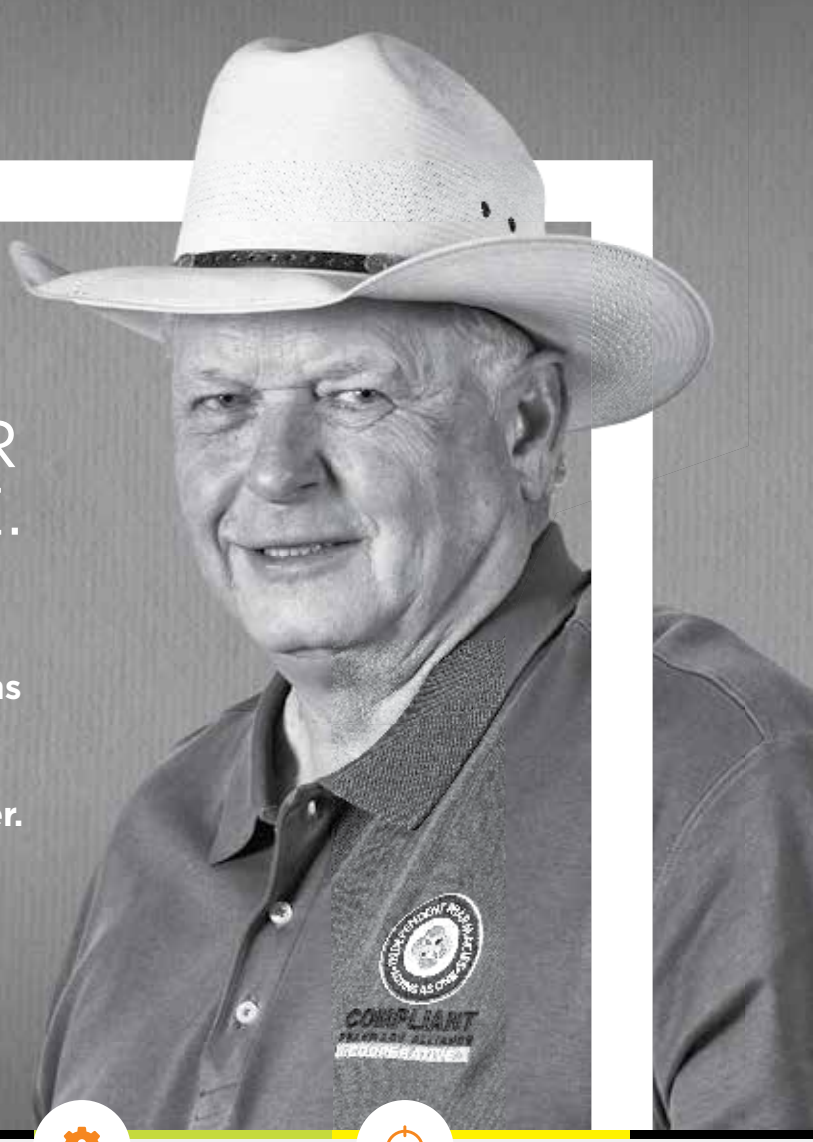

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