Diabetes & chronic adherence problems
PAGE 20

How to fight claims denials
PAGE 58

Medical Economics®

JUNE 10, 2013

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ACOs

silver bullet OR misfire?

Taking aim at the economic impact

ADVANSTAR MEDICAL COMMUNICATIONS GROUP

VOL. 90 NO. 11

Medical Economics®

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SARAH KLIFF
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JUNE 10, 2013

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Money

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Taking aim at the economic impact of ACOs

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- Exploring the long-term impact on healthcare costs
- Probing the financial arrangements for physicians

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How to collect on insurance claims denials

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Erline C. Franks
Can you bill an AWV with missing components?

The advertiser index is on page 79.

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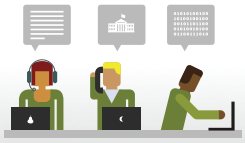

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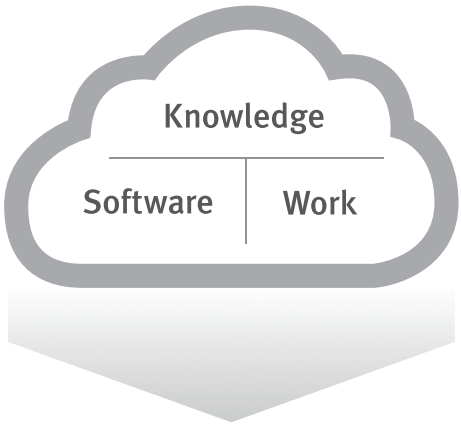

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Slightly more than one-third of Americans support the law today, versus 46% who favored it when it was passed in 2010. http://ow.ly/l83LZ

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When insurers won't pay for the Patient-Centered Medical Home, patients might.

—Joseph E. Scherger, MD

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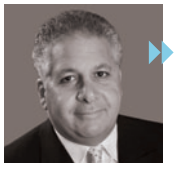

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from the Trenches

> Ultimately the patients will need to start speaking up. As they get more frustrated with the changes they experience on their end, they will be the voice. Physicians' voices aren't as powerful any more, or as listened to.
>
> **Kimberly Corba, DO,** ALLENTOWN, PENNSYLVANIA

PATIENTS' VOICES MUST BE HEARD

I am writing to thank Craig Wax, DO, for his commentary, "A physician's toughest choice: Accept an offer or remain independent," in the December 25, 2012, issue of *Medical Economics* (From the Board). I am still in private practice—not owned by a hospital or any other organization. It will be 10 years in July since we opened our doors.

I am a small practice with two full-time employees. We all work hard and together. We are all invested in making this practice last as long as possible while navigating this tidal wave of healthcare reform.

We are doing very well and rate extremely highly with insurance carriers as they continually evaluate us on quality care issues/measures. Each carrier has different requirements with some overlap in standards, but not enough to make it easy in any way whatsoever. This is in addition to converting to electronic health records and participating in meaningful use and getting our Patient-Centered Medical Home certification. I am happy to say these ventures are going well, and we are managing to do it with little outside help.

Although I am on staff at two large local hospitals, and although they occasionally reach out to community practices—the few that are left—the help and advice on the processes/logistical part of the above procedures we receive from the hospital systems is limited, because they need to funnel their resources into the vast number of owned practices.

We end up forging ahead mostly alone. So far we are very happy, overworked, and gratified all at the same time.

Like Wax, I am skeptical about how this all may end up. I was out of residency during the period of the late 1990s to which Wax refers, and experienced the Allegheny fiasco that occurred in Philadelphia at that time. The whole healthcare system in the city was turned upside down. It was awful.

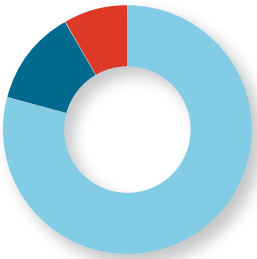
A large hospital system purchasing and managing practices? It didn't work then, can it work now? It was a different platform then, but the same *modus operandi* -- consolidation and control, private business then versus government business now.

Ultimately, the patients will need to start speaking up. As they get more frustrated with the changes they experience on their end, they will be the voice. Unfortunately, the physicians' voices aren't as powerful anymore, or as listened to. In the meantime I am laying low and doing what I do best, taking care of my patients. I have hope that the rest will fall into place.

Thank you for the best wishes to your colleagues in the last paragraph, Dr. Wax. There are a few of us still taking the road less traveled. It is good to hear the support of fellow physicians!

Kimberly Corba, DO
ALLENTOWN, PENNSYLVANIA

In your opinion, how will ACOs fare?



- They'll fail miserably.
- Some will fail, some will succeed.
- They'll improve quality and reduce costs.

Check out this issue's comprehensive coverage of Accountable Care Organizations, starting on page 30.

> The Patient-Centered Medical Home (PCMH) is conceptually the direction in which we, as a country, should be headed…The philosophy of PCMH is very consistent with the basic tenets of primary care, especially family medicine and the residency training we received.
>
> **Stephen F. Staten MD, ABFP,** ST. LOUIS, MISSOURI

MEDICAL HOMES ARE RIGHT FOR PRIMARY CARE

I am writing in response to the letter to the editor in the April 10, 2013, issue from Edward Volpintesta, MD ("Single-payer system would simplify care"). I disagree with his comments regarding the medical home and its value, cost, and amount of work involved. Also, his proposal for a single-payer system and its perceived benefits are not well founded.

The Patient-Centered Medical Home (PCMH) is the direction in which we should be headed, in my opinion. The philosophy of PCMH is very consistent with the basic tenets of primary care, especially family medicine and the residency training we received.

Having a nurse care manager in our office setting has demonstrated the value of an organized, population-based approach to caring for our patients. We have demonstrated in just a short period of time the cost- effectiveness of using a patient registry and the discipline of a PCMH model in improving patient care and outcomes.

A single-payer system would be much like Medicare /Medicaid. If we move toward a single payer monopoly, the already inefficient (and at times ineffective) Medicare/Medicaid-type system will become even more so.

Competition in the marketplace in anything leads to excellence. We physicians need to expect more value for our patients and not succumb to the idea of a single-payer monopoly, but rather demand better from our multiple payer system.

Keep up the strong work, primary care physicians, and continue to lead the way for our suffering but fixable system for present and future generations of physicians.

Stephen F. Staten MD, ABFP
ST. LOUIS, MISSOURI

MOC: WE SHOULD BE HELD TO THE SAME STANDARDS

After reading the article "Get involved to help end MOC" (Talk Back, January 25 issue) and then Lois Nora, MD's article (Viewpoint, October 25 issue), I felt it necessary to provide a counterpoint.

As a participant in the MOC program, I understand and agree with the need to "remain knowledgeable and skillful in our disciplines and care about providing safe, evidence-based and compassionate care to patients" (as Nora stated). What galls me is that this program has failed in bringing its mission to fruition.

We have all seen physicians who claim board certification as part of their credentials. I know for a fact that very few patients will inquire to determine the date of the certification. Whatever the excuses given by those who have been 'grandfathered' into permanent board status, the fact is that ALL physicians should be required to participate in the MOC program. Since we are all physicians in the end, we should all be held to the same standards.

Robert M, Kleinhaus, MD
ABILENE, TEXAS

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*__Source:__ Employee Morale Survey conducted by Carbonview Research, Inc., 2013

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AAFP CALLS ON CMS FOR TELEPHONE, ONLINE, AND CARE PLAN PAYMENTS

The American Association of Family Physicians (AAFP) is renewing its call for the Centers for Medicare and Medicaid Services (CMS) to pay physicians for telephone evaluations, care plan oversight services, and online evaluations.

Specifically, AAFP wants CMS, under the Medicare physician fee schedule, to dial in seven new service codes using established relative value units when provided by primary care physicians as an interim strategy until this work is recognized under a care management fee.

These services and codes include:

Telephone evaluation and management services (CPT codes 99441-99443)

Collection and interpretation of physiologic data (CPT codes 99091)

Domiciliary, rest home, or home care plan oversight services (CPT codes 99339-99340)

Anticoagulant management (CPT codes 99363-99364)

Medical team conferences (CPT codes 99366-99367)

Care plan oversight services (CPT codes 99374-99380)

In addition, AAFP is asking CMS to pay for online evaluation and management service (CPT code 99444) when the service is provided by primary care physicians.

"The existing E/M codes do not adequately reflect the scope of our responsibilities and the complexity of the care that we provide in the office and other outpatient settings," counters Glen Stream, MD, MBI, board chair of AAFP. "Primary care E/M services should be valued higher than E/M services provided by other specialists."

PROVIDERS STUMBLE AFTER RECENT HIPAA AUDITS

When it comes to securing and protecting patient health information, physician practices under 50 providers fared the worst in a recent audit by the U.S. Department of Health and Human Services' Office for Civil Rights (OCR).

In fact, Linda Sanches, MPH, an OCR senior adviser, reports that only two of the 64 healthcare providers in the audit passed without problems.

While OCR's audit on privacy and security also included health plans and healthcare clearinghouses, the report says that significant compliance issues exist among physician practices.

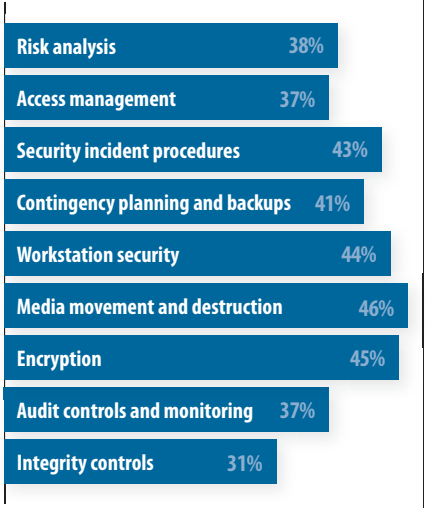
OCR evaluated practices related to security (administrative, physical and technical safeguards), breach notification, and privacy [access to patient health information (PHI), administrative requirements, uses and disclosures of PHI, etc.]. Security problems accounted for 60% of the findings and observations. Data privacy problems were noted in 30% of the audits, while only 10% were attributed to data breach notifications.

Small practices, OCR notes, "struggled with all three audit areas."

Nearly 50% of the smaller practices posted negative findings and observations related to compliance of uses and disclosure of PHI, another 30% were dinged for not having acceptable administrative requirements in place, 30% had compliance problems related to patient access, and another 31% had findings and observations related to notice of privacy practices for PHI.

Many of the audit problems, Sanches says, were triggered simply because providers were unaware of the requirements. She urged physicians to evaluate the regulations and conduct a compliance assessment to help protect PHI from breaches.

Security compliance problems for practices with 50 and fewer providers



Source: HHS, Office for Civil Rights, 2013

@ For a detailed look at HIPAA compliance, check out *Medical Economics'* comprehensive coverage by using this shortened URL: http://ow.ly/lprdM

Medical schools scramble to boost PCP numbers

MORE THAN 76 PERCENT of medical schools have launched or are planning to build at least one initiative to increase interest in primary care specialties.

And while recently released Association of American Medical Colleges (AAMC) data note a slight increase in enrollment of first-year medical students in both MD and DO programs, some physicians question whether the increases have been too little too late as demand for primary care physicians (PCPs) escalates.

"Amid expected shortages of PCPs," the AAMC report says, "schools are implementing policies and programs designed to encourage student interest in primary care."

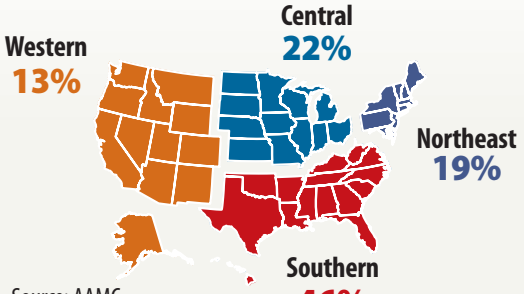
To help stave off the anticipated shortage of 90,000 PCPs by 2020, medical schools have been increasing enrollment steadily and are on pace to hit projections by 2017 with 21,434 first-year medical students. Whether or not those new doctors will enter the primary care ranks is another matter entirely.

In the AAMC survey, medical school administrators also report concern over the numbers of clinical training spots for students.

"Respondents are concerned about the number of sites, the supply of both primary care and specialty preceptors and competition for clinical training sites."

AAMC is collaborating with the American Association of Colleges of Nursing, American Association of Colleges of Osteopathic Medicine, and the Physician Assistant Education Association to explore these issues in greater detail.

Percent of 2002-2017 growth by region of the United States



Source: AAMC

IRS STAFFS UP FOR OBAMACARE

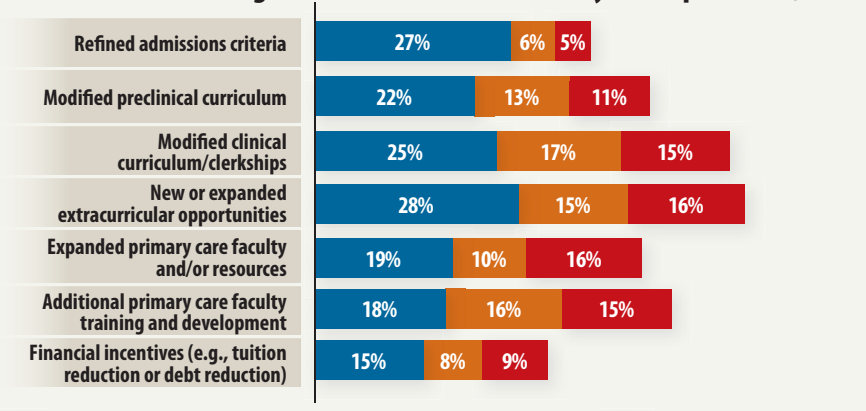
The Internal Revenue Service (IRS) has 700 full-time staffers devoted to the implementation of the Affordable Care Act (ACA), and some pundits believe that number may grow to a minimum of 5,000 employees, according to a recent report in *Forbes*.

IRS' new role will be to verify eligibility and monitor whether a business carries qualifying health coverage or remains exempt from the law's penalties, *Forbes* reports.

The American Association of Family Physicians says the IRS' role in implementing ACA will not involve physicians directly. And their oversight authority will not involve access to a physicians' medical records as some news organizations implied.

Nonetheless, IRS will administer 47 tax provisions related to ACA including "the right to levy a penalty against businesses and individuals who don't provide or acquire insurance."

Initiatives to Encourage Student Interest in Primary Care Specialties, 2012



Established (2 years or more) **Recently implemented** (less than 2 years) **Planned** (within the next 2 years)

Note: Schools could select more than one initiative

Summary of current and projected first-year enrollment to medical schools

2017:	21,434
2016:	21,255
2015:	21,053
2014:	20,654
2013:	20,059
2012:	19,517
2002 (base):	16,488

Source: AAMC

Doctor's Bag

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MONITORING SYSTEM MEASURES HAND HYGIENE COMPLIANCE

An electronic hand hygiene compliance monitoring system could be a positive addition to your practice. Based on the World Health Organization's (WHO's) "Save Lives: Clean Your Hands" and "Five Moments for Hand Hygiene" recommendations, the DebMed GMS (Group Monitoring System) measures the hand hygiene compliance of healthcare workers who come into contact with patients.

Recently patented core technologies within the DebMed GMS collect data on how many times physicians wash and/or sanitize their hands.

The system uses an evidence-based algorithm to pre-determine the expected number of times the physicians should be washing and/or sanitizing their hands.

By dividing the actual hand hygiene events by the expected number of opportunities for hand hygiene, the system calculates the practice's compliance rate in real-time.

Studies have shown that traditional hand hygiene compliance monitoring methods like direct observation and self-reporting are inaccurate and unreliable, so the system is a significant advancement over other current compliance methods.

International patents are still pending.

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Your practice might benefit from the ThinkCentre Edge 62z, the all-in-one PC from Lenovo. Featuring a space-saving 18.5-inch display and compact design, the PC is ideal for confined workspaces that require multiple PCs, like nursing stations and patient rooms. Providing 65% more space savings than a typical 20-inch monitor, the PC can also be mounted to the wall to give physicians quick access to information.

Equipped with 3rd generation Intel Core i3 processors, the PC features six USB 2.0 ports and Integrated Intel HD graphics. The PC is also ENERGY STAR 5 compliant; has an 87% power supply unit for efficient energy usage and increased cost savings; and consumes less than 0.5 watts of electricity when turned off, meeting the Energy Using Products (EuP) 2013 energy efficiency requirement.

Prices for the PC start at $549.

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DURABLE TABLET ASSISTS WITH EHR CAPTURE, REVIEW

The upgraded Panasonic Toughbook H2 rugged handheld tablet PC includes improved features for mobile physicians including a faster processor, expanded storage, and enhanced battery life.

The 3.5 lb. Toughbook H2 has a fully-sealed design, with no fan vents or exposed ports, and can be easily disinfected to reduce the spreading of infections among patients. The device is also a secure platform for barcode medication administration, vitals capture, and electronic medical health records capture and review.

Certified for shock-absorbent durability, including the ability to survive a 6-foot drop, the Toughbook H2 runs on Microsoft Windows 7 and features standard USB 3.0, serial, and Ethernet ports. It also has Wi-Fi and Bluetooth.

Available from Panasonic resellers starting at $3,349, the Toughbook H2 is backed by a three-year limited warranty.

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Trends

Growing diabetes problem signals adherence challenges

Engaging patients in their treatment plan can improve outcomes, experts say

by **JEFFREY BENDIX, MA** *Senior editor*

HIGHLIGHTS

01 Controlling the effects of diabetes usually requires patients to make significant—and difficult—changes to their lifestyle and diet.

02 Support and encouragement from the patient's physician, family members, and friends are key to successful adherence to a treatment plan.

About 19 million Americans have diabetes, and the American Diabetes Association (ADA) estimates the rate of increase for the disease at 7% to 8% annually. "I don't know any other chronic disease that's growing at 8% each year. That's why we're sounding the alarm," says John Anderson, MD, president of medicine and science for the ADA.

EFFECTIVE MANAGEMENT of Type 2 diabetes—which includes between 90% and 95% of all diabetes cases—usually involves a multi-pronged approach that includes drug therapies and lifestyle changes. The challenge for primary care physicians (PCPs) is getting patients to adhere to the plan. A 2010 study in *The New England Journal of Medicine* found that between 33% and 48% of patients with diabetes did not meet targets for blood pressure, glycemic control, or low-density lipoprotein levels, three of the main symptoms of the disease.

"We know that if we can get people to exercise more and change their eating habits to lose a certain percentage of weight, we markedly reduce the rate at which pre-diabetic patients turn into full diabetes," says Anderson.

Patients with Type 2 diabetes do not produce enough insulin to convert blood sugars (glucose) into energy for the body, causing glucose levels build up in the body. If left untreated, high glucose levels can lead to complications such as blindness, loss of limbs, kidney failure, and neuropathy. The disease can also exacerbate the effects of conditions such as high blood pressure and high cholesterol levels. The ADA puts the annual cost of all forms of the disease at about $245 billion, including $176 billion in direct medical costs and $69 billion in reduced productivity.

In light of diabetes' growing prevalence, it's not surprising that a wide and ever-expanding range of drug therapies and monitoring technologies are available to help doctors and patients cope with the disease and limit its effects. Anderson cites as examples the development of a new Incretin class of medications and the U.S. Food and Drug Administration's recent approval of a new class of sodium-glucose co-transporter 2 inhibitors.

In addition, the explosion of health-related apps has given physicians and patients new tools to help with diabetes management. (A summary of some of the latest apps that can help people with diabetes can be found at: http://forecast.diabetes.org/apps-jan2013).

IMPROVING ADHERENCE

In most cases, however, physicians prefer to try controlling the disease—or better yet, preventing it—by emphasizing lifestyle changes—which gets back to the challenge of adherence. For many years the standard approach was simply to tell patients what they needed to do and leave it to them to figure out how to do it. But research, as well as doctors' own experiences, has demonstrated the limitations of this approach.

"What everyone has been finding is that patients often don't do what you tell them to do," says Richard Waltman, MD, a family and geriatric practitioner in Tacoma, Washington, and a *Medical Economics* editorial consultant. "So the key is to get them to tell themselves what to do. What I've learned to do is to give patients the data [of their condition], show them the benefits of treatment, and ask them what they want to do. That way it becomes their plan.

"If someone isn't ready to change, nothing works," Waltman adds. "When they are ready, everything works."

Other techniques suggested by experts and by PCPs with experience in treating diabetic patients include:

Encouragement

Patients of Patricia Roy, DO, a family practitioner in Muskegon, Michigan, receive a report card that grades them on important diabetes metrics such as blood pressure, glycated hemoglobin (A1c), and low-density lipoprotein levels, as well as frequency and results of eye and foot exams.

"Our pay-for-performance scores, and therefore our income, increased significantly by giving our patients these report cards," says Roy, who is also a *Medical Economics* editorial consultant. "I am continually amazed at how often they show them to their family, and how often they hang them on their refrigerator at home," she adds.

Support

The involvement and support of family and friends is a significant element in patient success when it comes to making diet and lifestyle changes. "We often talk about diabetes being a disease of the entire family," notes Anderson. "What good does it do to discuss diet with the husband alone when he never shops or cooks? You have to consider the family dynamics, who's in charge of what at home."

"It's really important to appreciate how much support

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VIDEO

Diabetes prevention

View a National Diabetes Education video on Type 2 diabetes prevention.

Visit http://1.usa.gov/16erUvn

"THE KEY IS TO GET [PATIENTS] TO TELL THEMSELVES WHAT TO DO. I'VE LEARNED TO GIVE PATIENTS THE DATA [OF THEIR CONDITION], SHOW THEM THE BENEFITS OF TREATMENT, AND ASK THEM WHAT THEY WANT TO DO. THAT WAY IT BECOMES THEIR PLAN."

RICHARD WALTMAN, MD

"IN A ONE-ON-ONE VISIT THE DOCTOR ONLY HAS SO MUCH TIME AND USUALLY ENDS UP DOING MOST OF THE TALKING. IN A GROUP VISIT THE PATIENTS GET TO TALK AND HELP EACH OTHER OUT."

EDWARD SHAHADY, MD

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and encouragement is needed to make the kinds of changes that most patients with Type 2 diabetes need to make," says Molly Cooke, MD, FACP, president of the American College of Physicians and a practitioner in the general internal medicine division at the University of California-San Francisco. "So one of the things I do with my patients is encourage them to look for a buddy, or join a weight management program where there's a social dimension to help them with that change in behavior."

Teamwork

PCPs can also benefit from a team approach to providing diabetes care for patients, especially in light of the time pressure most of them face. "It would be nice to be able to spend 30 minutes with every patient, but we don't have that luxury, Anderson points out. "So as a PCP you have to be very efficient. You've got to have a team approach to dealing with diabetic patients."

Current staff members often can be helpful, especially in smaller or rural practices, says Edward Shahady, MD, medical director of the Diabetes Master Clinician Program in Fernandina Beach, Florida and former president of the ADA's North Florida/South Georgia chapter. "A lot of family practices will have someone in the office who's learned a lot about diabetes, and they can help with simple education tasks," he notes.

Anderson recommends the use of a nurse educator and dietician to help with patients with diabetes. Practices unable to hire additional staff can often refer patients to community resources, such as local hospitals, for nutrition counseling, smoking cessation, and other resources related to diabetes management, he adds.

Group appointments

The value of this technique, doctors say, is that it enables patients to learn from and support each other in attaining their goals. Shahady began teaching residents how to conduct group visits a decade ago when he was a professor of family medicine at the Florida State University School of Medicine. "In a one-on-one visit, the doctor only has so much time and usually winds up doing most of the talking," he says. "In the group visit the patients get to talk and help each other out."

Cooke cites the example of a woman having difficulty attaining her goal of walking 30 minutes a day because of her responsibilities of housework and caring for her grandchildren. "It's more helpful if someone else in the group says, 'I had that problem too and I tried this.' So they end up coaching each other."

Those who hold group appointments say they are also useful for educating patients. Shahady, for example, says he will often ask patients to bring in items of canned and packaged foods so that group members can help each other learn how to read the labels for calories and sodium and fat content. Cooke began offering instruction in using glucose meters after a group visit where patients brought in their meters and she discovered that half of them had dead batteries. "The patients didn't understand them well enough to know they don't work if the battery is dead," she says.

Group appointments can be structured in a variety of ways depending on the needs of the patients and preferences of the physician. Some begin with an instructional session, either by the physician or a specialist such as a dietician or pharmacist, whereas others will be open discussions and/or questions from patients about challenges they're facing. In all cases, however, doctors recommend limiting attendance to no more than about 12. "Any more than that you're going to have a lecture," Shahady says.

Shahady adds that he bills for the group visits using standard evaluation and management (E/M) codes, but doing so requires careful documentation. (See "Billing for group visits.") "The rules for E/M codes don't say one on one, they say face to face," he notes. "So if I'm talking to the group about A1c, even if a patient doesn't get involved with the discussion, I can enter something on her chart that hemoglobin A1c was discussed."

THE AFFORDABLE CARE ACT

The coming rollout of the Affordable Care Act (ACA), in conjunction with the emergence of payment models such as accountable care organizations, have given some doctors

Coding and billing for group appointments

Physicians sometimes are reluctant to hold group appointments for their patients with diabetes because they fear they won't be able to code and bill for them correctly. Eric Shahady, MD, medical director of the Diabetes Master Clinician Program in Fernandina Beach, Florida, has written extensively about the benefits of group visits and offers the following suggestions on his Web site, www.masterclinician.org, from which this is excerpted:

"Without coding the symptom or the diagnosis to show why the treatment was necessary, third parties may not reimburse you for the service. Documentation is the key and most established patients qualify for current procedural terminology (CPT) code 99213 or 99214 if they are properly documented.

99213 DOCUMENTATION:

A 99213 requires a chief complaint, one to three questions about the patient's diabetes (frequency and values of self monitored blood sugars, vision, feet, exercise, diet etc.), one review of systems (ROS) question, medical decision-making (MDM) requiring low-complexity care of diabetes, an assessment of controlled diabetes, and a plan that deals with the diabetes. Use a controlled diabetes International Classification of Disesases-9th revision code such as 250.00 for Type 2 controlled, or 250.01 for type 1 controlled. The fifth digit indicates control and the fourth digit indicates complications.

99214 DOCUMENTATION:

A 99214 requires four questions related to the patient's diabetes, two ROS questions, and one question about either past med history and or social history. Include in the documentation evidence that the patient is an uncontrolled diabetic not at target and how you will be attempting to bring the patient into control. Documenting the attempt to bring the patient into control satisfies the moderate complexity MDM requirement

Other documentation that indicates uncontrolled and moderate complexity includes some of the following:

1. Numbers that are out of control, such as A1c, LDL, blood pressure
2. Patient not obtaining eye consult or other consults
3. Complications are present like retinopathy (dilated eye exam positive), neuropathy (monofilament or vibratory sense decreased), nephropathy (creatinine increased), angina, stroke, chest pain, myocardial infarction, or hypertension
4. Modifications in their care such as more exercise, diet, eye exam, or urine testing.
5. Increasing a medication dosage or starting a new med, or suggestions for increased adherence to medications
6. Discussion of side effects of medications, review of drug interactions (note where you found the information.)
7. Advice and discussion of how to adhere to lifestyle changes

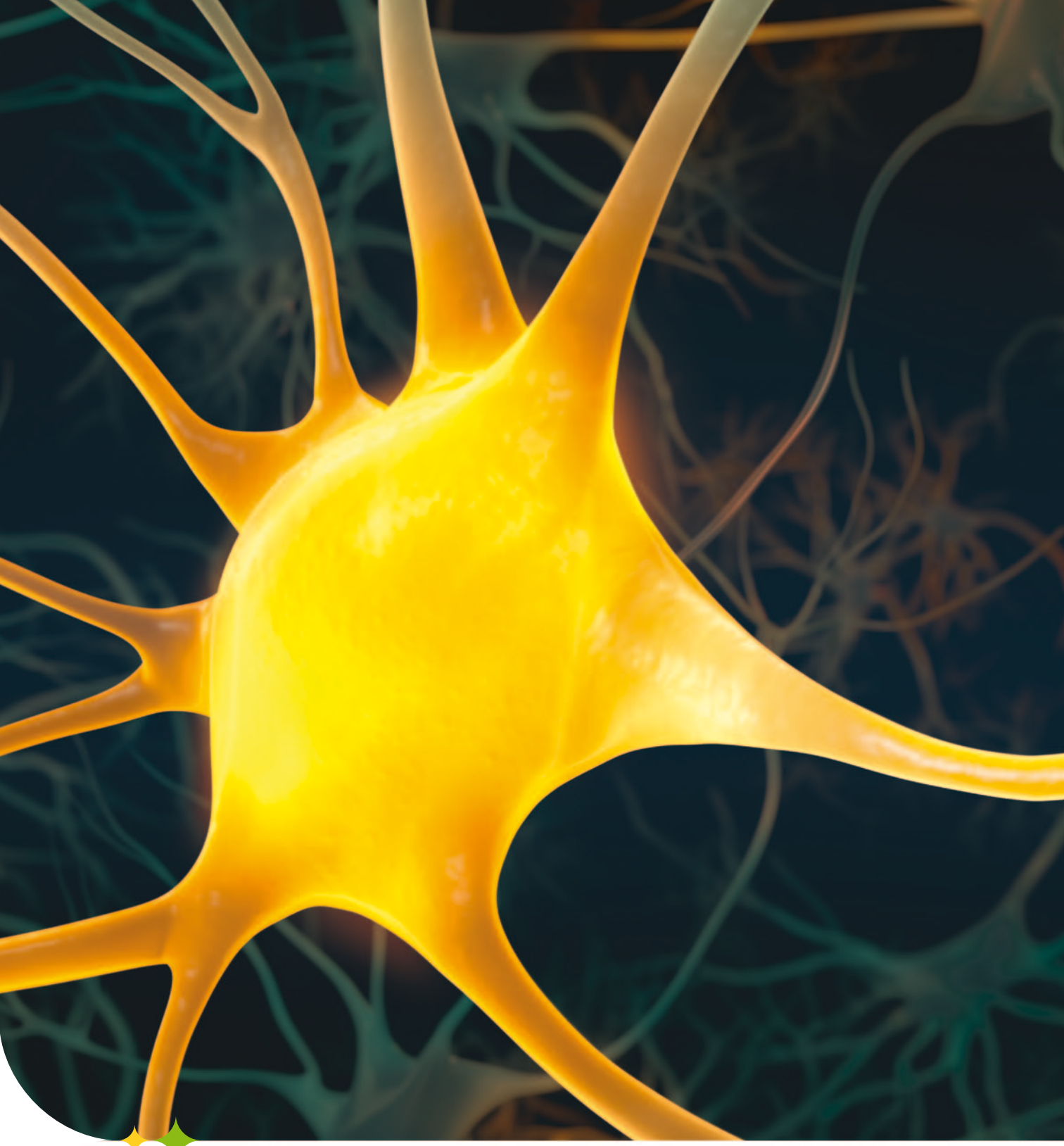
For group visits you do not need to do any exam other than vital signs to code a 99213 or 99214 for established patients as long as you have satisfied the history and level of complexity requirements as indicated above.

Source: www.diabetesmasterclinician.org

ground for cautious optimism regarding improvements to diabetes care. Shahady thinks the expansion of Medicaid eligibility and limitations on insurance companies excluding people for pre-existing conditions under the ACA should benefit many of those who have the disease. "I've had many, many patients tell me they can't get insurance because they are diabetic," he says.

Cooke thinks physicians will benefit from payment models that allow them to be compensated for coordinating the care among specialists, such as nephrologists and cardiologists, that patients with diabetes frequently require. "Having that patient cared for in a system that makes it easy to understand what other clinicians are doing and coordinating the care will be good for complex chronic illnesses like diabetes," she says. ◘

@ More information on diabetes care and management is available through the Modern Medicine Resource Center at www.modernmedicine.com/resource-center/diabetes



*Based on a randomized, double-blind, placebo-controlled, 90-day, phase IIb trial.

Axona is a prescription **medical food** intended for the clinical dietary management of the metabolic processes associated with mild to moderate Alzheimer's disease.

Cautions: Axona should be used with caution in patients who are at risk for ketoacidosis, for example, patients with a history of alcohol abuse and poorly controlled diabetics; or those who have a history of inflammation of the gastrointestinal system, metabolic syndrome, and/or renal dysfunction. Axona contains caseinate and whey (dairy), and lecithin (soy).

CONTAINS: MILK AND SOY.

Please see full prescribing information at www.about-axona.com.

References: 1. Henderson ST. Ketone bodies as a therapeutic for Alzheimer's disease. *Neurotherapeutics*. 2008;5(3):470-480. **2.** National Institute on Aging. Alzheimer's disease [fact sheet]. http://www.nia.nih.gov/sites/default/files/alzheimers_disease_fact_sheet_0.pdf. Reprinted September 2012. Accessed December 7, 2012. **3.** Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond)*. 2009;6:31. **4.** Reger MA, Henderson ST, Hale C, et al. Effects of β-hydroxybutyrate on cognition in memory-impaired adults. *Neurobiol Aging*. 2004;25(3):311-314.

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ACOs: Taking aim at the economic impact

by **BETH THOMAS HERTZ,** *Contributing Author*

HIGHLIGHTS

01 More flexibility and control are two driving factors that have spurred the growth of physician-led ACOs this year.

02 Experts are still debating if ACOs represent a "silver bullet" or misfire for runaway healthcare costs, but most agree the ACO trend is changing the dynamics of healthcare delivery.

03 Physicians are experimenting with many different models of funding – from joint ventures to intregrated healthcare systems.

The payer system is changing and physicians face a fundamental choice when it comes to joining an accountable care organization (ACO)—get involved now and influence the outcome, or simply abdicate the role and let hospitals and payers determine the future. ▸▸

▸▸ **THAT'S THE MESSAGE** from Randall Curnow, MD, MBA, chief medical officer of Summit Medical Group based in Tennessee. Summit Medical Group has an ACO, Summit Health Solutions, with more than 35,000 Medicare beneficiaries.

Still, although even nationally recognized Harvard Business School professor Clayton Christensen and others predict the model will ultimately fail, the ACO trend is changing healthcare delivery. And the number of ACOs keeps climbing.

In March 2012, hospital-led ACOs outnumbered those headed by doctors nearly two to one (91 to 45), explains Neil Kirschner, PhD, senior associate of regulatory and insurer affairs for the American College of Physicians (ACP). But with the latest round of ACO approvals from the Centers for Medicare and Medicaid Services (CMS) earlier this year, physician-led organizations pulled ahead of hospitals (202 to 189).

However, while physician-led ACOs are currently the most numerous, they are generally smaller than those run by hospitals. According to CMS, roughly half of all ACOs are physician-led organizations that serve fewer than 10,000 beneficiaries. About 20% of ACOs include community health centers, rural health clinics, and critical access hospitals that serve low-income and rural communities.

WHY PHYSICIAN-LED ACOs CONTINUE TO GROW

"If physicians want to play a role in delivery

Thinkstock/iStockphoto

reform, ACO participation will be a necessity," Curnow says. "A passive ACO philosophy will allow hospitals and payers to dictate the future to physicians."

Another force pushing physicians to form ACOs comes from Medicare, which offers ways to participate that have all the upsides of being in an ACO with no financial risk if they don't achieve savings, says Thomas Merrill, a senior analyst at Leavitt Partners. This lack of risk appeals to physicians wanting to enter the market cautiously, he says.

However, he calls the resulting growth of physician-led ACOs a tricky proposition. "Their numbers seem to be equal to hospital-led groups but Medicare is distorting this. The groups are not equal on a commercial-contract basis," Merrill says.

Many are slowly adding commercial contracts, having used Medicare as a "safe way to get started," he says.

Kirschner agrees that Medicare is providing a "roadmap for the development of ACOs" that eases groups into getting involved without losing money or violating anti-trust laws.

Another factor driving physicians to form ACOs, he says, is that physician-led groups achieve savings differently than ones owned by hospitals. Physician groups work to save money by keeping patients out of the hospital by taking better care of them upfront. Hospital-led ACOs focus on better managing patients once they are admitted.

"Physician groups may have more freedom to work out how to succeed in a shared savings plan than a hospital," Kirschner says.

As some physician groups have experienced success in a Patient-Centered Medical Home model, they have learned the skills that are necessary to succeed as an ACO, he adds.

In fact, the National Committee for Quality Assurance (NCQA) recently launched a program to acknowledge specialty practices that work well with primary care physicians (PCPs). The Patient-Centered Specialty Practice Recognition recognizes specialty practices that successfully coordinate care with PCPs and each other and that meet the goals of providing timely access to care and continuous quality improvement, according to the NCQA website.

The site says the program also addresses reducing the duplication of tests, measuring performance, and improving communication with patients.

A question of accountability?

8 OUT OF 10 PHYSICIANS

believe that patients' unhealthy lifestyles have a major influence on overall healthcare system costs.

Source: Deloitte 2013 Survey of Physicians

IMPACT ON HEALTHCARE COSTS

Merrill says the question of whether ACOs, particularly physician-led ones, will lower health care costs overall is one that is often debated at Leavitt Partners.

"We don't know if the ACO model represents a silver bullet, but they are leading to substantive changes," he says. "We have our doubts that they will lower costs overall but they may slow the growth rates."

One of the greatest changes ACOs represent is a paradigm shift, as providers realize they must provide population-based care, he says.

"They can't just work in silos anymore," Merrill says. "They need to collaborate with other parts of the healthcare system and physician-led ACOs may have an advantage as doctors listen best to other doctors. They don't like hospitals telling them what to do."

Kirschner believes that physician-led ACOs may lead to lower costs over time as value-oriented care increases.

"This is a very different type of care delivery," he says. "It requires a transformation of both primary care and the specialty arena. Until those changes occur, savings won't come."

DOES OWNERSHIP MATTER?

While physician-led groups have some attributes on their side, at least one expert says that ownership of an ACO is not the key that

"THERE MUST BE INTERNAL INCENTIVES TO ACHIEVE COST EFFECTIVENESS, QUALITY, AND SERVICE."

BRUCE BAGLEY, MD

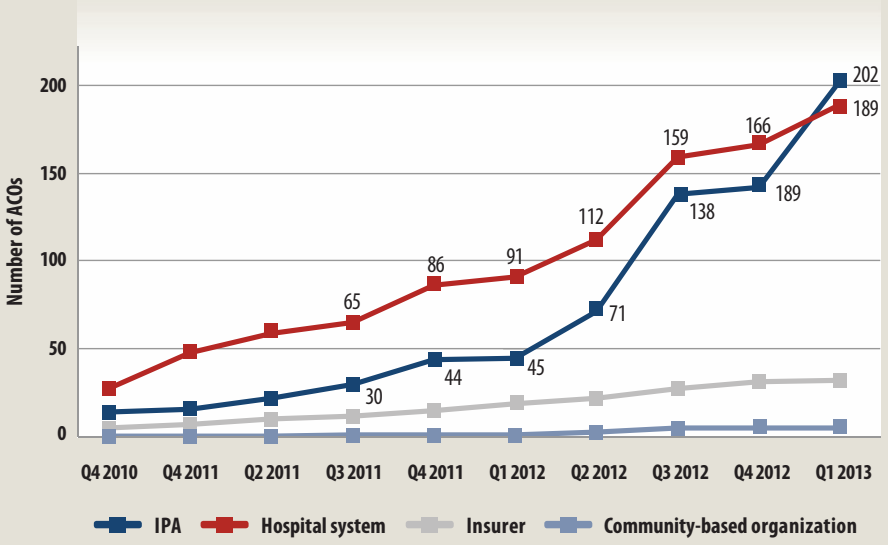
@ More information on ACOs is available through the Modern Medicine Resource Center at www.medicaleconomics.com/ACOresources

DEPENDING ON THE CONTRACTUAL RELATIONSHIP WITH THE PAYER, THE PHYSICIAN MAY BE FREED FROM VARIOUS PRIOR AUTHROIZATION AND SIMILAR ADMINISTRATIVE HASSLES."

NEIL KIRSCHNER, PHD

Accountable care organizations over time

Accountable care organizations (ACOs) have expanded dramatically, more than doubling in number since the start of 2011. Physician groups are now the largest backers of ACOs, with hospital systems a close second.



Source: Leavitt Partners Center for Accountable Care Intelligence

will decide if efficiency goals are realized.

"Physician leadership is not necessarily good or bad. Leadership alone does not dictate the success of an ACO," says Bruce Bagley, MD, interim president and chief executive officer of TransforMED, a subsidiary of the American Academy of Family Physicians (AAFP).

"If an ACO takes a global payment and does not change how resources are distributed internally, it doesn't matter," he says. "There must be internal incentives to achieve cost effectiveness, quality, and service."

Bagley says that the ideal structure may be community-led ACOs. Having representation from the community, hospitals, physicians, and business leaders may lead to the most transparent solutions.

"We need resources to be used wisely overall, not just in one group's interest," he says.

Physicians also need to get away from thinking that health plans and providers must have an adversarial relationship, Bagley adds.

"Some day they will be partners for cost-effective and efficient care that gets the best results for patients. The basic method of payment must change so that there is a shared sense of responsibility for cost, quality, and service," he says. ACOs must be set up for the right reasons, Bagley adds. They must have strong organizational integrity, optimize outcomes, and be patient-centered.

CHALLENGES UNIQUE TO PHYSICIAN-LED ACOS

Starting any ACO requires a large base of PCPs, solid information technology, and the administrative infrastructure to manage patients more robustly than ever, says Curnow.

Physician-led ACOs may have the access to PCPs, but the other two can be problematic, he says. These groups may lack the financial means and the historical experience with managing patients in a population-based manner that are required to succeed.

The start-up costs will vary greatly for each group, Merrill says, but it can be millions of dollars for larger ones. Less will be spent, and it will be spent differently, for smaller ones, he says.

Other obstacles faced by physicians looking to form an ACO include having to create higher levels of collaboration, with both PCPs and specialists, than they are used to.

"Physicians have seldom demonstrated the ability to effectively organize themselves into groups, agree

➔34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INVOKANA™ is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA™.
- Severe renal impairment (eGFR <30 mL/min/1.73 m^2), end stage renal disease, or patients on dialysis.

WARNINGS and PRECAUTIONS

- **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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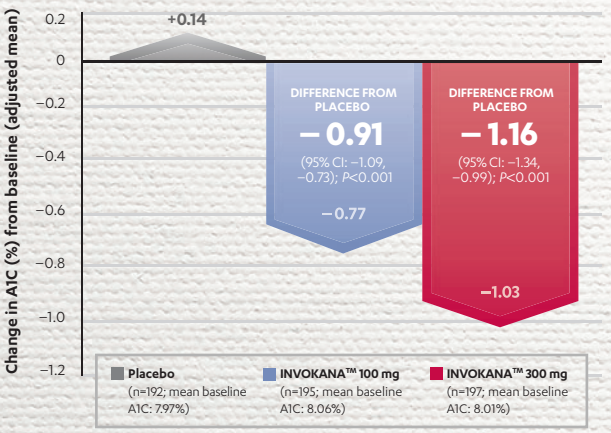
A1C Reductions as Monotherapy

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

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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
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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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]*.

INVOKANA™ (canagliflozin) tablets

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, e.g., 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.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms *[see Warnings and Precautions]*. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients that vaginal yeast infection may occur and provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Genital Mycotic Infections in Males (e.g., Balanitis or Balanoposthitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) may occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of balanitis and balanoposthitis (rash or redness of the glans or foreskin of the penis). Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Hypersensitivity Reactions: Inform patients that serious hypersensitivity reactions such as urticaria and rash have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction or angioedema, and to take no more drug until they have consulted prescribing physicians.

Urinary Tract Infections: Inform patients of the potential for urinary tract infections. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur.

Active ingredient made in Belgium

Finished product manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Licensed from Mitsubishi Tanabe Pharma Corporation

10282400

K02CAN13080B

janssen

(Even) more MedEc

SEE WHAT YOU MAY HAVE BEEN MISSING IN OUR ENEWSLETTER

Price often outweighs patient loyalty

DO your patients like you enough as a physician to pay more? Would they switch physicians to save money on their health plan?

A recent HealthPocket survey revealed that 34% of patients polled would rather reduce their health plan costs than keep their current physician. Among those patients, more than half said they would switch doctors for $500 to $1,000 saved per year. Another 8% would hold out for $1,000 to $2,000 in annual savings, whereas a mere 7.5% say they would only switch physicians if they would save $3,000 or more annually.

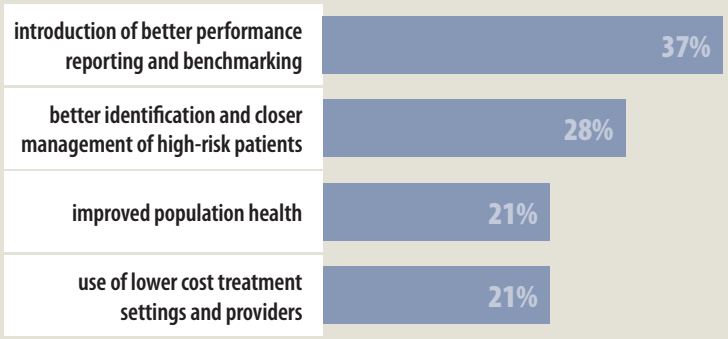
The good news is that 40% of survey respondents said they would not change their doctor, no matter what the savings.

"Our poll found that while some consumers feel strongly about keeping their current physician, many others are surprisingly open to moving around based on cost," says Steve Zaleznick, executive director for consumer strategy and development at HealthPocket. "Regardless of what happens with the [Affordable Care Act] in terms of healthcare premiums, consumers will need to investigate their options to find ways to save money and determine whether their current doctor will still be covered under the plan they want."

Assessing the ACO impact

The majority of physicians report that accountable care organizations (ACOs) will have some success at improving healthcare quality overall.

The Deloitte 2013 Survey of Physicians asked physicians about the impact of ACOs:

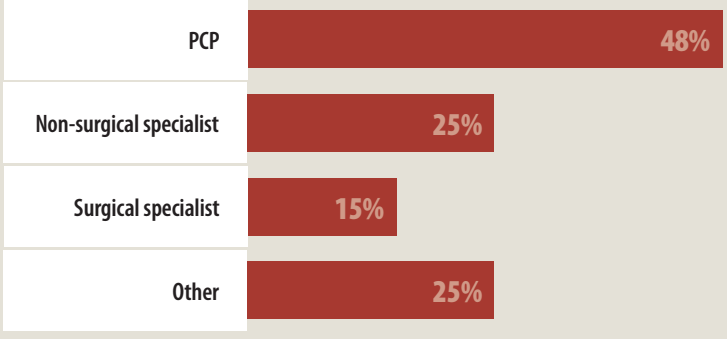


Source: Deloitte 2013 Survey of Physicians

Familiarity with ACOs & Patient-Centered Medical Homes

77% the number of physicians familiar with ACOs and Patient-Centered Medical Homes, a 27% increase from 2011.

BY MEDICAL SPECIALTY



Source: Deloitte 2013 Survey of Physicians

➔32 on clinical guidelines, and devise ways to equitably distribute money," Curnow says.

Having professional administration in place to support such necessary functions is a key first step, Curnow says, as is becoming a patient-centered medical home.

A QUESTION OF AUTONOMY?

No doubt at least some physicians are seeking to form ACOs out of a desire to have greater autonomy in their work. However, Bagley believes that many of them will find that autonomy is an impediment to success.

"Physicians should have clear decision-making authority over diagnostic and therapeutic matters (but) that does not mean that everyone just does what they want. Physicians have to agree on best practices, using systems like the electronic health record registries, e-prescribing, and generic drug use. They must standardize treatment to the degree that it is possible," he says.

"Autonomy may be the ultimate cultural issue that will make this transition difficult."

Kirschner also sees physician autonomy as a difficult concept.

"Depending on the contractual relationship with the payer, the physician may be freed from various prior authorization and similar administrative hassles. On the other hand, the ACO environment encourages the development of shared treatment protocols that generally must be followed by the participating providers," he says. "These protocols are typically developed by the participating providers and aim to improve efficiency and increase quality and patient safety." It is unclear if physician-led ACOs have more or less leverage in negotiating with third-party payers and hospitals. Variables such as existing competition will matter more than ACO ownership, experts say.

However, Kirschner says physicians in a physician-led ACO will likely have a greater say in issues such as how care is delivered and revenue shared, and the nature of the contract with the payer, than in an ACO dominated by a hospital.

HOW THIS DIFFERS FROM CAPITATION

Some physicians are wary of forming or joining ACOs because they remember the failed efforts at capitation that occurred 2 decades ago. Curnow stresses, however, that ACOs are diffent beasts.

"We have so much more technology and resources available to us today to pursue population management," he says. "Also, ACOs emphasize the importance of quality standards. Access to shared savings only comes through the creation of quality metrics, and patient satisfaction is part of that. This is not just about trimming costs."

With capitation, patients were often stuck in a plan. With ACOs, if they are not happy with the care they are receiving, they can go elsewhere. This makes ACOs more sustainable and valuable, he says.

FINANCIAL MODELS

Many models of funding are being tried for physician-led ACOs, Curnow says. Some are physician-owned, some are joint ventures with capital partners, and others are integrated systems with primary care as well as specialist ownership.

The typical economic model will be that patients are assigned to an ACO based on their PCP. A benchmark budget will be established, most likely based on recent years' expenditures, and the ACO will need to provide the resources to generate value.

"Fee-for-service is not going anywhere anytime soon. There will always be room for it," he says. "But more and more money will begin to be tied to performance."

Kirschner says financial arrangements will vary, depending on the model that is being used by the ACO. For example, are most participants employees of the larger entity or are they independent providers participating under the ACO umbrella?

"One relatively common sharing arrangement consists of a combination of a portion of the shared revenue shared equally, a second portion based on the productivity of the provider (for example, relative value units produced), and a third portion based on quality measures," he says.

Bagley agrees that there are no fixed rules yet, but says that generally the global payment received by the ACO will be distributed in proportion to the value contributed by each component.

"Each component (such as primary care, specialty care, hospital, imaging, lab etc.) would have to demonstrate its contribution to the effectiveness and efficiency of the overall enterprise. If they are distributed in the same way they are now, then nothing will happen regarding the cost escalation," he says.

With commercial payers, ACO contracts generally still resemble fee-for-service arrangements but offer incentives for achieving savings, Merrill adds.

"Most ACOs are built on a fee-for-service chassis," he says. "At the end of the year, they reconcile how much has been saved and bonuses are paid accordingly."

If done right, this can be a significant amount of money, according to Kirschner. Adding longer office hours and a 24-hour triage phone service with access to patient records alone can avoid many costly hospitalizations.

WILL PHYSICIAN-LED ACOs LAST?

As for the question of whether physician-led ACOs are sustainable, Curnow says they show immense promise.

"They let physicians advocate for the needs of patients, especially if the reimbursement model changes to diminish volume-based payments," he says. "Physician-led groups can be strong, effective advocates for their patients in a way that creates satisfaction, quality, and access. They can yield higher satisfaction for physicians and patients while lowering costs."

Merrill says, however, that the system of no-risk ACOs is probably not sustainable in the long term. "It is more of a transition and will likely lead to a more shared model of risk in the future," he says.

"The path may not be easy," Curnow says. "A lot of the things we need, such as better EHR technology, are hard to come by," he says. "It will take time and patience."

But he encourages physicians not to be dissuaded. "We all need to come to terms with the fact that things are changing and remember why we are doing it," he says. "Develop a concrete, transparent plan to get there. It may be a messy transition getting off the hamster wheel of fee for service, but it is worth it, for doctors, for patients, and for society."

Changing Patient Behaviors

The success of any accountable care organization (ACO) requires actively engaging patients in their own care. By working together, physicians and patients can achieve more transparency, coordination of care, and accountability, says Randall Curnow, MD, MBA, chief medical officer of Summit Medical Group in Tennessee.

Patients want to be educated about their health and about the most efficient ways to access quality care, he says. They do not want to end up in the Emergency Department any more than you want them there.

"Teach them how to make their lives better," he says. "They want a more efficient system too."

Bruce Bagley, MD, interim president and CEO of TransforMED, a subsidiary of the American Academy of Family Physicians, stresses that physicians need to not only engage patients, but also their families and caregivers.

Primary care physicians should use techniques including motivational interviewing, setting shared goals, and offering alternative ways to help patients improve their health, such as participating in a support group or utilizing home monitoring.

"We cannot just give them a prescription and tell them to come back in 6 months," Bagley says. "If we put more effort into lowering BMI instead of just managing medications, it would really pay off."

Neil Kirschner, PhD, senior associate of regulatory and insurer affairs for the American College of Physicians, says ACOs may need to hire care coordinators to follow up with patients about how they are doing with healthy initiatives, such as eating better, exercising more, or stopping smoking, but they need to tread gently.

"You don't ever want to become punitive with patients," he says. "They may not be able to make all of the changes you are asking of them and pushing too hard can be a lose-lose."

PCMH: A closer look at a trend changing healthcare delivery

While the model could reinvent primary care, little is known about the impact on independent practices

by **GAIL GARFINKEL WEISS**

HIGHLIGHTS

01 The advantages of a PCMH can be financial, experts say. In fact, a PCMH practitioner can earn an additional $12,000 to $15,000 a year, depending on the size of the patient panel.

02 While it has been well documented that the goals of a PCMH are to save money in healthcare expenditures long term, the model is built on offering coordinated care and chronic disease management to improve quality of care.

The Patient-Centered Medical Home (PCMH) holds great hope for primary care physicians in improving care and reaping rewards from a value-based reimbursement model. But it will also require seismic changes in the way most practices operate.

According to family physician Conrad Flick, MD, the biggest change when his Raleigh, North Carolina, practice became a PCMH was that roles and tasks for clinical and clerical staff were more clearly defined. "The PCMH expectation is that we are responsible for providing the best care we can as a team, not as a group of individual providers," says Flick.

Adopting the PCMH model also prompted Flick and his colleagues to communicate with patients in a more organized fashion. "Quality care is a two-way conversation between patient and provider," Flick adds.

Indeed, becoming a PCMH requires going from episodic patient care to continuously accessible communication and care, explains Joseph E. Scherger, MD, a family physician in La Quinta, California, and a *Medical Economics* editorial consultant. This means fewer but longer office visits—about 10 or 12 per day for most practices, according to Scherger—as well as increased online contact with patients.

THE PATIENT-CENTERED APPROACH

Jeffrey J. Cain, MD, a family physician in Denver, Colorado, and president of the American Academy of Family Physicians, sees numerous pluses in the PCMH model. "The PCMH helps achieve the triple aim of improved quality and outcomes, and reduces costs while helping to increase physician satisfaction," he says.

In establishing a PCMH, Fred Ralston, Jr., MD, an internist in Fayetteville, Tennessee, and past president of the American College of Physicians, says that his practice, in effect, "set up a process of continuous quality improvement without the level of pain I would have expected. It is very refresh-

ing to have others working with you in a team-based approach to reach common goals."

For some PCMHs, the advantages are financial as well as professional. Payers are finding that PCMH practices help patients avoid unnecessary trips to the hospital, says Peggy Reineking, director of clinician recognition programs for the National Committee for Quality Assurance, one of the key organizations that certify PCMHs. According to Reineking, savings are also realized when PCMHs reconcile medications to avoid errors, tests are coordinated to avoid duplication, and referrals to other clinicians are synchronized to reduce the likelihood of conflicting care plans.

For these and other reasons, payers—both public and private—are offering monetary incentives to practices that become PCMHs. Cain notes that the Centers for Medicare and Medicaid Services (CMS) is taking the lead with the Comprehensive Primary Care Initiative, in which private payers join with Medicare and Medicaid to offer practices enhanced payment for effectively providing patient-centered care. "This is part of a movement to shift payment from volume—that is, fee for service—to quality," says Cain, whose practice has achieved PCMH recognition.

Independent of CMS, some commercial payers, including Blue Cross Blue Shield, provide financial rewards to physicians who successfully establish PCMHs. Blue Cross Blue Shield of Tennessee, for instance, launched its patient-centered medical home program in 2008. "We began with a small pilot and now work with 30 physician groups across Tennessee," says Kevin N. Raynor, the company's senior project manager.

Like other payers that endorse the medical home model, Blue Cross Blue Shield of Tennessee (BCBST) monitors the performance of its PCMH participants. "We've seen tremendous improvements in quality of care that we expect will, over time, reduce emergency room visits and inpatient admissions," says Raynor.

Are you ready to deliver patient-centered care?

The American Academy of Family Practitioners offers this checklist:

Do you have processes to ensure patients' access to care?

- ☐ Same-day appointments
- ☐ Extended hours for access to care
- ☐ Physician access to the medical chart 24/7 to inform care decisions
- ☐ Ability for patients to select their own physician
- ☐ Utilization of secure e-mail for communication with patients
- ☐ Web protal for patients to request Rx refills, schedule appointments, etc.
- ☐ Procedures to accommodate patients' barriers to care (including transportation, physical, and cognitive barriers)
- ☐ Linguistically and culturally appropriate services

Do you engage patients in shared decision making?

- ☐ Discuss treatment options in an unbiased way
- ☐ Consider patients' health goals and priorities
- ☐ Provide patients with condition-specific decision aids
- ☐ Have decision-making discussions with patients after they have reviewed decision aids
- ☐ Record patient preferences and ensure follow through on decisions

Does your practice support patient self-management?

- ☐ Assess patient and caregiver self-management abilities
- ☐ Utilize motivational interviewing to coach patients
- ☐ Consider home monitoring of patients' chronic conditions
- ☐ Engage family and caregivers in care plans
- ☐ Offer health coach support

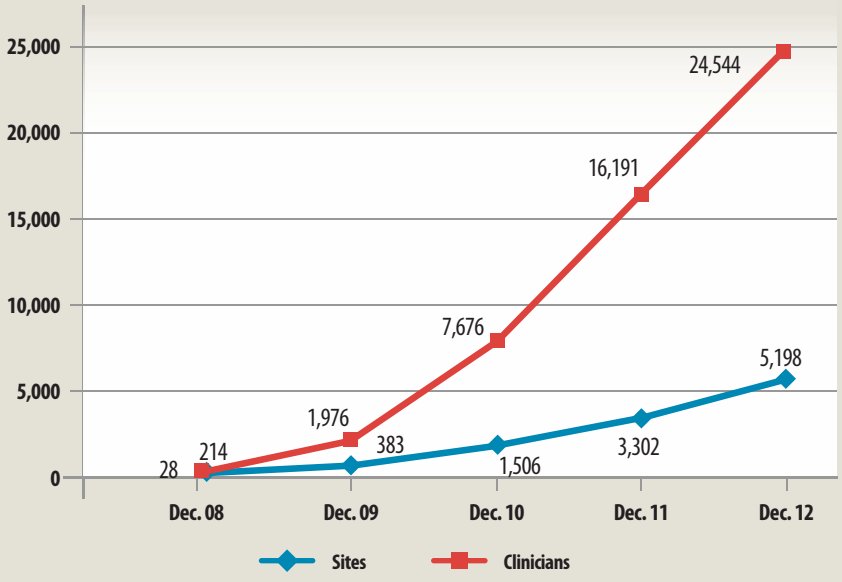
Do you assess and improve your patients' experience of care?

- ☐ Conduct patient satisfaction surveys on a regular basis
- ☐ Establish a patient adivosry panel to guide practice and quality improvement
- ☐ Conduct patient focus groups when needed

Soure: American Academy of Family Physicians

HEALTH POLICY ANALYSTS SAY THAT PRACTICES THAT HAVE ACHIEVED PCMH RECOGNITION WILL BE MUCH BETTER PREPARED THAN THEIR COUNTERPARTS TO PARTICIPATE IN ACCOUNTABLE CARE ORGANIZATIONS.

Primary Care Transformation to PCMH*



*Clinicians and practice sites across the country that earned National Committee for Qualit Assurance (NCQA) PCMH recognition.

Source: NCQA

BCBST's "performance bonus model" enables physicians to earn extra dollars based on defined performance metrics. "Our measures are HEDIS-based (see "Defining and Measuring Success" below) and are applied to six chronic conditions—diabetes, asthma, coronary artery disease, congestive heart failure, hypertension, and COPD," says Raynor, who adds that a PCMH practitioner can earn an additional $12,000 to $15,000 annually, depending on patient panel size. "Performance targets are set for each measure," he says. "We intend to move to outcome-based measures as the program matures."

Where insurers won't pay, patients might. "In California, with so much capitated managed care, insurance payers have not been providing PCMH care coordination payments," says Scherger. Instead, the patients in Scherger's practice who want to participate in the PCMH pay an annual membership fee that provides them with unlimited online communication directly to their doctor, longer visits, and better care coordination.

In addition, health policy analysts have stated that practices that have achieved PCMH recognition will be much better prepared than their counterparts to participate in accountable care organizations (ACOs). Much like a PCMH, an ACO is defined on www.healthcare.gov, a Web site managed by the U.S. Department of Health & Human Services, as "a group of healthcare providers who give coordinated care, chronic disease management, and thereby improve the quality of care patients get." In accordance with the Patient Protection and Affordable Care Act of 2010, payment for ACOs is tied to achieving healthcare quality goals and outcomes that result in cost savings.

TIME, RESOURCES AND REIMBURSEMENTS

When it comes to reimbursements and bonuses, there are ➔43

Resources to help you evaluate becoming a PCMH

Many physicians are so busy practicing that they don't step off the treadmill and give time to research and prepare for change, says Judy Capko, a practice management consultant in Thousand Oaks, California.But there are many resources to help physicians navigate the conversion into a PCMH.

SOME SOURCES INCLUDE:

MedicalEconomics.com/PCMHresources

Medical Group Management Association (www.mgma.com)

Physician Office Managers Association of America (www.pomaa.net)

The American Academy of Family Physicians' Web site, for one, features guidelines on recognition, and information on organizational, technological, and other aspects of the PCMH (www.aafp.org/online/en/home/membership/initiatives/pcmh.html).

The National Committee for Quality Assurance's many PCMH-related online resources include a brochure, "A New Model of Care Delivery: How Patient Centered Medical Homes Enhance Primary Care Practices" (www.ncqa.org/Portals/0/PCMH%20brochure-web.pdf), that outlines the organization's PCMC recognition standards.

The Patient-Centered Primary Care Collaborative, www.pcpcc.net, is a coalition of organizations, physicians, patient advocates, health plans, and hospitals that have joined forces to encourage primary care practices to implement the PCMH model. The site has information about the history of PCMHs and instructions on how to transform your practice into a medical home. The site also features a film that explains the PCMH to patients.

Delta-Exchange, www.transformed.com/delta-exchange/, features online seminars and articles on how to attain PCMH recognition, as well as blogs and discussions about the challenges of PCMH transformation.

The American College of Physicians' online PCMH resources (http://www.acponline.org/running_practice/delivery_and_payment_models/pcmh) include **articles** titled "Understanding the PCMH," "Costs, Benefits, and Incentives," and "PCMH in Action." Another ACP online tool, **Medical Home Builder** (www.medicalhomebuilder.org), offers guidance on the medical home model that is customized for each practice, as well as assessments of multiple components of the model. "Many doctors, particularly those of us in primary care, have seen a variety of fads in medicine come and go," says Fred Ralston, Jr., an internist in Fayetteville, Tennessee, and past president of the American College of Physicians. "The ACP has featured the medical home in meetings and publications and linked it to real world practice. This validation from a trusted source makes many doctors more willing to take a look."

"The ACP has featured the medical home in meetings and publications and linked it to real world practice. This validation from a trusted source makes many doctors more willing to take a look."

➔40 still a host of unanswered questions.

"At this point," says Flick, "many insurers in the area where I work want what PCMH practices have to offer. But few are providing any increased payment or different payment structures to assist practices in transformation or help them maintain the process once initiated."

Moreover, becoming a PCMH takes work, Cain acknowledges. "It can be very challenging for a busy primary care practices to transform into a PCMH, and there are often up-front costs," he says. These expenses may include the purchase and implementation of an electronic health record, conducting patient satisfaction surveys, and training staff to engage in team-based care and support patients in self-managing their health."

Cain continues, "Negotiating the vary-

ing expectations and requirements of multiple payers can create difficulties for new PCMHs. It takes time and can even hinder productivity initially when practices are working out the kinks as they re-engineer processes and the way they do business."

There is a commitment of staff time and financial resources, and Flick says that a return on investment is not assured.

"Our government and payers seem to agree that developing a PCMH is the right thing to do," he says. "What we lack, however, is reliable data about how the transformation will affect practices—especially independent practices—financially. Will it allow them to expand services and coverage, or will it be a financial burden? As the accrediting organizations' standards and regulations increase, the cost of doing business also increases—with no guarantee that payments will increase to cover the additional expenses. That said, we still believe it is the right thing to do for our patients and our community."

DEFINING AND MEASURING SUCCESS

The success of a PCMH in meeting its chief goals—in particular, improving patient health via coordination of care—is commonly gauged by using the National Committee for Quality Assurance's Healthcare Effectiveness Data and Information Set (HEDIS). "There are national benchmarks for these HEDIS criteria and they allow for PCMH practices to be compared with other groups," says Scherger.

Among the areas looked at:

- Percentage of patients receiving certain preventive services, such as mammography, colonoscopy, and other cancer screenings.
- Percentage of patients with chronic diseases—including diabetes, hypertension, hyperlipidemia, asthma, and heart failure—in good control. For example, how well controlled are diabetic patients' sugars? Are patients who have diabetes getting annual eye and foot exams?
- Percentage of patients age 65 and older who received a pneumococcal vaccination.
- Percentage of patients age 18 and older who were queried about tobacco use and who received cessation intervention.

Nonclinical evaluation measures include:

- Extent to which physicians provide continuous care.
- Extent to which physicians coordinate care with other clinicians.
- Use of information technology to enhance patient care, communication, and education.
- Patient satisfaction scores.

Because PCMHs are about providing high-quality and efficient patient care—the right care at the right time in the right place—you must prove this through electronic documentation, Flick says. Benchmarks need to be agreed upon and then met. "It is no longer sufficient to 'feel' like we are doing a great job with our patients; we need to able to show we are making a difference and that the processes we put in place change our metrics for the better. It is not enough to say we saw X number of diabetics with decreased hemoglobin A1cS in the last couple of weeks. The question has now become: 'What does your data from the last two years show?' And then we must constantly update our benchmarks to continuously improve."

PCMH'S IMPACT

Video archives

In this video, Robert Gabbay, MD, PhD of the Penn State Hershey Medical Center talks about the PCMH and its impact on primary care delivery. Go to MedicalEconomics.com/PCMHresources.

Visit www.MedicalEconomics.com/PCMHresources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Can care coordinators answer access problems predicted for primary care?

By reducing no-shows, they may help your bottom line while helping you improve the health of patients

by **MATT BOLCH**

HIGHLIGHTS

01 Care coordinators can help raise patient awareness of the importance of managing chronic conditions, a critical consideration as emerging care models have physicians and others assuming more financial risk.

02 The ultimate goal of such programs is to find the shortest path to the best care for the neediest patients, reducing waste in the healthcare system.

As more people become eligible for healthcare under the Affordable Care Act, the question of access will become paramount.

Missed appointments can have a three-fold negative effect, hitting provider revenue, affecting the health of patients who miss appointments, and limiting access for other patients who could have filled missed slots.

"We're a self-serve society, but it doesn't translate to healthcare," says Lynne McCabe, director of the community care coordination program at Mercy Health in Cincinnati, Ohio. "Patients need someone to help them navigate."

Fortunately, a handful of studies and pilots show promise for the personal touch to not only help patients make appointments but also to raise awareness of the importance of managing chronic conditions to improve overall health. The latter is a critical consideration as physicians and other healthcare professionals as well as payers assume more financial risk in accountable care organizations, Patient-Centered Medical Homes (PCMHs), and other emerging care models.

REMINDER CALLS WORK

A study published in the *American Journal of Medicine* in 2010 showed a correlation between reminder calls and fewer missed appointments. Nearly one in four patients at an outpatient multispecialty clinic who did not receive a reminder call missed an appointment. That number was reduced to 17.3%

➔48

"WE'RE A SELF-SERVE SOCIETY, BUT IT DOESN'T TRANSLATE TO HEALTHCARE. PATIENTS NEED SOMEONE TO HELP THEM NAVIGATE."

LYNNE McCABE, DIRECTOR, COMMUNITY CARE COORDINATION PROGRAM, MERCY HEALTHCARE

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"PATIENTS WILL NOT BE THE ONLY ONES WHO BENEFIT.... BUT THE BENEFIT HAS TO BE AT THE INDIVIDUAL LEVEL."

YVONNE COOK, PRESIDENT, HIGHMARK FOUNDATION

➔46 through the use of automated calling and 13.6% when a real person made the call.

The job titles and descriptions vary widely, but many large practice groups, health systems, payers, and others are looking to embed patient navigators or care coordinators at the point of care. These people help guide patients through the care delivery process, resulting in fewer missed appointments, more effective use of healthcare services, and lower overall claims.

A recent year-long pilot at MetroHealth Cancer Care Center in Cleveland, Ohio, for example, resulted in a dramatic improvement in the patient no-show rate through the use of two full-time navigators. In just 3 months, the reduction in no-shows for those receiving radiation therapy equaled a navigator's yearly salary.

Accenture, the global management consulting firm, helped fund the Cleveland pilot and recently signed on to provide pro bono support for a program from the Highmark Foundation to implement patient navigator programs at three rural western Pennsylvania hospitals. The foundation has committed $254,500 to fund two patient navigators each at Allegheny Valley Hospital, St. Vincent Health System and Jameson Health System.

Goals of the program include increasing access to care, improving outcomes, saving money, and developing the workforce, says Yvonne Cook, president of the Highmark Foundation.

"We're looking for significant return on investment," Cook says, citing the Cleveland pilot. "Patients will not be the only ones who benefit. Hospitals will, too, because of lower costs. But the benefit has to be at the individual level."

Mercy Health is expanding its navigator program after a pilot program brought a return of $5 for every $1 spent, McCabe says. The system's 1-year pilot, which ended in May 2012, brought hospital admissions among the high-risk pool down by one-half. Readmissions were cut by one-third, with a similar reduction in emergency department visits.

The system is in the midst of certifying its 35 primary care offices as PCMHs, and the 30 case managers either on the payroll or part of the expansion will become part of the staff at each facility. Some case managers worked at multiple practices with an ideal maximum patient load of 150.

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Visit http://bit.ly/Yzmck8

MINIMIZE PATIENT EFFORT

McCabe says the pilot showed that a personal touch with high-risk patients means that patients are more connected to their care. Each patient is contacted at least once a month, with the most at-risk patients being contacted as often as three times a week. Having a single point of contact means that medication reviews, referrals and other healthcare needs can be met with a minimum of effort on the patient's part.

And that's the ultimate goal: finding the shortest path to the best care for the neediest patients.

Nurses and social workers who play a navigator-type role will be critical in the near future as more people gain coverage through Medicaid expansion and insurance exchanges. A majority of the new enrollees will be previously uninsured people who could be unfamiliar with the healthcare delivery system.

In addition, certain areas of the country could experience physician shortages, longer patient wait times, and delays in securing appointments. Reducing no-shows could help avoid unnecessary waste.

Best practices for employee handbooks

Outline the practice's policies and legal obligations first, experts say

by **RACHAEL ZIMLICH**, *Associate Editor*

HIGHLIGHTS

01 Very few items are required to be contained in an employee handbook. The shorter your handbook, the less the likelihood that an error will occur.

02 Make sure what actually happens in your practice is reflected in your handbook—or change the handbook to match actual practices.

03 Policies must be consistently applied across all employees, regardless of what is stated in the handbook.

While employee handbooks serve a very important role, keep them simple and to-the-point, and outline the practice's most salient expectations and legal obligations when creating them, experts say.

"Some people treat a handbook like *The Grapes of Wrath*. It shouldn't be a novel," says labor relations attorney Kristin Erenburg, JD, of Walter Haverfield in Cleveland, Ohio. "A handbook should state the policies that apply to the employees, and that's it. It's surprising how few things are actually required."

A handbook should offer an overview of an employer's expectations and legal obligations, an employees' rights, and it also should describe what an employee can expect from his or her employment with the company. The more detail included, she says, the more changes and addendums will be required as benefits change. And if an employer does not make those updates, Erenburg says, the practice leadership can get into trouble by not following the practice's own policies.

She also recommends keeping "legalese" out of a handbook.

WHAT TO INCLUDE

So what should an employee handbook contain? Lori Christenson, PHR, human resources coordinator for Clayton L. Scroggins Associates, a management consulting agency for doctors, says she generally suggests including:

- a general disclaimer;
- a statement of the business' goals and missions;
- appropriate employee definitions;
- a description of the company work week;
- sexual harassment, disability, and medical leave policies;
- a statement of employee benefits; and
- an outline of the company's discipline policies.

Erenburg's recommended handbook checklist includes:

- an at-will statement explaining the nature of the employment relationship and how it could be changed,
- a statement that the handbook is general guidance and that it can be changed at the discretion of the employer and without prior written notice, and
- statements about equal employment and non-discrimination policies.

Erenburg adds that employers also should include information about:

- family medical, jury duty, and military leave; and
- vacation, holiday, bereavement, sick leave, or other paid time-off policies.

Other crucial inclusions for a handbook, she says:

- workplace conduct standards, including policies on workplace violence, anti-harassment, and dress codes;
- employment classifications;
- employee benefits;
- payment schedules and information

on timesheets or timekeeping requirements;
- work hours;
- attendance;
- absences,
- reporting late or leaving early;
- policies on information security and personal safety;
- guidelines on the appropriate use of technology; and
- standards for employee breaks.

WHAT TO EXCLUDE

Omit verbiage related to salaries or payment rates, because this kind of information could be misconstrued as a contract and could cancel out any at-will disclaimers, Erenburg says.

Employers should remember that in litigation, any statements made in a handbook—even ones made with the best intentions—could come back to haunt them, Erenburg says.

"You really want to keep things short and sweet in a handbook," she says.

PUTTING IT TOGETHER

Although guidelines are helpful, Erenburg advises that employers consult an attorney who specializes in staying up-to-date on labor laws before drafting a handbook. Admitting that this advice sounds self-serving, she says that this step is critical because handbooks are not a "one-size-fits-all" product.

Local governments and states also may have laws that apply to handbooks, so check with them as well before starting the process, she adds.

Once it is created, a handbook should be distributed to employees at the time of hire, Erenburg says, and the employer should have each employee sign a paper document acknowledging receipt. That goes for updates, too. All but three states have laws on the books that permit electronic signatures on documents, but Erenburg says that a hard-copy document is still the best bet.

➔54

Optional items

Items that can, but do not have to be, included in employee handbooks, according to Kristin Erenburg, JD, of Walter Haverfield in Cleveland, Ohio, are policies on:

performance reviews,

extended leaves of absence that are not covered by Family Medical Leave Act,

payroll deductions,

how to report and resolve workplace conflicts,

employee referrals,

job postings, and

employer references.

Lori Christenson, PHR, human resources coordinator for Clayton L. Scroggins Associates, a management consulting agency for physicians, says she also advises that a policy allowing nursing mothers time to express their milk be included. Although not a requirement, she says employed nursing mothers need such a policy, and an employer could face legal action without one.

Christenson also recommends policies prohibiting firearms and smoking in the workplace.

Finally, she says that it is important to address employee relationships, especially in medical practices. Given the small size of most doctors' offices, Chistenson says, office relationships can be tricky situations to manage.

"Of course, we discourage [employee relationships], but if people have them, there should be guidelines on how they need to take measures not to impact other people at work," she says.

The employee perspective

If you are a newly hired employee, you can do little if you see something in a handbook that you simply do not like, according to labor relations attorney Kristin Erenburg, JD, of Walter Haverfield in Cleveland, Ohio.

"Employers can put whatever they want in these handbooks, and if you don it like it, you don't have to work there," she adds. "Right now, nine times out of 10, someone is so grateful to have landed a job, even if there's something they don't like, they hope the company doesn't really mean it or enforce it."

It is another matter when an employee sees something in a handbook that violates his or her rights, however. In that case, Erenburg says, it is up to the individual to decide whether he or she wants to work at the company. The applicant or employee then can report the violation to the National Labor Relations Board or the Equal Employment Opportunity Commission, the agencies that would investigate the matter.

Both agencies are very active right now, making it even more important that employers stay up-to-date on policies and requirements, Erenburg says.

LOOKING FOR MORE ON WORKPLACE POLICIES?

Go to MedicalEconomics.com and simply enter Human+Resources in the search field. Some related stories include:

The workplace policies that could make or break you
(*Medical Economics*, March 10, 2013)

The National Labor Relations Board sample social media policy
(*Medical Economics*, March 10, 2013)

Prevent toxic employees from poisoning your practice
(*Medical Economics*, Dec. 25, 2012)

Diminished cerebral glucose metabolism: A key pathology in Alzheimer's disease

More than three decades of research have revealed that diminished cerebral glucose metabolism (DCGM), also known as glucose hypometabolism, is a key underlying pathological change in the Alzheimer's brain.[1] DCGM leaves a large portion of the brain's energy needs unfulfilled and correlates with cell death and cognitive dysfunction.[2] DCGM occurs years before clinical symptoms of cognitive decline become evident.[1] Targeting DCGM represents a promising new therapeutic strategy for patients with Alzheimer's disease (AD).

The brain depends on glucose for cognitive function

The human brain is one of the most metabolically active organs in the body and metabolizes a large amount of glucose to produce adenosine triphosphate (ATP).[1] Despite its high energy demands, the brain is relatively inflexible in its ability to utilize substrates for energy production and relies almost entirely on circulating glucose for its energy needs.[1,2] This dependence on glucose puts the brain at risk if the supply of glucose is interrupted, or if its ability to metabolize glucose becomes defective.[2] If the brain is not able to produce ATP, synapses cannot be maintained and cells cannot function, ultimately leading to impaired cognition.[2]

DCGM is a well-characterized feature of AD

DCGM was an early observation in AD. Studies from almost 30 years ago found a 17%-24% decline in cerebral glucose metabolism in patients with AD, compared with age-matched controls.[3] Numerous imaging studies have since confirmed this observation.[1]

Abnormally low rates of cerebral glucose metabolism are found in a characteristic pattern in the AD brain, particularly in the posterior cingulate, parietal, temporal, and prefrontal cortices. This pattern is reproducible and has even been proposed as a diagnostic tool for AD.[1]

DCGM occurs early in the disease process

In a pivotal study, Reiman and colleagues demonstrated how early the pathology can begin. The study compared cerebral glucose metabolism in patients with probable AD and young adults (mean age 30.7 years) at high genetic risk of AD (APOE4 carriers). The young adult APOE4 carriers showed no signs of cognitive impairment or plaque deposition, yet DCGM was detected in the same areas of the brain as subjects with AD.[4]

DCGM is not exclusive to APOE4 carriers. By the time Alzheimer's has been diagnosed, DCGM occurs across genotypes APOE3/E4, APOE3/E3, and APOE4/E4.[5]

Given that DCGM occurs before other clinical changes occur, it is unlikely to be due to the gross cell loss observed in AD.[2]

Targeting DCGM in AD

Improving memory performance by chronically raising glucose levels has had some success in animal models and humans. However, this approach is impractical and may not address the problem of DCGM, particularly as glucose levels generally remain normal in AD. This has led to the exploration of alternative fuel sources, such as ketones, to help fuel the brain.[2]

Fueling the brain with ketones in neurodegenerative diseases

During times of diminished cerebral glucose metabolism, the brain is able to use ketones as a back-up fuel source. When glucose levels are low, for example when food is scarce, the liver is naturally triggered to generate ketones as a survival mechanism.[1]

In AD, this natural ketone back-up system can be harnessed to address DCGM. Research has shown that exogenously raising ketone levels is neuroprotective *in vitro* and can enhance memory and cognition *in vivo*.[6-8,10] Indeed, ketogenic diets have a long and successful clinical history. However, they can be impractical, particularly in patients with AD.[2]

Safe elevation of ketone levels

Inducing ketosis through the administration of medium-chain triglycerides (MCTs) has produced promising results in AD. MCTs have unique ketogenic properties due to their medium fatty acid chain lengths. Importantly, MCTs are converted to ketones regardless of other macronutrients consumed; therefore, no dietary restrictions are required.[1]

Now, there is a prescription **medical food** available that safely increases the concentration of ketones. Axona® contains MCTs that are converted to ketones in the liver and then transported to the brain to be used as fuel along with glucose.[9]

Fuel memory and cognition by targeting DCGM in AD

In a phase IIb, 90-day clinical trial, Axona enhanced memory and cognition in APOE4(-) patients with mild to moderate AD. Approximately 80% of trial patients took Axona in combination with one or more approved medications for AD. At the end of the trial period, patients continued with their existing medication, but stopped taking Axona. During this time, the significant effects of Axona ceased.[10]

Axona is the only available prescription therapy that addresses diminished cerebral glucose metabolism, an underlying pathology of AD. Current treatments only target symptoms of the disease.[1] Adding Axona to traditional therapies addresses different aspects of AD at the same time and can help make the biggest impact in enhancing memory and cognition.[10]

References: 1. Henderson ST. Ketone bodies as a therapeutic for Alzheimer's disease. *Neurotherapeutics.* 2008;5(3):470-480. **2.** Costantini LC, Barr LJ, Vogel JL, Henderson ST. Hypometabolism as a therapeutic target in Alzheimer's disease. *BMC Neurosci.* 2008;9(Suppl 2):S16. **3.** de Leon MJ, Ferris SH, George AE, et al. Positron emission tomographic studies of aging and Alzheimer disease. *AJNR Am J Neuroradiol.* 1983;4(3):568-571. **4.** Reiman EM, Chen K, Alexander GE, et al. Functional brain abnormalities in young adults at genetic risk for late-onset Alzheimer's dementia. *Proc Natl Acad Sci USA.* 2004;101(1):284-289. **5.** Corder EH, Jelic V, Basun H, et al. No difference in cerebral glucose metabolism in patients with Alzheimer disease and differing apolipoprotein E genotypes. *Arch Neurol.* 1997;54(3):273-277. **6.** Reger MA, Henderson ST, Hale C, et al. Effects of β-hydroxybutyrate on cognition in memory-impaired adults. *Neurobiol Aging.* 2004;25(3):311-314. **7.** Kashiwaya Y, Takeshima T, Mori N, et al. D-β-Hydroxybutyrate protects neurons in models of Alzheimer's and Parkinson's disease. *Proc Natl Acad Sci USA.* 2000;97(10):5440-5444. **8.** Van der Auwera I, Wera S, Van Leuven F, Henderson ST. A ketogenic diet reduces amyloid beta 40 and 42 in a mouse model of Alzheimer's disease. *Nutr Metab (Lond).* 2005;2:28. **9.** Axona [prescribing information]. Broomfield, CO: Accera, Inc.; November 2012. **10.** Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond).* 2009;6:31.

For more information on DCGM in Alzheimer's disease, visit **www.dcgm.com**.

> "TRY TO KEEP THE HANDBOOK AS GENERAL AS POSSIBLE AND AS FLEXIBLE IN THE LANGUAGE AS POSSIBLE."
>
> MARK D. SCROGGINS, MSBA, CPA, CHBC, CLAYTON L. SCROGGINS ASSOCIATES

➔52

"Some courts really scrutinize whether these people really opened that email," she cautions.

MATCH POLICIES, ACTIONS

In addition to the dos and don'ts of handbook-writing, Mark D. Scroggins, MSBA, CPA, CHBC, a management consultant with Clayton L. Scroggins Associates, says that physician practices need to remember that although an accurate handbook helps, what happens in a practice is what really matters.

Scroggins, a *Medical Economics* editorial consultant, says he has witnessed doctors passing out a handbook that says one thing, then adopting a completely different way of handling various benefits.

"What's frustrating for the employees is, they have a 6-year-old signed handbook, but the doctor changed procedures since then," he says. Often, the employees will ask which practice they are supposed to follow.

The handbook is not a legal document, Scroggins adds. Sometimes a doctor's actions may not match the handbook, but the practice's leaders must be consistent for all employees, regardless of what the handbook states. For example, if one nurse receives a particular benefit—even if it is not specified in the handbook—then all the nurses should receive the same benefit.

"Try to keep the handbook as general as possible and as flexible in the language as possible," he adds. "That way, the doctor can operate in a greater realm."

CODING
Can you bill if a component of an AWV is dropped? [62]

FINANCIAL STRATEGIES
The financial impact of adding a provider [65]

Money

How to challenge and collect on insurance claims denials

ERISA regulations open up new ways for physicians to collect

by **RICHARD J. QUADRINO, JD**

HIGHLIGHTS

01 While ERISA governs insurance policies purchased by employees and families, it does not typically address billing and coding issues from providers. The key? It opens up new ways for physicians to fight back against denials.

02 When it comes to denials, closely monitor the 30-day timing of the EOB, and investigate the specificity of rules and language that excuses a medical provider's obligation to appeal a claim denial.

There are many approaches that can be implemented by doctors and hospitals to maximize their revenue stream by challenging a health insurer's denials of claims in the commercial insurance area. This article focuses on the tools available in the federal law called ERISA that can be used by these medical providers to increase collections.

USING THESE METHODS will not only help with collections on current and future claims, but can provide the basis for dusting off piles of older, denied claims that medical providers have forgotten about or written off.

The first task is to get an understanding of how to use Employee Retirement Income Security Act's (ERISA) many rules. Rather than adhering to an insurer or claims administrator's "bulletins," "payment guidelines," or "manual," the focus should be placed on the use of ERISA rules. This accomplishes two things. First, ERISA can actually make the medical provider's in-network provider agreement legally non-binding as to some of the billing or coding rules that are used to deny claims. And second, when ERISA's claims regulations are violated, the provider can argue that the

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"A well-armed medical provider, however, who either learns and implements the rules, or hires qualified legal counsel, is likely to the get the insurer to come to a settlement based upon these rule violations."

➔58 claim decisions are not legally valid and that the claims are immediately payable. When playing on this turf, medical providers will discover new and more effective avenues for getting paid.

In the world of commercial health insurance, nearly all of the insurance polices purchased today are obtained by employers for their employees and families. These group insurance benefits are "employee welfare benefit plans" governed by ERISA. Therefore, no matter what state you practice in, these rules apply to your patients' employer-sponsored health insurance plans. And under the new federal healthcare law, the ERISA claims regulations even apply to claims under plans sponsored by federal, state, and local employees that are typically not governed by ERISA.

1/ Pre-emption of portions of the provider agreement

ERISA provides that once it governs an area, it "preempts"; i.e., it takes over and wipes out all other law that could apply. Thus, on questions of whether a particular claim or service is "covered," it is not the provider agreement, provider manual, or other health insurer created internal rules that apply.

Instead, as the U.S. Supreme Court makes clear, the claims are governed by the employee's health plan document. The health plan documents, adopted by employers and distributed to employees, typically do not address billing or coding issues. Therefore, claims cannot be denied on such grounds because the language of the health plan does not authorize it. And since the health plan is the only document that can define coverage, any internal insurance company rule, guideline, or manual provision that the insurer attempts to use to deny claims is both irrelevant and preempted by ERISA. This concept alone is a "game-changer" that medical providers should employ to challenge improper claim denials.

2/ Using ERISA's claims regulations

There are three basic sets of ERISA rules that medical providers need to become familiar with: (1) the timing rules regarding an insurer's response to a claim, (2) the specificity rules as to an insurer's denial in an explanation of benefits (EOB), and (3) the rules that excuse a medical provider's obligation to appeal a claim denial.

Timing: ERISA's regulations provide that a health insurer must respond to a claim within 30 days of receiving it. If the insurance company wants more time to consider the claim, it must notify the medical provider that it needs additional time. If the notification for more time is sent before the 30 days expires, then the insurer gets an additional 15 days. If the health insurer blows either the initial 30-day deadline or an extended deadline, the late-arriving EOB is legally not valid. If a late EOB alleges that a service was not medically necessary, for example, the health insurer can be precluded from asserting that defense to the claim because it was asserted too late. Thus, instead of arguing about medical necessity, how the claim was coded, or whether too many services were allegedly performed in a given visit, the medical provider can simply demonstrate the lateness and demand payment in full.

While there are court decisions that confirm this point, health insurers will likely be reluctant to admit their obligations in this regard, for fear of opening the floodgates. A well armed medical provider, however, who either learns and implements the rules or hires qualified legal counsel, is likely to get the insurer to come to a settlement based on these rule violations.

Specifics required: The ERISA regulations require health insurers to explain the reasons for a claim denial, with specificity. Most EOBs fail this test, and thus they are not legally valid. In addition, if the denial is for an alleged lack of medical necessity, the regulations further require the insurer to provide either "... an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request." Have you ever seen an EOB that complies with this regulation? Probably not. And again, there are consequences for a violation. If the EOB

is insufficient, it can be argued that it is the equivalent of no response at all. And no response equals a late response; i.e., a violation of the above 30-day rule. Thus, claims that fail to meet this test are also candidates for a demand for immediate payment, regardless of the true merits of the claim, the patient's condition, or how the billing was coded.

Getting around the appeal requirement: There are many ways in which a medical provider can be excused from the appeal requirement. If the appeal requirement can be excused, then older claim denials that were never appealed are still "alive" and can be pursued for collection. In addition, the provider can also save precious time and resources by avoiding the frustrating process of faxing dozens of pages that get ignored or rejected.

The ERISA claims regulations state that if the claims administrator violates the regulations, then an appeal is not necessary. And that makes sense. For example, if an EOB is vague—and thus violates the regulations—how can a medical provider tender a proper appeal if the true reason for a denial is unknown? Thus, appealing under these circumstances is excused. This rule applies to any type of regulatory violation and can be relied upon to press forward with collection on many of the medical provider's older claims denials that were never appealed.

Medical providers should pursue the use of these rules against the health insurers. Armed with the right tools and represented by qualified ERISA health insurance counsel, medical providers can put together large groups of denied claims and pursue payment in a cost effective manner. ◘

The author is a founding partner of Quadrino Schwartz. His practice includes consulting, litigation, trials, and appeals in the areas of insurance litigation and claims, class actions, and business and complex litigation. The law firm has offices in Garden City and New York, New York. Send your legal questions to medec@advanstar.com.

@ For more on insurance claims denials go to Medicaleconomics.com and enter "insurance claims denials" in the search field. Some related stories include:

"Appeals of claims denials surprisingly successful." (Medical Economics, May 11, 2011.)

Coding Insights

CAN YOU BILL AN AWV OR IPPE WITH MISSING COMPONENTS?

Q If a patient refuses to allow the physician to do a component of the Annual Wellness Visit (AWV) can the physician still bill Medicare?

BASED ON THE Medicare guidelines, a provider submitting a claim to Medicare Part B for the initial (G0438) or subsequent (G0439) AWV or the Initial Preventive Physical Examination (IPPE, also known as the Welcome to Medicare Visit) (G0402) must complete all elements as required by instructions.

If a provider does not perform one or more of the elements, he/she did not perform the complete service and therefore cannot submit the service to Medicare.

However, check with your local Medicare carrier because some carriers are coming to understand that there are situations when a provider cannot obtain all of the elements – or when all the elements are not medically necessary for each patient. If a provider makes the determination that an element is not medically appropriate for the patient or if the patient refuses an element of the services, the provider needs to document this information in the medical record. In these situations, the charges can still be submitted to Medicare for reimbursement.

WILL ICD-10 BE DELAYED?

Our organization is concerned about putting resources toward ICD-10 training too early if the date is going to be pushed back again. Can you tell us if the ICD-10 transition date is definite?

During a recent eHealth Town Hall, Centers for Medicare and Medicaid Services (CMS) Acting Administrator Marilyn Tavenner confirmed the October 1, 2014, ICD-10 deadline and encouraged everyone to work diligently toward a successful transition.

CMS is committed to inform and help the health-care industry prepare for ICD-10, and is now offering thumb drives packed with ICD-10 resources, which are available on CMS's ICD-10 website, found at: www.cms.gov.

IF A PROVIDER MAKES THE DETERMINATION THAT AN ELEMENT IS NOT MEDICALLY APPROPRIATE... HE OR SHE NEEDS TO DOCUMENT THIS INFORMATION IN THE MEDICAL RECORD.

HERE IS AN ICD-10 EXERCISE THAT MIGHT HELP YOU GET READY FOR THE TRANSITION

As a continuation of our ICD-10 readiness series, below is an exercise that will help you familiarize yourself with the ICD-10 coding. Keep in mind that all ICD-10 codes begin with a letter. In these scenarios, the codes begin with the letter "I."

A patient was seen today for a follow-up of his benign hypertension. What is the correct diagnosis code?

The correct ICD-10 code is: I10 (Essential (primary) hypertension. This code includes: high blood pressure, hypertension (arterial) (benign) (essential) (malignant) (primary) (systemic). In the ICD-10 coding system, the practitioner will no longer have to document whether the patient's hypertension is benign or malignant. ◘

*Answers to readers' questions were provided by **Erline Franks,** CCS-P, CMRS, an associate director at SS&G Healthcare. Send your practice management questions to **medec@advanstar.com**.*

Financial Strategies

WEIGH YOUR OPTIONS, AND DO THE MATH WHEN ADDING A NEW PROVIDER

By **JUDY BEE**

It seems like a good problem. Your practice is so popular that new patients can't get in fast enough, and your established patients are clamoring for appointments. While you try your best to accommodate everyone, your family and staff complain that the practice's work hours are being stretched.

EVENTUALLY, YOU conclude you need to add a provider to keep up with demand. But then the question arises, do you add another physician, or bring in a midlevel provider, such as a nurse practitioner or physician's assistant? Chances are your patients would prefer to see a physician, and a physician can bill at a higher level than a midlevel.

On the other hand, a physician will also command a higher salary than a midlevel. If you're in solo practice you may not have the space to accommodate another physician. And if the new physician doesn't work out, terminating his or her employment can be awkward and bring negative attention on the practice within the community.

If you don't want to add another physician, a midlevel may be a viable alternative. Midlevels bill at a lower rate—most payers reimburse for 80% of what they pay an MD. A midlevel can help free you from some routine patient management and phone work, and allow you to use your time more productively. The midlevel might, for example, focus on chronically ill but stable patients, leaving you time to see patients with more complex problems and/or acute same-day needs. And the potential problems stemming from dismissing a midlevel are less severe than with a physician.

The drawback of adding a midlevel is that it may cause unhappiness among some of your patients who had been used to getting their care from you, which may cause some of them to leave. Also, some managed care contracts do not allow for midlevels, so be sure to check that yours do before bringing a midlevel on board.

What will a new provider add to your practice's bottom line? That will vary depending on your practice's circumstances and the provider's skills, experience, and efficiency, but the calculation is straightforward. Revenues will be whatever the provider bills for. Costs will be the provider's base salary plus about 25% for insurance and taxes. You will also need to include supplies, an amount that is generally set at 6% of a practice's collections. Whatever is left is additional profit to your practice.

Adding a new provider is among the most important, and difficult, decisions a medical practice owners face. Carefully weighing all the factors in advance can avoid harmful consequences later on.

Calculating the financial impact of a midlevel*

	Per hour	Per month	Annual
Payer reimbursement	$69.60		
Midlevel salary	$40.38	$7,000	$84,000
Taxes/insurance	$10.10		
Supplies (6% of collections)	$ 4.18		
Total pay	$54.66		
Profit potential ($69.60-$54.66)	$14.94		

*Based on seeing one patient per hour billed using Current Procedural Terminology code 99213.

The author is a principal with Practice Performance Group, La Jolla, California, and a Medical Economics *editorial consultant. Send your practice finance-related questions to* **medec@advanstar.com**.

MOBILE TRENDS
Deloitte: Mobile has yet to capture patient care [72]

THE EXCHANGE
Public HIEs grow to 56, but it's painfully slow [73]

Technology

Use mobile charge capture to boost your bottom line

The right mobile app can help you better track lost revenue and payment delays

by **JOHN A. MALONIS, MD AND GURPREET BAJAJ, MD**

HIGHLIGHTS

01 In studying three codes, this practice found a significant increase in consults and charges.

02 Mobile charge capture helped the practice increase charges by 13%, and the technology helped improve the speed of the billing process.

Mobile charge capture technology can ease frustration brought about by lost charges, payment delays, data entry errors, and inaccurate billing information. Mobile charge application technology enables you to improve patient care, increase revenue and loser billing administration costs.

AS ORTHOPEDIC SURGEONS our practice is centered on patient care for fractures, arthritis, and sports medicine. A large part of our practice takes place in the hospital where we care for injured patients, be it during the day, night or on weekends. While it was obvious we were very good at taking care of our patients, it was difficult for us to find time to write down procedure and diagnosis codes and then get them to our office billing staff. The mobile charge capture application on our smart phones proved the solution to this problem. We use this technology to follow our patient list daily, code our cases and consults, and transmit daily logs to the billing staff in real time.

THOUGHTS ABOUT ROI

Mobile charge capture gives you compelling return on investment by:

- Reducing lost charges,
- Increasing revenue,

→68

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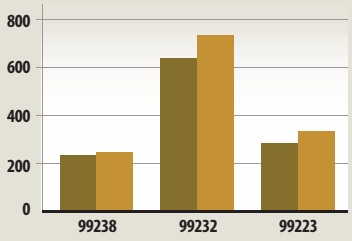
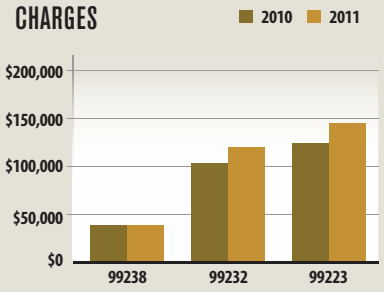
Dr. A

NUMBER OF PATIENT VISITS



This chart displays the growth in the number of patients billed for these sample CPT codes before and after using maxRVU. In 2011, Dr. A was able to complete procedure 99223 335 times vs 2010's 283 times, an increase of 52 patients; procedure 99232 734 times in 2011 vs 636 in 2010, an increase of 98 patients; and procedure 99238 244 times in 2011 vs 234 times in 2010, an increase of 10 patients. Dr. A was able to complete more work while using the mobile charge capture solution, maxRVU and saw about 160 more patients.

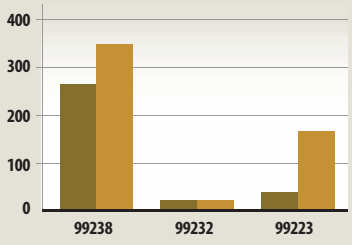
CHARGES



This chart displays the growth in the dollar amount of charges billed for CPT codes before and after using maxRVU. In 2011, Dr. A was able to capture charges for procedure 99223 in the amount of $146,407 vs 2010's $125,171, an increase by about $20,000; procedure 99232 in 2011 $121,311 vs 2010's $105,369, an increase of about $15,000; and procedure 99238 in 2011 $39,920 vs 2010's $38,275, an increase of about $1,700. With all three procedures listed above, Dr. A was able to increase charge capture by about $37,000.

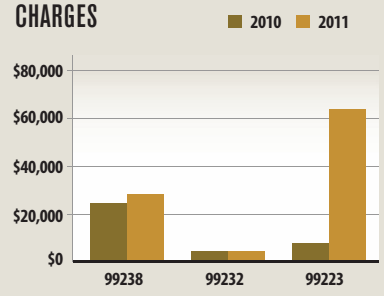
Dr. B

NUMBER OF PATIENT VISITS



This chart displays the growth in the number of patients billed for these sample CPT codes before and after using maxRVU. In 2011, Dr. B was able to complete procedure 99223 158 times vs 2010's 13 times, an increase of 145 patients; procedure 99232 23 times in 2011 vs 24 in 2010, a decrease of 1 patient; and procedure 99238 330 times in 2011 vs 277 times in 2010, an increase of 53 patients. Dr. B was able to complete more work while using the mobile charge capture solution, maxRVU and saw about 197 more patients.

CHARGES



This chart displays the growth in the dollar amount of charges billed for CPT codes before and after using maxRVU. In 2011, Dr. B was able to capture charges for procedure 99223 in the amount of $68,221 vs 2010's $5,824, an increase by about $63,000; procedure 99232 in 2011 $3,864 vs 2010's $3,690, an increase by about $200; and procedure 99238 in 2011 $30,210 vs 2010's $25,041, an increase of about $5,000. With all three procedures listed above, Dr. B was able to increase charge capture by about $68,000.

➔66

- Expediting the billing process,
- Expediting payer payment,
- Reducing denial processing costs,
- Reducing "no authorization" write-offs,
- Increasing caregiver adoption,
- Increasing administrative staff efficiency,
- Decreasing administrative costs,
- Streamlining compliance examinations, and
- Improving rounding efficiency

GOING MOBILE

Our practice uses maxRVU, a product by gingerCube Inc. It lets us input our patients' information, share rounding notes, helps code surgeries and consults with CPT and ICD codes, and ensures that we remain Health Insurance Portability and Accountability Act (HIPAA)- compliant.

We started using the product in March of 2011, and saw good results right away. About 3 months ago, we decided to review what difference the mobile charge capture made on our bottom lines. Anecdotally, we know our billers are no longer waiting for us to submit charges for them to bill nor pressuring us for clarification of codes, and we are no longer losing billing sheets in our cars or finding our kids using them to draw pictures.

The revenue cycle is smoother too. We—the physicians—do the coding without hesitation and in full compliance with HIPAA and other regulations. No longer does illegible handwriting gum up the works. We sensed that the mobile phone capture app increased our practices' profitability, but what would the cold, hard numbers reveal?

In the spirit of research, limiting confounding variables, and trying to draw accurate conclusions, we decided to study three codes that are commonly used by all doctors treating hospital patients regardless of specialty: 99223—initial hospital care; 99232—subsequent hospital care; and 99238—hospital discharge. We looked at the number of times these codes were used before we adopted maxRVU and while using the product.

➔70

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THE TECHNOLOGY HELPS OUR BILLERS TO BE MORE EFFICIENT, WHICH AVOIDS OVERTIME AND ENHANCES CONSISTENT DELIVERY OF CHARGES AND REVENUE.

➔68

We also looked at the charges resulting from the use of these codes and the collections from these codes.

The data show a significant increase in consults and charges, which can be seen from the accompanying graphs.

COLLECTIONS INCREASE

We conclude that this technology helped increase our captured charges by about 13%, which is significant. In this environment of diminishing reimbursement, you should capture and charge for all of the work that you do. With a mobile charge capture application we are able to collect more money.

This study did not take into consideration how this application helped our practice improve its financial health in ways that are not so easily calculated. We proved that with this application, we were able to capture charges in a timely fashion with no loss of chargeable visits. By getting the charges to our biller in real time, we sped up the billing process. The technology helps our billers to be more efficient, which avoids overtime and enhances consistent delivery of charges and revenue. There is no loss of revenue due to late billing or time filing issues. We believe that no physician should be without a good mobile charge capture application.

Other mobile charge capture resources

There are many product offerings for physicians when it comes to mobile charge capture software.Here are some of the products listed through the Healthcare Information and Management Systems Society (HIMSS).

Please note, this listing is not meant to be comprehensive, nor does it serve as an evaluation or endorsement of the mobile charge capture device. Most management experts would advise you to conduct a thorough review of your practice needs and assess how the software and/or applications fit with your expectations.

ADP Advanced MD, Inc.: *advancedmd.com*
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FormFast Inc.: *formfast.com*
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Tech News

PHYSICIANS ARE GOING MOBILE, BUT NOT FOR DATA ENTRY OR SCRIPT WRITING

A recent 613-physician survey from consulting firm Deloitte found that 57% of physicians do not yet use mobile technology to access electronic health records (EHRs), e-prescribe, or communicate with patients regarding their health status.

WHAT'S MORE, nearly 44% of those nonusers report that their work-setting does not provide (and remains unwilling to use) personal devices. Nearly 30% of the non-user respondents are concerned about patient privacy and another 26% of the physicians report that apps and programs are not suited for physician needs.

While this survey shows that only 43% of respondents have adopted mobile technology, other surveys show a much higher rate. For example, Manhattan Research found that 72% of physicians have adopted tablet computers, primarily the iPad. The same 2,950-physician survey found that 70% of physicians use medical reference app Epocrates on their smartphones, and 50% use the app on their tablets.

Another March study from Kantar Media found that 74% of physicians use smartphones for professional reasons, and 38% use both a smartphone and tablet for professional purposes.

So what's a health information technology observer to make of these apparent discrepancies? While the surveys where all conducted separately and asked questions in different ways, an observer might conclude that while there is a widespread adoption rate, these devices have yet to be used by the majority of physicians to help them collect or disseminate information from patient encounters.

Harry Greenspun, MD, senior adviser at the Deloitte Center for Health Solutions, adds the one key technology trend Deloitte's data reveals is there is a "digital divide" that exists between doctors who are enthusiastic and early technology adopters and those who aren't.

As technology-adopting physicians' capabilities grow and outpace those of their technophobic counterparts, that divide is going to become more apparent to consumers, Greenspun predicts.

Asked about the data point that showed 78% of nonadopters don't plan to change soon, Greenspun half-jokingly referred to doctors in that camp as clinging to a "not now, not ever, not any way" mentality toward integrating certain technology into their practices.

Ultimately, it may be patients clamoring for more technology options from their physicians—such as access to medical records from smartphones—that pushes previously reluctant doctors to embrace technology.

"There's still a good chunk of doctors who are hoping that this whole thing just goes away," Greenspun says. "There'll be a real push to bring them back into the fold, and a lot of that will be driven by consumer demand."

ONE KEY TECHNOLOGY TREND DELOITTE'S DATA REVEALS IS THE 'DIGITAL DIVIDE' THAT EXISTS BETWEEN DOCTORS WHO ARE ENTHUSIASTIC AND EARLY TECHNOLOGY ADOPTERS AND THOSE WHO AREN'T.

Tech Talk

ELECTRONIC HEALTH INFORMATION EXCHANGE IS COMING—BUT SLOWLY

by **ROBERT ROWLEY,** *MD*

One of the goals of the federal electronic health records (EHR) incentive program—also known as Meaningful Use (MU)—has been to make it possible to quickly and easily exchange clinical information in electronic form between providers in separate locations using different EHR systems.

Stage 1 of MU was focused mainly on getting physicians off of paper charts and onto an EHR, whereas Stage 2, which starts in 2014, puts more emphasis on information sharing between care settings. In fact, health information exchange is among the requirements doctors must meet to qualify for MU2 financial incentives.

EHR vendors challenged

Information exchange, or interoperability, poses a significant challenge for EHR vendors, because until now EHRs have not been designed to communicate with one another—and in fact have little financial incentive to do so.

Fortunately, other solutions to the interoperability problem are starting to materialize. Among these is the development of a standardized structure for the continuity of care documents (CCDs) and continuity of care records (CCRs) generated by EHRs, as well as secure protocols for transmitting them between providers, because EHRs must be able to export and receive data from these files to receive MU2 certification.

Exchange networks growing

Even more important is the growth of health information exchange networks that provide a set of common standards to their members for sending and receiving data electronically. These are being created by private hospitals and integrated health systems, as well as by states and other public entities. The federal Office of the National Coordinator for Health Information Technology has provided funding for 56 public entities.

In addition, six major EHR vendors recently announced plans to form their own consortium, the CommonWell Health Alliance, with the goal of promoting and certifying a national infrastructure with common standards and policies for health information exchange.

The Direct Project

The Direct Project, a consortium of EHR vendors, medical organizations, government agencies, and consultants, is yet another emerging method for transmitting messages securely and in standardized formats between different EHR systems. Direct Project protocols are expected to be part of MU2-certified EHR systems beginning in 2014.

Independent practitioners may find accessing interoperability technologies more challenging, at least at first. Regional extension centers, state and local medical societies, and local hospitals are potential sources for information about health information exchanges. The exchange itself will provide information about service agreements, costs, and privacy and interoperability standards.

Our healthcare system and technology infrastructure has a long way to go before we can send patient data quickly, reliably, and securely between providers in different locations who use different EHR systems. The good news is that we have made considerable progress towards reaching that goal recently, and I feel confident that we will attain it in the next few years. ◻

The author is a healthcare information technology consultant in Hayward, California, and author of the blog RobertRowleyMD.com. Send your health information technology questions to ***medec@advanstar.com****.*

Q&A

➔80 patients. We have to ask ourselves whether some less-demanding parts of primary care should be handled more often by nonphysicians. Take the way that anesthesiologists and nurse anesthetists work together, for example. One anesthesiologist can be in charge of several patients at a time, with the help of nurse anesthetists, who handle the less-challenging parts of the cases. The anesthesiologists are nearby, able to step in when needed. But by sharing patients with nurse anesthetists, the anesthesiologists are able to practice more efficiently.

IF WE CONTROL HEALTHCARE COSTS IN THE UNITED STATES, LOTS OF PEOPLE ARE GOING TO MAKE LESS MONEY, ESPECIALLY HIGHLY PAID...SPECIALISTS.

In what ways do you think the primary care landscape will look different in 20 years?

Only a fool prognosticates in public! But I never said I wasn't a fool. I have no crystal ball, but I hope that the role of PCPs expands over the next couple decades. I hope we more often manage large teams of allied health professionals, as well as better coordinate care for our patients in consultation with our subspecialty colleagues. Good primary care has potential to control healthcare costs while maintaining or improving healthcare quality. ■

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Q&A

WHY THE FREE MARKET ISN'T A CURE-ALL FOR HEALTHCARE

It's comforting yet overly simplistic to think that most healthcare problems in the United States could be solved by letting the power of an unregulated free market do its work, according to Peter Ubel, MD, an internist, behavioral scientist, and Duke University public policy professor. Medical Economics *recently spoke with Ubel to get his take on some of the most pressing issues in primary care, health policy, and medicine.*

There seems to be a large faction of doctors who think that unleashing the free market will solve most of America's healthcare woes. The impression I got from reading your piece in The Atlantic about price transparency was that the exact opposite is true: More free-market reforms could easily increase costs without improving quality. What do you think the effect would be of unleashing free markets on healthcare?

The free market is a wonderful thing, when it enables consumers to make informed choices about which products to buy. But medical consumers, a.k.a. patients, often have a hard time making the kind of savvy choices that will bring discipline to the market. Moreover, they are often in positions of making high-stakes, emotional decisions, in short time spans, without fully understanding their choices. To make matters worse, many physicians I've spoken with say they feel it would be inappropriate to discuss the cost of care with patients, especially when they face life-or-death decisions. Hard to imagine how the market, on its own, will work effectively in such circumstances. We need to bring more market efficiency to healthcare, but it is unrealistic to think that a completely unregulated free-market is going to solve our problems.

For the United States to get health costs under control, do you think it's necessary to reduce the amount of money physicians make?

If we control healthcare costs in the United States, lots of people are going to have to make much less money, including hospitals, pharmaceutical companies, device manufacturers, and, yes, physicians, especially highly paid procedural subspecialists. I'll be quite upset if changes in the healthcare marketplace caused general pediatricians and family practitioners to make less money. But we cannot afford to continue to have our wonderful colleagues in orthopedic surgery, interventional cardiology, and the like make the kind of money they currently make. Right now, subspecialists in the United States often make two or three times as much money per year as their peers in Canada or Europe. In the long run, we need to reduce physician subspecialty income. To do that in an acceptable way, however, we also need to both reduce the cost of medical education and reform our malpractice system, so these reductions in income are not as painful.

Why do you think the primary care shortage is overblown?

Sometimes we focus too much on the primary care physician (PCP) shortage without paying attention to broader issues about what kind of primary care providers should be offering what types of primary care to which

➔ 74