BUILD YOUR WEALTH

Avoid money mistakes

Choose the right adviser

Save through group purchasing

Grow with ancillary services
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A physician’s guide to financial success

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Cover: VERSUSstudio/Stock.Adobe.com

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For first-line constipation therapy, stick with the leader

The AGA recommends PEG laxatives (like MiraLAX) as a first-line constipation treatment

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✔ #1 GI-recommended laxative for over 10 years

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Use as directed on product labeling or as directed by your doctor.
Bayer, the Bayer Cross, and MiraLAX are trademarks of Bayer.
Increase revenue and improve patient care with mobile-enabled remote monitoring

Medicare’s Chronic Care Management (CCM) program looked like a big opportunity for primary care physicians when it launched in 2015. The Centers for Medicare & Medicaid Services (CMS) offered to pay practices about $40 per patient per month (now $45) for between-visit management of Medicare patients with two or more chronic conditions. But relatively few primary care practices have taken on CCM, partly because meeting the expansive requirements of CCM appeared quite difficult, and most groups have not been able to justify hiring extra nurses or outside services to perform the care management interactions.

Medical practices that want to keep their patients healthier while also tapping into this new revenue stream are looking for ways to make CCM more efficient and less costly—which is where mobile-enabled remote patient monitoring (mRPM) comes in. This type of technology, which typically includes a dashboard for the physician practice and a patient-friendly mobile app for check-ins between appointments, can greatly enhance communication between providers and patients. In addition, patients become more aware and engaged in their own care without overburdening the practices. This technology enables consistent patient monitoring between face-to-face appointments—a key CCM requirement. Furthermore, it is more efficient and cost-effective than phone-based monitoring, where only one patient can be contacted at a time and data must be recorded by a team member rather than automatically.

To read more, visit bit.ly/remote-patient-monitoring

Bloggers

“‘There’s this interesting little concept in psychology called ‘pratfall effect.’ It turns out that we like people who have a few flaws much better than we like people who seem ‘perfect’ or invincible. So, if a physician has nothing but five-star reviews, they may seem intimidating and be perceived as less likeable than the doctor that has mostly five stars and one or two one-star reviews.’”

— Rebekah Bernard, MD, on using psychology to manage negative patient reviews

“Often, when we’re on Facebook and reading controversial articles, we end up in an echo chamber, hearing the same arguments that reaffirm our own pre-existing beliefs. This confirms our own feelings, blocking out all other dissenting opinions.”

— Jonathan Kaplan, MD, MPH, on the role of confirmation bias in online physician reviews

Topic Resource Center

REVENUE CYCLE MANAGEMENT

- Treat revenue cycle management as a strategic process
- Can a digital employee transform the revenue cycle?
- Mitigating claims risk in medical necessity

For more, visit bit.ly/practice-RCM

Slideshow Spotlight

Top 10 most in-demand medical specialties

Doximity studied medical job postings in 2016 and 2017. The good news is physician job postings grew in most specialties analyzed. The bad news is your specialty may not be one of them.

To view, visit bit.ly/10-in-demand-specialties.
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The nation’s largest physician-owned insurer is now expanding in New York.
Physicians need to focus on patient care, not patient reporting

The recent article “Payment Reform: Washington pitches new rules to reimburse doctors” (September 10, 2018), focuses once again on changing medicine from patient care to patient reporting.

I practice in a rural setting where consulting specialists are 45 to 60 minutes away. We take care of injuries, acute and chronic life threatening illnesses and complex patients with four or more diagnoses. To try and charge one payment for most of these complex patients will just exacerbate the tendency that is growing to put up signs “One complaint only.” And why should I study all information about what new drugs should not be used with renal failure, with certain race related blood pressures, with changing drug susceptibilities, etc., if I get paid the same for making a referral to the consulting specialist to avoid mistakes and make me more money because I can see more patients. So patients have to travel, miss work, incur additional expense, time away from family, etc.

I have been practicing the specialty of family medicine for 54 years and will retire in December. I know it is all about money. What the proposal for single pay for a routine primary care visit (whatever that is) will accomplish is to encourage new physician students to go into other specialties (yes, Family Medicine is a specialty).

New laws want to give Nurse Practitioners free hands without supervision. Since their training and ongoing education is not up to Family Medicine standards what does that suggest to you?

Money in medicine is a primary consideration but it cannot be a trump card that takes everything else off the table.

Joe Baum, MD
FLOYD, VA.

Physicians can recapture passion for medicine through political advocacy

In “How physicians can regain their passion for medicine” (September 10, 2018 issue), Ben Levin, MD, gives some practical advice for recapturing the passion that made them choose medicine in the first place. But his ideas for regaining autonomy left out the most important thing of all: the need for political advocacy.

Physicians must unite and protest publicly—with passion and persistence. That cannot be repeated enough.

Our instincts tell us that it’s the right thing to do.

But the courage to unite and speak up forcefully to defend our professional autonomy are qualities that have been bred out of most of us in medical school.

Without advocacy his suggestions will only continue and increase our servitude to insurers—and the other forces that are extending their control over the way medicine is practiced.

We cannot let timidity and fear of retaliation hold us back.

The practice of medicine is at stake. More importantly, our souls and our self-esteem are at stake as well.

Edward Volpintesta, MD
BETHEL, CONN.

“Money in medicine is a primary consideration but it cannot be a trump card that takes everything else off the table.”
Study: Payers must do more to cover opioid alternatives

A recent cross-sectional study of 45 Medicaid, commercial, and Medicare Advantage plans found most health plans covered at least physical and occupational therapy and chiropractic care for chronic non-cancer pain, but there was little evidence of coverage of acupuncture and psychological interventions, which research has found are effective alternative treatments. Here’s a summary of the results, published in the *Journal of the American Medical Association Network Open*.

### What treatments do payers cover?

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical therapy</td>
<td>44 of 45 plans</td>
</tr>
<tr>
<td>Occupational therapy</td>
<td>43 of 45 plans</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>30 of 45 plans</td>
</tr>
<tr>
<td>Transcutaneous electrical nerve stimulation</td>
<td>10 of 15 Medicaid plans</td>
</tr>
<tr>
<td>Steroid injections</td>
<td>9 of 15 Medicaid plans</td>
</tr>
</tbody>
</table>

“We found that there is spotty coverage of several treatments that have evidence of effectiveness for treating pain.”

—James Heyward, MPH, Johns Hopkins Center for Drug Safety and Effectiveness, study author

5 insurer policies/non-opioid alternatives for pain recommended by the study:

1. Health plans almost always cover physical and occupational therapy as well as chiropractic care for chronic pain, but other evidence-based treatments are less commonly covered.
2. Payers must do a better job of increasing coverage of non-pharmacologic treatments for chronic pain, rather than focusing solely on reducing the overprescribing of opioids.
3. Inconsistent rules that limit access (visit limits, referral requirements, prior authorization, etc.) suggest a need for best practices for coverage and management of these treatments by insurance plans.
4. Other aspects of coverage such as prescriber training, and network size, also will play a role in patient access to treatments.
5. Plans are moving fast to improve coverage for pain patients, so some positive steps have already been taken.
Suture removal: Is it separately billable?

When a surgeon sutures the skin during a procedure, the reimbursement for the removal of the sutures is bundled or included in the allowance from the original procedure. Sutures are a common element of the wound closure performed immediately after a surgical procedure.

However, occasionally suture removal may be reimbursed separately. One such circumstance would be when an emergency department physician places the sutures to close an open wound. The patient normally is directed to follow up with his/her primary care physician or pediatrician to have the sutures removed. When an established patient visits a physician who did not place sutures for the sole purpose of removing them, a 99211 (office or other outpatient visit for the evaluation and management of an established patient) may be reported.

The clinician must document an examination of the wound and any other body systems or organs that may be involved and specify the medical decision-making pertaining to the wound. The provider then should report the appropriate evaluation and management (E/M) code (99201–99205, 99211–99215), and the suture removal is bundled into the encounter code reported and is not reported separately.

Suture removal service might also be coded and submitted to a payer for reimbursement when a child requires suture removal under anesthesia. Children are often stressed and upset about suture removal, and it is difficult to keep them still enough to perform the procedure. So the clinician may feel removal under anesthesia is best interests for the patient. When a procedure is scheduled in a procedure or operating room where anesthesia (other than local) is administered, the removal of sutures is billable. The documentation should support the reason that the more involved suture removal procedure was necessary, as well as whether or not the original surgeon is removing the sutures. This helps determine which of the two codes should be reported.

<table>
<thead>
<tr>
<th>Code</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>15850</td>
<td>Removal of sutures under anesthesia (other than local) same surgeon</td>
</tr>
<tr>
<td>15851</td>
<td>Removal of sutures under anesthesia (other than local) other surgeon</td>
</tr>
</tbody>
</table>

Renee Dowling is a coding and billing consultant with VEI Consulting in Indianapolis, Ind. Send your billing and coding questions to medec@ubm.com.
Among Peppermint Oils – IBgard® Stands Alone

In the ACG (American College of Gastroenterology) IBS 2018 Monograph, heartburn was recognized as an issue with older, “burst” technology.¹

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Recommend IBgard…By Name.

³ Cash BD, Epstein MS, Shar SM. Peppermint oil with site specific targeting is an effective therapy for irritable bowel syndrome with mixed bowel habits. Internal Medicine Review. 2017; doi:10.18103/imr.v3i9.565.
⁴ Among gastroenterologists who recommended peppermint oil for IBS. Alpha ImpactRx ProVoice survey (September 2017).

Individual results may vary. Medical foods do not require prior approval by the FDA but must comply with regulations. The company will strive to keep information current and consistent but may not be able to do so at any specific time. Generally, the most current information can be found on ibgard.com.
BUILD YOUR WEALTH

A physician’s guide to financial success

Physicians are beset from all sides with advice on how to manage their money, both personally and for their practices. But where should you begin? In this issue, Medical Economics features advice from financial experts on what every primary care physician should do right now to better invest their money and find new revenue opportunities to create a sound financial future.

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Five common financial mistakes and how to avoid them

by JAMES F. SWEENEY Contributing author

Physicians are among the highest-earning and best-educated professionals in the country, but their combination of education and income does not prevent them from making personal financial mistakes.

“Money is like a [foreign] language to them,” says W. Ben Utley, CFP, owner of Physician Family Financial Advisors in Eugene, Ore. “None of this is rocket science, but it’s the first time for a lot of [physicians]. They don’t know how a bank works or what a CD is.”

Indeed, the lengthy education and single-minded focus it requires to launch and maintain a career as a physician doesn’t leave a lot of time to become educated on personal finances. Financial errors can wreak havoc in doctors’ careers and personal lives. And because physicians begin earning later than most professionals, they have less time to accumulate wealth or to recover from errors.

Below are five common financial mistakes doctors make and ways to avoid them:

LACK OF PLANNING

Most doctors earn higher than average salaries and they can mistakenly think that negates the need for financial planning.

That was the case with a surgeon client of Joel Greenwald, MD, CFP, owner of Greenwald Wealth Management in St. Louis Park, Minn. The client earned $450,000 a year. He and his wife, who didn’t work, had three children headed to college.

“They’ve just been sort of winging financial planning,” Greenwald said. “They hadn’t had a financial planner and hadn’t dedicated themselves to doing it on their own.” Consequently, the family hadn’t saved enough money to send the children to college and the surgeon had to push back his retirement age by several years.

Planning is particularly important for physicians because, while they usually make comfortable livings, they typically don’t start earning it until their late 20s or early 30s, well after other professionals.

“Doctors get a really late start, like 10 years behind everyone else, and they’ve got to make up for lost time,” says Ryan Inman, MBA, owner of Physician Wealth Services in Las Vegas and creator of the Financial Residency blog and podcast.

MISHANDLING STUDENT LOAN DEBT

Student loan debt is a reality for most physicians, particularly younger ones. A recent Medical Economics survey of physicians of all ages found that two-thirds had more than $90,000 in debt upon graduating medical school, and that 30 percent had more than $200,000 in debt. The American Medical Association found that the average medical student in 2016 graduated with $190,000 in debt. And there are a number of mistakes in handling that debt that can have long-term repercussions for physicians’ careers and personal lives.

The worst mistake is to ignore student loan debt, says Greenwald: “Many [doctors] are consumed by debt, but they’re also paralyzed by it. They can’t see how they’re ever going to get out of it. They don’t know where to start.”

Ignoring the debt won’t make it go away; it will just make it grow. Thus, medical school students should begin planning their loan repayment before they graduate, advisors say. Doctors with multiple loans from commercial lenders should consolidate and refinance them at a lower interest rate as soon as possible, adding that a fixed rate loan is preferable to one with an adjustable rate.
Mistakes to avoid

**WHAT TO LOOK FOR IN A FINANCIAL PLANNER**

Unlike in healthcare where every certification and qualification is earned, anyone can call themselves a financial planner. There are no certifications, exams, registrations, or coursework required. That means there are a lot of unqualified planners out there. Here’s how to avoid them and find one that will be right for you:

**Hire a Certified Financial Planner.**
To earn the CFP designation, a planner must pass a test administered by the Certified Financial Planner Board of Standards and commit to continuing education on financial matters and ethics. A CFP is the financial equivalent to a primary care doctor, dealing with the client’s overall financial health. Another important designation is Registered Investment Advisor (RIA). It means the adviser is registered with the Securities and Exchange Commission (SEC) and provides investment advice for a fee.

**Make sure the planner is a fiduciary.**
Here’s another area in which healthcare and financial planning differ significantly: A planner is not obligated to give you the advice most beneficial for you. Many planners earn money from selling investments and other financial products and it is perfectly legal for them to sell something that is not optimal for a client, but that earns them a commission. Their standard is “suitability,” meaning an investment should be appropriate, but doesn’t have to be the best or conflict-free. By contrast, a fiduciary is legally obligated to act in the client’s best interest at all times. Beginning Oct. 1, 2019, all CFPs must adopt the fiduciary standard.

**Understand how the planner is paid.**
Planners earn their money either from commissions or by charging hourly or flat fees. A commission is a fee paid when a financial product is bought or sold, and this can create an incentive for planners to push unnecessary sales and purchases. Other planners charge a fee for advice. This can be a flat fee for a specific task, such as developing a financial plan, or an annual fee, such as 1 percent of all assets under management. The fee-only system is a better way to receive unbiased advice.

**Hire a planner who works with other doctors.**
The planner doesn’t have to work solely with healthcare providers, but they should be experienced in the issues physicians face, such as student loan debt, says Joel Greenwald, MD, CFP, owner of Greenwald Wealth Management in St. Louis Park, Minn.

**Run a background check.**
Ask if the planner has ever been convicted of a crime or been investigated by a regulatory body or industry group. The Financial Industry Regulatory Authority has a page that explains each adviser professional designation and links to the organizations that issued the designation. Clients can check for complaints on the organization pages. The SEC also has a site which allows clients to check the credentials and disciplinary record of advisers. Ask for references of current clients with goals and finances similar to yours. Check to make sure credentials are current.

**Ask around.**
Consult with colleagues to find out if they are happy with their planners. Look for those in financial situations similar to your own (children, career stage, etc.)

**Beware of boasts.**
Avoid planners who claim they always beat the market or who promise extraordinary returns. They’re either exaggerating, or worse, likely to take unwelcome risks.

Sources: The National Association of Personal Financial Advisors represents fee-only fiduciary advisors. Members of the Garrett Planning Network are CFPs available for smaller projects for an hourly fee.
**Money**

**Mistakes to avoid**

or for a for-profit hospital is disqualifying.

From an overall financial standpoint it's often a mistake to choose a higher salary in a for-profit practice than a lower-paying job that qualifies for PSLF, Utley says. Recently, he advised married primary care physicians to take jobs with nonprofits rather than in a for-profit organization. He based his advice on their anticipated combined earnings of about $400,000 and a combined debt of $775,000. He estimated they would have to earn $1.5 million before taxes in order to pay off the debt and earning that $1.5 million would require delivering about $10 million in medical care.

In the end, the couple would be significantly better off financially by taking jobs that would allow much of their debt to be forgiven under PSLF than by earning more, but having to repay the entire debt, Utley says.

Inman offers another PSLF tip: The program requires 120 months of payments before loan forgiveness and offers a variety of income-based repayment plans. Because the monthly payments are calculated on the borrower's income the previous year, most new residents, who did not earn anything as medical school students, do not actually owe any money the first year. However, they can still make zero-sum payments that first year to earn credit for 12 monthly payments.

“Not starting those payments right away can cost them thousands of dollars at the back end,” Inman says.

**EXPANDING LIFESTYLE TOO QUICKLY**

Most doctors earn relatively little during their training, but when they complete their training and get jobs suddenly they find themselves with substantial incomes—sometimes as much as five times more than they earned as residents. And that can be a problem, says Inman.

Flush with larger salaries and coming off years of relative austerity, many new physicians adopt an expensive lifestyle. "Immediately, they think, 'I need a big house and a car. I want a loan. I'll deal with the debt later',” Inman says.

That can start a disastrous, career-long habit of putting an expensive lifestyle ahead of investing and saving. "Once they start inflating the lifestyle, it's hard to go back in the other direction," Inman says.

He advises young physicians to give themselves a “raise” of $60,000 to $90,000 over their earnings as residents and live within that budget. The rest of the money should go to paying off student loans, savings, and investments, he says.

Newly employed physicians should wait at least a year until buying a house, says Utley. Doctors often change employment after a year or two in their first job and having to sell a recently purchased house can lead to a loss, or at least complicate a relocation, he says.

**TAKING OUT A PHYSICIAN MORTGAGE LOAN**

Lenders know that many doctors emerging from residency are eager to buy their first home. However, most young physicians do not yet have the savings to make a large down payment or a lengthy work history.

That would be enough to prevent most applicants from getting a mortgage, but many lenders make exceptions for physicians because they know they are good credit risks and eventually will earn a large salary, says Inman.

Lenders are so eager to get doctors' business that they’ve created mortgages with special terms, such as zero percent down and no requirement for private mortgage insurance. Banks will accept a job offer letter as proof of income and don’t count student loans as part of the debt-to-income ratio used to decide if an applicant is creditworthy. However, to compensate for the generous terms, these mortgages come with higher interest rates that often are adjustable. The result can be tens of thousands more in interest payments than

**“Doctors get a really late start, like 10 years behind everyone else, and they’ve got to make up for lost time.”**

—RYAN INMAN, MBA, OWNER, PHYSICIAN WEALTH SERVICES, LAS VEGAS
would be paid under a conventional loan, Inman says.

Those special terms can be hard to resist, but Inman says they can tempt doctors into taking on too much debt too soon, particularly when a house payment is coupled with student loan debt.

NOT PLANNING FOR RETIREMENT
Physicians tend to retire later than most professionals and later than they originally planned. According to a 2016 study in the journal Human Resources for Health, one of the main reasons for delaying retirement is insufficient savings and continuing financial obligations.

Saving for that retirement goal while simultaneously repaying student loan debt can seem contradictory, but a financial planner can show physicians how to get started.

“Many [doctors] are consumed by debt, but they’re also paralyzed by it. They can’t see how they’re ever going to get out of it. They don’t know where to start.”

— JOEL GREENWALD, MD, CFP, OWNER, GREENWALD WEALTH MANAGEMENT, ST. LOUIS PARK, MINN.

Careful planning and avoiding mistakes like those described above can make it easier for physicians to achieve financial security while pursuing the career they love. The important thing, Greenwald says, is to be proactive.

“Ignoring it and thinking it’s all going to work out is a mistake,” he says.

### THE MONEY FEARS OF YOUNG PHYSICIANS

#### U.S. RESIDENT PHYSICIANS’ TOP FINANCIAL CONCERNS (% very concerned)

- **34%** Paying off medical school debt
- **25%** Having enough money to retire
- **21%** Funding college for children
- **19%** Providing for elderly parents
- **19%** Having enough disability insurance


#### AVERAGE ANNUAL SALARIES

- **$415,000** — Cardiologists
- **$271,000** — Ob/gyns
- **$230,000** — Internists
- **$212,000** — Family practitioners
- **$205,000** — Pediatricians

Source: 89th Annual Medical Economics Physician Report

#### RESIDENT PHYSICIAN RETIREMENT SAVINGS

- **46%** less than $25,000
- **32%** haven’t started saving yet
- **10%** $25,001-$50,000
- **6%** $50,001-$100,000
- **5%** $100,001-$500,000

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*/**See reverse for details.
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   - Federal tax ID number
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   - Owner’s Social Security Number^
   - Owner’s home address and phone number^®
   - Manager’s name

2. We’ll fax or email an enrollment form for you to sign.

3. After your application is approved, a representative will contact you to schedule an orientation at your earliest convenience. You’ll also receive materials in the mail.

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1Cardholder Engagement Study, Q2 2018.
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**Subject to the representations and warranties in the CareCredit Agreement with Participating Providers, including but not limited to only charging for services that have been completed or that will be complete within 30 days of the initial charge, always obtaining the patient’s signature on in-office applications and the cardholder’s signature on the printed receipt.
^Patriot Act requirement.
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ISR0318LF-GEN
defended your honor last week,” my patient said.

“Thank you,” I said, curious. I hadn’t known my honor was under attack.

The defender of my honor was a woman who has been my patient for 15 years, who has gone through terribly difficult life situations, who has multiple health and emotional conditions, and who is on Medicare. Apparently, a nurse was in her home helping with the care of her mother, who is also a patient of mine. When the nurse asked the name of her PCP, my patient gave my name and the nurse reacted negatively. “Rumor has it,” the nurse told her, “Dr. Lamberts left his old practice so he could charge a lot of money and take care of wealthy people.”

“I stood up and shook my finger at her,” my patient explained. “You don’t know what you are talking about! Dr. Lamberts has taken care of us for years, and I wouldn’t ever have another doctor. He doesn’t charge a lot, and when I was having problems with money, he cut my fee in half.” She was agitated even talking about it, which made me smile. “That woman backed off because both mother and I were upset by what she said. I think she was afraid we’d attack her!”

The misunderstanding my patient defended me against is a common one, but one of many objections people have to the practice model. I faced these objections when I first wrote about my intent to do DPC, and recently these objections were again voiced by Timothy Hoff.

Initial response was simply to prove my critics wrong by building a practice that answered these questions. “It can’t be done” is best answered with “I did it.” But often these discussions take on the tone or tenor of a political or religious discussion. Defenders of DPC (including many DPC docs) are zealous in their defense, emotionally charged because this practice is life-changing. I regained my life and my love of medicine when I switched to the practice model. So when someone attacks DPC, it’s akin to having someone attack your spouse, your children, or your faith. But such discussions aren’t constructive, because the passion in the response makes it appear emotional, not rational.

So I will try to take a rational approach to the criticisms of DPC. I want to put aside passion, listen to criticisms, and address them reasonably. I’ll focus on the most frequent objections I hear.

**OBJECTION 1: DPC IS ELITIST**

This is the objection faced by my patient (and Dr. Hoff’s article). The argument is that most people cannot afford the monthly fee, so only wealthy people can afford the care. In truth, I charge between $35 and $75 per month (not $50-$200 as said by Dr. Hoff), based on age. I do not charge more for complicated patients, management of difficult medical conditions. I am in sync with the majority of DPC practices in my billing.

As to the “elitist” criticism, there is a significant difference in the average income in my current practice compared to my old one, but it’s the opposite of what is suggested. I serve a lower income socioeconomic population than I used to, there are more self-employed, uninsured, and even unemployed patients. Why is this? I think it is the predictability and transparency of cost that makes DPC appealing.

There are some who cannot afford even the $35 to $75 I charge. Some of these (like my patient defender) I am able to help by discounting their price, either temporarily (for life circumstance) or long-term. As for others who cannot afford those fees, these problems are not mine to solve, as they are the societal problem of poverty, distribution of wealth, and unemployment that I cannot fix. DPC is a practice model, not a panacea.

Despite this, many low-income
It’s time for transparency in medical school costs

people value my care enough that they find the money to pay regularly. This includes the poor, as well as a sizable Medicare population. I believe that good primary care will often significantly reduce the cost by giving care to problems before they become serious (such as diabetes and hypertension).

**OBJECTION 2: DPC IS NOT SCALABLE**

I left a practice of 3,000 patients (although that number is nearly impossible to truly quantify accurately), and now have a “large” DPC practice of 750 patients. It’s simple math to see the problem: what happens if all primary care doctors make this change? What will happen to the 75% of patients who did not follow me to the new practice? What would happen if 75% of all Americans were left out by their primary care doctors?

This is a real problem that can’t be ignored if physicians start changing to DPC in significant numbers. But there are several things that offset the apparent loss of physicians for patients. First, DPC is far better for the doctors, and will likely slow the burnout rates afflicting primary care at this time. An alarming number of doctors are retiring early, quitting medicine for other professions, or avoiding primary care in the first place, something that will itself reduce the availability of primary care doctors. DPC once again makes primary care enjoyable to those in it and appealing to those considering it.

The second offsetting factor is the significant improvement in care quality. I see between 6 and 10 patients per day on average, which is one third of what I was seeing in my previous practice. When I saw the high volumes in my old practice, I didn’t feel like I was giving good care to anyone. I didn’t have the time to listen, to teach, to work through problems. Now I feel I can give excellent care to everyone in my practice. So, what is more valuable to society: giving poor care to 3,000 people or excellent care to 750? The answer to this depends on how wide the gulf is between the poor care in my previous practice and that in my DPC office. Subjectively, it’s not even close from my perspective. Objectively, the very low rate of attrition from my practice says my patients feel the same.

Finally, I would point out that DPC is not necessarily the endpoint in the evolution of primary care. It is, instead, an innovation of a malfunctioning business model. If DPC grows more and a shortage increases, further innovation will be necessary to close this gap. That does not, however, make the innovation wrong or ill-advised.

**OBJECTION 3: WHAT HAPPENS WHEN PATIENTS NEED SPECIALTY OR HOSPITAL CARE?**

This objection is based on a misconception of intent: it assumes that DPC is trying to be a global solution for the bigger problems in healthcare. I am not trying to do anything more for my patients than to offer them excellent and affordable healthcare. Doing so can (and does) reduce the need for specialty care, ER visits, and hospitalizations, but it doesn’t eliminate it. For this reason, I greatly prefer that my patients have insurance of some sort. But the problem of high-cost specialty and hospital care absolutely needs to be dealt with on a societal level.

A second misconception is that people assume that we are putting DPC up as an alternative to insurance. While this is absolutely not true, it is true that DPC replaces insurance for primary care itself. But I believe that insurance is not only inappropriate for primary care, it is harmful. It’s as if auto insurance covered oil changes, tire rotation, and other maintenance and repairs for your car. While this would seem appealing to some, it would significantly raise the cost of repairs, parts, and maintenance because the cost would no longer be transparent. Primary care is a low-cost service with the intent to decrease utilization of the rest of the healthcare system. It is the best chance to decrease unwanted and unnecessary care and reduce cost.

Our current system is terribly broken and in need of innovative ideas to keep it from bankrupting our citizens. While DPC may not be the solution for this, it certainly takes a number of steps towards some desperately needed changes: lower cost, less over-utilization, happier doctors and healthier patients.

And if you don’t believe me, I know someone who wants a word with you.

Rob Lamberts, MD, is a board-certified internist and pediatrician who runs Dr. Rob Lamberts, LLC, a direct primary care practice in Augusta, Ga. He also recently gave a TED talk on the DPC model. Have questions about DPC? Email medec@ubm.com.
Primary end point: A1C change from baseline at week 26

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>STEGALATRO 5 mg</th>
<th>STEGALATRO 15 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIFFERENCE FROM PLACEBO, %</td>
<td>-0.2</td>
<td>-0.7</td>
<td>-0.8</td>
</tr>
<tr>
<td>N=152; BL=8.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=155; BL=8.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=152; BL=8.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* N includes all randomized and treated patients with a baseline measurement of the outcome variable. At week 26, the primary A1C end point was missing for 10%, 11%, and 7% of patients, and during the trial, rescue medication was initiated by 16%, 1%, and 2% of patients randomized to placebo, STEGALATRO 5 mg, and STEGALATRO 15 mg, respectively. Missing week 26 measurements were imputed using multiple imputation with a mean equal to the baseline value of the patient. Results include measurements collected after initiation of rescue medication. For those patients who did not receive rescue medication and had values measured at 26 weeks, the mean changes from baseline for A1C were -0.2%, -0.8%, and -0.9% for placebo, STEGALATRO 5 mg, and STEGALATRO 15 mg, respectively.

b Intent-to-treat analysis using ANCOVA adjusted for baseline value, prior antihyperglycemic medication, and baseline estimated glomerular filtration rate (eGFR).

BL=baseline; LS=least squares.
**TO METFORMIN AND SITAGLIPTIN**

**Study design:** 463 adults with type 2 diabetes, inadequately controlled (A1C between 7% and 10.5%) on metformin (≥1500 mg/day for ≥8 weeks) and sitagliptin 100 mg once daily participated in a randomized, double-blind, multicenter, 26-week, placebo-controlled study to evaluate the efficacy and safety of STEGLATRO. Study subjects were randomized to STEGLATRO 5 mg, STEGLATRO 15 mg, or placebo administered once daily in addition to continuation of background metformin and sitagliptin therapy. The primary efficacy end point was the change from baseline in A1C at week 26.

STEGLATRO is indicated as an adjunct to diet and exercise for appropriate adults with type 2 diabetes. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

**SELECTED SAFETY INFORMATION**

**Contraindications:** STEGLATRO is contraindicated in patients with severe renal impairment, end-stage renal disease, or on dialysis, and/or a history of a serious hypersensitivity reaction to ertugliflozin.

**Hypotension:** STEGLATRO causes intravascular volume contraction. Symptomatic hypotension may occur after initiating STEGLATRO, particularly in patients with impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m²), elderly patients (≥65 years), patients with low systolic blood pressure, or patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

**Ketoacidosis:** Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been reported in patients with type 1 and type 2 diabetes receiving sodium glucose co-transporter 2 (SGLT2) inhibitors, including STEGLATRO. Some cases were fatal. Assess patients with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If ketoacidosis is suspected, STEGLATRO should be discontinued, patients should be evaluated, and prompt treatment should be instituted. Before initiating STEGLATRO, consider risk factors for ketoacidosis, including diabetic ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

*Additional Selected Safety Information on next page.*
SELECTED SAFETY INFORMATION (continued)

Acute Kidney Injury and Impairment in Renal Function: STEGLATRO causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors. Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury. Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m².

Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in patients treated with STEGLATRO in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

Lower Limb Amputations: An increased risk for lower limb amputation has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials with STEGLATRO, nontraumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5-mg group, and 8 (0.5%) patients in the STEGLATRO 15-mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established. Before initiating STEGLATRO, consider factors that may predispose patients to the need for amputations. Monitor patients and discontinue STEGLATRO if complications occur. Counsel patients about the importance of routine preventative foot care.

Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues: Insulin and insulin secretagogues (eg, sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

Genital Mycotic Infections: STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C): Dose-related increases in LDL-C can occur with STEGLATRO. Monitor and treat as appropriate.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

The most common adverse reactions associated with STEGLATRO (≥5%) were female genital mycotic infections.

Please read the adjacent Brief Summary of the Prescribing Information.
Breathlessness. In some but not all cases, factors predisposing to ketoacidosis such as insulin deficiency may be a contributing factor. In many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketosis may indicate pancreatic acinar insufficiency. In patients with type 1 diabetes, the diagnosis of ketoacidosis should be treated promptly. Patients with and without type 1 diabetes should be observed for signs and symptoms of ketoacidosis. Treatment of ketoacidosis may require insulin therapy and hospitalization. In patients with and without type 1 diabetes, the diagnosis of ketoacidosis should be treated promptly. Patients with and without type 1 diabetes should be observed for signs and symptoms of ketoacidosis. Treatment of ketoacidosis may require insulin therapy and hospitalization. In patients with and without type 1 diabetes, the diagnosis of ketoacidosis should be treated promptly. Patients with and without type 1 diabetes should be observed for signs and symptoms of ketoacidosis. Treatment of ketoacidosis may require insulin therapy and hospitalization. In patients with and without type 1 diabetes, the diagnosis of ketoacidosis should be treated promptly. Patients with and without type 1 diabetes should be observed for signs and symptoms of ketoacidosis. Treatment of ketoacidosis may require insulin therapy and hospitalization.

CONTRAINDICATIONS

Severe renal impairment, end-stage renal disease (ESRD), or diabetics [see Warnings and Precautions and Use in Specific Populations].

History of a serious hypersensitivity reaction to STEGLATRO.

STEGLATRO is not recommended for the treatment of type 1 diabetes mellitus.

STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m². Renal function abnormalities can occur after initiating STEGLATRO [see Adverse Reactions]. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m² [see Contraindications]. Initiation of STEGLATRO is not recommended in patients with an eGFR of 30 mL/min/1.73 m² to less than 60 mL/min/1.73 m² [see Warnings and Precautions and Use in Specific Populations]. Continued use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m². No dose adjustment is needed in patients with mild renal impairment.

CONTRAINDICATIONS

Severe renal impairment, end-stage renal disease (ESRD), or diabetics [see Warnings and Precautions and Use in Specific Populations].

History of a serious hypersensitivity reaction to STEGLATRO.

WARNINGS AND PRECAUTIONS

Hypoglycemia. STEGLATRO causes intravascular volume contraction. Therefore, symptomatic hypoglycemia may occur after initiating STEGLATRO [see Adverse Reactions] particularly in patients with impaired renal function (eGFR < 60 mL/min/1.73 m² [see Use in Specific Populations]), elderly patients (≥85 years), in patients with low systolic blood pressure, and in patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypoglycemia after initiating therapy.

Ketoacidosis. Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in clinical trials and postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium-glucose co-transporter-2 (SGLT2) inhibitors and cases have been reported in STEGLATRO-treated patients in clinical trials.Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) of STEGLATRO-treated patients and 0% of comparator-treated patients. Fatal cases of ketoacidosis have been reported in patients taking SGLT2 inhibitors. STEGLATRO is not indicated for the treatment of patients with type 1 diabetes mellitus (see Indications and Usage).

Patients treated with STEGLATRO who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with STEGLATRO may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, STEGLATRO should be discontinued; patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement.

In many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified.

Before initiating STEGLATRO, consider factors in the patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO, consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

Acute Kidney Injury and Impairment in Renal Function. STEGLATRO causes intravenous volume contraction and can cause renal impairment [see Adverse Reactions]. There have been postmarketing reports of acute kidney injury in some requiring hospitalization and dialysis in patients receiving SGLT2 inhibitors.

Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications (diuretics, ACE inhibitors, ARBs, NSAIDs). Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake (such as acute illness or fasting) or fluid losses (such as gastrointestinal illness or excessive heat exposure); monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO [see Adverse Reactions]. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m² [see Dosage and Administration, Contraindications, and Use in Specific Populations].

Urosepsis and Pyelonephritis. There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in STEGLATRO-treated patients in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated [see Adverse Reactions].

Lower Limb Amputation. An increased risk for lower limb amputation (primary of the toe) has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials in the STEGLATRO development program, non-traumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5 mg group, and 8 (0.5%) patients in the STEGLATRO 15 mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established.

Before initiating STEGLATRO, consider factors in the patient history that may predispose them to the need for amputations, such as a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers. Counsel patients about the importance of routine preventative foot care. Monitor patients receiving STEGLATRO for signs and symptoms of infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue STEGLATRO if these complications occur.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues. Insulin and insulin secretagogues (e.g., sulfonylureas) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue [see Adverse Reactions]. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

Genital Mycotic Infections. STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop these complications. Before initiating STEGLATRO, consider factors in the patient history that may predispose them to the need for antifungal agents. Monitor and treat as appropriate.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C). Dose-related increases in LDL-C can occur with STEGLATRO [see Adverse Reactions]. Monitor and treat as appropriate.

Macrovascular Outcomes. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

ADVERSE REACTIONS

Clinical Trials Experience. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Pool of Placebo-Controlled Trials Evaluating STEGLATRO 5 mg and 15 mg. The data in Table 1 are derived from a pool of three 26-week, placebo-controlled trials. STEGLATRO was used as monotherapy in one trial and as add-on therapy in two trials. These data reflect exposure of 1,029 patients to STEGLATRO with a mean exposure duration of approximately 25 weeks. Patients received STEGLATRO 5 mg (N=519), STEGLATRO 15 mg (N=510), or placebo (N=515) once daily. The mean age of the population was 57 years and 2% were older than 75 years of age. Fifty-three percent (53%) of the population was male and 7.5% were Caucasian, 15% were Asian, and 7% were Black or African American. At baseline the population had diabetes for an average of 7.5 years, had a mean HbA1c of 8.1%, and 19.4% had established microvascular complications of diabetes. Baseline renal function (mean eGFR 88.9 mL/min/1.73 m²) was normal or mildly impaired in 97% of patients and moderately impaired in 3% of patients.
Table 1 shows common adverse reactions associated with the use of STEGLATRO™ (ertugliflozin). These adverse reactions were not present at baseline, occurred more commonly on STEGLATRO than on placebo, and occurred in at least 2% of patients treated with either STEGLATRO 5 mg or STEGLATRO 15 mg.

Table 1: Adverse Reactions Reported in ≥2% of Patients with Type 2 Diabetes Mellitus Treated with STEGLATRO* and Greater than Placebo in Pooled Placebo-Controlled Clinical Studies of STEGLATRO Monotherapy or Combination Therapy

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo  N = 515</th>
<th>STEGLATRO 5 mg  N = 519</th>
<th>STEGLATRO 15 mg  N = 510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections†</td>
<td>3.0%</td>
<td>9.1%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections‡</td>
<td>0.4%</td>
<td>3.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Urinary tract infections†</td>
<td>3.9%</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
<td>3.5%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vaginal pruritus§</td>
<td>0.4%</td>
<td>2.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Increased urination†</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2.8%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.3%</td>
<td>1.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>1.0%</td>
<td>1.2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Thirst†</td>
<td>0.6%</td>
<td>2.7%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

* The three placebo controlled studies included one monotherapy trial and two add-on combination trials with metformin or with metformin and sitagliptin.
† Includes: genital candidiasis, genital infection fungal, vaginosis, vulvovaginal candidiasis, vulvovaginal mycotic infection, and vulvovaginitis. Percentages calculated with the number of female patients in each group as denominator: placebo (N=235), STEGLATRO 5 mg (N=252), STEGLATRO 15 mg (N=245).
‡ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=265).
§ Includes: vulvovaginal pruritus and pruritus genital. Percentages calculated with the number of female patients in each group as denominator: placebo (N=235), STEGLATRO 5 mg (N=252), STEGLATRO 15 mg (N=245).
¶ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=265).

Volume Depletion. STEGLATRO causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²). In patients with moderate renal impairment, adverse reactions related to volume depletion (e.g., dehydration, dizziness, postural, presyncope, syncope, hypotension, and orthostatic hypotension) were reported in 0%, 4.4%, and 1.9% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. STEGLATRO may also increase the risk of hypotension in other patients at risk for volume contraction (see Use in Specific Populations).

Ketoacidosis. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) ertugliflozin-treated patients and 0.3% of comparator-treated patients (see Warnings and Precautions).

Impairment in Renal Function. Treatment with STEGLATRO was associated with increases in serum creatinine and decreases in eGFR (see Table 2). Patients with moderate renal impairment at baseline had larger mean changes. In a study in patients with moderate renal impairment, these abnormal findings were observed to reverse after treatment discontinuation (see Use in Specific Populations).

Table 2: Changes from Baseline in Serum Creatinine and eGFR in the Pool of Three 26-Week Placebo-Controlled Studies, and a 26-Week Moderate Renal Impairment Study in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Week 6 Change</th>
<th>Placebo Mean (mg/dL)</th>
<th>STEGLATRO 5 mg (N=519)</th>
<th>STEGLATRO 15 mg (N=510)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1.39</td>
<td>1.38</td>
<td>1.37</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>46.0</td>
<td>46.8</td>
<td>46.9</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td>STEGLATRO 5 mg (N=519)</td>
<td>0.02</td>
<td>0.11</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.6</td>
<td>-3.2</td>
<td>-4.1</td>
</tr>
<tr>
<td>STEGLATRO 15 mg (N=510)</td>
<td>0.02</td>
<td>0.08</td>
<td>0.10</td>
</tr>
<tr>
<td>Moderate Renal Impairment Study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.71</td>
<td>1.71</td>
<td>1.71</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>1.71</td>
<td>1.71</td>
<td>1.71</td>
</tr>
<tr>
<td>STEGLATRO 15 mg (N=510)</td>
<td>1.71</td>
<td>1.71</td>
<td>1.71</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td>STEGLATRO 15 mg (N=510)</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.0</td>
<td>-2.7</td>
<td>-2.6</td>
</tr>
</tbody>
</table>

Renal-related adverse reactions (e.g., acute kidney injury, renal impairment, acute prerenal failure) may occur in patients treated with STEGLATRO, particularly in patients with moderate renal impairment where the incidence of renal-related adverse reactions was 0.6%, 2.5%, and 1.3% in patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. Lower Limb Amputation. Across seven Phase 3 clinical trials in which STEGLATRO was studied as monotherapy and in combination with other antihyperglycemic agents, non-traumatic lower limb amputations occurred in 1 of 1,450 (0.1%) in the non-STEGLATRO group, 3 of 1,716 (0.2%) in the STEGLATRO 5 mg group, and 8 of 1,693 (0.5%) in the STEGLATRO 15 mg group.

Hypoglycemia. The incidence of hypoglycemia by study is shown in Table 3.

Table 3: Incidence of Overall* and Severe† Hypoglycemia in Placebo-Controlled Clinical Studies in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Study Group</th>
<th>Placebo Mean (N=515)</th>
<th>STEGLATRO 5 mg (N=519)</th>
<th>STEGLATRO 15 mg (N=510)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>36.1</td>
<td>35.8</td>
<td>37.3</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>5 (3.2)</td>
<td>5 (3.4)</td>
<td>3 (2.1)</td>
</tr>
</tbody>
</table>

* Overall hypoglycemic events: plasma or capillary glucose of less than or equal to 70 mg/dL.
† Severe hypoglycemic events: required assistance, lost consciousness, or experienced a seizure regardless of blood glucose.
Genital Mycotic Infections. In the pool of three placebo-controlled clinical trials, the incidence of female genital mycotic infections (e.g., vulvovaginal candidiasis, genital infection fungal, vaginal infection, vulvitis, vulvovaginal candidiasis, vulvovaginal mycotic infection, vulvovaginitis) occurred in 3%, 9.1%, and 12.2% of females treated with placebo, STEGLATRO™ (ertugliflozin) 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). In females, discontinuation due to genital mycotic infections occurred in 0% and 0.8% of patients treated with placebo and STEGLATRO, respectively.

In the pool of male genital mycotic infections (e.g., balanitis candida, balanoposthitis, genital infection, genital infection fungal) occurred in 0.4%, 3.7%, and 4.2% of males treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). Males genital mycotic infections occurred more commonly in uncircumcised males. In males, discontinuations due to genital mycotic infections occurred in 0% and 0.2% of patients treated with placebo and STEGLATRO, respectively. Phimosis was reported in 8% of 1729 (0.5%) male ertugliflozin-treated patients, of which four required circumcision.

Laboratory Tests.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C). In the pool of three placebo-controlled trials, dose-related increases in LDL-C were observed in patients treated with STEGLATRO. Mean percent changes from baseline to Week 26 in LDL-C relative to placebo were 2.8% and 5.4% with STEGLATRO 5 mg and STEGLATRO 15 mg, respectively. The range of mean baseline LDL-C was 96.7 to 97.7 mg/dL across treatment groups (see Warnings and Precautions).

Increases in Hemoglobin. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline to Week 26 in hemoglobin were -0.21 g/dL (-1.4%) with placebo, 0.46 g/dL (3.5%) with STEGLATRO 5 mg, and 0.48 g/dL (3.5%) with STEGLATRO 15 mg. The range of mean baseline hemoglobin was 13.9 to 14.0 g/dL across treatment groups. At the end of treatment, 0.0%, 0.2%, and 0.4% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively, had a hemoglobin increase greater than 2 g/dL and above the upper limit of normal.

Increases in Serum Phosphate. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline in serum phosphate were 0.04 mg/dL (1.9%) with placebo, 0.21 mg/dL (6.8%) with STEGLATRO 5 mg, and 0.26 mg/dL (8.5%) with STEGLATRO 15 mg. The range of mean serum baseline phosphate was 3.53 to 3.54 mg/dL across treatment groups. In a clinical trial of patients with moderate renal impairment, mean changes (percent changes) from baseline at Week 26 in serum phosphate were -0.01 mg/dL (0.8%) with placebo, 0.29 mg/dL (9.7%) with STEGLATRO 5 mg, and 0.24 mg/dL (7.8%) with STEGLATRO 15 mg.


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Data.

Animal Data. When ertugliflozin was orally administered to juvenile rats from PND 21 to PND 90, increased kidney weight, renal tubule and renal pelvic dilatation, and renal mineralization occurred at doses greater than or equal to 5 mg/kg (13-fold human exposures, based on AUC). These effects occurred with drug exposure during periods of renal development in rats that correspond to the late second and third trimester of human renal development, and did not fully reverse within a 1-month recovery period.

In embryofetal development studies, ertugliflozin (50, 100 and 250 mg/kg/day) was administered orally to rats on gestation days 6 to 17 and to rabbits on gestation days 7 to 19. Ertugliflozin did not adversely affect developmental outcomes in rats and rabbits at maternal exposures that were approximately 300 times the human exposure at the maximum clinical dose of 15 mg/day, based on AUC. A maternally toxic dose (250 mg/kg/day) in rats (707 times the clinical dose), was associated with reduced fetal vitality, and a higher incidence of a ventricular septal defect. In the pre- and post-natal development study in pregnant rats, ertugliflozin was administered to the dams from gestation day 6 through lactation day 21 (weaning). Decreased post-natal growth (weight gain) was observed at maternal doses ≥100 mg/kg/day (greater than or equal to 331 times the human exposure at the maximum clinical dose of 15 mg/day, based on AUC).

Loctation.

Risk Summary. There is no information regarding the presence of STEGLATRO in human milk, the effects on the breastfeeding infant, or the effects on milk production. Ertugliflozin is present in the milk of lactating rats (see Data). Since human kidney maturation occurs in utero and during the first 2 years of life when lactation exposure may occur, there may be risk to the developing human kidney. Because of the potential for serious adverse reactions in a breastfeeding infant, advise women that the use of STEGLATRO is not recommended while breastfeeding.

Data.

Animal Data. The lactational excretion of radiolabeled ertugliflozin in lactating rats was evaluated 10 to 12 days after parturition. Ertugliflozin derived radioactivity exposure in milk and plasma were similar, with a milk/plasma ratio of 1.07, based on AUC. Juvenile rats directly exposed to STEGLATRO during a developmental period corresponding to human kidney maturation were associated with a risk to the developing kidney (persistent increased organ weight, renal associated with a risk to the developing kidney (persistent increased organ weight, renal pelvic and tubular dilations). In lactation day 21 (weaning). Decreased post-natal growth (weight gain) was observed at maternal doses ≥100 mg/kg/day (greater than or equal to 331 times the human exposure at the maximum clinical dose of 15 mg/day, based on AUC).

Data.

Pediatric Use. Safety and effectiveness of STEGLATRO in pediatric patients under 18 years of age have not been established.

Geriatric Use. No dosage adjustment of STEGLATRO is recommended based on age. Across the clinical program, a total of 876 (25.7%) patients treated with STEGLATRO were 65 years and older, and 152 (4.5%) patients treated with STEGLATRO were 75 years and older. Patients 65 years and older had a higher incidence of adverse reactions related to volume depletion compared to younger patients; events were reported in 1.1%, 2.2%, and 2.6% of patients treated with comparator, STEGLATRO™ (ertugliflozin) 5 mg, and STEGLATRO 15 mg, respectively (see Warnings and Precautions and Adverse Reactions). STEGLATRO is expected to have diminished efficacy in elderly patients with renal impairment (see Use in Specific Populations).

Renal Impairment. The safety and efficacy of STEGLATRO have not been established in patients with type 2 diabetes mellitus and moderate renal impairment. Compared to placebo-treated patients, patients with moderate renal impairment treated with STEGLATRO did not have improvement in glycemic control, and had increased risks for renal impairment, renal-related adverse reactions and volume depletion adverse reactions (see Dosage and Administration, Warnings and Precautions and Adverse Reactions). Therefore, STEGLATRO is not recommended in this population. STEGLATRO is contraindicated in patients with severe renal impairment, ESRD, or receiving dialysis. STEGLATRO is not expected to be effective in these patient populations (see Contraindications). No dosage adjustment or increased monitoring is needed in patients with mild renal impairment.

Hepatic Impairment. No dosage adjustment of STEGLATRO is necessary in patients with mild or moderate hepatic impairment. Ertugliflozin has not been studied in patients with severe hepatic impairment and is not recommended for use in this patient population.

OVERDOSAGE

In the event of an overdose with STEGLATRO, contact the Poison Control Center. Employ the usual supportive measures as dictated by the patient’s clinical status. Removal of ertugliflozin by hemodialysis has not been studied.

For more detailed information, please read the Prescribing Information. usp欣1035-11712/000
Revised 12/2017

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Pharmacy Benefit Managers: Are they to blame for high drug prices?

The Trump administration insists rebates cause inflated prices. What would it mean to physicians and patients if the system ended?

by KEITH LORIA  Contributing author

Earlier this year, a Senate committee held a hearing to review the Trump administration's plan to lower drug costs, with Alex Azar, secretary of the U.S. Department of Health and Human Services, testifying that pharmacy benefit managers (PBMs) are to blame for the high prices.

As part of his written testimony, Azar said that since PBMs are paid based on the number of rebates they negotiate, the possibility exists for them to retaliate against manufacturers who cut prices by dropping them from formularies or placing them on a higher tier.

"We may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed-price contracts," he said. "Such a system's incentives, detached from artificial list prices, would likely serve patients far better, as would a system where PBMs receive no compensation from the very pharma companies they're supposed to be negotiating against."

This, he said, would prevent PBMs from impacting prices, as a major criticism of the current system is that PBMs keep some of the rebates instead of passing them to consumers in the form of lower out-of-pocket costs.

The Pharmaceutical Care Management Association (PCMA), a national organization representing America's pharmacy benefit managers, strongly disagrees with this position. A recent study, "Reconsidering Drug Prices, Rebates, and PBMs," conducted by the healthcare consulting service Visante, shows that pharmaceutical manufacturers set prices unrelated to the rebates they negotiate with PBMs.

"Drug companies keep raising prices even when rebates go down," Mark Merritt, PCMA's president and CEO, said in a press release. "Simply eliminating plans' ability to negotiate price concessions would enrich drugmakers at the expense of patients, who'd not only face higher prices but higher premiums and out-of-pocket costs, too."

Furthermore, he says, PBMs have long encouraged manufacturers to offer payers alternative ways to reduce net costs, so the easiest solution is for drug companies to lower their prices.

Research by Express Scripts, a PBM based in St. Louis, shows prescription drug prices continue to rise, with the median price of brand medications increasing 232 percent from 2008 through 2017.

Perry Cohen, PharmD, CEO of the Pharmacy Group, a consultant to healthcare and pharmaceutical companies and organizations, says consumers are just looking to pay
a fair price for the value of a drug. Therefore, he says, if price fixing or anything else “fishy” is going on, the government should play a role in fixing it.

“The Trump administration has looked at it and said drugs are too expensive and they want to make them less expensive for the voting citizen,” Cohen says. “The big questions everyone is asking now are if their plan will make it better or worse for physicians or better or worse for patients.”

**IMPACT ON PATIENTS AND PHYSICIANS**

Todd Edgar, PharmD, senior vice president, payer access solutions for the consulting firm Precision for Value in Gladstone, N.J., says the administration’s goal is to remove the safe harbor protection for rebates, with the ultimate objective of eliminating them entirely.

“The goal is to drive the discount down to the consumer,” he says. “The rationale is that the consumer doesn’t benefit a whole lot from the rebates, and the entities tasked with controlling costs earn more rebate on a higher-priced drug.”

Edgar notes that patients who pay a fixed co-pay, initially wouldn’t see a change, but those who pay a co-insurance or a percentage of the drug cost could see a significant benefit if the rebate system ends. He cites an example of a hepatitis C patient who pays 25 percent of a $30,000 prescription, but if rebates were to end, would pay 25 percent of a $15,000 prescription.

The problem with this, Edgar adds, is that if rebates are no longer available as a revenue source for the PBMs and insurers, they would probably charge more for services they provided free in the past. Insurers could also raise co-pays and premiums to make up for the lost revenue.

In addition, Edgar says, ending rebates could result in a change in formularies and what preferred medications physicians would prescribe. Still, Edgar says, formularies change annually anyway, so he doesn’t see a huge change for physicians if rebates were eliminated.

“Formularies would stay in place, utilization management would stay in place, so there’s no less burden for the physician as far as writing drugs for their patients,” he says. “Rebates from a financial position have never touched physicians, so there’s no good or bad from that perspective.”

Meanwhile, Cohen says, the patient will be more aware of what they are actually paying for a drug.

Jennifer Luddy, a spokesperson for Express Scripts, says a simple solution for high drug costs, and one the company endorses, is for pharmaceutical companies to lower their list prices, rather than offering rebates.

Edgar warns that this is just one approach to the problem and the medical industry as a whole should consider several approaches and quantify them before following through with a plan.

Meanwhile, a study, “Drug Rebates Do Not Increase Costs to Consumers,” published in May from the University of Illinois, concludes that abolishing the rebate system would not lower drug prices, and may only be replaced by a more complex system.

Study author Anthony T. Lo Sasso, PhD, professor in health policy and administration at University of Illinois-Chicago and executive director of the American Society of Health Economists, concludes that blaming high drug prices on manufacturer rebates misconstrues the nature of the market for prescription drugs.

“We submit that these rebates are the product of a healthy negotiating process between pharmacy benefit managers and manufacturers, one that serves to inject a modicum of market discipline into a market where it would be otherwise absent,” he wrote in the study. “We see no reason that abolishing such a system would result in lower drug prices, and suggest that the most likely outcome from such a prohibition would be another, more convoluted system that imprecisely replicated the rebate system.”

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—ALEX AZAR, HHS SECRETARY
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Avoid denials when selecting Level 4 E/M office visit codes

by LISA A. ERAMO, MA  Contributing author

DOCUMENT TIME SPENT

The biggest mistake physicians make when selecting an E/M level based on time is not providing sufficient documentation regarding the extent of the counseling and coordination of care, says Patel.

For example, a physician might document, ‘I had a lengthy discussion with the patient for more than half of the visit.’ 

“That tells the payer nothing,” says Patel. “You can’t make a blanket statement and think that’s going to count on the payer or auditor side.”

She provides this example of proper documentation for billing CPT code 99204 based on time: “I spent 30 minutes out of the 45-minute appointment discussing specific chemotherapy options [list the options] and subsequent lifestyle effects of treatment that the patient may experience, such as [insert details].”

THINK ‘EXCEPTION’

Most of the time, physicians won’t actually be able to select the E/M level based on time because counseling and care coordination aren’t often the focus of the visit, says Patel.

Even when they are, there may be a more thorough counseling session that justifies the Level 4 code. However, physicians should be prepared to justify their choice if auditors ask for the documentation.

In the absence of clear and detailed documentation, physicians could be subject to post-payment audits if payers suspect they’re upcoding—something that’s relatively easy to do if documentation isn’t adequate, says Patel. In that case, “Medicare will pay you for the Level 4 established patient visit again and again,” she says. “You’ll be happy for a year, but then next year, they’re going to come back, look at you under a microscope, and recoup that money.”

If a payer denies an entire claim—and assigns no patient responsibility—the physician’s only recourse is to contact the payer to understand the reason for the denial and then correct and resubmit the claim or appeal it.

It’s a scenario probably familiar to many primary care physicians. A new patient presents with multiple chronic conditions. In most cases, the history, exam, and medical decision-making will drive the E/M level that the physician reports for billing.

However, what if the physician spends 30 minutes out of the 45-minute appointment counseling the patient on diabetes management? CPT guidelines permit E/M code selection based on time when face-to-face counseling and/or coordination of care accounts for more than 50 percent of the encounter. If the physician selects CPT code 99204 (Level 4 new patient office visit) for this encounter, does that mean the claim will pass payer scrutiny even if he or she only performed an expanded problem-focused history rather than a comprehensive one?

Not always, says Sonal Patel, CPMA, CPC, a healthcare coder and compliance consultant with Nexsen Pruet LLC, a business law firm in Charleston, S.C. Payers have been looking more closely at Level 4 E/M codes because of the higher payments associated with these codes, she says. If physicians choose a Level 4 E/M code based on time, their documentation must clearly describe what they did and why, she adds.

In the absence of clear and detailed documentation, physicians could be subject to post-payment audits if payers suspect they’re upcoding—something that’s relatively easy to do if documentation isn’t adequate, says Patel. In that case, “Medicare will pay you for the Level 4 established patient visit again and again,” she says. “You’ll be happy for a year, but then next year, they’re going to come back, look at you under a microscope, and recoup that money.”

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She provides this example of proper documentation for billing CPT code 99204 based on time: “I spent 30 minutes out of the 45-minute visit with the patient talking about their surgical options [list the specific options]. The patient had many questions and concerns, and we discussed the following pros and cons of each option [insert details].”

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HIGHLIGHTS

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Money

Level 4 E/M codes

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
<th>3 key components</th>
<th>Presenting problem</th>
<th>Typical time spent*</th>
<th>Threshold to be able to report prolonged services</th>
</tr>
</thead>
<tbody>
<tr>
<td>99204</td>
<td>Level 4 office or other outpatient visit for the E/M of a <strong>new</strong> patient</td>
<td>Comprehensive history, comprehensive exam, medical decision making of moderate complexity</td>
<td>Moderate to high severity</td>
<td>45 minutes spent face-to-face with the patient and/or family</td>
<td>75 minutes</td>
</tr>
<tr>
<td>99214</td>
<td>Level 4 office or other outpatient visit for the E/M of an <strong>established</strong> patient</td>
<td>Comprehensive history, comprehensive exam, medical decision making of moderate complexity</td>
<td>Moderate to high severity</td>
<td>25 minutes spent face-to-face with the patient and/or family</td>
<td>55 minutes</td>
</tr>
</tbody>
</table>

appropriate CPT code to report rather than a single E/M office visit code based on time, she adds.

For example, a physician spends more than half the visit providing smoking cessation counseling. In this case, it may be appropriate to a report a CPT code from the 99406-99407 code range for the smoking cessation counseling in addition to an E/M code with modifier -25 based on the three key components (i.e., history, exam, and medical decision-making). However, the E/M code with modifier -25 must be separate and distinct from the smoking cessation counseling, says Patel. The same may be true for several other types of services, such as:

- **Individual preventive medicine counseling and/or risk factor reduction** (99401-99404)
- **Alcohol and/or substance (other than tobacco) abuse counseling** (99408-99409)
- **Group preventive medicine counseling and/or risk factor reduction intervention** (99411-99412)
- **Psychotherapy** (90833, 90836, or 90838) [Note: These are add-on codes, meaning physicians must also report an E/M office visit code.]

As always, it’s important for physicians to review payer policies to determine whether the E/M code with modifier -25 will be paid in full, paid at a reduced rate, or not paid at all, Patel says.

Here’s another scenario: A patient presents

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Three documentation tips to avoid denials

1. **Document the total time spent face-to-face with the patient and/or family during the visit.**

2. **Specify how much time was spent counseling the patient and/or family or coordinating care.**

3. **Summarize specific details of your conversation with the patient and/or family (i.e., what you discussed with patient and/or family and why).**
with an acute asthma exacerbation. The patient stays in the office for 65 minutes more than what CPT deems the average time associated with that service to receive intravenous medication and monitoring until stable. In this case, it may be appropriate to report the E/M code based on the three key components (i.e., history, exam, and medical decision making) along with a separate code for prolonged services.

“The documentation must really support the fact that you’ve gone above and beyond the E/M code,” says Patel. “I don’t think all patients in the office setting would qualify for this type of extended service, but patients with acute exacerbations or uncontrolled diabetes mellitus are good examples of where prolonged services may be warranted.”

**FOCUS ON DIAGNOSIS CODES**

Diagnosis codes can help justify the rationale for selecting an E/M level based on time, says Patel. However, they can also call attention to potential upcoding. For example, payers will question why a physician spent more than half of a visit counseling a patient with an ear infection.

**WHAT TO DO WHEN A PAYER DOWN-CODES YOUR SERVICES**

Payers frequently down-code Level 4 E/M office visits during a pre- or post-payment audit when physicians don’t document all of the work they perform, says Leslie C. Murphy, JD, CHC, partner at King & Spalding, a healthcare law firm in Sacramento, Calif. Unless it’s documented, physicians have no way of proving they did the work, and payers certainly won’t give them the benefit of the doubt, she adds.

Do physicians have any recourse if a payer downcodes a Level 4 E/M office visit code? Possibly, says Murphy. First, they must review the explanation of benefits. How did the payer process the claim? Did the payer designate a certain amount as the patient’s responsibility? If so, the physician can almost always bill the patient directly for this amount. On the other hand, physicians cannot usually bill the patient for the difference between the billed charge (e.g., 99214) and the allowable (e.g., 99212). Physicians should review their contracts with each payer to determine whether and how much they’re allowed to bill the patient directly, she adds.

If a payer denies the entire claim—and assigns no patient responsibility—the physician’s only recourse is to contact the payer to understand the reason for the denial and then correct and resubmit the claim or appeal it, says Murphy.

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**What’s included in counseling & coordination of care?**

CPT describes counseling as a discussion with a patient and/or family members concerning one or more of the following areas:

- Diagnostic results, impressions, and/or recommended diagnostic studies
- Prognosis
- Risks and benefits of management/treatment options
- Instructions for management and/or follow-up
- Importance of compliance with chosen management options
- Risk factor reduction
- Patient and family education

CPT describes coordination of care as time spent arranging additional services and communicating with other professionals and the patient through written reports and telephone contact. For example, during a face-to-face visit, coordination of care could include referrals to specialists for managing diabetes, depressive disorder, or cardiovascular problems. When using time as the controlling factor for billing, physicians should summarize any conversations regarding care coordination and document the beginning and end time for the coordination of care in addition to the beginning and end time for the entire face-to-face visit.
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Grow your practice with ancillary services

by JULIE MILLER Contributing author

HIGHLIGHTS

- Some of the data required to evaluate the potential of a new ancillary service might include: how often the practice currently refers out the service; total investment costs, including staff and training; and the amount of reimbursement expected.

- Seniors comprise a growing share of the patient population for many practices today, and future considerations for ancillary services should include simple ways to serve their primary care needs.

Faced with rising operational costs and declining reimbursements, internal medicine practices are looking to diversify in ways that result in enhanced income. Experts say that adding ancillary services is one of the best options for physicians to consider to increase practice income.

Ancillary services—such as point-of-care labs, prescription dispensing, electrocardiogram (ECG), imaging, spirometry and others—can provide opportunities for added revenue while also benefitting patients. For example, offering mammograms in the office will save the patient a separate trip to the radiology lab. An immediate hemoglobin A1C test can help clinicians make better-informed treatment decisions during the visit. When administered by clinical support staff rather than the physician, the menu of services can be especially valuable. And the possibilities are extensive. Internists have dozens of ancillary-service options—many of which are becoming easier to adopt thanks to digital technologies.

“It’s not at all surprising to me that a lot of practices are providing a more comprehensive set of services within their own practices,” says Ann Greiner, president and CEO of the Patient-Centered Primary Care Collaborative (PCPCC). “There are positives and negatives, and it depends on the practice and the population served whether it makes sense.”

WHAT WORKS

In the 89th annual Medical Economics Physician Report, 73 percent of internal medicine and 84 percent of family medicine practices indicate they offer ECG—the most-cited offering. Lab services were the second-most popular offering, with 53 percent of internal medicine and 69 percent of family medicine practices providing them.

With overhead costs eating up a significant portion of revenue, practices need to be thorough in assessing the potential of each ancillary service. Physicians should approach the decision with the same data-driven mindset that they might use for any major investment.

“The most important step of making any change in your practice is understanding what the practice is going to look like when you come out on the other side,” says David Zetter, CPC, CHBC, founder and lead consultant with Zetter HealthCare in Mechanicsburg, Pa. “Nobody tends to do that. Really, it’s like getting into a car without GPS or a map and just driving. You have no idea where you’ll end up.”

Some of the data required to evaluate the potential of a new ancillary service might include: how often the practice currently refers out the service; total investment costs, including staff and training; and the amount of reimbursement expected. Practices should also know in advance what qualifications their payer contracts specify, such as Clinical Laboratory Improvement Amend-
ments certification, which may be required for lab services.

A fact-based approach will quantify the return on investment, Zetter says, but it must be examined with data from the practice, rather than general information from outside sources. Too many physicians adopt a new service only because they see someone else having success or because an equipment manufacturer has talked them into it.

Zetter says those that fail to take their own practice’s differentiators into account are less likely to earn the bottom-line impact they hope for. Each practice is unique, and the discrete factors must be accounted for in detail.

He compares the adoption of ancillary services to the initial adoption of electronic health records (EHRs). In haste, many practices signed on to the same system installed in other local practices or perhaps one that had been recommended by a colleague. However, the majority regretted getting locked into a system that ultimately didn’t meet their needs. Evidence seems to indicate as many as 75 percent of practices weren’t happy with their initial EHR choice, according Zetter.

“Everybody wants to move quickly, and they skip this step,” Zetter says of the due diligence process. “And that’s why you see so many fail.”

COST CONSIDERATIONS

Upfront costs for equipment can range from just a few hundred dollars to tens of thousands. However, practices might size up the return on investment in terms of patient volume.

A Holter monitor, for example, could cost $2,000, including the software, while reimbursement for each 24-hour monitoring procedure might be less than $200. Additional supplies, such as batteries and prep pads will add to the price tag, as will the staff time for setting up each test. All told, a practice might see a return on investment after completing just 25 studies.

In the Medical Economics survey, 18 percent of internal medicine and 21 percent of family medicine practices report that they offer Holter monitoring.

Imaging is a service that typically calls for comparatively larger upfront costs for equipment as well as recurring costs to pay trained technicians to capture the images in the office. Larger practices with multiple physicians and favorable insurer contracts have the most potential to profit from adding imaging services, but even then, volume is the key variable. More than 30 percent of practices responding to the Medical Economics survey say they offer radiology or imaging services.

In Frankfort, Ky., Steven Crum, MD, has been providing lab services, x-rays, mammograms and CT scans. Many of the services were adopted in his practice as long as 20 years ago. He says the lab has been one of the more profitable ancillaries, but reimbursement has declined for imaging.

And there’s a significant discrepancy between the office-based and hospital-based providers when it comes to imaging reimbursement, Crum says. For example, a simple x-ray that might bring his practice $40 in reimbursement might yield $250 for a hospital.

“Hospitals charge way too much for their imaging services,” Crum says. “There needs to be a middle ground. We need to be paid more for x-ray, and they need to be paid less to control medical costs.”

On a long-term basis, the maintenance contracts with the CT supplier have presented the biggest financial cost within the practice’s ancillary business, he says. Meanwhile, CT scans often require the added administrative burden of obtaining prior authorizations.

Crum’s practice contracts with Medicare, Medicaid and commercial payers. He advises other physicians to consider the reimbursement proposition before commit-
Ancillary services

Some cases, improved patient care can result in bonus payments, so a service that seems less profitable could still provide an indirect financial advantage.

**MACRA CONSIDERATIONS**

Experts also caution that billing and coding for ancillary services can’t be an afterthought. This includes some wariness about the Medicare Access and CHIP Reauthorization Act’s (MACRA) impact on ancillary services as payment moves from fee-for-service to quality-based reimbursement.

“It doesn’t do you any good to add reimbursable ancillary services if you undercode them,” says Keith C. Borglum, CHBC, a healthcare consultant in Santa Rosa, Calif.

Borglum is especially concerned about payers denying modifier -25 codes (separately identifiable evaluation and management service by the same physician on the same day of a procedure or other service), potentially resulting in nonpayment for ancillary services. Many payers, including Medicaid, don’t rec-

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### UNTAPPED OPPORTUNITIES

Based on responses to the *Medical Economics* 2017 Physician Report Survey, there are several untapped opportunities for practices to add reimbursable ancillary services. Addiction medicine and sleep medicine are rarely offered, according to respondents, yet, these two categories represent unmet needs among large numbers of patients.

#### Addiction medicine

The most recent data from the Substance Abuse and Mental Health Services Administration indicates that approximately 20.7 million individuals over age 12 had a substance use disorder in 2017, and only 12 percent were receiving treatment. Drug overdoses killed 70,000 people in 2017, according to preliminary estimates from the Centers for Disease Control and Prevention.

“It’s important that primary care is seen as part of the solution to the opioid epidemic,” says Ann Greiner, president and CEO of the Patient-Centered Primary Care Collaborative.

An internist’s role in care includes prescribing two of the drugs approved to treat substance use disorders: buprenorphine and naltrexone. Eight hours of training is required by federal law to prescribe buprenorphine, and as of September 1, 2018, there were 53,600 providers authorized to do so, including nurse practitioners and physician assistants where state law allows.

In Connecticut, Jeffrey Kagan, MD, offers medication administration for alcohol and opioid addiction. Injectable naltrexone is provided to patients in the office approximately once a month, and the gold standard of care calls for separate counseling with a therapist, social worker, or other behavioral health professional. Kagan says most of his naltrexone patients do follow through with counseling or Alcoholics Anonymous fellowship meetings.

“The newer patients are often referred here by their counseling programs,” he says. “Some of the ones who have been getting the drug for a couple of years may decide to decrease or eliminate the counseling or meetings.”

#### Sleep medicine

According to the American Academy of Sleep Medicine (AASM), 70 million Americans have sleep issues, and nearly 60 percent of those individuals have a chronic disorder, such as obstructive sleep apnea or insomnia. Sleep issues are also associated with comorbid conditions such as hypertension, stroke and type 2 diabetes.

Lawrence J. Epstein, MD, past president of AASM and instructor of medicine at Harvard Medical School, says primary care doctors should screen patients and ask about their sleep health. Those identified to be at-risk can be referred to an accredited sleep facility, or with appropriate training, a primary care physician can provide home-based testing as an ancillary service.

“To manage patients who are diagnosed with sleep apnea, a positive airway pressure therapy program can be run out of a primary care physician’s office if it is equipped to provide durable medical equipment services,” Epstein says.

There are a number of potentially reimbursable CPT codes for sleep medicine as well. Epstein cautions, however, that positive airway pressure therapy is reimbursable but requires substantial infrastructure and attention to federal and state regulations.
Mom of three. “First lady” of a megachurch. Head of a medical clinic in Haiti. Orthopedic surgeon. Author. Instagrammer. Dr. Sonya Sloan does it all. Having worked locum tenens since 2006, she’s found that she’s able to do it all – with a little help from the “village.”

“I want to focus on other ventures in life, not just medicine. Locums did exactly that for me, it afforded me the opportunity to have a life on my own terms,” she says. “I was able to be at home, pick and choose where I was going to travel, make great money, and then take time off to be with my family.”

Dr. Sloan has chosen to live the life of a locum tenens doctor for 12 years, sometimes picking assignments as short as five days, with the occasional six-month stint. Right now, Dr. Sloan is working with an underserved population in dire need of a physician.

Growing pains, and helpful tips from Dr. Sloan about working locum tenens

Although Dr. Sloan has a mostly positive perspective of locum tenens, she has some bits of advice and helpful tips for those wanting to learn more about locum tenens. Initially, her concern was being away from her three kids for an extended period of time when she takes non-local assignments.

“Finding someone to take care of my children if I take them with me on assignment is tricky at times, but it’s always worked out,” she says. “Once I had to fly my mom out to help when my daughter was ill and I wasn’t able to get away from my contract work. But I’ve been blessed to have people go out of their way to help.”

Locum tenens and the time to make a difference

Making a difference is a passion she shares with her husband, who is a senior pastor of a megachurch. She’s helped lead the church’s health ministry team, and they built a medical clinic in Haiti where they travel to help a population in dire need. Mission work is a priority for Dr. Sloan and her husband, and she’s found locum tenens gives her the flexibility to serve.

As if all this weren’t enough, Dr. Sloan is writing a book, The Rules of Medicine, which chronicles the day-to-day experiences of a doctor. They’re experiences doctors talk about with each other, but she thought it’d be an interesting what-to-expect book for upcoming physicians.

She’s also hoping to do a book tour, and working locum tenens rather than a permanent job gives her the opportunity to control when and how long to take time off to follow her dreams – every one of them.

To learn more about locum tenens and read about other physicians’ experiences visit locumstory.com
Physicians should review the specific requirements of modifier -25 as they relate to each payer in a practice’s mix.

Zetter anticipates that MACRA ultimately will set the payment standards nationwide.

“All payers look at quality, cost and outcomes, so you need to determine if this would increase the chances of your looking like a costly practitioner by adding these ancillary services in-house,” Zetter says. “If the cost to the patient and the payer is less when you refer out, you want to pay attention to whether you’re going to raise that cost by bringing it in-house. That eventually will affect your reimbursement, not only with Medicare, but all the commercial payers.”

FUTURE CONSIDERATIONS
A practice’s patient panel can be an important consideration in choosing an ancillary service that has the most potential to improve care. Diabetes and dementia are conditions that are increasingly being met with new digital tools that help the medical team better care for the patient between visits.

Crum anticipates he might begin offering 24-hour glucose monitoring for his patients with type 1 diabetes. Generally, the monitors record real-time data and track patterns. The data can be used to see how food, activity, and medication impact glucose levels, potentially predicting highs and lows so the patient can proactively manage issues.

The approximate cost for four monitoring kits is about $4,000, with a breakeven point at 20 patients. The practice is still in the process of quantifying the reimbursement, but it’s more about improving patient care, he says.

Seniors comprise a growing share of the patient population for many practices today, and future considerations might include ways to serve their primary care needs.

Jeffrey Kagan, MD, an internal medicine physician in Newington, Conn., and a member of the Medical Economics editorial board, provides a number of ancillary services, including a brief cognitive impairment assessment known as the Memory Orientation Screening Test (MOST), which he says is similar to the Mini-Mental State Examination (MMSE). The test is useful in detecting dementia in clinically unevaluated patients age 65 and older.

“The MOST test reimbursement can double the money you get from an office visit, while it only takes your medical assistant five to 10 minutes,” Kagan says. His practice pays a nominal licensing fee with each use of MOST, but the fee is reduced with higher volume. It’s reimbursed about $48 with CPT code 96120. By comparison, he says the MMSE test isn’t reimbursed for primary care.

It’s not at all surprising to me that a lot of practices are providing a more comprehensive set of services within their own practices. There are positives and negatives, and it depends on the practice and the population served whether it makes sense.”

—SAYS ANN GREINER, PRESIDENT AND CEO, PATIENT-CENTERED PRIMARY CARE COLLABORATIVE

Ancillary checklist
Considerations before offering an ancillary service:

- Reimbursement potential with current payer mix
- Administrative requirements and proper coding
- Clinical demand based on patient demographics and previous referrals for the service in question
- Market demand based on local service availability
- Regulations, including licensing or certification
- Staff requirements, including initial training and ongoing manhours
- Office space available to perform the service and store supplies and equipment
- Upfront investment in supplies and equipment
- Ongoing investment in supplies, equipment and maintenance
- Specialist care coordination, including interpretation of results or referral to specialty care
- Liability
Group purchasing: Save money by aligning with other physicians

by DEBORAH ABRAMS KAPLAN Contributing author

Doctors specialize in treating patients, not negotiating prices and ordering products. But when supply costs aren’t monitored, practices can suffer. It pays to periodically revisit the purchasing process to ensure your practice isn’t paying more than necessary. That means the practice should be looking at its current group purchasing organization (GPO) or physician buying group (PBG), or joining the best one for the practice.

Medical supply costs vary widely based on how much a practice buys, and the typical items they stock. Internal medicine practices offering few vaccines or specialty pharmaceuticals, and with no office lab, typically spend less than $10,000 per physician per year on medical supplies, says Zachary Sikes, president of Purchase Clinic, a GPO.

Savings can be significant when buying through a GPO or PBG. For example, Jay Shorr, founder and managing partner of Shorr Solutions, a medical practice consulting firm in Coral Springs, Fla., estimates savings of 5 percent to 25 percent depending on practice volume and items purchased when using a GPO. Practices buying vaccines or operating in-house labs with point-of-care testing will see higher savings, while those just buying commoditized medical/surgical supplies will save less.

“The more bulk you buy, the bigger your discount is going to be,” Shorr says. “Negotiating power is always in volume.”

GROUP PURCHASING ORGANIZATIONS

GPOs are the most common way to save money on medical and other office supplies. “Almost all GPOs offer just about everything involved in a medical practice, including office supplies, capital equipment, and purchased services,” says Sikes.

GPOs are membership organizations, typically with no fee. They aggregate sales to negotiate better manufacturer prices. They’re government regulated, and the vendor pays 1 to 3 percent fees to the GPO for items purchased.

The GPO concept got its start serving hospitals, and the largest ones now have divisions serving physician practices and other nonacute settings, as well.

One way GPOs differentiate themselves is using a general or committed model. A committed model means the physician commits to purchasing a specific percentage of annual supplies from the GPO. In return, they get lower pricing, but have more limited access.
Money

Group purchasing

“The more bulk you buy, the bigger your discount is going to be. Negotiating power is always in volume.”
—JAY SHORR, FOUNDER AND MANAGING PARTNER, SHORR SOLUTIONS, CORAL SPRINGS, FLA.

purchase choices, like one brand of bandages instead of five, or one brand of meningitis vaccines.

The committed GPOs use clinician boards to determine what items to carry. “They're making choices among the top brands and manufacturers in the country,” Sikes says. A general GPO contracts with many suppliers, offering customers more choice, but often at higher cost. Sikes says that internal medicine physicians save 11 percent on average annually when switching from a general to a committed GPO.

Even though volume orders affect pricing, small practices should consider joining a GPO, says Shorr, and the easiest way is to talk to the distributor about it.

PHYSICIAN BUYING GROUPS
PBGs emerged about the same time that GPOs started offering services to smaller practices, around 20 years ago, says Brian Greenberg, MD, a physician in Tarzana, Calif., and founder and president of Medical Practice Purchasing Group (MPPG).

Most PBGs started and continue to run primarily as vaccine purchasing groups, and that's still where the main value lies. “We ran into situations in the 1990s and earlier part of this century where there were more vaccines and more expensive vaccines, and the reimbursement really plummeted,” he says. The vaccine profits started disappearing during that time, he says, and groups like his began negotiating discounted contracts with vaccine manufacturers, based on loyalty and volume.

While both GPOs and PBGs offer vaccine discounts, Greenberg says that vaccine prices are better

Ordering through Amazon?

Physician practices are increasingly starting to order commoditized medical, office, and IT supplies through Amazon, says Rob Austin, MBA, director of healthcare consulting for Navigant. “You hear a lot about Amazon entering healthcare,” Austin says. “They’re probably going to get better prices than going through a GPO because they have better buying power.” That method won’t work for pharmaceuticals or medical devices, which are heavily regulated. “It’s starting to mainly happen with med/surg supplies, but not in a meaningful way. But I can see that changing for things like Band-Aids, tongue depressors and paper towels.”

Another reason is that no vendor is doing such a good job selling supplies to physicians and healthcare groups that Amazon has room to move in. “There’s really an opportunity for improvement. It doesn’t seem super efficient how (healthcare organizations) buy things,” Austin says.
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Looking toward the future
MEDENT is looking to the future regarding alternative payment models under MACRA.

It is important to note that while you may hear that Meaningful Use is going away and will not exist anymore, this is not completely accurate. The Medicare EHR Incentive Program, commonly referred to as Meaningful Use, itself will be sunsetting with the onset of MIPS. However, the requirements for Stage 3 are actually being consumed by the Advancing Care Information Performance category and MEDENT is fully engaged with these new incentive programs. One of the first programs to go live is CPC+.

MEDENT has submitted a letter of intent to CMS for participating. If your practice is concerned about having a comprehensive system that can deliver alternative payment models, please contact us at MEDENT. We are prepared and can help your practice achieve these goals and requirements. MACRA was signed into law in 2015 and changes Medicare reimbursement by creating a Quality Payment Program. MIPS, CPC+ and APMs are all part of this: This program:

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Money
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“Partnering with a GPO who has the right contract portfolio, both in terms of supplier/product mix, pricing and solutions is important when making decisions.”

—JESSICA COOLEY, VICE PRESIDENT OF STRATEGY IMPLEMENTATION AND ACCOUNT MANAGEMENT, PROVISTA, A NONACUTE PROVIDER GPO

with PBGs because of the commitment model and volume ordered. While PBGs are less popular with internal medicine physicians than GPOs, internists who buy a lot of vaccines may benefit from PBG participation. Vaccines can be a large practice expense. For Greenberg, vaccines account for as much as 30 percent of his own practice costs.

As office manager for an independent, single-physician internal medicine practice in Torrance, Calif., Marla Munro says that using a PBG cuts their costs significantly. They buy a range of pharmaceuticals, from flu to travel vaccines, plus testosterone injections for patients. She used to pay $65 per testosterone vial, and through the PBG the practice is paying around $30. Using the PBG has become “absolutely necessary for our viability,” Munro says.

Those using a committed PBG program must buy their vaccines from vendors in the program, though, or the PBG risks losing its deeper discounts. Greenberg says that vaccine companies verify the doses and brands of vaccines purchased by physicians through market research reports.

Physicians ordering vaccines
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Money

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“Almost all GPOs offer just about everything involved in a medical practice, including office supplies, capital equipment, and purchased services.”

—ZACHARY SIKES, PRESIDENT, PURCHASE CLINIC, A GPO

GPOs may have threshold for size or volume based on their focus. Practice size should not matter if the GPO has expertise in the physician practice space with solutions that are scaled to meet their unique needs.

Revisit pricing every year or two and compare distributors and GPOs. Practices can belong to multiple GPOs, so long as one of them is not a committed GPO in which the practice would have a contractual obligation to purchase from them. Put the top 10 to 20 items the practice purchases out for bid.

“Let your vendors do the work of pricing it if they want your business,” says Shorr. Even if the staff does the purchasing, the physician may want to also review prices.

Munro says she whenever she makes purchases, she quickly compares prices through her PGB vendors and outside vendors online to make sure she’s getting the best price.

If you’re using a general GPO model, find out if a committed model would still provide you with the supplies you want, but save additional money. “If so, a smaller physician practice may be able to standardize to one supplier for some items and get lower pricing,” says Cooley.

While periodic reviews are important, those just buying office and general medical supplies shouldn’t spend a lot of time on pricing. Find the best distributor and make sure you’re enrolled in a GPO, says Rob Austin, MBA, director of healthcare consulting for Navigant. More research time is necessary if the office orders a lot of pharmaceuticals, implants or specialty physician items.

“Pharmaceuticals are expensive. It can make sense to spend more attention on it,” Austin says.

Lastly, consider if your distributor is performing additional services like stocking and ordering supplies. The typical office manager is overworked, and may be willing to pay more for the additional help. Evaluate if the help is worth the additional cost, and if ordering online would be a better option.

40 or other supplies directly from vendor won’t notice a change, other than price, as the physician’s membership number is automatically associated with the account. Many PBGs also offer other services, like discounted medical/surgical supplies, phone service, business insurance, and savings on medical malpractice insurance.

TIPS FOR SAVING MONEY AND FINDING A GPO

A Medical Group Management Association survey shows that 25 percent of its members were not aware of what GPO or GPOs they belonged to, and 33 percent were unsure if they were saving money through the GPOs. Practices can find out GPO memberships by asking the distributor. Then ask if there are other money-saving options.

“There’s competition out there. See what other options are for aggregation groups for purchasing,” Austin says. Reach out to peers about their experiences and the breadth of their GPO contracts.

Don’t base GPO choice on what your hospital uses.

“The needs of a physician office are very different from a hospital. Therefore, partnering with a GPO who has the right contract portfolio, both in terms of supplier/product mix, pricing and solutions is important when making decisions,” says Jessica Cooley, vice president of strategy implementation and account management at Provista, Vizient’s nonacute provider GPO. “Some
Use shared services to improve Diabetes counseling

by JORDAN ROSENFELD  Contributing author

Diabetes is among the most common chronic diseases, affecting upward of 30.3 million in the United States as of 2015, according to the American Diabetes Association.

The scope of the disease has a significant impact on physician practices. According to a 2016 report in Primary Care Diabetes, showed that 48 percent of all patients with diabetes (and no other chronic condition) were made to primary care physicians.

Shared diabetes services may be essential to successfully treating patients with this disease without overburdening physicians.

Dhruv Khullar, MD, MPP, a physician at New York-Presbyterian Hospital and an assistant professor in the department of healthcare policy and research at Cornell University in New York, says that incorporating shared services such as diabetes care and behavioral health within practices is increasing.

He says there is "A growing body of evidence that suggests either co-locating these types of services within a practice, or having very easy seamless access to them can really help improve patient outcomes."

SHARE TO SURVIVE

Khullar says that integrating services is one way smaller physician practices may be able to survive in the face of healthcare reforms that put greater burdens on them.

“There’s not just one way to share services such as hiring a diabetes educator,” Khullar says. He recommends physicians think broadly—ranging from looking for opportunities to obtain some of these services through hospital affiliations, to partner with other small physician practices that might have such a person on staff, or to collectively share the costs of such an educator.

There might even be ways to get these services through payers, Khullar says. "Some commercial payers might pay for or pay partially for these types of services, particularly [under] capitated agreements.” He recommends that physicians evaluate the needs of their practice to discover the best possible strategy for shared services.

Jason C. Baker, MD, assistant professor of clinical medicine and attending endocrinologist at Weill Cornell Medicine in New York, says that integration of care has always been very important in diabetes treatment.
He outlines an ideal model in which a physician is in charge of medications and orders labs and follows up on them. Then, a certified diabetes educator and/or nutritionist delves into the day-to-day issues about how a patient can keep his or her health at an optimal level.

Integrated care is easiest when physicians and diabetes counselors are in the same location, Baker says. This allows for ease of sharing charts, notes, and communication, but in his own practice, he prefers a referral-based system. “I like to be able to pair personalities together, different nutritionists and educators to different patients,” Baker says.

He acknowledges that a downside of this approach is that it makes communication more complicated. “Unless you’re at a very large comprehensive diabetes center, you have various written reports being shared, faxed, emailed, and scanned into the EHRs and it can get a bit messy,” he says.

Baker says the benefit of an in-house diabetes educator is that the provider comes to the physician’s office and they can enter notes directly into patient charts, which alleviates communication issues, and reduces the problem of chasing each other down by phone.

The potential downside is that having an in-house educator locks patients in with...
Operations

that person. In that regard, he says, a physician practice will have to decide what is more important to them—being able to offer patients a variety of practitioners or having seamless communication in-house.

Another benefit of in-house integration with diabetes services is that it makes it easier for the patient to obtain better care. "Patients tend to not show up for appointments and get the care that they need if there are barriers to that care," Baker says, such as having to travel to more than one location, or scheduling appointments on separate days. "So anything one can do to make it easier for patients will ultimately help their care."

Additionally, he says, it can make things easier for the provider because, aside from overseeing the big picture of the patient’s care, the physician can best spend their energy on coordinating care from a big-picture perspective, and can communicate with the patient to let them know he or she will be speaking further with an educator or specialist.

However, if a physician is having difficulty determining which aspects of diabetes care to offload to a third party, Baker recommends that physicians delegate tasks such as teaching patients how to use an insulin pump or glucose meter, and nutritional counseling.

Certain mental health-related disorders such as binge eating and anorexia, which Baker says are common in diabetes, will probably need to be referred to a behavioral health professional.

"It’s not going to be possible for the physician, who many times has just twenty minutes, to do what they need to do and make treatment decisions," Baker says.

**Boost Revenue**

Another benefit of shared services, particularly if a physician hires additional staff, is that it could bring extra income to a practice by increasing the number of patients that can be seen.

However, he cautions that financial gain should not be the only driver of such a program. Essentially, it’s important for physicians to strike the right balance between productivity and quality. "I think it tends to dilute out the care when there's a really high volume of people coming through an office," Baker says.

Evaluating when and how to hire additional staff is a decision each practice has to make individually, says Khullar. "For some, it may make sense to hire someone full time. For others, it might be better to share one clinician across several practices."

He says some services may be available through different mechanisms. "In some cases, insurers might help cover the cost, and in others, a local health system might. It's also important to take into account any downstream savings or health improvements that might result when calculating the upfront cost of hiring an additional care team member."

Regardless of how a practice goes about it, Baker says sharing services is a key part of diabetes patient care. "I think that somebody who tries to do everything on their own is not going to be successful with the majority of [diabetes] patients. You have to have a group to work with you."

**Editor's note:** The intricacies of running a medical practice and meeting myriad patient needs have increased to say the least. But there's one solution for both issues: shared services. This occasional series will look at possibilities that physicians likely aren't benefitting from and how they can use shared services to improve the care their patients receive.
My favorite analytic tool in Microsoft Excel is the pivot table. Rather than relying on the confusing and canned reports provided by our EHR, I use pivot tables to see the data I want to see, sort it how I want, and produce meaningful reports.

For those unfamiliar, pivot tables are a powerful way to summarize, sort, filter, and group data. They are a feature of Microsoft Excel to analyze data (e.g., a report of billed charges and reimbursements) in a spreadsheet with ease. Physicians can quickly organize and sort information while including or excluding the data displayed. Here are ways that I have used pivot tables to benefit our practice.

1. **Provider utilization**
   Like many specialty practices covering multiple hospitals, we had assigned physicians to certain hospitals and had not changed this resource allocation for several years. Using data from our practice management system and EHR, I created a pivot table looking at the return on investment for each physician’s hospital work. Within the pivot table, I showed procedures, consults, RVUs, and other comparative information. The table demonstrated significant differences in utilization and resulted in changes to our hospital coverage. Not coincidentally, revenues increased.

2. **Referrals**
   In the past, we used our canned practice management system reports to look at referrals by provider. These reports were not timely nor useful. We now have a pivot table linked to our practice management system server that is updated daily. It permits us to study referral trends by referring physician or practice, receiving physician or practice, or type of referral. It permits us to see changes on a real-time basis and address referral changes quickly. This data has enabled us to improve our service by being more responsive to concerns of referring physicians and has contributed to increased referrals.

3. **E/M coding**
   Even as Medicare prepares to ‘simplify’ Evaluation and Management (E/M) coding guidelines, physicians continue to be audited by Medicare and private payers for overcoding. We use a pivot table to evaluate coding patterns, both relative to Medicare data (Medicare E/M by Specialty 2016) and among our providers. This data has identified probable undercoding and overcoding, permitting us to address both through additional education. I also find that sharing this comparative data among my providers results in ‘right-sizing’ the coding of those who historically code very conservatively. As a result, revenues have increased.

4. **Reimbursement**
   Analyzing your fee schedules using canned reports is tedious at best. If you’ve tried to run a report showing what each payor pays for a set of CPT codes, you know what I mean. A pivot table allows one to slice and dice information by code by payer to look at variances, identify underpayments, and negotiate better terms. I have used data from our pivot table to improve reimbursement across the board for some payers and for certain codes for other payers.

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**GETTING STARTED**

Two resources to learn more about pivot tables:

Healthcare consultant Nate Moore offers free step-by-step tutorials on using both Excel and Excel pivot tables at mooresolutionsinc.com. These short videos use real (de-identified) data from medical practices as examples.

Better Data, Better Decisions: Using Business Intelligence in the Medical Practice by Nate Moore and Mona Reimers.

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**Tech Talk**

Get better data by using pivot tables

Lucien W. Roberts, III, MHA, FACMPE, is a practice administrator in Virginia. Send your technology questions to: medec@ubm.com
Treating LGBTQ patients: 4 ways to address their needs

by MILLY DAWSON  Contributing author

W orking near New York City, To-chi Iroku-Malize, MD, MPH, MBA, the chair of family medicine for Northwell Health, cares for many patients in the LGBTQIA (lesbian, gay, bisexual, transgender, queer, intersexual or asexual) community. She has given serious thought and effort into making each one of these patients feel accepted, valued and welcomed in her practice.

"People in this special population of patients may feel that the healthcare system, including providers and institutions, is not up to recognizing their culture or their needs," she says.

Research supports that feeling. A large literature supports the finding that people who depart from traditional heterosexual norms feel disrespected and marginalized in healthcare settings. The literature also shows that these patients do in fact receive poorer quality care than people who fit prevailing norms.

Stigma leads to avoidance of healthcare encounters, the research has found, and such avoidance of primary care takes its toll.

“When patients feel there is stigma, this can increase depression among them,” says Iroku-Malize. “The patients, especially the youth among them, are at increased risk of both depression and suicide.” If patients sense that there is stigma against them, that can also lead to increased substance abuse, in terms of alcohol, smoking, and other drugs, all of which leads to more long-term chronic illness, explains Iroku-Malize.

Physicians do not have to become experts in caring for patients in this population, says Iroku-Malize. “You just need to be aware of this population and get the basics of how to approach the patient.”

Here are five ways Iroku-Malize suggests physicians can make clear that LBGTQIA patients will be treated with the same respect and high-quality care any other patients receive. (Note: Many LBGTQIA people also use “queer” as an umbrella term for the entire group, and in the rest of this article that will be the term used.)

1. QUESTIONS TO ASK

Start with two fundamental questions you can ask on intake forms. They are:

What is your current gender identity?
Check all that apply:

- Male
- Female
- Female-to-male (FTM)/transgender male/trans man
- Male-to-female (MTF)/transgender female/trans woman
- Genderqueer, neither exclusively male nor female
- Additional gender category/(or other), please specify
- Decline to answer, please explain why

HIGHLIGHTS

- Use the patient’s preferred pronoun consistently. Place a prominent note in the patient’s chart in such a way everyone who cares for that person will see it and know how to address them.
- Be self-aware enough to recognize if your own discomfort or disapproval disqualifies you from caring for a gender-nonconforming patient.
What sex were you assigned at birth on your original birth certificate? Check one:

☐ Male
☐ Female
☐ Decline to answer, please explain why

You will need to do basic preventive screenings based on the assigned sex at birth. This means that a person who had been assigned male gender at birth and who now identifies as a transgender woman still needs to have the health of their prostate monitored. Likewise, a person assigned female gender at birth and who now identifies as a transgender man will need pap smears done.

Other physical exams and tests may be called for depending on whether or not the person has had surgery as part of their transition, and the stage of any such surgery.

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ADDRESSING THE PATIENT

“The biggest thing healthcare providers don’t know about is what to call these patients,” says Iroque-Malize. Ask the patient what pronoun they prefer—he/she/they/ze or some other pronoun. (“Ze” is one of several relatively new pronouns. It is preferred by some transgender people and by some who consider themselves neither male nor female, and therefore find “he” and “she” inappropriate and hurtful.

Use the patient’s preferred pronoun consistently, and make sure that other staff members do so as well. Place a big note in the patient’s chart in such a way everyone who cares for that person will see it and know how to address them.

In a related matter of language, if you need to do an exam that involves the genitals, ask the patient how they refer to those areas of their body. In that kind of situation, if you need to do a cervical exam, go slowly and be circumspect.

“You have to gain trust and make this exam as comfortable as possible acknowledging that they identify as male,” says Iroku-Malize. You might need to gently explain each step of the exam. “Okay, I am about to approach x and I will do this and do that.”

Taking the time to respect their sensitivities and use their preferred words affirms the patient’s identity, she explains. “Everything I do as a primary care provider acknowledges who they are as a person,” she says.

“Be honest with the patient,” says Iroku-Malize. “Say, I am not experienced with this and I need you to guide me in what is appropriate and not appropriate.” Tell them that you need their help to gain their trust and be as helpful as possible.

OWN YOUR LIMITATIONS

Be self-aware enough to recognize if your own discomfort or disapproval disqualifies you from caring for a gender-nonconforming patient. If so, be prepared to refer those patients to clinicians who will welcome and care for them well. If there is no one in your area that seems appropriate, you may need to learn about good telemedicine options.

Iroku-Malize says that her healthcare system, Northwell Health, has established a dedicated referral service for members of the queer community. This simplifies the patients’ search for quality care.

BE WELCOMING

If you have pictures of happy families in that area, include families of different sorts. “Even having a small rainbow flag in the waiting room says to patients, ‘You are welcome here,’” says Iroku-Malize.

Make sure that your staff understands the basics of serving queer patients. “Anyone working in primary care has to be culturally sensitive to the gender identities of patients coming in,” says Iroku-Malize.

Training resources are available. For instance, the Human Rights Campaign Foundation offers resources to healthcare providers. Be curious and willing to keep learning.

Queer patients are likely to have had unwelcoming encounters elsewhere. In fact, you may be the third or fourth primary care provider that a gender-nonconforming person has turned to, and the first three or four may have been condescending, dismissive or judgmental says Iroku-Malize.

She emphasizes that being willing to listen and learn and wanting to help are all that it takes to make a big difference in the lives of these vulnerable patients.
after ten years as a hospitalist, my job continues to get more and more interesting. The new horizons of patient experience present a series of ongoing challenges. A few months ago, for instance, I admitted a 93-year old female, Ms. X, with bilateral pneumonia with shortness of breath, cough, and a temperature of 101°F. The Emergency Department chest x-ray revealed bilateral extensive consolidation, and the patient was put on the appropriate treatment regimen. She started showing improvement after the fifth day of admission with reduced shortness of breath and resolution of the fever. While progress was slow, the patient and her three children remained upbeat. Her two sons had come from out of state to help their sister, who was living in the same town as their mom and was the main caregiver.

Unfortunately, on the sixth day of admission, I was paged STAT to attend to Ms. X, who was in respiratory distress. With many thoughts crisscrossing my mind, I rushed to the aid of this elderly patient. After a couple of breathing treatments and oxygen administered via the nasal canal, she quickly stabilized. The repeat x-ray showed no change in lung status, and the pulmonologist added chest physiotherapy and Mucinex to the treatment plan. These changes helped her to improve. The next day, however, she continued to have respiratory distress, which was not resolvable. An echocardiogram to rule out congestive heart failure exacerbation was normal, and her response to IV Lasix during the crisis period was minimal. However, this respiratory distress continued, even after nine days of admission. Both the patient and the family were worried about her deteriorating health and decreased food intake.

On the ninth day, I was called into the patient room for a talk. Ms. X looked at me and said, “Doctor B, you are a good doctor and you are trying your best. You know I am not young anymore. I have been experiencing a great deal of suffering, and I am having continual difficulty breathing. Can you let me go peacefully?”

Surprised and somewhat emotional, I looked at her to make sure she was mentally oriented and that her decision-making capacity was intact. Meanwhile, the daughter and two sons asked if we could talk outside. I readily agreed and took them to an empty patient room and closed the door.

Ms. X’s eldest son said, “Doc, it appears that my mom is suffering and not likely to make a full recovery, despite your continuous care. And now she has even stopped eating. How can we end this suffering?” I looked at the other two children, who were both nodding their heads in confirmation.

“I feel that expanding the boundaries of physician’s services and going the extra mile to make a real difference in the lives of patients is not only our professional duty as doctors but also a human obligation that we owe all the people in our care.”

Expanding the paradigm of patient-centered care: patient, family and dog dynamics

By Ramegowda Belakere, MD, PhD
By then, I had realized Ms. X was not recovering from her extensive pneumonia and that her chances of recovery were severely affected by her COPD due to passive smoking, old age, low nutrition, and her fragile body. She was extremely weak and was now refusing to eat. After careful consideration, I offered them hospice care. I explained that this is an end-of-life care process, the aim of which is to keep terminally ill patients comfortable during their final days. The family agreed for their mom to be placed in a home hospice.

After this meeting, I went to back Ms. X’s room and started my conscious conversation. I explained that she was not getting better and that her health was worsening day-by-day due to extensive pneumonia with underlying COPD. I said, “I understand that you are suffering. But you should know that there is hope. The option is to place you under the care of hospice service, which concentrates on the patient’s comfort rather than the cure.”

Ms. X was happy to hear this option. She immediately said, “Let me join the Lord.” I fully agreed with her decision and said that I would arrange for hospice care at home. The patient asked, “Can you arrange for it today?” I knew the process of arranging hospice care takes some time, and I told her it would take at least 24 hours. Ms. X’s daughter said, “Do your best, Doc. Her dog, who has been with her for ten years, has been waiting anxiously for her every day by the front door window. If she could go home today, that would make her dog happy. And perhaps my mom would be extremely happy too.”

**FROM CURE TO COMFORT AND THE URGE TO MAKE A DOG HAPPY**

With fresh guilt at sacrificing the dog’s happiness if Ms. X did not go home that day, I swung into action without hesitation. Bypassing the case management protocols, I called a hospice agency directly to arrange a consultation to evaluate Ms. X for home hospice placement. After a couple of hours, the agency arrived and approval was granted. I signed all the appropriate papers, and the agency assured me that it was not a problem to arrange for home placement that day, as this patient had original Medicare.

At 6 p.m., while on my rounds, I received another phone call from the hospice agency, saying, “Dr. B, there is a problem. We cannot accept her today. But it should be possible tomorrow.” This information broke my heart. Furthermore, the agency did not know that my patient-centered care paradigm also included a loving dog, who was waiting for her owner to return home. I thought about this for a few minutes and decided that I did not want to simply give up. So, I called them back and asked, “Can you not provide hospice care in a patient’s own bed?” I requested again that she be allowed to go home that day, and then I finally told them about the pet dog who was waiting to see my patient. This may have tugged their heartstrings as the lady from the hospice agency agreed to provide care in Ms. X’s own bed at her house. The patient was discharged that day and taken home without further delay.

This was such a joyful moment. I was so emotional about the whole patient experience scenario that I locked myself in my room and thanked my emotions for sparking my motivation to display empathy and help this patient. This in turn led to an expansion of my patient-centered care paradigm to include a beloved pet in my decision-making process. My instincts in this scenario reminded me that I was blessed to be a doctor, learning life lessons while helping the needy.

I feel that expanding the boundaries of physician’s services and going the extra mile to make a real difference in the lives of patients is not only our professional duty as doctors but also a human obligation that we owe all the people in our care. Compassion-filled care not only comforts patients but also elevates doctors’ motivation levels and enriches our people skills.

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**Editor’s note:** Patient names were changed to preserve privacy.
id you get your $200 worth today?

I often pose this question to medical students training in my primary care clinic. It’s simple math: the average annual tuition and assorted costs of the average medical education is $200 per day. Given this cost, should we be surprised if our students shift their mindsets to that of a consumer, demanding a quality product? I often pondered this when I was a medical student, notably when tasked with such vacuous work as fixing a broken printer or hand carrying a urine sample across the hospital. This is not to devalue teamwork, nor the underlying lessons to be harvested from responding to changing environments. Rather, with mountains of rising debt it is reasonable to wonder what medical students are getting in return for their investment.

A 2018 report from the U.S. Department of Education notes the average physician now graduates with $246,000 in loans. These numbers have more than doubled since 2000 with median debt at $90,000, while salaries certainly have not risen in concert. One recent graduate friend spends nearly $7,000 per month on loan repayment, while a second paid $50,000 last year toward interest without touching his principle. Much of this debt is inflated by what can be considered hidden costs outside traditional tuition: $1,000 on my first day for medical equipment, $3,355 for exam fees and unanticipated travel costs for increasingly competitive residency interviews. A close friend applying to neurosurgery programs had to take out a loan to cover the $17,000 cost to travel to dozens of interviews.

Solutions to this problem are clear: decrease total cost of tuition, decrease hidden expenses, decrease total time of medical education, decrease interest rate impact, reenact subsidized loans, or enhance or front load repayment. These options are easy to list but are increasingly challenging to address. However, the recent announcement of free tuition for all NYU School of Medicine students (though not inclusive of living and hidden expenses) may represent a milestone for disruption and competition within our current model. While few institutions have the endowment to replicate this undertaking, it raises an opportunity for upheaval of entrenched expectations.

To offer additional transparency, I challenge medical schools to openly publish average debt at graduation alongside annual tuition costs. This publication of the debt load of the graduating class could be an ideal metric for medical school competition. The major caveat here is that indebtedness is not always a marker for lower cost, but can be a proxy for social status or parental contribution. Additionally, acknowledgment of accrued undergraduate and pre-medical school debt, as well as prevention of financial cherry picking, must be built into this paradigm. This could inspire a race to the floor, as opposed to our current steady trot upwards. A step in the direction of transparency would drive competition. Given the cost of living in New York City, I suspect that many public schools in rural areas could potentially best NYU in this regard.

That $200 daily cost is the extravagant equivalent of a magnum bottle of Dom Perignon Champagne daily. It must be curtailed. If not, our bright future physicians may toast their medical dreams goodbye and seek a path with less financial burden.

Aaron George, DO, is a family physician practicing in his hometown of Chambersburg, Penn. He was an Andlinger fellow in health policy with the Center for Public Health in Vienna, Austria, and has been awarded both the Bristol-Myers Squibb award for excellence in graduate medical education, as well as recently named one of the 40 under 40 physicians by the Pennsylvania Medical Society.
Best advice ever given to you by a peer

Maria Young Chandler, MD, MBA
Business of Medicine / Pediatrics
Irvine, Calif.

“Treat your life as a business (Me, Inc.) and you’re the CEO.”

George G. Ellis, Jr., MD
Internal Medicine
Boardman, Ohio

“One of my professors once told me the day you stop learning is the day you hang up your stethoscope.”

Antonio Gamboa, MD, MBA
Internal Medicine / Hospice and Palliative Care
Austin, Texas

“Focus on your family, and don’t let your wife and kids ever feel like they don’t know you anymore.”

Jeffrey M. Kagan, MD
Internal Medicine / Hospice
Newington, Conn.

“The hospital is not your friend.”

Melissa E. Lucarelli MD, FAAFP
Family Medicine
Randolph, Wis.

“Always thank a patient for asking about your family or about your health, and always send a sympathy card when your patient dies.”

Joseph E. Scherger, MD
Family Medicine
La Quinta, Calif.

“Spoken words evaporate. Written words are eternal.”

Salvatore Volpe, MD
Pediatrics/Internal Medicine / Pediatrics
Staten Island, N.Y.

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“Doctors get a really late start [on financial planning] ... and they’ve got to make up for lost time.”

RYAN INMAN, MBA, OWNER, PHYSICIAN WEALTH SERVICES

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“Anything one can do to make it easier for [diabetes] patients will ultimately help their care.”

JASON C. BAKER, MD, ASSISTANT PROFESSOR, WEILL CORNELL MEDICINE

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