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Medical Economics®

AUGUST 25, 2013

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PAY-FOR-PERFORMANCE:

THE END OF FEE-FOR-SERVICE, AS WE KNOW IT?

ADVANSTAR MEDICAL COMMUNICATIONS GROUP VOL. 90 NO. 16

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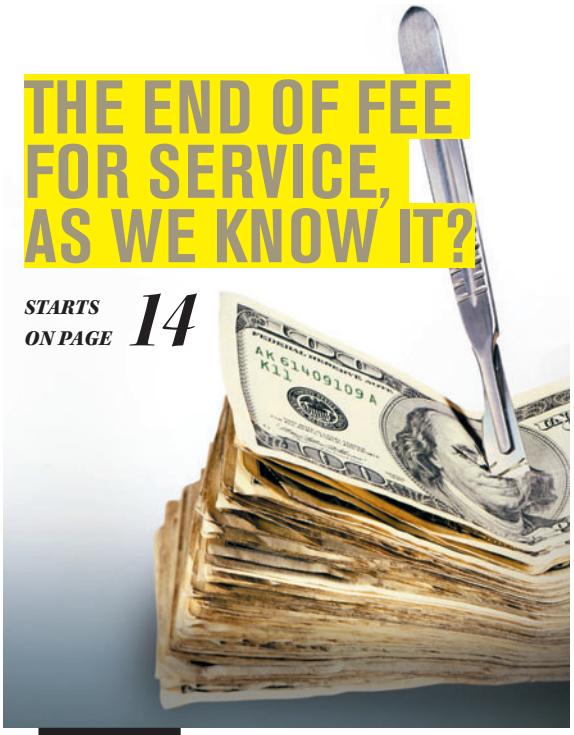

THE END OF FEE FOR SERVICE, AS WE KNOW IT?

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COVER STORY | MONEY

Pay-for-performance and quality metrics are said to bring value to the healthcare system. In primary care, this contribution has been undervalued, and most believe it will impact payment from Medicare, Medicaid and private payers.

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How to bill Medicare for telehealth services

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Martin Serota, MD
Care coordination strategies

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Medical Economics is the leading business resource for office-based physicians, providing the expert advice and shared experiences doctors need to successfully meet today's challenges in practice management, patient relations, malpractice, electronic health records, career, and personal finance. *Medical Economics* provides the nonclinical education doctors didn't get in medical school.

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"Meaningful use can provide helpful guidelines when adopting quality metrics for your practice."

—Rosemarie Nelson, HEALTHCARE CONSULTANT

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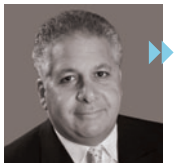

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thoughts from **CRAIG M. WAX, DO**

ACA: IT'S NOT WHAT THE DOCTOR (OR VOTERS) ORDERED

Natural consequences means allowing a behavior or circumstance to determine the outcome without other intervention. The American people have spoken. They are envious of the promise of socialized healthcare as promoted in other countries such as Canada. Americans' fantasy of Canadian-style "healthcare for all" is, in actuality, a two-tiered system. One tier is the government owned and run system with all its delays and access issues. The other tier is the direct patient pay system for people who want their care now and are willing to pay for it.

The American people elected a Congress and a president who made this their goal. The "stakeholders" were at the table with lobbying money and powerful political favors. These groups included Washington politicians, the American Hospital Association, the Pharmaceutical Research and Manufacturers of America, the American Medical Association, the American Association of Retired Persons, the health information technology industry, big business, and unions, among many others.

Notably missing were practicing physicians and patients. Each powerful entity got their paid politicians to write their own part of the law to get their "buy-in," figuratively and literally. Congress passed the legislation, in the dark of night, without everyone reading the entire 2,800-page law.

What American voters thought they wanted was a socialized health insurance safety net for all citizens. What they got was the Affordable Care Act, aka "Obamacare." Instead of the government owning and operating the healthcare system, as in Canada, it has been sold to private corporate interests but with rules by government law. Hospital-owned accountable care organizations (ACOs) will dominate the landscape. Even the U.S. Supreme Court violated the constitution by upholding the mandate for each citizen to buy a health insurance policy that must conform to government specs, thereby costing more than plans do now.

The consequences of Obamacare are now becoming evident. It increases the price of each insurance policy. Every citizen must buy a policy from an approved vendor or face a monetary penalty. Care will be rendered by huge hospital-centric ACOs that know nothing about efficiency, economy, cost-savings, or the practice of personal medicine. Hospital ACOs are investing millions in development in hopes of "shared savings," from Medicare, Medicaid, and private health insurance plans. A Canadian style two-tiered system is forming that is resulting in similar issues of access, costs, and care delays.

Americans, too, will be forced to choose between government promises of taxpayer-funded hospital ACO impersonal healthcare, or the direct patient pay model used since the beginning of recorded time. You can argue with natural consequences, but cannot escape them. ■

Q Have a contrary opinion you would like to share? Let's debate the merits of ACA.

Tell us via email: medec@ advanstar.com

"INSTEAD OF THE GOVERNMENT OWNING AND OPERATING THE HEALTHCARE SYSTEM...IT HAS BEEN SOLD TO PRIVATE CORPORATE INTERESTS BUT WITH RULES BY GOVERNMENT LAW."

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> There will be very little that any one group will be able to do to...repair our broken [healthcare] system. But together, we could become a much more efficient healthcare system. That won't happen if the leaders of physician organizations...dismiss the contributions that APCs offer the American healthcare landscape.
>
> **Nichole Bateman, MPAS, PA-C** MIAMI, OKLAHOMA

APCs PLAY A VITAL ROLE IN HEALTHCARE DELIVERY

I appreciate your article on the willingness of patients to see Advance Practice Clinicians (APCs) ("Patients Open to Expanded Role of Physician Assistants, NPs," June 25, 2013.) As a physician assistant (PA) with 2 decades of clinical experience, I have rarely had occasion for a patient to refuse my care.

As PAs, we don't see just ear infections and sore throats and leave the physician to deal with "more complicated" patients. In our practice, we all see what walks in the door—everything from chest pain that needs emergency hospital transport to the laceration that needs suturing to the hypertensive, dyslipidemic, diabetic individual with coronary artery disease, to coughs, colds, and sore throats. We epitomize what it means to work in a team setting and patients who access care in our clinic know they will be well cared for regardless of the initials behind our names.

My physician colleague comes to me with questions regarding patient care as often as I go to him, and he doesn't look over my shoulder with every suture I place, each chest x-ray I interpret, and every assessment/plan of care I develop. He knows that patients receive great care from both PAs in our office and is professionally respectful to us as his colleagues.

It seems to be a waste of energy to flame turf wars when it will take every qualified professional to deliver healthcare to the masses that are about to flood the system. We should be embracing one another and the skills each well-trained professional brings to the table.

Market demand and access-to-care issues will redirect and require much from those of us in healthcare. There will be very little that any one group will be able to do to stop the upcoming changes and repair our broken system. But together, we could become a much more efficient healthcare system. That won't happen if the leaders of physician organizations such as the American Medical Association and the American Academy of Family Physicians continue their territorial rants that dismiss the contributions APCs offer the American healthcare landscape.

We all need to get out of our boxes and get creative. Those who do will survive the steamroller of change. Those who don't will either get out of medicine or be miserable within it.

Nichole Bateman, MPAS, PA-C
MIAMI, OKLAHOMA

MEDICAID MUST KEEP HIGHER REIMBURSEMENT RATES

If Medicaid is serious about attracting primary care physicians to take on new patients, the reimbursement rate cannot revert after 2014 ("Higher Medicaid payments coming soon," July 10, 2013.) What's the incentive for the physician other than a short-term bump in revenue? The hassles that come with Medicaid are not worth the effort.

Mike Robertson
BATESVILLE, INDIANA

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HIGH COSTS TO REPEAL SGR SLOW PROGRESS

A U.S. House of Representatives Committee voted to abolish the sustainable growth rate (SGR) formula, but the abolition's progress stalled after lawmakers failed to address how to pay for it, reports the American Academy of Family Physicians (AAFP).

Estimates of SGR's repeal vary between $139 billion and $200 billion.

The AAFP and the American College of Physicians have lobbied Congress to repeal SGR this year and replace it with a system that recognizes the complexity of primary care office visits and strengthens the role of primary care in the healthcare system. Without the SGR repeal, physicians face the continued threat of 25% reductions to Medicare payments.

In a June letter, the AAFP told Congress that performance measures should be only one component of payment reform.

"You need to include payment for the coordination of care across delivery settings and for complex conditions," the letter stated. "Finally, the system should include payment for services rendered, which fee-for-service does. But the AAFP believes (and the evidence shows) the balance of these three elements – namely, fee- for-service, care coordination and performance improvement – should be focused on primary care."

PAYMENT, WORKLOAD ARE BARRIERS TO INCREASED E-COMMUNICATION

Though medical practices know the benefits of increasing electronic communication with patients, it is still viewed as a disadvantage, according to an August 2013 study conducted by *Health Affairs*.

In 2008, *Health Affairs* found that only 7% of medical practices were using electronic communication. The journal interviewed six national and regional medical group leaders, and found that out-of-date payment models was a leading cause that prevented practices from embracing electronic communication.

"Unfortunately, traditional payment models are not equipped for a shift from care provided predominantly in the office to care provided electronically," the report stated.

Only one plan charged patients for e-visits, where a physician provided a clinical decision via phone, e-mail or Web video that would have normally been given in an office. This group negotiated with private payers for reimbursements for e-visits, and they were valued less than face-to-face office visits. Others that offered e-visits under fee-for-service models were not paid for.

Another group initially charged patients an annual fee of $60 for unlimited electronic communication with physicians, but eliminated the fee when a competing group began offering similar services for free.

Also, practice staff said that electronic communication increased their workloads. Though some participants reported answering up to 50 emails a day from patients, many did not didn't have a specific time delegated to electronic communication.

Group leaders reported benefits of electronic visits and communication with patients that included an increase in patient satisfaction, convenience, efficiency and higher quality care with better outcomes.

CO-MANAGING GERIATRIC PATIENTS COULD IMPROVE CARE

WHEN PRIMARY CARE physicians and nurse practitioners (NPs) co-manage care for geriatric conditions, it improves the quality of patient care.

That was the conclusion raised by a study by Reuben D.B. et al, published by the Journal of the American Geriatrics Society, that sought to determine if the management of patients in implementing the Assessing Care of Vulnerable Elders (ACOVE)-2 model could also improve care. The ACOVE-2 model includes case finding, delegation of data collection, structured visit notes, physician and patient education, and links to community resources.

The study, conducted in two primary care practices, screened 1,084 patients. Of those, 658 (61%) screened positive for more than one condition, and 485 were randomly selected for chart review. An NP saw 49% for co-management.

Overall, study participants received 57% of recommended care, the authors state. Quality scores for all conditions (falls, 80% vs 34%; urinary incontinence, 66% vs 19%; dementia, 59% vs 38%) except depression (63% vs 60%) were higher for individuals who saw an NP.

More delays expected for Medicaid parity reimbursements

FOR SOME, increased Medicaid reimbursements will be nearly 11 months late.

In fact, some states won't begin getting those larger Medicaid payments to physicians until December, Matt Salo, executive director of the National Association of Medicaid Directors, told *American Medical News* recently.

As a provision of the Affordable Care Act (ACA), Medicaid reimbursements for primary care physicians (PCPs) would be boosted to the same levels of those paid by Medicare—but only in 2013 and 2014. Increases in Medicaid fees are expected to average about 73% but will vary by state, according to a study by the Kaiser Family Foundation Commission on Medicaid and the Uninsured.

The idea behind the temporary boost was to help persuade more physicians to accept Medicaid patients, many of whom will obtain health insurance through the ACA's Medicaid expansion. About 33% of primary care physicians didn't accept new Medicaid patients in 2011 and 2012, according to a July study in *Health Affairs.*

PCPs in several states, including Florida, Massachusetts and Michigan have begun receiving the higher payments, but most have not, according to the National Association of Medicaid Directors.

Eligibility for the higher payments extends to primary care physicians working in fee-for-service as well as managed-care settings, and includes:

- physicians who self-attest to being board-certified in the specialties of family medicine, general internal medicine, or pediatric medicine;
- subspecialists related to the specialties as recognized by the American Board of Medical Specialties, the American Osteopathic Association, or the American Board of Physician Specialties, and can also self-attest that they are board-certified;
- physicians practicing family medicine, internal medicine, or pediatrics who self-attest that at least 60% of their Medicaid claims for the prior year were for the evaluation and management codes specified in the final regulation implementing the applicable section of the ACA.

MANAGING NEW REIMBURSEMENT MODELS RANK AS TOP PHYSICIAN CHALLENGE, SURVEY SAYS

Profitability is getting more elusive for many office-based practices, according to the 2013 Physicians Outlook Survey by Wolters Kluwer Health.

Because of increasing economic pressure, nearly 48% of physicians say they will be focused on increasing the practice's efficiency. Thirty-four percent of physicians surveyed say they plan to explore different business models and another 31% will adopt technology to improve clinical decision-making.

The top physician challenges include: managing changing reimbursement models, financial management, spending sufficient time with patients and dealing with the impacts of the Affordable Care Act (ACA), the survey says.

Healthcare information technology adoption, ACA/increasing legislation, uninsured patients, population and demographic changes and hospital acquisition of physician practices ranked as the top contributors to increasing costs.

Top physician challenges

	very challenging	somewhat challenging	not too challenging	not at all challenging
Managing shifting reimbursement models with payers	44%	47%	7%	2%
Financial management (cost management/ increasing costs/ declining reimbursement rates)	50%	40%	9%	1%
Spending sufficient time with patients	48%	40%	10%	2%
Dealing with impacts of ACA	43%	41%	13%	3%
Keeping up with the latest research	26%	57%	15%	2%
Improving patient care	20%	58%	20%	2%
Utilizing healthcare information technology in my practice	29%	48%	19%	4%
Managing increasing new patient volume	25%	48%	24%	3%

Source: Wolters Kluwer Health

Doctor's Bag

The latest in drugs, devices, technology, and more

RAPID TEST APPROVED TO DETECT HIV-1 ANTIGEN, HIV ANTIBODIES

The FDA has approved a rapid HIV test for the simultaneous detection of HIV-1 p24 antigen and antibodies to both HIV-1 and HIV-2 in human serum, plasma, and venous or fingerstick whole blood specimens. As an aid in the diagnosis of HIV-1 and HIV-2 infection, the test also independently distinguishes results for HIV-1 p24 antigen and HIV antibodies in a single test.

The Alere Determine HIV-1/2 Ag/Ab Combo test can be used by professionals in outreach settings to identify HIV-infected individuals. The test does not distinguish between antibodies to HIV-1 and HIV-2, and is not intended for screening blood donors.

Detection of HIV-1 antigen permits earlier detection of HIV-1 infection than is possible by only testing for HIV-1 antibodies. It can also distinguish acute HIV-1 infection from established HIV-1 infection when the blood specimen is positive for HIV-1 p24 antigen but negative for HIV-1 and HIV-2 antibodies.

With early detection, the test can reduce additional HIV transmission. The CDC estimates that about 50,000 people are infected with HIV in the U.S. each year. Of the more than 1 million people living with HIV in the U.S., 20% haven't been diagnosed.

Orgenics, Ltd.(Alere, Inc.) www.alere.com | www.alere.co.il

FDA GREENLIGHTS ABUSE-DETERRENT HYDROCODONE

Atlantic Pharmaceuticals, Inc. has completed a successful Pre-Investigational New Drug Meeting with the FDA on a single component, immediate release, abuse-deterrent hydrocodone (ATLP-03). Currently, all prescription products containing hydrocodone have additional active ingredients that may be unnecessary or detrimental to patients. Hydrocodone is also often abused.

ATLP-03 does not contain any additional active ingredients and is formulated with SMART/Script, Atlantic's patented abuse deterrent system. SMART/Script was designed to resist attempts to easily extract a drug from an oral dosage form, and with the ability to sequester and reduce the drug release from a tampered and abused dosage

The technology can be applied to immediate and sustained release drug candidates. ATLP-03 may be pursued under the FDA's abbreviated 505(b)2 NDA program.

Atlantic Pharmaceuticals, Inc. (404) 994-5135 | www.atlanticpharma.com

PATIENT KIOSK JOINS ONLINE MARKETPLACE

Clearwave Corporation's Patient Self Service Kiosk and Real-time Eligibility Verification solution has joined Greenway Medical Technologies' online Marketplace as a certified API solution for users of Greenway's PrimeSUITE platform, an EHR and practice management solution. With PrimeSUITE, the kiosk has been proven to deliver value-added interoperability allowing providers to administer high-quality, cost-effective care.

Patients can scan their driver's licenses and insurance cards, remit payments, and check in at the kiosk. Insurance eligibility is verified in real-time at check-in, and scanned images, updated demographics and payments are transmitted in real-time to PrimeSUITE.

Average registration time is less than 3 minutes and the kiosk elminates redudant paperwork. Staff and patients alike enjoy that the kiosk streamlines check-ins and eliminates routine questions.

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Learning to make quality pay

Help is available to meet the challenges caused by the growing trend away from fee-for-service and toward compensation based on outcomes—if you know where to look

by **BETH THOMAS HERTZ,** *contributing author*

HIGHLIGHTS

01 Taking advantage of exisitng programs that pay bonuses for quality, such as meaningful use of electronic health records, can significantly help a practice's bottom line.

02 One solution to the challenge of patient noncompliance is to find a colleague who has had success with improving compliance and learn what techniques he or she uses to achieve it.

Physicians want to deliver quality care to patients, and most want to get off the hamster-wheel life of earnings that are driven solely by volume. But the shift to pay based on quality metrics is a scary new world too. ▸▸

▸▸ **"PHYSICIANS ARE** used to being rewarded for someone walking through their door but the people who are buying healthcare today understand [that] that approach is costing the country a lot," says Jeffrey Cain, MD, FAAFP, president of the American Academy of Family Physicians (AAFP).

Cain believes, however, that being paid for results is good news for primary care physicians (PCPs) because they bring a tremendous amount of value to the healthcare system. "(That value) has been under-recognized in the way that we've been traditionally been paid in fee-for-service," he says.

GettyImages/Stockbyte/Steve Wisbauer

The changing approach will affect payments from Medicare and Medicaid, as well as private payers, he says.

Medicare already offers several programs through which physicians can earn bonuses for quality, he says. For example, Meaningful Use (MU) bonuses for effective use of electronic health records (EHRs).

"You can earn $39,000 in the course of 2013 to 2016 if you start participating in 2013," Cain says. "But if you wait until 2014 to begin participating, then you've lost about $15,000 of that. By 2015, they start penalizing you."

The same thing happens with electronic prescribing, he says. Starting to do it now nets you a .5% bonus from Medicare. But if you are not e-prescribing by next year, you will face a 2% penalty.

FOCUS ON WHAT YOU ARE ALREADY DOING

Between MU, the coming adoption of International Classification of Diseases-10th Revision (ICD-10), and the formation of accountable care organizations and health insurance exchanges, adopting quality metrics can feel like just one more demand being piled on, says Rosemarie Nelson, a practice management consultant with MGMA Health Care Consulting Group and a *Medical Economics* editorial consultant.

There are several different types of quality metrics identified by the U.S. Department of Health and Human Services that quantity patient access to care, outcomes and experience. There are also quality metrics that assess structure of healthcare organizations (nurse to patient ratio) and the process of the way healthcare is administered to patients.

"There is a point where a wall goes up and the physician and practice administrator say, 'Enough.' Because of that, it is hard to think through each one individual issue separately," she says. But she stresses that the shift to quality metrics isn't so bad. Many practices are already pursuing certain quality metrics through MU, and even those that are not attesting to MU may still be reporting through the Physician Quality Reporting System (PQRS). "They can focus on those quality metrics they are already reporting on," she says.

Stage 2 of Meaningful Use will align with the PQRS, Nelson adds. "It's a perfect starting block. As physicians actually report on those metrics and manage their behaviors and patient interactions, they can start to reap the benefits because they will learn from themselves how effectively they are working through these quality metrics," she says.

> "The challenge for PCPs is that it's a different kind of caring for folks. It's not just waiting for a patient walk through your door. It's reaching out to the patient."
>
> —JEFFREY CAIN, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

For example, having alerts that pop up when a patient with diabetes hasn't had a foot exam is something many practices already do. "But now you are going to get 'extra credit' or avoid a penalty for this," she says.

Look for opportunities to take on the basics, she advises, such as heart disease or diabetes, as a way to encompass many of the early quality efforts. MU has 38 quality metrics, she says. Pursue the ones that are pertinent to your patient base. "Even things as basic as making sure all the kids are immunized are quality metrics you can use. Build those alerts into your system and monitor them," Nelson advises.

GETTING STARTED

Teresa Koening, MD, MBA, senior vice president and head of the clinical integration practice at The Camden Group, a healthcare consulting firm, suggests that physicians eyeing the path of quality metrics start by analyzing their own environment. Take a hard look at your operations, specifically revenue collections, expenses, payer contracts, and involvement in fee-for-quality programs, Koenig says.

"Where are you struggling? What do you want to control? What are your options as we move into this new model of payment?" she says. "Physicians are really smart people, but often they are too busy to really evaluate all these different aspects of their office."

QUALITY BONUS OPPORTUNITIES

Several Medicare-sponsored programs, including meaningful use (MU) of electronic health records, e-prescribing (eRX), and the Physician Quality Reporting System (PQRS) offer opportunities for financial bonuses tied to the quality of care your practice provides. Early implementation of these programs will enable you to maximize the payments you receive and avoid penalties for non-implementation.

The table below shows the potential financial impact of different implementation dates of MU, eRX, and PQRS for a private practice of three physicians with $1.425 million annual revenue and a 20% Medicare payer mix.

IF PRACTICE BEGINS MEANINGFUL USE OF EHR, ERX, AND PQRS IN 2013*

	Total	MU	eRX	PQRS
2013	$43,575	$45,000	-$2,850	$1,425
2014	$37,425	$36,000	$0	$1,425
2015	$24,000	$24,000	$0	
3-year total	$105,000	$105,000	-$2,850	$2,850

IF PRACTICE BEGINS MEANINGFUL USE OF EHR, ERX, AND PQRS IN 2014*

	Total	MU	eRX	PQRS
2013	-$4,275	$0	-$4,275	$0
2014	$31,725	$36,000	$5,700	$1,425
2015	$19,725	$24,000	$0	-$4,275
3-year total	$47,175	$60,000	-$9,975	-$2,850

* Calculations based on implementation before the end of the calendar year.

Source: American Academy of Family Physicians, "Medicare initiatives: Bonuses and penalties"

Make sure you are heading toward the new model, she says, and making the most of your market's opportunities for quality rewards. Also, make sure you have maximized grant money from the government or other sources to get fully functional with an EHR system. "To survive in the new world, you are going to have to be able to transmit electronically and you will have to put your data into some type of health insurance exchange," she says.

Nelson also recommends that physicians take an objective look at their data. Query your EHR about how well you are doing on some patient subset, such as how many diabetic patients have a certain hemoglobin A1C reading. Nelson says that any physicians will be shocked by what they find. "Everyone feels they are doing the best job possible, yet we have practices that don't measure up," she says.

NOTIFY YOUR PAYERS

Nelson suggests that once practices have compiled this data, they present their highlights to their largest payers to show how well they are doing. "Everyone complains that payers don't pay enough," she says. "Don't presume that because you are not aware of an incentive plan that it doesn't exist. It may very well exist. You have to look for where these incentives are." Often, payers target large physician groups for these initiatives, so small practices need to drive participation themselves, she adds.

QUALITY PROGRAMS

Cain suggests physicians ask themselves a few questions: "Am I participating with meaningful use with my EHR? Am I participating in the PQRS program? If I'm in a large group, am I participating in the value-based modifier program? Am I getting ready for ICD-10?"

With PQRS, physicians can get bonuses for participating in 2013 and 2014. Those bonuses become penalties in 2015 and 2016 for not participating, how-

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➔16 ever. "The payments that are received and the penalties are 'look back' penalties," Cain says. "Physicians need to start participating now because otherwise their wallet is going take the hit in the future."

That's also true for the value-based payment modifier program, which is for physician groups of 25 or more, he says. Groups that show higher quality and lower cost based on this year's data will be getting payments in a year or two. "Again, this is challenging because they are 'look back' payments. So it is important physicians are active now in understanding if they are qualified to participate in the value based payment modifier program," he says.

However, some penalties can be removed for practices that start to participate in quality improvement activities in the future, he notes, so it is not just now or never.

PATIENT NONCOMPLIANCE

Patient noncompliance is a huge variable in achieving high-quality data, most experts agree. No matter what you do, some patients won't quit smoking, exercise, or lose weight. Nonetheless, "in the newer healthcare systems, we are going to be responsible for all of our patients," Cain says.

He notes that some physicians are better at helping their patients quit smoking than others and suggests physicians try to learn from them. "By using active collaboration with our patients and understanding the stages of change and understanding behavioral health approaches, we can be more effective," Cain says. "It is going to be frustrating to be held responsible for someone else's behavior but the good news is we will be reimbursed for being more effective at it. We have to be able to ask ourselves how we are doing for making certain patients are taking their medications, coming back for visits, and monitoring their blood pressure and such."

An example of a problem that can arise, Nelson says, is when patients with diabetes skip regular checkups because they know they have not been following their regimen well and don't want to get a lecture. Then they get sick with an acute problem such as influenza and have to come in. The patient needs a comprehensive diabetes appointment as well as an acute visit, but the scheduler has only put them in for a 15-minute slot.

"Too many doctors will merely treat the acute problem and ask the patient to return for diabetes follow up care, but the patient won't do it," Nelson says. Practices that are committed to quality will say that no matter why that patient came in, we are going to take care of all his or her issues, she adds.

Technology can help facilitate this, she says. For example, have the alert that the patient is overdue for a diabetic visit pop up at the scheduler's desk, not just the nurse/doctor's screen. Then the scheduler knows to schedule them for a longer visit. "That is a key operational secret that people don't get from their vendors," Nelson says.

Koenig notes that physicians may start getting some help with patient adherence as more employers and health plans are adding rewards for employees for achieving certain health benchmarks, such as lowering their weight or quitting smoking.

DEFENSIVE MEDICINE

Koenig encourages physicians to be careful to avoid engaging in defensive medicine as they shift to quality metrics. Follow the care guidelines of your colleagues whenever possible, she says, citing a study published in the *New England Journal of Medicine* that showed physicians only follow guidelines about 55% of the time. "Medicine is as much an art as a science, so hitting target guidelines 100% of the time is not appropriate for every patient, but 55% is a bit low," she says.

When you do deviate from standard guidelines, be sure you understand why, she says. "We are doing too much of the wrong stuff," she adds.

Documenting care using qualified health information systems will help alleviate the pressures of possible malpractice suits and help you keep track of patient history so that you aren't ordering unnecessary tests. Physicians should be documenting all treatments based on evidence-based clinical guidelines, and also consulting with other physicians about patient care with EHRs.

LIVING IN THE GAP

Although Cain and the others are optimistic about the future of primary care as quality metrics start to drive payments, they agree it represents a challenge now because most practices are still being paid for volume. "We are smack dab in the middle," he says. "The analogy I like to use is that it is a bit

> Don't presume that because you are not aware of an incentive plan that it doesn't exist. It may very well exist. You have to look for where these incentives are."
>
> —ROSEMARIE NELSON, PRACTICE MANAGEMENT CONSULTANT, MGMA HEALTH CARE CONSULTING GROUP

like you are standing on a dock and there's a boat that getting ready to leave, and you've got one foot on the dock and one foot on the boat. And you have to decide if you are going to stay on the dock or get on the boat. Or are you going to get wet?

"For family doctors, it is important to understand the things that are in motion now. They don't have a choice of getting on the boat or not for things like PQRS, Meaningful Use, or e-prescribing. It's important to start to understand the components of the Patient-Centered Medical Home (PCMH) and its ability to improve quality and lower cost," he says.

REACHING OUT TO PATIENTS

Cain says that both public and private payers are seeing the value of encouraging PCMHs. "If insurance companies invest in the medical home, we can decrease the number of unnecessary emergency room visits and hospitalizations," he says. "The challenge for PCPs is that it's a different kind of caring for folks. It's not just waiting for a patient walk through your door. It's reaching out to the patient."

PCMH models reward practices in nine different areas for adhering to standards focused on interoperability and cross-functional health information between teams of physicians. This model focuses heavily on healthcare information technology, with many of the measurements relying on communication between physicians and with physicians and patients.

By taking steps such as having a care manager call patients to see how well they are doing with their care plan, patients will be healthier and will spend less money on their care. And physicians will be rewarded.

He notes that the AAFP's TransforMED program helps primary care practices become high-performing PCMHs. "As practices move toward a PCMH model, they start better understand their practices," he says. "Often when a small to mid-size practice adopts the PCMH model, they also improve work flow in ways that help them in their current business model."

NEXT STEPS

Going forward on the quality metrics journey, Koenig advises physicians to get help from resources such as their local medical society. "Don't spend a lot of money getting help," she advises. "But do the basics as appropriate for your environment. If there is a hospital or health system you work with, ask if they have any supports you can use. Are there other medical groups in your same situation you can bounce ideas off of?

"Unfortunately, this transformation necessitates that physicians prepare for the new normal while also living in the present," she says. "As long we can keep it around good patient care and doing the right things, I think we can survive, but it's not easy. There is no magic wand."

The movement to pay for quality rather than volume could eventually benefit PCPs by recognizing the value the tremendous amount of value that PCPs bring to the healthcare system and compensating them accordingly.

Physicians can ease the transition to quality-based compensation by taking advantage of government bonus payment programs such as those associated with meaningful use and the PQRS.

Soft reimbursements may call for harder negotiation with payers

Convincing payers to change contracts may seem like a losing battle, but experts say getting what you want isn't impossible

by **DONNA MARBURY, MS**

HIGHLIGHTS

01 Knowing the monetary value of your relationship with payers is the first step in negotiations.

02 Non-monetary changes to your payer contracts can make your practice run more efficient.

The divide between practitioners and insurance companies continues to grow as regulations mount and reimbursements shrink. Being prepared with the right numbers and list of demands could help private payers be more flexible during contract negotiations.

After owning her own practice for more than 30 years, Rebecca Jaffe, MD, MPH, says she has never been successful negotiating with private payers on contracts. "The big payers don't want to negotiate with small practices in any way. They say take it or leave it," says Jaffe, owner of Jaffe MD and Associates in Wilmington, Delaware.

Many practice owners can relate to her frustrations, as reimbursements shrink and communications with private payers often make them feel like small fish in a big pond. Size matters when it comes to negotiating with private payers, and the reality is that small practices are at a disadvantage. Experts agree that insurance companies don't make negotiating the specifics of contracts an easy process. But they say it can (and should) be done.

"Every practice needs to engage payers about rates," says Reed Tinsley, a healthcare consultant in Houston, Texas. "How do you know what you can and cannot change in a contract if you don't try?" The biggest mistake that many practitioners make is thinking that negotiating contracts is a waste of time.

WHAT'S YOUR RELATIONSHIP STATUS?

Before calling a payer to demand more from them, it is important to know the current value of the relationship you already have. Tinsley says this starts with creating a spreadsheet with your top eight payers and your top 25 current procedural terminology (CPT) codes to analyze financial performance of the payers and their reimbursements. This will help you to identify what increases in reimbursements you want and be able to quantify it to payers.

"What you are currently getting

9 points to consider when negotiating with payers

Whether you are a novice or a seasoned negotiator, payer contracts can be complicated and difficult to interpret, even with an attorney or consultant by your side. Nancy Brown, chief financial officer and partner at Think Big Health Care Solutions, has a list of nine points to always keep in mind during debates with payers.

1. **It's business, not personal.** Many practitioners take the process personally (and why not, it is their livelihood), but the truth is it is a part of doing business.

2. **Know the rules of engagement.** Who is going to be accessing you through the contract? Self-insured plans? Fully-insured plans? Is this a leased network? Each will have its own "rules of engagement" that you need to be aware of.

3. **What your practice can and can't live without.** You're not going to get everything you want – a negotiation is just that – and in the end you WILL have to compromise on some points.

4. **Are you willing to walk away?** Know before you go in which procedures or terms that, if not met, will cause you to walk away from the table. Know which ones you are going to use as concessions to get what you really want.

5. **Read everything.** Read the contract very carefully for terms and clauses that are one-sided such as amendment provisions, definition of medical necessity, rate changes, timely filing provisions, prevailing contract, and termination.

6. **State laws apply.** Be aware of your state laws and how they affect the way insurers do business. For example, be aware of timely-payment rules and take-back rules.

7. **Be aware of the contract term.** Many payers want to sign providers to long-term (3 or more years) contracts. Does your contract have built in increases to keep pace with inflation or other considerations?

8. **Make sure rates are clear.** If the rates are based on a proprietary fee schedule, you need to know what they are before signing. If the rates are based on Medicare, is it current/prevailing or another year? If current/prevailing, what will you do if the rates drop significantly? Are there multiple plans under this payer and do you have the fee schedules for all of them?

9. **Know what isn't covered.** Be clear on what the contract is NOT covering, i.e. what procedure codes are not covered, procedures with very low reimbursements, or require you to use a specific outside vendor.

is the floor, and what you optimally want is the ceiling," Tinsley says. "You want to negotiate between the ceiling and the floor. The definition of a successful negotiation is any betterment of the current situation."

KNOW THE MARKET

How many other solo practitioners or specialists are in your area? How many patients do you have with this payer? Knowing these numbers are important, because they put your demands into perspective.

"The more patients you have with a particular insurance company, the more willing they will be to work with you because they don't want to lose your business or lose the contract with employers," says Melody Irvine, medical consultant and owner of Career Coders LLC in Loveland, Colorado.

However, if you know you have substantial competition from other practices, be prepared to play hardball with payers. It will be important for you to stress that your goal is to create a better, cost-effective healthcare experience and be able to show payers the numbers. "For example, if a solo practitioner is trying to negotiate better rates with a payer, most likely the payer will tell them something to the effect of, 'We have 100 providers in this area that will see your patients if you don't want to accept our terms,'" says Nancy Brown, chief financial office and partner of Think Big Health Care Solutions in Wellington, Florida.

TALKING THE TALK

Once you decide exactly what you want in your payer contracts, an important step is deciding who is going to do the negotiating. This depends on who in the office is the most confident and has the most experience with complex negotiations. Many physicians hire consultants or attorneys because they lack the time to talk to payers themselves. If you want to do your own negotiating, it's important to make sure you can keep your emotions and your business separate.

"Negotiating a practice's contract must always be done by the most

qualified person the practice can find/afford. These contracts are legal documents that can be confusing and damaging to the practice. It's not going to matter how efficient and well-oiled your practice operations are if the contracts are poorly written/negotiated," Brown says, adding that someone with a cool head should be doing most of the talking with payers. "Ultimately, they may need to bring the practitioner in to finalize the deal or talk peer-to-peer with the insurance company's medical director, but that is it."

Your business manager, a consultant, or a healthcare attorney often has more experience with negotiating. "There are always risks involved in negotiating contracts, and the doctors feel caught between their ability to keep their practices open and contracts that are unreasonable. I always feel it's good for a healthcare attorney to view the language of the contract," Irvine says.

TACKLING REIMBURSEMENTS

Reimbursement will be the biggest area of debate in the contract. To make sure your requests are reasonable, you will have to focus on procedures you perform most often.

"Calculate your revenue per visit. Calculate the total dollars you received for your work over the previous 12 months and then divide that by the total number of visits. Next make the same calculation for each insurance company. Run reports to look at the top CPT codes you bill and compare reimbursement with your all your insurance contracts. This analysis will help you identify low payments for codes that you use frequently," Irvine says.

Brown says requesting flat rates for in-office procedures is smart because these are often easier for patients and lower costs for payers.

It is important to know how your rate would compare to a hospital or surgery center. It is also important to know what other area physicians charge for similar services. If you are already cutting costs with certain procedures, now is the time to bring those numbers to the negotiating table.

"If you have done the procedure in-house already, use your practice's data to your advantage—if the data shows improved outcomes from performing the procedure in-house," Brown says. "If you've been doing it outside of the office and wish to continue, you'll need to provide the insurance company with evidence of improved outcomes, lower admittance rates, etc."

NON-FINANCIAL NEGOTIATIONS

There are areas to negotiate in your contacts beside reimbursement. The long-term goal of any contract negotiations should be a more fair landscape for patient care, and cutting down paperwork could make your and your staff's workflow easier. Tinsley suggests asking payers to eliminate preauthorizations and other back-end documentation for common services you provide that the payer has never denied in the past.

Irvine says to it's important to go over coverage for wellness, preventive care, and ancillary services that you already offer or may be adding to your practice within the year. She adds that you should negotiate adding language that allows you to get out of any agreements that aren't working.

"Write a 90-day out into the contract. If you find yourself in a bad contract where you're just losing money hand-over-fist, you can get out in 90 days without cause," Irvine says. Clauses that ask for prompt communication with the payer are also important. "Make sure the contract did not revert back to the original contract before negotiations," she adds. "Eliminate retroactive denials—demands for refunds on claims that can be many years old. Have wording in your contact that would prohibit health plans from rescinding payment [after a certain amount of time] after receiving the claim."

MEETING PAYERS HALFWAY

Negotiating with payers doesn't always have to be a David-versus-Goliath showdown. You are instrumental in showing the payer how changes in your contract can lower the overall cost of healthcare for them as well. Tinsley says it is important to show payers how you practice efficient and cost-saving healthcare—and you should be paid for that too.

"Some payers agree that doctors need a raise, but they don't want the word to get out," Tinsley says. "The reason why outcomes are so important is, if a payer agrees that you are operating cost effectively, but won't give you a raise, they are saying they don't care about cost-effective healthcare."

Tinsley says that you could request a temporary increase in a service, such as a complex nosebleed, that requires more intensive treatment, but would keep a patient out of the emergency department. If you agree to evaluate the cost-effectiveness of this increase for a year, and it saves costs for the payer, it's a win for both parties.

WHEN TO WALK

Jaffe says she had to walk away from a payer that paid her less than her costs for immunizations. "Some patients left the practice because their employer had the insurance. We revisited the contract two times to make sure it was the right decision," she says.

If a payer is costing you time and money, then you may want to consider walking away from contract work with them. This doesn't necessarily mean your relationship is over. "You might make more money being out-of-network with certain payers," Tinsley says.

In a situation where you are deadlocked with a stubborn payer on an important clause, you may be able to circumvent them altogether. "Some physicians are now even working directly with employers. Direct agreements compensate the physician fairly without compromising potential savings for the employer," Irvine says.

@ MORE RESOURCES

Prepare for negotiating contracts with payers
bit.ly/12aQ4FN

Financial Strategies

MANAGING CASH AND OPERATING REVENUE IN YOUR PRACTICE

By **DONNA MARBURY, MS**

Cash and checks are still important to most medical practices, even in a paperless world. Here are some tips to keep your daily paper transactions simple and safe.

Petty cash, cash drawer needs

Petty cash should be used for smaller purchases for the practice or other reimbursements, and should be limited to about $100.

The cash drawer is for patient transactions, which could be up to $300.

Managers need to keep dollars orderly and to a minimum, says Keith Borglum, health care business consultant in Santa Rosa, California, and a *Medical Economics* editorial consultant.

Keeping money safe

The threat of employee theft is very real, and is usually a result of a lack of security measures.

Chris Zaenger, healthcare consultant, and a *Medical Economics* editorial consultant, offers these practical ways to keep money safe:

- Make daily deposits, starting each day with new deposit slips.
- Split morning and afternoon front desk collections and reconciliations at lunch breaks or when the afternoon shift begins.
- Keep cash and checks in a locked and fire safe cabinet or safe with lockable drawers.
- Staff must lock the cabinet when leaving the station for any reason regardless of length of time.

Technology for check management

Electronic check scanners can accept and deposit checks wirelessly, syncing to your bank account and accounting software. This can save time for your employees and provide a quick, paperless way to manage billing and invoicing.

First, make sure your bank can accept electronic checks and find out if there is a limit to how many they will process in a month. However, it's important that employees shred paper checks and other financially sensitive material in a timely manner, Zaenger says.

He adds that banks that offer services that scan checks with mobile devices are not a good idea for medical practices. "I am not a fan of the cell phone for financial and Health Insurance Portability and Accountability Act reasons at this time due to Internet concerns as well as stolen phones," Zaenger says.

LINKS TO RELATED MATERIAL

Keeping tabs on practice finances
bit.ly/1bvuWNu

Managing petty cash no petty matter
bit.ly/14LnQTg

Operating cash in checking accounts

You should have 2 to 3 weeks' worth of expenses in your active business checking account so your staff can manage payments, Borglum says.

"All extra money should be swept into a higher interest rate account. If you have online banking, you can set this up automatically," he says, adding that if your monthly expenses are $20,000, your checking account should have $10,000 to $12,000 in the account. "This will also reduce embezzlement and hacking," he says.

Zaenger says that the business checking account should be able to withstand the ebbs and flows of cash in your practice.

"Stay aware of when there may be disruptions in cash flow, such as a new doctor who is not yet credentialed, Medicare delaying payments or claims processing, the post office reducing delivery days, converting project management software or adding an electronic health records system," he says.

Coding Insights

HOW TO BILL MEDICARE FOR TELEHEALTH SERVICES

Telehealth services are listed in the proposals for Medicare changes in 2014. What are these services, and as a practitioner, am I eligible to bill for them?

THE MEDICARE, Medicaid and Benefits Improvement and Protection Act of 2000 provided for an expansion of Medicare payment for telehealth services. Coverage and payment include consultations, office visits, individual psychotherapy, and pharmacologic management, which must all be delivered via a telecommunications system and substitute for an in-person encounter.

Later, the list of telehealth services was expanded to include subsequent hospital care services, subsequent nursing facility care services, individual psychotherapy, pharmacologic management, psychiatric diagnostic interview examination, and many others. The eligible geographic areas include rural health professional shortage areas (HPSA) and counties not classified as a metropolitan statistical area.

For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site practitioner and the Medicare beneficiary. The patient must be present and participating in the telehealth visit.

Medical practitioners who can bill for a covered telehealth service vary by state law, but they may include:

- **physician,**
- **nurse practitioner,**
- **physician assistant,**
- **nurse midwife,**
- **clinical nurse specialist,**
- **clinical psychologist,**
- **clinical social worker, and**
- **registered dietician or nutrition professional**

The service provided must be within a practitioner's scope of practice under state law.

An originating site is the location of an eligible Medicare beneficiary at the time the telehealth service occurs. These may include a hospital, the practitioner's office, a critical access hospital (CAH), a rural health clinic, a federally qualified health center, a hospital-based or critical access hospital-based renal dialysis center, a skilled nursing facility, or a community mental health center.

A distant site is where the practitioner is located at the time the telehealth service is provided. Payment for the telehealth service is equal to the current physician fee schedule amount for the service.

For 2014, the Centers for Medicare and Medicaid Services is proposing to modify the regulations describing eligible telehealth originating sites to include HPSAs located in rural census tracts of urban areas, as determined by the Office of Rural Health Policy. This change will more appropriately identify sites within urban HPSAs that have rural characteristics and improve access to telehealth services in shortage areas.

Benefits to remote areas of using telehealth may include:

- **transmission of medical images for diagnosis and advice on disease prevention,**
- **health advice in emergency cases,**
- **patient care and promotion of good health via patient monitoring and follow-up.**

The nonclinical uses of telehealth technologies include: distance education, such as grand rounds and patient education; research; patient remote admission; and online information and health data management. Telehealth services afford doctors and hospitals the ability to share resources, and they provide incentives for reducing the number of readmitted patients.

*The answer to our reader's question was provided by **Maxine Lewis, CMM, CPP, CPC-I, CCS-P,** president of Medical Coding & reimbursement in Cincinnati, Ohio. Send your practice management questions to **medec@advanstar.com**.*

GAME CHANGER?
He plans to change the world, one patient at a time [34]

THE RX BALANCE
How one physician treats pain and monitors for addiction [37]

Operations

Making dollars and sense of lifestyle medicine

Is the new trend of focusing on nutrition, fitness, and other wellness goals profitable for your practice?

by **DONNA MARBURY,** *MS*

HIGHLIGHTS

01 Lifestyle medicine is becoming more popular as physicians help patients meet wellness goals.

02 Learning a new way to communicate with patients can help them gain more control over their own healthcare goals.

03 There are several buisness models for lifestyle medicine that are profitable for primary care physicians and specialists.

Physicians frustrated with treating patients who are sick instead of helping them stay well are turning toward preventive and lifestyle medicine techniques. However, a new practice philosophy can be risky, possibly costing patients and dollars. ▸▸

▸▸ **EXPERTS SAY** that with the right strategy, practices that invest in lifestyle medicine now are at the forefront of the next big change in healthcare.

In 2007, John Principe, MD, was close to quitting medicine after 20 years of practicing primary care medicine in Palos Heights, Illinois. He was losing his passion for healthcare, but gaining an interest in cooking. He decided to attend the Harvard Healthy Kitchen's Healthy Lives Program, and realized that lifestyle medicine was the answer to aligning his business with his new interests. The transition has not been an easy one, however.

"Many of (my patients) embraced the change in focus. Others were resistant and did leave the practice as this approach was not the pill for every ill they were accustomed to. They also tended to be patients that were passive about their healthcare," Principe says. He

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> "DOCTORS WANT TO PRACTICE COST-EFFECTIVE, EVIDENCE-BASED MEDICINE, THAT IS ALSO VALUE-DRIVEN HEALTHCARE."
>
> —WAYNE DYSINGER, MD, MPH, DIRECTOR OF THE LIFESTYLE MEDICINE INSTITUTE, LOMA LINDA UNIVERSITY

24 still practices primary care, but his office now offers massage therapy, acupuncture, nutritional counseling, and classes on stress reduction and physical activity. His office even has a kitchen where he teaches patients healthy cooking.

"It is a difficult process that requires much time and energy," says Principe, now in his third year with his overhauled practice, WellBeingMD. "It requires you to go against the tide of healthcare reform, but in the end, it can be one of the most rewarding and satisfying professional endeavors that one can undertake."

Principe is one of a growing number of physicians who are diving into lifestyle and preventive medicine.

"We hear doctors saying, 'I just want to help people get healthier, and I want to get paid for it.' The big question they ask is, 'how do we make money from this?'" says Edward Phillips, MD, assistant professor of physical medicine and rehabilitation at Harvard Medical School. In 2007, Phillips founded the Institute of Lifestyle Medicine (ILM) at Harvard University.

"When I looked at the medical marketplace, there was about $3 trillion spent on sickness and about $500 million spent on wellness. No one was preparing doctors for the new realities that many of the illnesses we were treating were non-communicable diseases. We were not prepped in medical school to talk about exercise, nutrition, and smoking cessation. So we aimed to retrofit doctors to handle the epidemics of physical inactivity and obesity," Phillips says.

Since its inception, ILM has had more than 6,800 clinicians worldwide take online and in-person classes covering topics such as weight and stress management, prescribing exercise, and nutrition. Phillips says that he is beginning to see interest from Patient-Centered Medical Homes, accountable care organizations (ACOs) and hospital administrators. "We are on the verge of moving beyond the early adopters," he says.

WHAT IS LIFESTYLE MEDICINE?

In July 2010, the *Journal of the American Medical Association* published results of a 2-year project with the American College of Lifestyle Medicine and the American College of Preventive Medicine, outlining lifestyle medicine standards for primary care physicians. The study included 15 evidence-based standards for smoking cessation, nutrition, exercise, and other behaviors linked to chronic conditions.

The study made a distinction between lifestyle medicine and other alternative and complementary treatments. "Lifestyle medicine allows physicians to stay in an evidence-based place. Integrated medicine isn't evidence-based. This is the first step in recognizing the current healthcare system is very sick itself," says Wayne Dysinger, MD, MPH, director of the Lifestyle Medicine Institute, chair of the Department of Preventive Medicine and director of the Lifestyle Medicine Track of the Family and Preventive Medicine Residency at Loma Linda University.

Dysinger has also seen the rise of interest in lifestyle medicine in the past few years. The American College of Lifestyle Medicine started its annual conference in 2011, attracting 50 clinicians. This year, Dysinger expects more than 300 clinicians to attend the October conference. He continues to give presentations and seminars to a growing number of interested physicians.

"Doctors want to practice cost-effective, evidence-based medicine, that is also value-driven healthcare," Dysinger says. "There is evidence that sending someone through an intensive therapeutic lifestyle change program is cheaper and works just as well if not better than surgical procedures."

LIFESTYLE MEDICINE IN PRACTICE

Doctors are already moving toward advising patients about their lifestyle choices. In 2010, more than 30% of adults were advised to begin or continue exercise, a 10% increase from 2000, according to the National Health Interview Survey conducted by Centers for Disease Control and Prevention. Training in lifestyle medicine takes this a step further in helping doctors to lead patients, while empowering them to make health choices.

"We are teaching doctors how to build a relationship with patients. If you feel you are wrestling with a patient, this training will make you feel like you are dancing. Fundamentally, it's a different way to approach the patient," Phillips says. "I have to pass the power to the patient through psychological coaching and motivational interviewing."

Physicians can use continuing medical education (CME) units to take classes to learn more about lifestyle medicine. Some organizations offer additional classes outside of CMEs for specialization, and Loma Linda University in Southern California offers the nation's only master of public health degree in lifestyle medicine.

Training through classes and conferences might include ways to write prescriptions for exercise, detailed to steps per day, target heart rate and days per week. Clinicians are also taught to discuss behaviors and attitudes that lead to poor lifestyle choices. Phillips recognizes that this type of conversation and relationship-building may not come naturally to busy clinicians.

"You can't ask people to do something they haven't been trained to do. We talk about behaviors: how many glasses of water per day, and how many fruits and vegetables per day. In our classes, we do exercises on how you say it, and how you write an exercise prescription," Phillips says.

THE BUSINESS OF LIFESTYLE MEDICINE

There are several different models that primary care physicians (PCPs) and specialists can adopt to incorporate lifestyle medicine in their practices, says Sandy Lawson, coowner of SD Lawson and Associates and executive director of ILM. "PCPs are well positioned to be successful in lifestyle medicine. With specialists it can take more time and can be more costly," Lawson says. "We are currently at a stage where doctors are providing preventive services, but they are still being underpaid under the fee-for-service model. They just have to be creative in ways they set up their practices."

Integrating lifestyle medicine philosophy into every patient interaction through using books and videos are easy, low-cost

LIFESTYLE MEDICINE INCENTIVES

ACCOUNTABLE CARE ORGANIZATIONS (ACOS)

Under this model, physicians receive bonuses for reducing healthcare costs and keeping patients out of the hospital. Payments are not restricted to fee for service, so some services including counseling, telehealth, and classes could pay if they enhances patient health.

PRIVATE PAYERS

Blue Cross Blue Shield of Massachusetts introduced one of the largest payer reform models in 2009 through alternative quality contracts (AQCs). With this model, physicians are paid a set rate for a certain amount of patients. If a patient's health improves based on certain parameters, physicians earn bonuses.

MEDICARE WELLNESS EXAM

Only 17% of seniors received initial preventive and annual wellness exams covered by Medicare, according to a 2012 poll by the John A. Hartford Foundation. This provides an opportunity for staff to closely monitor older patients and schedule wellness exams during other visits.

> "We are currently at a stage where doctors are providing preventive services, but they are still being underpaid under the fee-for-service model. They just have to be creative in ways they set up their practices."

—SANDRA LAWSON, CO-OWNER, SD LAWSON AND ASSOCIATES, WESTFORD, MASSACHUSETTS

ways to teach patients about chronic disease prevention. Some PCPs also choose to identify patients who already have problems exacerbated by poor lifestyle choices and offer special services. For example, group appointments that include 10 to 15 patients can offer a series of classes on nutrition and stress management that can be billed to Medicare.

"These are still medical visits around the lifestyle problems that the patients are facing, so it would fall under fee for service," Lawson says, adding that extra services including fitness and cooking classes are billed separately and paid by the patient.

Specialists often have to be qualified to provide new services by payers and set up separate offices and support services to begin practicing lifestyle medicine. Most specialists also rely on referrals from PCPs or other specialists such as cardiologists, and direct marketing to patients for business.

Lawson also encourages all physicians practicing lifestyle medicine to add ancillary services for additional revenue streams. "I haven't seen one lifestyle medicine practice that hasn't been enhanced through other services. Many doctors rent space to yoga teachers and other specialists who charge patients separately, but then the doctor gets paid in rent. Some do extensive training in vitamins and supplements, learning what works and what doesn't, and have relationships with those companies to sell products a la carte to patients," he says.

Physicians range between small, incremental changes to add lifestyle medicine into their practices; or drastic changes to their whole practices, where patients pay directly for personalized wellness services. Principe admits that converting his practice to one geared toward lifestyle medicine was costly, but he has no regrets.

"It was a large financial commitment to make these changes as we re-built our physical space to incorporate a teaching kitchen and educational center," Principe says. "To be truly a physician and health care protector will take courage, dedication and patience. It truly is the road less travelled."

@ LIFESTYLE & PREVENTIVE MEDICINE ORGANIZATIONS & INSTITUTIONS

American College of Preventive Medicine
www.acpm.org

American College of Lifestyle Medicine
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Lifestyle Medicine Association
www.lifestylemedicineassociation.com

Lifestyle Medicine Institute
www.chiphealth.com

Preventive Medicine Research Institute
www.pmri.org

The Institute of Lifestyle Medicine
www.instituteoflifestylemedicine.org

BUSINESS OF MEDICINE:

Summit to guide physicians through SWEEPING MANDATES

"The only thing more expensive than education is ignorance." **Benjamin Franklin**

Healthcare is in a historic transition.

In fact, an array of government-led programs and mandates, all with compliance deadlines, will fundamentally change the way physicians deliver healthcare in office-based practices.

From the influx of millions of new patients through the Affordable Care Act's (ACA) insurance mandate to new compensation models rewarding the quality of patient care, these changes all pose major challenges for physicians as they relate to participation and compliance.

In fact, that's precisely why the Institute for Continuing Healthcare Education (ICHE) and the Jefferson School of Population Health (JSPH) are organizing the third Business of Medicine Summit on October 12-13, in Philadelphia. In partnership with *Medical Economics*, and in consultation with the American College of Physicians (ACP), ICHE and JSPH will host a team of management, policy, medical, and financial experts to help physicians craft real-world strategies to succeed in a rapidly changing healthcare profession, explains Cathy Pagano, CCMEP, president of ICHE.

"We want to empower physicians to succeed in a very confusing time in healthcare. Our experts will cover much ground in this two-day summit with a goal of helping physicians stay ahead of government mandates, and looming deadlines, and give them the tools to prepare their practices to meet all of these business challenges in 2014 in order to provide the best care for their patients," Pagano says.

Business of Medicine Program Chair Michael S. Barr, MD, MBA, FACP, senior vice president of the division of medical practice, professionalism, and quality for ACP, agrees.

"There is much significant

Getty Images/Lifesize/Thomas Barwick

pressure on physicians and their teams for 2013, extending into 2014 and beyond," Barr says. "It's just as important to consider how each of these challenges and mandates will reshape medical delivery for practices."

Together, physicians can succeed and advance the care they deliver to patients and improve their business knowledge and understanding of these requirements. The goal of this summit is to teach physicians how to overcome some of these core business challenges, and help them rediscover the reasons they became physicians in the first place.

The highly interactive, two-day program will begin with an inspirational keynote presentation on the search of joy in practice by Drs. Christine and Tom Sinsky, internists at Medical Associates Clinic and Health Plans in Dubuque, Iowa. They will introduce summit attendees to a number of innovations gathered from physicians around the country who are taking novel approaches to solving complex management problems through an American Board of Internal Medicine (ABIM) study of innovations in primary care. According to Christine Sinsky, the impetus for the project is focused on better understanding burnout among the nation's cadre of primary care physicians, which remains a significant threat to strengthening the U.S. healthcare system. As part of this project, they conducted site visits at 23 high-performing practices, and plan to share their findings at the summit.

Other presentations will assess the impact of the ACA insurance exchanges on practicing physicians, and help clarify the requirements of the Physician Quality Reporting System. Training and implementation strategies for ICD-10, health information technology and making meaningful use 2 and 3 meaningful will also be addressed. Presentations will also focus on coding, risk adjustments and performance-based reimbursements. Interactive sessions will examine the growth of value-based reimbursements.

To register for the summit, go to www.bizmedicine.org.

PROGRAM AT A GLANCE

Business of Medicine, Oct. 12-13, 2013, Philadelphia | CME Certified

IN SEARCH OF JOY IN PRACTICE: INNOVATIONS IN PATIENT-CENTERED CARE

Christine Sinsky, MD, and Thomas Sinsky, MD, of Medical Associates Clinic and Health Plans in Dubuque, Iowa

ADVANCED OFFICE-BASED CODING

Jeannine Z. Engel, MD, FACP, assistant professor in the Division of Oncology at the University of Utah School of Medicine

HEALTH INFORMATION TECHNOLOGY: MEANINGFUL USE 2 AND 3

Michael Zaroukian, MD, PhD, FACP, professor of medicine at Michigan State University

PRACTICAL ICD-10 STRATEGIES FOR OFFICE-BASED PRACTICES

Rosemarie Nelson, MGMA Consulting

WHAT YOU NEED TO KNOW ABOUT THE PHYSICIAN QUALITY REPORTING SYSTEM

Richard Jacoby, MD, director of Thomas Jefferson University's Physicians Ambulatory Improvement and Bettina Berman, RN, BS, CPHQ, CNOR, project director for quality improvement at the Jefferson School of Population Health

VALUE-BASED REIMBURSEMENTS

Robert Doherty, senior vice president of Governmental Affairs and Public Policy, American College of Physicians

SMALL MEDICAL PRACTICE MANAGEMENT: NEW CHALLENGES AND SURVIVAL STRATEGIES

John H. O'Neill, DO, FACP, Bayview Internal Medicine, Inc.

PHYSICIAN COMPENSATION, STARK LAWS AND SUNSHINE ACT

Alice Gosfield, JD, Of Alice G. Gosfield & Associates, PC

HOW THE ACA AND NEW PAYMENT MODELS WILL AFFECT YOUR PRACTICE

Robert Doherty, senior vice president of Governmental Affairs and Public Policy, American College of Physicians

CHANGES FROM THE VANTAGE POINT OF ABMS

Richard J. Baron, MD, MACP, president and chief excecutive officer of the American Board of Internal Medicine

BUILDING BETTER PRACTICE EFFICIENCIES/ BENCHMARKING DATA

Joan Hablutzel, MBA-HA, MGMA Consulting

OTHER TOPICS SLATED:

-Corporate structure
-Tax reduction
-Benefit planning

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WHAT'S AT STAKE? AND THE BIZMED SOLUTIONS

ACA'S BROAD REFORMS

In 2014, 14 provisions are slated to go into effect, including the rollout of the health insurance exchanges. While more details will be unveiled as the exchanges begin open enrollment, management experts believe they will have a major impact on practices in terms of managing more patients, fielding questions, verifying insurance eligibility, and collecting revenue.

THE BIZMED SOLUTION:
ROBERT DOHERTY, senior vice president of Governmental Affairs and Public Policy of the American College of Physicians will offer an update on key ACA provisions starting in January, and identify strategies to help physicians plan for change.

THE PQRS CHALLENGE

The Physician Quality Reporting System (PQRS) will quickly become the norm as Medicare and government incentives call for adoption of quality metrics to influence reimbursements. The goal: reward physicians for keeping patients out of the hospital. The catch: You may lose some reimbursements for non-adherent patients.

THE BIZMED SOLUTION:
RICHARD JACOBY, MD, director of Thomas Jefferson University's Physicians Ambulatory Improvement, and Bettina Berman, RN, BS, CPHQ, CNOR, of Jefferson School of Population Health, will help you maximize reimbursements.

SURVIVAL STRATEGIES FOR PHYSICIANS

Change means uncertainty and opportunity. History teaches us that great upheaval also produce tremendous innovation. So, what's in store for office-based physicians in 2014?

THE BIZMED SOLUTION:
JOHN H. O'NEILL, DO, FACP, of Bayview Internal Medicine will outline survival strategies for practices.

INNOVATIONS IN PRIMARY CARE

The business challenges in an environment of tight reimbursements and escalating costs are real for physicians. And most office-based practices have been faced with new pressure as it relates to patient volume, productivity, efficiencies, implementation of EHRs, use of other technologies, staffing, patient communication and more.

THE BIZMED SOLUTION:
DRS. CHRISTINE AND TOM SINSKY, internists at Medical Associates Clinic and Health Plans at Dubuque, Iowa, will introduce summit attendees to a number of innovations gathered from physicians around the country as part of an American Board of Internal Medicine (ABIM) study of innovations in primary care.

THE CODING CONUNDRUM

The complexities associated with coding will likely take on greater significance for physicians as reimbursements, services and incident to billing becomes more complex. What are some of the most important strategies for office-based physicians related to coding, risk adjustments, performance-based metrics and fee-for-service?

THE BIZMED SOLUTION:
Coding expert **JEANNINE Z. ENGEL, MD, FACP**, assistant professor in the division of Oncology at the University of Utah School of Medicine will address all of these and offer advice related to E/M levels of care.

HEALTH INFORMATION TECHNOLOGY

While more than half of the market is using electronic health records in practice, there is much more knowledge needed to capture incentives and continue progress toward the government's meaningful use 2 and 3 requirements.

THE BIZMED SOLUTION:
MICHAEL ZAROUKIAN, MD, PHD, FACP, professor of Medicine at Michigan State University and noted authority on EHR implementation and use will guide you through the process, step-by-meaningful-step.

THE TRANSITION TO ICD-10

While it's been widely reported that the transition to the International Classification of Diseases, 10th Revision will be a monumental transition for healthcare, at the practice level physicians and staff will need to prepare for the 2014 implementation.

THE BIZMED SOLUTION:
ROSEMARIE NELSON, a practice management consultant with MGMA, will offer practical approaches to training and preparing the team for the inevitable transition. Remember, everyone on your staff will have to possess a basic understanding of ICD-10, and this meeting will arm you with tools to prepare.

VALUE-BASED REIMBURSEMENTS

The new payment models making their way to market will be considered value-based. What are they, and how can you make certain you are

capturing the quality of care you are delivering patients?

THE BIZMED SOLUTION:
BOB DOHERTY, senior vice president of ACP, will offer an invaluable update on value-based models quickly becoming in vogue.

A NEW KIND OF TRANSPARENCY

Stark laws, new Sunshine Act reporting requirements are taking on greater importance. We are entering an age of transparency; and you will need to know more about the legalities of all of these subjects this year.

THE BIZMED SOLUTION:
Noted healthcare attorney **ALICE G. GOSFIELD, JD** offers practical advice on both of these important subjects.

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- Physician Quality Reporting System
- New and emerging payment models
- Meaningful Use 2 and 3
- Tax reduction strategies
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The Whole Child Center, in Oradell, New Jersey, combines traditional pediatric care services with an integrative approach to wellness. Some of its less-traditional services include: infant massage, nutritional counseling, clinical homeopathy, yoga and mind/body therapies.

To life, and the pursuit of wellness

Practice finds success with integrative approach to medicine

by **DANIEL R. VERDON**, *Group Content Director*

HIGHLIGHTS

01 Practices that help model healthy behavior will ultimately change it, especially as it relates to nutrition, development, exercise and mind/body connection.

02 Physicians are educators, and their tools include patient health apps, lab reports, motivational communication, group meetings within the practice, classes, and special events.

HE WANTS TO CHANGE THE WORLD—one patient at a time.

In fact, pediatrician and author Lawrence Rosen, MD, of Oradell, New Jersey, founder of the Whole Child Center, combines a traditional practice in less-than traditional ways. The practice says it blends integrative medicine with ecologically sustainable healthcare for children and families.

"We are struggling in healthcare to do just that—to create health," Rosen explains. "Not just cheaper care, but better care. What does it mean to be healthier? At the same time we need to recognize that there are significant economic difficulties in our healthcare system." As a result, healthcare needs wholesale changes as it relates to how and why pediatricians and family physicians provide healthcare, Rosen says.

Consider the types of diseases most primary care physicians are seeing—obesity, asthma, autism, attention deficit disorder, metabolic disorders in adults. "We are treating sicker and sicker people later in life with after-the-fact solutions," Rosen says. A truly preventive strategy, he adds, is not just patient-to-patient, but a philosophical decision we have to make as a country and as a society as it relates to long-term outcomes.

Rosen made the philosophical switch after 20 years of practice. The Whole Child Center, a four-physician practice with a pediatric nurse practitioner and clinical coordinator, combines traditional adult therapies with integrative approaches to nutrition, fitness, and mindfulness.

Similarly, the practice combines traditional pediatric care services with services

The approach to medicine is really about engaging patients in many new ways. The Whole Child Center aims to teach patients how to remain healthy through visits, classes and even events.

such as nutritional counseling, acupuncture, clinical homeopathy, nutritional counseling, yoga, Reiki, infant massage, mind/body therapies (biofeedback, hypnosis, and guided imagery), and prenatal and preconception consultations.

The practice was built to help facilitate and enhance the relationship between its doctors, staff, and patients. Rosen, with Heather Jeney, MD; Stacey M. Linwood, MD; Penelope Gay Sheely, MD; Rebecca Ganz, CPNP; and Karen Overgaard are trying model healthy lifestyles early on for children and families.

It's also about engaging patients. "We want to give patients a voice, empower them whether it's using mobile technological solutions or access to their healthcare through a patient portal and guide them through solutions that promote wellness and health prevention," Rosen says. During a typical 30-minute encounter, 25 minutes are spent with the physician. He calls it quality time. "We are trying to develop relationships over time, and that is exactly how communication develops, and it's crucial to how we keep kids healthy," he says.

The approach, Rosen adds, is really about engaging patients in many different ways. Physicians are educators, and their tools include not only a stethoscope but also patient health apps, lab reports, motivational communication, group meetings within the practice, classes, and special events. The technological tools available today to facilitate that communication are helping exponentially, Rosen adds.

Along with being considered one of the first green pediatric

➔ 36

Getting social

Social media can be a powerful tool to help educate and engage the community in healthcare.

A case in point is **Lawrence Rosen, MD**, founder of the Whole Child Center in Oradell, New Jersey. Rosen uses Facebook (search for The Whole Child) to share information about the practice and health education. He has 23 videos on a YouTube channel, and he is just as actively using Twitter (@LawrenceRosenMD).

"It quickly became evident to me that this is a great way to engage the community. I could share information about our practice, and about other health activities in the community or things related to integrated health that supported the mission or the work we are doing. It's also a way to allow families, patients or parents, share what's happening in their lives," he says.

Most people, he adds, are not asking for healthcare advice either. "If it happens, and they are a patient, we ask them to contact us offline; and if they are not, we ask them to contact their healthcare provider." In 2013, his social media work netted the practice The Beautiful Award from athenahealth for its holistic approach to child care.

Check out his YouTube videos at *bit.ly/14M7dXu*

➔35 practices in the United States, the Whole Child Center was also designed to use technology to facilitate communication among patients and staff. Close to 70% of the practice's patients now use a patient portal (athenahealth), Rosen says. "Our phone call volume dropped in half, and it has not just been patients calling about health issues. That's included laboratory notifications, appointment requests and those kind of things."

The center's practitioners decided to keep computers out of the examination rooms because they do not want to distract from the encounter, but Rosen uses an iPad to facilitate education. He enters his notes into the electronic health record following the encounter. This approach to medicine has not only helped him improve adherence rates, but it has changed some of his patients' lives and habits.

"When people are engaged and feel control over their own health, they get excited—even more so than just being compliant, they are vested (in their own health)." And that's what is really going to change healthcare.

Going green

SO, WHAT IS A GREEN PRACTICE?

"It's about being mindful of the [impact of the] environment on health and the impact of healthcare on the environment," explains Lawrence Rosen, MD, founder of the Whole Child Center in Oradell, New Jersey.

The broad definition of a green design is a facility that uses materials that have been either recycled, produced locally, are energy conserving, and are non-toxic and non-allergenic. Rosen's practice, considered one of the first green pediatric practices in the country, was designed by DRG Design Group. It uses everything from natural linoleum flooring tiles to PVC-free leather furniture to nontoxic stains and sealers.

PRACTICE WHAT YOU PREACH

Pediatrician Lawrence Rosen, MD, founder of the Whole Child Center in Oradell, New Jersey, and author of the book, "Treatment Alternatives for Children," offers this prescription for healthy living in a blog post on athenahealth.com.

Rx food

EAT REAL FOOD

Teach your kids that eating is a mindful process, one that is not only about ingesting calories but also about nourishing your body, mind, and soul. Eating is and ought to be a community activity.

Rx activity

MOVE YOUR BODY

"Experience what author Richard Louv calls the 'transformative power of the natural world' and refuse to let your children suffer from nature deficit disorder."

Rx rest

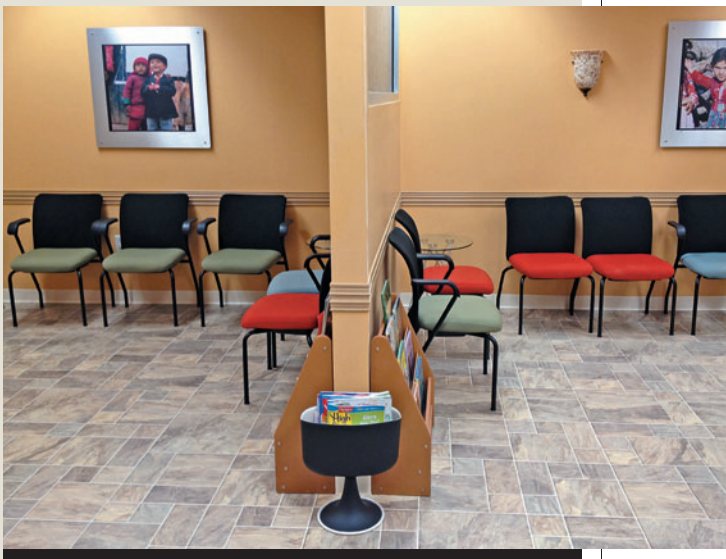
MAKE SLEEP A PRIORITY

Create opportunities for rest, especially for teens. They always need far more sleep than they get.

Rx mindfulness

BE HERE NOW

Help your children build their stress-coping toolboxes. Take time to look someone in the eyes, listen to her story, and let her know that you hear her. Be willing to sit in the mud until it settles and the water clears.



THE GREEN EVOLUTION: The Whole Child Center is said to be one of the first "green" practices in the United States, and it uses everything from "enviroleather" to many energy-conserving building materials.

PERSPECTIVE

Confronting the opioid dilemma

Deciding whether to prescribe potentially addictive medications to treat chronic pain poses difficult ethical choices for physicians

by **ELIZABETH BADE,** *MD*

HIGHLIGHTS

01 Prescribing opioids for non-cancer patients may relieve their pain temporarily, but can have dangerous long-term consequences.

02 Demonstrating empathy and taking the time to listen to a patient's story are important first steps towards the goal of weaning the patient from opioid use.

When I graduated medical school, I distinctly remember reciting the Hippocratic oath. I was a little disappointed to learn that *primum non nocere* ("First, do no harm") was not actually part of the oath. (It is still attributable to Hippocrates, but from a body of work other than the oath itself.) Non-maleficence is, however, one of the basic tenants of medical ethics, along with autonomy, beneficence, and justice.

Balancing non-maleficence and beneficence can be challenging to say the least, and most certainly is part of the "art" of medicine. I find that I face this challenge often when I am treating patients with controlled substances— especially opioid medications.

BALANCING TREATMENT AND RISK OF ABUSE

I know I am not alone in struggling with how to best prescribe some of these medications; there is a plethora of literature describing medico-legal ramifications, appropriate and inappropriate uses, and proper diagnoses. The fact is there is little evidence to support the use of daily opioid medication for non-cancer pain, yet millions of people in this country use these medications for everything from low back pain to arthritis to mysterious unidentifiable abdominal pain. And the doctors that started these medications were all practicing under the tenant of beneficence.

No one likes to see a fellow human suffer, but what is the best way to really help? I know of colleagues that simply no longer write chronic opioid prescriptions. For me, that is too black and white. I know there are people that benefit from daily use of these medications, take them as prescribed, and increase their overall health and well- being by appropriately treating their chronic pain. I also know there are far too many doctors who are willing to prescribe these medications without much thought to the consequences for the patient's life, so I made a conscious choice to examine my pain management practices.

The first patient to cause me to critically evaluate the use of daily opioids was a young woman who suffered from juvenile rheumatoid arthritis. We will call her Julie. I had been out of residency only a couple of years when I met Julie. She came to see me a few years after her diagnosis with juvenile rheumatoid arthritis. I met Julie's mother after volunteering to do some educational talks at a local school, and she thought I might be able to help sort out some of Julie's health issues.

Julie suffered from joint pain—a lot of joint pain. She had been to see multiple specialists, had suffered from pericarditis, and had been hospitalized multiple times with side effects and symptoms

"At times I blamed julie for...her addiction to the [pain] medications despite all of the negative side effects. But...she was following her doctor's directions...and who can blame her for being afraid of that kind of pain again?"

both of her disease and its treatments. In short she had endured a great deal already at a very young age.

What I first noticed when I met her, however, was that Julie was barely able to stay awake. Her mother did most of the talking for her, despite the fact that Julie was in her early 20's. Furthermore, Julie kept a notebook with her at every appointment to help her remember things to discuss with me, including basic symptoms. When I looked at her medications, I quickly realized why. I had never seen anyone on a dose of oxycodone so high. At one point she was taking over 300 milligrams per day, with additional short- acting medications. In fact, she wasn't really sure how much she was taking since she hardly kept track anymore. She was just taking pills all day long trying to "ease" her pain.

CONFRONTING A CRISIS

Julie and her mother recognized that this intelligent, beautiful young woman had been turned into a drug-addicted zombie unable to communicate her own symptoms at a doctor's visit without notes. Neither, however was convinced that stopping the medication altogether would actually help.

Julie and I struggled to understand this disease together. I did more research on pain medications and their side effects when Julie started experiencing seizures and thyroid problems, and stopped having her period—all attributed to the high doses of opioids she was taking.

When we started lowering her doses many of these issues went away. She started to have a personality, and it was actually fun to watch her reemerge. Through many visits, many compromises, and frequent tears from both of us, we managed to get her down to less than 150 mg of oxycodone daily, put her on a regular schedule of opioid use, and see a substance abuse counselor to help her deal with the addiction side of her treatment along with the chronic pain.

Even though she knew things were bad, these were not easy changes for Julie to make. She was so afraid to experience pain the way she had when she was first diagnosed, so afraid of being left without treatment, it took months to get her to start decreasing her doses. Although she acknowledged the positive aspects of reducing her pain medications, she did not see any potential benefits from weaning or stopping completely. I strongly encouraged her to change her diet, exercise more, and learn tai chi, most of which she made feeble attempts at, but didn't stick with.

I made a point of celebrating the small victories with her. I celebrated when she was able to finally attend a baseball game again, and I will never forget the joy on her face when she told me about running to catch a United Parcel Service delivery person—the first time she had run in years.

Julie's mother once told me that she harbored guilt for pushing Julie's previous doctor to treat her more aggressively. But she couldn't stand watching Julie suffer with so much pain. How different would Julie's life have been if she had been sent for mindfulness training, for tai chi training, for counseling to help her manage living with chronic pain at her first diagnosis instead of being put on ever-increasing doses of opioids?

I admit that at times I blamed Julie for wanting an easy way out and for her addiction to the medications despite all of the negative side effects and evidence that they were not helping her. But really, why is it her fault? She was following her doctor's directions to stop her suffering and who can blame her for being afraid of that kind of pain again? None of my suggestions were as quick and easy as taking a pill, and she was incredibly brave in trusting me throughout our relationship to continue to cut back on her medications without knowing how she would feel.

LEARNING MORE ABOUT CHRONIC PAIN MANAGEMENT

I have had countless other patients since then whom I have felt much more confident in maintaining on lower doses of opioid medications because of Julie. I also have educated myself on better ways of managing these medications and chronic pain. Although not everyone is happy with my philosophy of care, I certainly have met patients that make me realize that I am not wrong to offer alternatives and refuse certain treatments.

Recently I had a new patient, "Kate," walk into my office. She was previously seen by my partner. The old notes said Kate had come in asking for a refill of oxycodone while she was in town

➔40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- **Hypotension:** INVOKANA™ causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA™, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA™ in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

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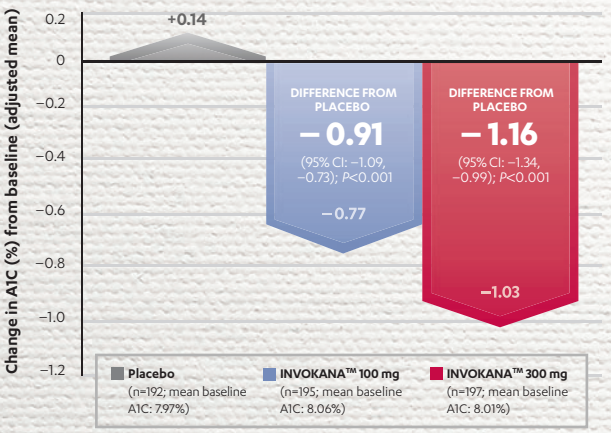
INVOKANA™ monotherapy provided statistically significant A1C reductions vs placebo at 26 weeks[1]

A1C Change From Baseline With INVOKANA™ Monotherapy[1]



Effect on Weight*

Statistically significant weight reductions vs placebo at 26 weeks (*P*<0.001)[1]

>> Difference from placebo†:
100 mg: −2.2%; 300 mg: −3.3%

Impact on Systolic Blood Pressure (SBP)*

Statistically significant SBP lowering vs placebo at 26 weeks (*P*<0.001)[2]

>> Difference from placebo†:
100 mg: −3.7 mm Hg; 300 mg: −5.4 mm Hg

INVOKANA™ is not indicated for weight loss or as antihypertensive treatment.

***Prespecified secondary endpoint.**

†Adjusted mean.

A1C Reductions vs Sitagliptin

INVOKANA™ 300 mg demonstrated greater A1C reductions vs sitagliptin 100 mg, in combination with metformin + a sulfonylurea, at 52 weeks (*P*<0.05)[1]

>> Difference from sitagliptin†: −0.37%

Incidence of Hypoglycemia

Monotherapy over 26 weeks:
100 mg: 3.6%; 300 mg: 3.0%; placebo: 2.6%[1]

With metformin and a sulfonylurea over 52 weeks:
INVOKANA™ 300 mg: 43.2%; sitagliptin 100 mg: 40.7%[1]

>> Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue

Convenient Once-Daily Dosing[1]

>> Recommended starting dose: INVOKANA™ 100 mg

>> Dose can be increased to 300 mg in patients tolerating 100 mg, who have an eGFR of ≥60 mL/min/1.73 m^2 and require additional glycemic control

The most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.

References: 1. Invokana [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; 2013. **2.** Stenlöf K, Cefalu WT, Kim KA, et al. Efficacy and safety of canagliflozin monotherapy in subjects with type 2 diabetes mellitus inadequately controlled with diet and exercise. *Diabetes Obes Metab*. 2013;15(4):372-382.

Learn more at INVOKANAhcp.com/journal

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION *(continued from first page)*

WARNINGS and PRECAUTIONS *(cont'd)*

- **Impairment in Renal Function:** INVOKANA™ (canagliflozin) increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.
- **Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin 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 INVOKANA™.
- **Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.
- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic drug.

DRUG INTERACTIONS

- **UGT Enzyme Inducers:** Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (eg, rifampin, phenytoin, phenobarbitol, ritonavir) must be co-administered with INVOKANA™ (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA™ 100 mg once daily, have an eGFR greater than 60mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and requiring additional glycemic control.
- **Digoxin:** There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA™ 300 mg. Patients taking INVOKANA™ with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** There are no adequate and well-controlled studies of INVOKANA™ in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at ≥0.5 times clinical exposure from a 300-mg dose.

  These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers:** It is not known if INVOKANA™ is excreted in human milk. INVOKANA™ is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA™ showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing

human kidney. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from INVOKANA™, a decision should be made whether to discontinue nursing or to discontinue INVOKANA™, taking into account the importance of the drug to the mother.

»**Pediatric Use:** Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.

»**Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).

»**Renal Impairment:** The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

The efficacy and safety of INVOKANA™ have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA™ is not expected to be effective in these patient populations.

»**Hepatic Impairment:** No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA™ has not been studied in patients with severe hepatic impairment and it is therefore not recommended.

OVERDOSAGE

»There were no reports of overdose during the clinical development program of INVOKANA™ (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

ADVERSE REACTIONS

»The most common (≥5%) adverse reactions were female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions in ≥2% of patients were male genital mycotic infections, vulvovaginal pruritis, thirst, nausea, and constipation.

K02CAN13149

Please see Brief Summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

Janssen
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Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

April 2013 K02CAN13075

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus *[see Clinical Studies (14) in full Prescribing Information]*.

Limitation of Use: INVOKANA is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA *[see Warnings and Precautions]*.
- Severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end stage renal disease or patients on dialysis *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA *[see Adverse Reactions]* particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (e.g., angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Impairment in Renal Function: INVOKANA increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA *[see Adverse Reactions]*. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.

Hyperkalemia: INVOKANA can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia *[see Adverse Reactions]*.

Monitor serum potassium levels periodically after initiating INVOKANA in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin 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 INVOKANA.

Genital Mycotic Infections: INVOKANA increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections *[see Adverse Reactions]*. Monitor and treat appropriately.

Hypersensitivity Reactions: Hypersensitivity reactions (e.g., generalized urticaria), some serious, were reported with INVOKANA treatment; these reactions generally occurred within hours to days after initiating INVOKANA. If hypersensitivity reactions occur, discontinue use of INVOKANA; treat per standard of care and monitor until signs and symptoms resolve *[see Contraindications and Adverse Reactions]*.

Increases in Low-Density Lipoprotein (LDL-C): Dose-related increases in LDL-C occur with INVOKANA *[see Adverse Reactions]*. Monitor LDL-C and treat per standard of care after initiating INVOKANA.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA or any other antidiabetic drug.

ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

- Hypotension *[see Warnings and Precautions]*
- Impairment in Renal Function *[see Warnings and Precautions]*
- Hyperkalemia *[see Warnings and Precautions]*
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions]*
- Genital Mycotic Infections *[see Warnings and Precautions]*
- Hypersensitivity Reactions *[see Warnings and Precautions]*
- Increases in Low-Density Lipoprotein (LDL-C) *[see Warnings and Precautions]*

Clinical Studies 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 the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy *[see Clinical Studies (14) in full Prescribing Information]*. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the population was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m^2).

Table 1 shows common adverse reactions associated with the use of INVOKANA. These adverse reactions were not present at baseline, occurred more commonly on INVOKANA than on placebo, and occurred in at least 2% of patients treated with either INVOKANA 100 mg or INVOKANA 300 mg.

Table 1: Adverse Reactions From Pool of Four 26–Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections†	3.2%	10.4%	11.4%
Urinary tract infections‡	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections¶	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

* The four placebo-controlled trials included one monotherapy trial and three add-on combination trials with metformin, metformin and sulfonylurea, or metformin and pioglitazone.

† Female genital mycotic infections include the following adverse reactions: Vulvovaginal candidiasis, Vulvovaginal mycotic infection, Vulvovaginitis, Vaginal infection, Vulvitis, and Genital infection fungal. Percentages calculated with the number of female subjects in each group as denominator: placebo (N=312), INVOKANA 100 mg (N=425), and INVOKANA 300 mg (N=430).

‡ Urinary tract infections includes the following adverse reactions: Urinary tract infection, Cystitis, Kidney infection, and Urosepsis.

§ Increased urination includes the following adverse reactions: Polyuria, Pollakiuria, Urine output increased, Micturition urgency, and Nocturia.

¶ Male genital mycotic infections include the following adverse reactions: Balanitis or Balanoposthitis, Balanitis candida, and Genital infection fungal. Percentages calculated with the number of male subjects in each group as denominator: placebo (N=334), INVOKANA 100 mg (N=408), and INVOKANA 300 mg (N=404).

Thirst includes the following adverse reactions: Thirst, Dry mouth, and Polydipsia.

Abdominal pain was also more commonly reported in patients taking INVOKANA 100 mg (1.8%), 300 mg (1.7%) than in patients taking placebo (0.8%).

Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients participating in placebo- and active-controlled trials.

The data combined eight clinical trials *[see Clinical Studies (14) in full Prescribing Information]* and reflect exposure of 6177 patients to INVOKANA. The mean duration of exposure to INVOKANA was 38 weeks with 1832 individuals exposed to INVOKANA for greater than 50 weeks. Patients received INVOKANA 100 mg (N=3092), INVOKANA 300 mg (N=3085) or comparator (N=3262) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline, the population had diabetes for an average of 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m^2).

The types and frequency of common adverse reactions observed in the pool of eight clinical trials were consistent with those listed in Table 1. In this pool, INVOKANA was also associated with the adverse reactions of fatigue (1.7% with comparator, 2.2% with INVOKANA 100 mg, and 2.0% with INVOKANA 300 mg) and loss of strength or energy (i.e., asthenia) (0.6% with comparator, 0.7% with INVOKANA 100 mg and 1.1% with INVOKANA 300 mg).

In the pool of eight clinical trials, the incidence rate of pancreatitis (acute or chronic) was 0.9, 2.7, and 0.9 per 1000 patient-years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

In the pool of eight clinical trials with a longer mean duration of exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 17.6 per 1000 patient years of exposure to comparator, INVOKANA

100 mg, and INVOKANA 300 mg, respectively. Upper extremity fractures occurred more commonly on INVOKANA than comparator.

In the pool of eight clinical trials, hypersensitivity-related adverse reactions (including erythema, rash, pruritus, urticaria, and angioedema) occurred in 3.0%, 3.8%, and 4.2% of patients receiving comparator, INVOKANA 100 mg and INVOKANA 300 mg, respectively. Five patients experienced serious adverse reactions of hypersensitivity with INVOKANA, which included 4 patients with urticaria and 1 patient with a diffuse rash and urticaria occurring within hours of exposure to INVOKANA. Among these patients, 2 patients discontinued INVOKANA. One patient with urticaria had recurrence when INVOKANA was re-initiated.

Photosensitivity-related adverse reactions (including photosensitivity reaction, polymorphic light eruption, and sunburn) occurred in 0.1%, 0.2%, and 0.2% of patients receiving comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Other adverse reactions occurring more frequently on INVOKANA than on comparator were:

Volume Depletion-Related Adverse Reactions: INVOKANA results in an osmotic diuresis, which may lead to reductions in intravascular volume. In clinical studies, treatment with INVOKANA was associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m^2) and age 75 years and older (Table 2) *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations]*.

Table 2: Proportion of Patients With at Least one Volume Depletion-Related Adverse Reactions (Pooled Results from 8 Clinical Trials)

Baseline Characteristic	Comparator Group* %	INVOKANA 100 mg %	INVOKANA 300 mg %
Overall population	1.5%	2.3%	3.4%
75 years of age and older†	2.6%	4.9%	8.7%
eGFR less than 60 mL/min/1.73 m^2†	2.5%	4.7%	8.1%
Use of loop diuretic†	4.7%	3.2%	8.8%

***** Includes placebo and active-comparator groups

† Patients could have more than 1of the listed risk factors

Impairment in Renal Function: INVOKANA is associated with a dose-dependent increase in serum creatinine and a concomitant fall in estimated GFR (Table 3). Patients with moderate renal impairment at baseline had larger mean changes.

Table 3: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

			Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Pool of Four Placebo-Controlled Trials	Baseline	Creatinine (mg/dL)	0.84	0.82	0.82
		eGFR (mL/min/1.73 m^2)	87.0	88.3	88.8
	Week 6 Change	Creatinine (mg/dL)	0.01	0.03	0.05
		eGFR (mL/min/1.73 m^2)	-1.6	-3.8	-5.0
	End of Treatment Change*	Creatinine (mg/dL)	0.01	0.02	0.03
		eGFR (mL/min/1.73 m^2)	-1.6	-2.3	-3.4
			Placebo N=90	**INVOKANA 100 mg N=90**	**INVOKANA 300 mg N=89**
Moderate Renal Impairment Trial	Baseline	Creatinine (mg/dL)	1.61	1.62	1.63
		eGFR (mL/min/1.73 m^2)	40.1	39.7	38.5
	Week 3 Change	Creatinine (mg/dL)	0.03	0.18	0.28
		eGFR (mL/min/1.73 m^2)	-0.7	-4.6	-6.2
	End of Treatment Change*	Creatinine (mg/dL)	0.07	0.16	0.18
		eGFR (mL/min/1.73 m^2)	-1.5	-3.6	-4.0

***** Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 80 mL/min/1.73 m^2 and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

INVOKANA™ (canagliflozin) tablets

In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 50 mL/min/1.73 m^2 (mean baseline eGFR 39 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m^2 (mean baseline eGFR 48 mL/min/1.73 m^2), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA was associated with an increased incidence of renal-related adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, renal impairment, and acute renal failure), particularly in patients with moderate renal impairment.

In the pooled analysis of patients with moderate renal impairment, the incidence of renal-related adverse reactions was 3.7% with placebo, 8.9% with INVOKANA 100 mg, and 9.3% with INVOKANA 300 mg. Discontinuations due to renal-related adverse events occurred in 1.0% with placebo, 1.2% with INVOKANA 100 mg, and 1.6% with INVOKANA 300 mg *[see Warnings and Precautions]*.

Genital Mycotic Infections: In the pool of four placebo-controlled clinical trials, female genital mycotic infections (e.g., vulvovaginal mycotic infection, vulvovaginal candidiasis, and vulvovaginitis) occurred in 3.2%, 10.4%, and 11.4% of females treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections on INVOKANA. Female patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrence and require treatment with oral or topical antifungal agents and anti-microbial agents *[see Warnings and Precautions]*.

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.6%, 4.2%, and 3.7% of males treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Male genital mycotic infections occurred more commonly in uncircumcised males and in males with a prior history of balanitis or balanoposthitis. Male patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents than patients on comparators. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised male patients treated with INVOKANA and 0.2% required circumcision to treat the phimosis *[see Warnings and Precautions]*.

Hypoglycemia: In all clinical trials, hypoglycemia was defined as any event regardless of symptoms, where biochemical hypoglycemia was documented (any glucose value below or equal to 70 mg/dL). Severe hypoglycemia was defined as an event consistent with hypoglycemia where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained). In individual clinical trials *[see Clinical Studies (14) in full Prescribing Information]*, episodes of hypoglycemia occurred at a higher rate when INVOKANA was co-administered with insulin or sulfonylureas (Table 4) *[see Warnings and Precautions]*.

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

Monotherapy (26 weeks)	Placebo (N=192)	INVOKANA 100 mg (N=195)	INVOKANA 300 mg (N=197)
Overall [N (%)]	5 (2.6)	7 (3.6)	6 (3.0)
In Combination with Metformin (26 weeks)	**Placebo + Metformin (N=183)**	**INVOKANA 100 mg + Metformin (N=368)**	**INVOKANA 300 mg + Metformin (N=367)**
Overall [N (%)]	3 (1.6)	16 (4.3)	17 (4.6)
Severe [N (%)]†	0 (0)	1 (0.3)	1 (0.3)
In Combination with Metformin (52 weeks)	**Glimepiride + Metformin (N=482)**	**INVOKANA 100 mg + Metformin (N=483)**	**INVOKANA 300 mg + Metformin (N=485)**
Overall [N (%)]	165 (34.2)	27 (5.6)	24 (4.9)
Severe [N (%)]†	15 (3.1)	2 (0.4)	3 (0.6)
In Combination with Sulfonylurea (18 weeks)	**Placebo + Sulfonylurea (N=69)**	**INVOKANA 100 mg + Sulfonylurea (N=74)**	**INVOKANA 300 mg + Sulfonylurea (N=72)**
Overall [N (%)]	4 (5.8)	3 (4.1)	9 (12.5)
In Combination with Metformin + Sulfonylurea (26 weeks)	**Placebo + Metformin + Sulfonylurea (N=156)**	**INVOKANA 100 mg + Metformin + Sulfonylurea (N=157)**	**INVOKANA 300 mg + Metformin + Sulfonylurea (N=156)**
Overall [N (%)]	24 (15.4)	43 (27.4)	47 (30.1)
Severe [N (%)]†	1 (0.6)	1 (0.6)	0

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies (continued)

In Combination with Metformin + Sulfonylurea (52 weeks)	**Sitagliptin + Metformin + Sulfonylurea (N=378)**		**INVOKANA 300 mg + Metformin + Sulfonylurea (N=377)**
Overall [N (%)]	154 (40.7)		163 (43.2)
Severe [N (%)]†	13 (3.4)		15 (4.0)
In Combination with Metformin + Pioglitazone (26 weeks)	**Placebo + Metformin + Pioglitazone (N=115)**	**INVOKANA 100 mg + Metformin + Pioglitazone (N=113)**	**INVOKANA 300 mg + Metformin + Pioglitazone (N=114)**
Overall [N (%)]	3 (2.6)	3 (2.7)	6 (5.3)
In Combination with Insulin (18 weeks)	**Placebo (N=565)**	**INVOKANA 100 mg (N=566)**	**INVOKANA 300 mg (N=587)**
Overall [N (%)]	208 (36.8)	279 (49.3)	285 (48.6)
Severe [N (%)]†	14 (2.5)	10 (1.8)	16 (2.7)

* Number of patients experiencing at least one event of hypoglycemia based on either biochemically documented episodes or severe hypoglycemic events in the intent-to-treat population

† Severe episodes of hypoglycemia were defined as those where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained)

Laboratory Tests: *Increases in Serum Potassium:* Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*. In this trial, increases in serum potassium of greater than 5.4 mEq/L and 15% above baseline occurred in 16.1%, 12.4%, and 27.0% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. More severe elevations (i.e., equal or greater than 6.5 mEq/L) occurred in 1.1%, 2.2%, and 2.2% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with moderate renal impairment, increases in potassium were more commonly seen in those with elevated potassium at baseline and in those using medications that reduce potassium excretion, such as potassium-sparing diuretics, angiotensin-converting-enzyme inhibitors, and angiotensin-receptor blockers *[see Warnings and Precautions]*.

Increases in Serum Magnesium: Dose-related increases in serum magnesium were observed early after initiation of INVOKANA (within 6 weeks) and remained elevated throughout treatment. In the pool of four placebo-controlled trials, the mean change in serum magnesium levels was 8.1% and 9.3% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to -0.6% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, serum magnesium levels increased by 0.2%, 9.2%, and 14.8% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Serum Phosphate: Dose-related increases in serum phosphate levels were observed with INVOKANA. In the pool of four placebo controlled trials, the mean change in serum phosphate levels were 3.6% and 5.1% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to 1.5% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, the mean serum phosphate levels increased by 1.2%, 5.0%, and 9.3% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C) and non-High-Density Lipoprotein Cholesterol (non-HDL-C): In the pool of four placebo-controlled trials, dose-related increases in LDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in LDL-C relative to placebo were 4.4 mg/dL (4.5%) and 8.2 mg/dL (8.0%) with INVOKANA 100 mg and INVOKANA 300 mg, respectively. The mean baseline LDL-C levels were 104 to 110 mg/dL across treatment groups *[see Warnings and Precautions]*.

Dose-related increases in non-HDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in non-HDL-C relative to placebo were 2.1 mg/dL (1.5%) and 5.1 mg/dL (3.6%) with INVOKANA 100 mg and 300 mg, respectively. The mean baseline non-HDL-C levels were 140 to 147 mg/dL across treatment groups.

Increases in Hemoglobin: In the pool of four placebo-controlled trials, mean changes (percent changes) from baseline in hemoglobin were -0.18 g/dL (-1.1%) with placebo, 0.47 g/dL (3.5%) with INVOKANA 100 mg, and 0.51 g/dL (3.8%) with INVOKANA 300 mg. The mean baseline hemoglobin value was approximately 14.1 g/dL across treatment groups. At the end of treatment, 0.8%, 4.0%, and 2.7% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

DRUG INTERACTIONS

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and require additional glycemic control *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Digoxin: There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA 300 mg *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Patients taking INVOKANA with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs *in utero* and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

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

Geriatric Use: Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA *[see Clinical Studies (14.3) in full Prescribing Information]*.

Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300 mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were 75 years and older *[see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]*. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*. These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m^2); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions]*.

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations *[see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

(Even) more MedEc

SEE WHAT YOU MAY HAVE BEEN MISSING IN OUR ENEWSLETTER

Income tops list of doctors' concerns

MORE THAN HALF of the physicians questioned in The Medicus Firm's 2013 Physician Practice Preference survey said compensation is their greatest career concern. According to the survey, just 32.8% of physicians were satisfied with their 2012 compensation. Those results may explain why 27.8% of physicians are considering a career change.

Financial concerns show no signs of going away. Almost three-fourths of physicians anticipate that their 2013 income will remain about the same, or decrease from their 2012 earnings.

What's limiting physicians' income? Thirty percent of doctors say its reimbursement, while about 12% blame changes stemming from healthcare reform.

Nearly one-third (30.7%) of practicing physicians say that financial reward is the main factor in their desire to change practices, while 24.2% say the quality of the practice is a reason for changing.

The most popular practice setting is single-specialty group or partnership, accounting for 28.4% of the practicing physicians surveyed. By contrast, about 28% of in-training physicians prefer hospital employment.

The survey included 2,568 physicians representing 19 specialties in 50 states.

"Kate...was always open to alternative methods of coping with the pain, but no one had taken the time to listen to her before—Perhaps because writing a script is a faster way to get on to the next patient."

➔38 for a funeral. My partner had refused the refill without any past records, and the only diagnosis left in Kate's chart was "drug seeker."

When I met Kate 2 years later, she had moved back to the area and her medication list now included a long-acting morphine in addition to the oxycodone. As Kate told her tale of being diagnosed with degenerative joint disease in her neck and back, followed by a diagnosis of fibromyalgia, I was already mentally practicing my speech about how opioid pain medications are not ideal for this type of pain and that there are many harmful side effects that can be avoided with alternative pain regimens.

WEANING OFF PAIN MEDICATIONS

I explained that I would not recommend these medications for her diagnosis, but I could fill a small prescription to help her wean off of daily use. She stopped my rehearsed speech and said she hadn't been on the long-acting morphine for the last 2 months and was hoping not to start it again. She was OK without a refill of oxycodone as well, and wanted alternative therapies that wouldn't leave her feeling doped up or like an addict. Kate was willing to suffer with more pain if she could be functional and live a fuller, richer life. What a different outcome than what I was expecting from the visit!

In subsequent visits Kate still has not asked for any opioids. In fact, she has thanked me on multiple occasions for taking the time to listen and not simply push drugs on her that she does not want—a very different approach from how she felt she had been treated in the past. She was always open to alternative methods of coping with the pain, but no one had taken the time to listen to her before—perhaps because writing a script is a faster way to get on to the next patient, a mistake I almost repeated.

Despite the fact that Kate was ready to accept other treatments by the time I met her, that visit—and therefore her life—could have gone very differently. I could envision a scenario in which I was in a hurry that day and didn't want to go through my whole speech. I could have simply filled her prescriptions and she may have taken them, thinking that drugs were the only alternative because that was what every doctor offered.

Without seeing the harm that had been done to Julie, I don't think I would have developed the protocol for managing pain that helped me not jump to a prescription for Kate. It is undeniable that our patients affect our practice: these two women may have never met each other, but I like to think that Julie's suffering from an addiction helped Kate to avoid the same.

REMEMBERING THE LESSONS

I have not forgotten the lessons from Julie or Kate when I see patients in pain. I do my best to discuss realistic, functional goals of pain management and to develop a written plan of care and treatment agreement to review with each patient. I discuss my philosophy that daily opioid use is hazardous, and should be minimized or completely avoided whenever possible.

I frequently ask myself whether I am creating an addiction and therefore doing more harm than good with my opioid treatments—even when the patient insists that these drugs are the only things that help as they look to me for relief. Patients suffering with severe pain can complicate treatment further. If they feel you have an easy cure and are keeping it from them, it's more difficult to convince them that mindfulness and exercise will eventually help them with their pain—just not in the same way as the instant relief from taking a pill.

It has taken much time, learning, and practice to feel more comfortable with these patient scenarios, and I still encounter challenges and ethical dilemmas with each new patient. But having learned from one patient's suffering I believe I can help others avoid it.

Sir William Osler, the "father of modern medicine," said, "As physicians we should strive to cure a few, help most, but comfort all." There are so many medications and treatments available to us as physicians today, but at what cost? Perhaps when considering our ethical questions of beneficence vs. non-maleficence we need to remember that although we have access to medications that can ease suffering, there are consequences and trade-offs to using them. Most of our patients will land in the "comfort all" category not by what we prescribe, but by our offering an empathetic ear, listening to their story, and discovering what they, as individuals, really need.

Practical Matters

CARE COORDINATION: TRANSITION BETWEEN PROVIDERS CAN BE THE MOST DANGEROUS FOR PATIENTS

by **BY MARTIN SEROTA, MD** *and* **ANTHONY RIDLEY, MAOM, BHCS, LVN**

The Affordable Care Act (ACA) has reshaped the rules of engagement for practices—big and small. The core provisions align with the Institute for Health Care Improvement's "Triple Aim," which emphasizes improving the patient experience of care, improving the health of populations, and reducing the per capita cost of healthcare.

ALL PHYSICIANS SHOULD expect their future revenue streams to be tied to their ability to improve the patient experience, while bending the cost curve. The healthcare industry is looking to the Patient Centered Medical Home (PCMH) as a vehicle to achieve these goals. One of the major roles of the PCMH is care coordination. Practices organize care around patients by working in teams to track and coordinate that care over time.

The solo physician or small practice used to have the advantage in care coordination. Not only were they able to provide care in the inpatient, outpatient and other institutional settings, but they also had a narrower network of healthcare specialists and roles to interact with. Following up on referrals and "closing the loop" occurred with less effort than can occur with our current complex healthcare system.

Today, small practices share in the problems of larger ones. As our care for health conditions have advanced in complexity, so have the teams of individuals who participate directly or indirectly in the care of our patients. This often results in the patient having a different physician and/or team for every diagnosed condition, and at every setting.

For this reason, care coordination—the key to quality and cost-effective care—has become an even greater challenge. The gaps in care coordination are exacerbated by the fact that it is often not considered a reimbursable service, so the professionals absorbing the costs aren't necessarily the ones receiving the financial benefits.

Patients who go to the emergency department, and are then admitted to the hospital, are one of the most common examples of patients in need of care coordination. These patients typically will see several physicians during their stay. Patients requiring transitional care (to a skilled nursing facility or long-term care facility) are often followed by another provider, before finally going to their home and back to their

➔42

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Practical Matters

➔41 primary care provider.

Transitions between providers and care settings can be one of the most dangerous periods during a patient's journey through the healthcare system, and they are fraught with potential errors, mainly due to poor communication and coordination.

For example, providers may have given incomplete information about diagnoses, allergies, treatments, or care plans. But the largest concern is potential medication discrepancies due to inadequate or incorrect medication reconciliation at each transition. Depending on payer source and physician preference, patients may receive duplicate medication (generic, brand and/or class). They may also receive unclear instructions on how to use each medication and which previous medications may need to be discontinued. Patients are significantly more likely to incur a hospital admission or re-admission when they have at least one medication discrepancy.

PCMH providers can employ tools to fill the gaps in care coordination. Not all are needed, but each one plays a valuable role in coordinated patient care.

CARE COORDINATION IS INTEGRAL TO HIGH-QUALITY, PATIENT-CENTERED CARE THAT LEADS TO BETTER OUTCOMES, AND LOWER TOTAL COST OF CARE.

These tools include:

- **An integrated electronic health record and Health Information Exchange can each provide for timely access to records.**
- **E-referral systems can facilitate a seamless referral tracking mechanism complete with alerts for follow-up and a loop back of patient records to both the primary care physician and specialist.**
- **But, even the most advanced health information technology capabilities still require a dedicated staff member to access and command the care coordination efforts of the PCMH.**

While small practices may vary in the skills and discretionary funding necessary to dedicate staff to care coordination, many of their partners, such as independent physician associations and health plans, have integrated care coordination models that providers can tap into.

The majority of managed care systems identify care coordination needs based on utilization triggers, which can include specific diagnoses, prevalence of referrals, and the total cost of care. There are also community-based organizations, including multipurpose senior services programs (MSSPs) and community-based care transitions programs (CCTP), which can assist in care coordination. MSSPs often start as an outpatient referral for senior patients who need assistance with housing, personal care, or chores.

The CCTP is relatively new. These 102 sites across the nation have partnered with the Centers for Medicare and Medicaid Services to reduce hospital readmission rates for Medicare fee-for-service patients. The core work of the CCTP provider is to coach the patient return to primary care as quickly as possible after a hospital discharge, to impart self-management skills, and to facilitate "warm handoffs" whenever possible. For the small practice PCMH, the key is finding the right combination of these elements to build a successful team.

Care coordination is integral to high-quality, patient-centered care that leads to better outcomes and lower total cost of care.

Whether you are in solo practice or are part of a large integrated system, the principles are the same— timely, accurate information and "warm handoffs" to be sure that the patients gets all the care they need, when they need it, while avoiding duplicate or unnecessary care. ◘

Martin Serota, MD *is vice president and chief medical officer with AltaMed Health Services.* ***Anthony Ridley*** *is supervisor of Case Management, Medical Management with AltaMed Health Services.*

Tech News

STUDY SHOWS WHAT PHYSICIANS MUST DO TO ENGAGE PATIENTS IN THEIR EHRS

by **BRANDON GLENN**

Much of the national discussion on electronic health records (EHRs) adoption has focused on physicians, but getting the most out of this technology will require significant buy-in by patients.

A RECENT STUDY by researchers affiliated with Virginia Commonwealth University that was published in the *British Medical Journal (BMJ)* examined the factors that could drive patients toward greater usage of personal health records (PHRs) that were made available to them by their primary care physicians.

For physicians, patient adoption of PHRs is no small matter. To obtain bonuses associated with stage 2 meaningful use, physicians not only must provide online access to PHRs and be able to exchange secure messages electronically with patients, but they also must ensure that at least 5% of patients actually use both of those features.

In the *BMJ* study, researchers conducted focus groups with 28 patients from eight family practices across Northern Virginia that offered PHRs to patients. Participants were split evenly between users and nonusers of the technology.

Perhaps the first key takeaway for physicians is that researchers found patients were much more likely to engage with their PHRs if their personal clinician endorsed the technology.

"A key element of engaging patients to use a PHR extends beyond the tool's design and includes how it is presented to patients and integrated into their care experience," the study states.

Across the focus groups, researchers identified three key themes about how patients wanted to be engaged in their PHRs. Patients prioritized 1) novel, relevant content to their care 2) records they could trust for accuracy, privacy and security and 3) a high level of functionality, which facilitated care and communication, plus provided personalized information.

Here's a little more detail on each of those themes:

- **Relevance:** A few patients said that upcoming appointments with their clinicians prompted them to register on their physician's EHR system. Many noted that the invitation to register was received at a time that wasn't connected to any care needs, and that made them less likely to register. The implication is that physicians should send registration invitations either just before or just after patients' scheduled appointments.
- **Trust:** Patients viewed physician endorsement of an EHR system as an indication that their protected health information was secure. Physician endorsement also made patients more likely to trust the accuracy of content and recommendations contained in their online records. Interestingly, patients expressed "strong opposition" to sharing health information with their insurance companies, because they feared it could lead to future denial of coverage.
- **Functionality:** Certainly, patients wanted their PHRs to facilitate communication with physicians and contain their personal health information, but many wanted more. For example, patients identified personalized advice, prompts to discuss those recommendations with physicians and the ability to prioritize recommendations as being "very important," according to the study.

The researchers note several limitations with the study, the most prominent of which appears to be demographics. Focus group participants were predominantly women (64%), white (93%), more than 50 years old (86%) and all reported having attended at least some college.

Tech News

MU2 REQUIREMENTS RAISE CONCERNS AMONG PROVIDER ORGANIZATIONS

As the starting date for Stage 2 of the meaningful use (MU2) program draws near, two major provider organizations are asking the government to loosen the requirements to qualify for the program.

IN A JOINT LETTER to U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius, the American Medical Association and the American Hospital Association called for a "realignment" of the MU requirements "to ensure a safe, orderly transition to Stage 2."

The associations want HHS to:

- **Allow providers who have qualified for Stage 1 MU to be able to qualify for Stage 2 using either 2011 or 2014 MU-certified editions of electronic health records (EHRs).** Allowing use of both editions, they say, would help alleviate the shortage of 2014-certified editions that meet the MU2 requirements. As of mid-July, only 11 EHRs were 2014 certified, compared with 313 that were 2011 certified. (A spokesman for the Health Information Management Systems Society (HIMSS) says, "HIMSS is working with our HIMSS Analytics team and healthcare community partners to assess overall readiness for Meaningful Use Stage 2."
- **Establish a 90-day reporting period for the first year of each new stage of MU, similar to what was done for Stage 1.** "This change will allow upgrades [to EHR systems] to be spread out over time, rather than being clustered on certain dates," the associations say.
- **Offer more flexibility to providers in meeting Stage 2 requirements so as to ameliorate the "all or nothing" problem.** Under the current rules, they note, failure to meet any part of an MU objective, or missing a threshold by even a small amount, is considered failure to meet the requirements.
- **Extend each stage of MU to at least 3 years for all providers.** Doing so would recognize that "vendors need time to develop usable and safe upgrades, and providers need time to implement systems and optimize their use," the associations say.

The associations say greater flexibility in implementing MU2 would especially benefit smaller medical practices and those serving rural communities. They cite studies published in the journal Health Affairs that found higher rates of EHR adoption among "physicians in practices with 11 or more physicians, in practices owned by a hospital or academic medical center, and in counties where less than 15% of the population was in poverty."

An additional concern regarding MU2 was raised last year by four powerful members of the Ways and Means Committee in Congress. The representatives wrote to Sebelius to express "serious concern" that MU2's standards for interoperability—the ability of different EHR systems to communicate with one another—are weaker than those under MU1.

The MU2 rules "fail to achieve comprehensive interoperability in a timely manner, leaving our healthcare system trapped in information silos," the authors said, and urged Sebelius to suspend incentive payments and delay penalties until HHS develops universal interoperability standards.

EHRs linked to patient loyalty

A new study suggests a possible link between a physician's office use of electronic health records (EHRs) and patients' loyalty to the practice.

Close to 24% of patients

say they are currently using EHRs, according to the EMR Patient Impact Study, which was conducted by Aeffect Inc and 88 Brand Partners. Many of those current EHR users (67%) say that Web systems for e-mailing physicians, filling prescriptions and making appointments are very influential in their choice of a physician.

A wide majority of patients using EHRs (82%) report being more satisfied with their quality of care, and more satisfied with access to information and clear communication from their physicians. Overall, patients who use EHRs are more satisfied with their physicians compared with those who don't use any electronic communication with their physician's office (78% versus 68%).

"The study's findings clearly indicate a strong link between EMR users and their confidence in the quality of healthcare they receive," says Tamara O'Shaughnessy, vice president of Aeffect. "There is solid evidence that the investment providers continue to make in EMR systems is likely to put adopters at a competitive advantage and yield dividends beyond the expected operational efficiencies—namely it will enhance patient loyalty and satisfaction."

The study comes on the heels of a report released by the Centers for Disease Control that found that 72% of physicians have adopted some sort of EHR system. Physicians who have met meaningful use standards for stage 1 of EHR implementation must start implementing stage 2 standards by 2014, which requires that 5% of patients must access their information online.

Guide to EHR contract terms now available

A new guide to help physicians negotiate contract with electronic health record (EHR) vendors is available from the Office of the National Coordinator for Health Information Technology, part of the U.S. Department of Health and Human Services.

The report, "EHR Contracts: Key Contract Terms for Physicians to Understand," examines seven important terms frequently used in EHR contract negotiations. Among them:

- **Limitation of liability.** When claims arise, a physician's contract with his or her vendor may include a financial cap for damages and exclude certain types of damages. "Limitations of liability are a common business practice to limit the financial risk of the EHR technology developer for claims that might arise from problems with the EHR system," the guide says.
- **Dispute resolution:** If a dispute between the vendor and physician arises, this provision will determine if it must be settled by litigation or by arbitration. "The dispute resolution provisions of an EHR contract are among the most important to ensure continuity of patient care and business operations," the guide says.
- **Termination and wind down:** These components are critical for physicians who want to switch EHR vendors, while not disrupting their access to patient data. "Despite the potential need to transition between EHR technologies, some standard EHR technology developer contracts fail to provide for termination and wind down services," the guide says. "Thus, how your contract addresses the transition from one EHR technology to another should be well understood."

"THE STUDY'S FINDINGS CLEARLY INDICATE A STRONG LINK BETWEEN EMR USERS AND THEIR CONFIDENCE IN THE HEALTHCARE THEY RECEIVE."

—TAMARA O'SHAUGHNESSY, VICE PRESIDENT, AEFFECT

The ONC guide, which was created by the research and consulting firm Westat, contains explanations of four other legal terms: indemnification and hold harmless; confidentiality and non-disclosure agreements warranties and disclaimers and intellectual property disputes.

ONC emphasizes that the guide is not a substitute for professional legal advice. "Each healthcare organization presents its own unique circumstances. Purchasers should consult an experienced attorney for assistance in contract negotiations," the guide advises.

@ The guide can be viewed at bit.ly/14E0vnY

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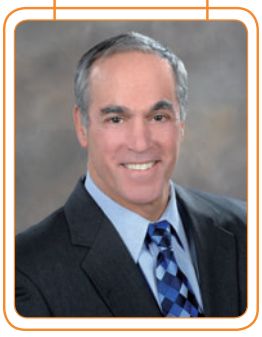

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Policy

AMA ASSAILS PROPOSED MEDICARE PHYSICIAN PAYMENT CUTS AS 'ARBITRARY'

BY ALISON RITCHIE

In its summary of key provisions, the American Medical Association (AMA) criticized several components of the proposed 2014 Medicare Physician Fee Schedule.

As part of its proposed rule released in July, the Centers for Medicare and Medicaid Services (CMS) is calling for large payment reductions for more than 200 services, which it claims are misvalued because physician offices receive larger reimbursements than ambulatory surgical centers or outpatient departments at hospitals would receive for the same services. The 2014 proposal would cap physician payments for those services at the same amount the hospitals receive.

The AMA calls this policy "arbitrary" and defends the higher payment for services in physician offices. Using CPT code 88367 as an example, the AMA says this rule would cut that reimbursement to physicians by 79%.

"For hospitals, payments above and below the cost of service are assumed to average out over time," the summary says. "But physicians… cannot offset their losses this way. The AMA will aggressively oppose this proposal and seek to delay implementation until the RUC can review these codes."

The summary also addresses the AMA's Specialty Society Relative Value Scale Update Committee (RUC), which recently has faced public scrutiny after an article critical of its neutrality appeared in The Washington Post in July. The AMA stated that through objective screens and cross-specialty review, the RUC successfully identified incorrectly valued services that resulted in $2.5 billion in redistribution within the Medicare Physician Payment Schedule.

USING CPT CODE 88367 AS AN EXAMPLE, THE AMA SAYS THIS RULE WOULD CUT THAT REIMBURSEMENT TO PHYSICIANS BY 79%.

The AMA also expressed concern over several other CMS provisions including:

- **The Value-Based Payment Modifier:** "The AMA has repeatedly argued that the Value-Based Modifier is a flawed concept that cannot be equitably applied across the board to all physicians," the summary says. "Efforts to repeal the proposal, slow its expansion, limit potential penalties, and eliminate the two-year lag between performance and adjustment years will continue."
- **Liability for Overpayments:** Previously, Medicare had three years to recover overpayments, but that was extended to five years by the American Taxpayer Relief Act of 2012. The AMA says it will oppose the extension in its comments on the fee schedule.
- **Physician Compare:** Although the AMA expressed its approval of several recent changes to the Physician Compare website, the AMA says its disappointed CMS is planning to expand without "ensuring the accuracy of the underlying database."

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