PHYSICIANS GIVE FIRSTHAND ACCOUNT OF BOSTON BOMBINGS

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Explain your reasoning when you disagree with another doctor's diagnosis or treatment plan.

—Lee J. Johnson, JD

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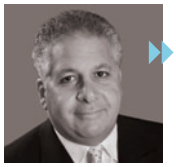

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JULY 10, 2013

Volume 90
Issue 13

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SPECIAL REPORT

Policy

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COVER STORY | POLICY

Thousands of pages of regulation are guiding key government-led mandates. Our coverage cuts through the red tape for 2013 and 2014.

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- ACA's sweeping reforms
- Medicare/Medicaid pay parity
- Get paid for transitional care management
- Physician Quality Reporting System

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FINANCIAL STRATEGIES

Keith Borglum, CHBC
8 tips to reduce the use of collection agency referrals

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

MEDICAL ECONOMICS *(USPS 337-480) (Print ISSN: 0025-7206, Digital ISSN: 2150-7155) is published semimonthly (24 times a year) by Advanstar Communications Inc., 131 W. First St., Duluth, MN 55802-2065. Subscription rates: one year $95, two years $180 in the United States & Possessions, $150 for one year in Canada and Mexico, all other countries $150 for one year. Singles copies (prepaid only): $18 in US, $22 in Canada & Mexico, and $24 in all other countries. Include $6.50 for U.S. shipping and handling. Periodicals postage paid at Duluth, MN 55806 and at additional mailing offices. Postmaster: Send address changes to Medical Economics, PO Box 6085, Duluth, MN 55806-6085. Canadian GST Number: R-124213133RT001 Publications Mail Agreement number 40612608. Return undeliverable Canadian addresses to: IMEX Global Solutions, PO Box 25542 London, ON N6C 6B2 CANADA. Printed in the USA.*

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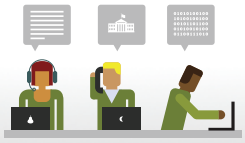

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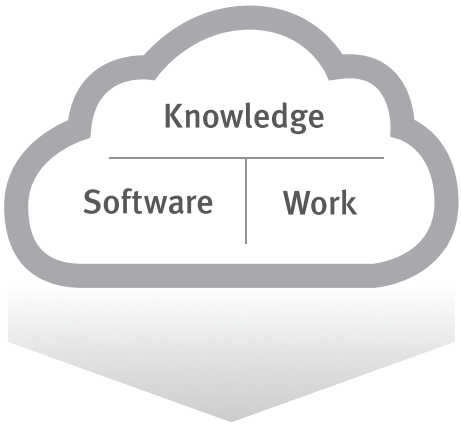

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MEDICAL ECONOMICS WEEKLY, EPISODE 6

In the latest edition of Medical Economics Weekly, we explore why physicians are growing increasingly frustrated with their electronic health records systems, discuss a study showing that emergency department employees are spending a great deal of time on Facebook and other social media sites, and ask the question, 'Do smartphones make you look prematurely old?'

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DISEASE CLASSIFICATION
Is #obesity a disease? The AMA is considering classifying it as one. http://ow.ly/m7jDc via @forbes

PHYSICIAN REIMBURSEMENTS
AAFP wants CMS to pay #physicians for telephone evaluations, care plan oversight services, online evaluations. http://bit.ly/17CNAoe

MEDICARE PENALTIES
Do #Medicare readmissions penalties disproportionately affect #hospitals that serve the poor? http://ow.ly/m6g00 via @KHNews.

INTEROPERABILITY
Solutions to the information exchange problems between #EHRs are slowly materializing http://bit.ly/1bHi5WD

PHYSICIAN DEMAND
RT @vannschaffner: The distorted "market" doesn't encourage people to choose primary care, the demand is for specialists and subspecialists.

MEDICAL APPS
Top 5 most popular smartphone #medicalapps for physicians: Epocrates, Medscape, MedCalc, Skyscape, Doximity http://ow.ly/m0HQc

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Thoughts from **DANIEL R. VERDON,** *Group Editor*

DOCTOR, THIS MIGHT HURT A LITTLE

You are facing one of the greatest transitions in your professional career.

So much so, that the operational changes required due to this growing regulatory burden may be insurmountable for some practices.

As the insurance exchanges that are part of the Affordable Care Act (ACA) begin enrollment next month, remember that this is just part of a larger regulatory agenda to reduce costs, open access to healthcare, improve care delivery, and become more transparent in the way you communicate with patients and your colleagues.

As part of it, your pay will also be more closely tied to outcomes; you will be asked to open up your patient panels; and you will be incentivized or penalized by an array of government-led initiatives to re-engineer healthcare delivery.

Your medical decisions will likely be questioned in more ways than they are currently by payers, hospitals, specialists, pharmacies, your patients and your EHR; and all the while, you will need to improve your systems to protect patient health information, and accommodate an entirely new segment of the population that has had little or no access to healthcare.

You will need a wealth of information to understand and respond to patient questions regarding ACA. You will likely need to fortify your business operations to manage copays as a result of high-deductible premiums. And that means you will need to keep a close eye on billing and patient charges. Who could forget the transition to ICD-10 coming up in 2014?

And while all of this is going on, you are going to have to more closely rely on your healthcare team to make certain your patients act on recommendations to reverse their poor health choices contributing to seemingly runaway health problems like obesity and diabetes.

The operational challenges are real, and, in some cases, dire for smaller practices with limited staffs and tight cash flow.

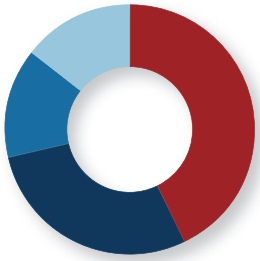
Even as physicians face this cascade of change, primary care physicians need to lead the profession through it.

That is what motivated *Medical Economics* to take a close look at the multiple regulatory issues facing primary care this year and next (starting on page 29.) From the impacts of ACA, quality payment measures, the meaningful use 2 requirements for electronic health records, Health Innsurance Portability and Accountability Act compliance, Medicaid expansion and parity, all the way to new Occupational Saftety and Health Administration rules, our cover story's goal is to inform and educate about key provisions you face in the coming months and help you plan for their implementation.

> "THE CHALLENGES ARE REAL, AND IN SOME CASES DIRE FOR PRACTICES WITH LIMITED RESOURCES."

While the policy pundits talk about improving healthcare delivery to patients, remember that we want you to remain just as healthy—personally and professionally.

What's your biggest complaint about your EHR system?



More than 40 EHR developers have pledged adherence to a new 'code of conduct' for improving interoperability and data security. But critics say the code is vague and won't lead to meaningful changes in the industry.

See page 15 for more on the story.

> The information I have at my fingertips and the available capacity to communicate with my patients is remarkable. Equally incredible is the expectation of those who are empowered to define just what is "quality healthcare" in this new era of accelerating change.

H. Andrew Selinger, MD, FARMINGTON, CONNECTICUT

MUCH IS NOW GIVEN TO, AND EXPECTED OF, DOCTORS

A verse from the Book of Luke in the New Testament reads, "To whom much is given is much required." On a recent Monday morning a retired pharmacist friend of mine asked, "Ready for the week?" Another senior chimed in, "You don't go to the hospital anymore, do you? How come?"

I thought for a moment and answered them both, "There's so much more expected from us these days, it's impossible to do both jobs and do them well."

That's when the expression above popped into my head. The information I now have at my fingertips and the available capacity I have to communicate with my patients is just remarkable. Equally incredible is the expectation of those who are empowered to define just what is "quality healthcare" in this new era of accelerating change.

Gone are the days when it's one doctor and one patient in a room having a conversation, and the discussion and treatment plan remain unique to that one relationship. Documentation, measurement, and accountability now define modern-day medicine.

Oh, how doctors and other healthcare providers struggle to preserve what's personal while embracing the need for "big data." But you see, some of the wonderful innovations—like voice-activated dictation—do not permit the collecting of clinical data for measurement. In fact, to prove our worth to the powers that be that control licensure, certification and critical funding we must click the right box and often enter data hundreds if not a thousand or more times a day. Only in this way can we demonstrate our value to these large corporate, state, and federal entities.

Not a bad undertaking and absolutely necessary to get a handle on the quality and cost of the care we deliver, just very difficult to manage and yet stay focused on the needs of the patients with whom we connect over and over again during the course of our day.

Delivering healthcare today feels like being that young child who always needs to learn, acquire new skills and make their way in the world. Fits and starts, failures and successes, two steps forward one and half steps back-that is the definition of our progress.

Be patient with your doctors and everyone everywhere who touches you with healthcare. We are doing our best to embrace change.

H. Andrew Selinger MD
FARMINGTON, CONNECTICUT

COVER IMAGE QUESTIONABLE

Given the wave of gun violence plaguing this country, your cover photo of a bullet shooting through an object (*Medical Economics*, June 10, 2013) was not well thought out.

Kerry K. Swindle, MD, FAAFP
TUCSON, ARIZONA,

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CMS UNVEILS HOSPITAL OUTPATIENT CHARGES FOR FIRST TIME

The Centers for Medicare and Medicaid Services (CMS) released hospital outpatient charge data for the first time.

According to Health and Human Services Secretary Kathleen Sebelius, "A more data driven and transparent healthcare marketplace can help consumers and their families make important decisions about their care. The administration is committed to making the health system more transparent and harnessing data to empower consumers."

The release includes estimates for average charges for 30 types of hospital outpatient procedures, such as clinic visits, echocardiograms, and endoscopies.

The data set includes the hospital's name, location, average charge for a given procedure. and Medicare's payment comparison.

MEDPAC REPORT AIMS TO EVEN PLAYING FIELD BETWEEN HOSPITALS, INDEPENDENTS

A Medicare commission's report to Congress wants to even the payment disparity for some procedures performed in hospital outpatient departments (OPD) and office-based practices.

In fact, the Medicare Payment Advisory Commission (MedPAC) says, "Payment variations across settings urgently need to be addressed because many services have been migrating from physicians' offices to the usually higher paid OPD setting, as hospital employment of physicians has grown."

The focus is not on increasing pay to office-based physicians, however, but decreasing costs to OPDs.

While MedPAC recognizes there are cost variables between hospitals and office-based practices, it has identified 66 groups of services provided in OPDs and freestanding offices "that meet the commission's principles for aligning payment rates across settings."

Medicare's payment rates often vary for the same ambulatory services provided to similar patients in different settings, such as physicians' offices or OPDs, the report says. "For example, in 2013, Medicare pays 141% more for a level II echocardiogram in an OPD than in a freestanding physician's office. These variations raise questions about how Medicare should pay for the same service when it is delivered in different settings."

The report also introduces a payment model called competitively determined plan contributions, delves into detail regarding improving care for dual-eligible beneficiaries—including care coordination— and outlines a plan to reduce hospital readmissions through hospital penalties and bundling post-acute care services.

MEDICARE'S PAYMENT RATES OFTEN VARY FOR THE SAME AMBULATORY SERVICES PROVIDED TO SIMILAR PATIENTS IN DIFFERENT SETTINGS.

According to the Association for Independent Doctors, this disparity in reimbursement levels has contributed to the decline in the numbers of physicians in independent private practice.

In fact, the association reports that the number of independent doctors (i.e. those not employed by hospitals) as a percentage of total doctors has declined from 57% in 2000 to a projected 36% in 2013, while the number of hospital-employed physicians has skyrocketed.

"By pursuing the guidance set forth in the MedPAC Report, and lowering high reimbursements to hospitals, Congress can promote at least three important objectives:

1. ***reduce U.S. government spending;***
2. ***lower cost of health care for patients when they seek health care services at hospitals***
3. ***help level the playing field between hospitals and independent doctor practices, by alleviating marketplace distortions that contribute to hospital consolidation and excess market power."***

AMA report: Patients coughing up 25% of the medical bill

YOUR PATIENTS ARE responsible for nearly 25% of the medical bill, according to the National Health Insurer Report Card from the American Medical Association (AMA).

The association, for the first time, analyzed direct patient expenses through copays, deductibles and coinsurance. The findings: patients are paying nearly one-quarter of "the amount that health insurers set aside for paying physicians."

AMA Board Member Barbara L. McAneny, MD, adds, "Physicians want to provide patients with their individual out-of-pocket costs, but must work through a maze of complex insurer rules to find useful information. The AMA is calling on insurers to provide physicians with better tools that can automatically determine a patient's payment responsibility prior to treatment."

Some of the other findings from this year's report card:

- **Error rates dropped** significantly from nearly 20% in 2010 to 7.1% in 2013. Among all payers, Medicare led the pack with an accuracy rating of 98.1%.
- **Claim denials dropped** 47% in 2013, AMA says, after a spike in 2012 data for most commercial payers. The overall commercial payer denial rate dropped from 3.48% in 2012 to 1.82% in 2013. Cigna had the lowest denial rate at .54% and Medicare had the highest at 4.92%.
- **Response times** for medical claims improved from 2008 to 2013, AMA reports. Humana had the fastest median response time of six days, while Aetna was the slowest at 14 days.

Ambulatory payment classifications (APC) with the largest reduction in program spending and beneficiary cost sharing

APC	Description	Total program spending (in millions)	Cost Sharing (in millions)
269	**Level II** echocardiogram w/o contrast	-308.5	-61.7
207	**Level III** nerve injections	-170.3	-34.1
377	**Level II** cardiac imaging	-168.5	-33.7
209	**Level II** extended EEG, sleep, and cardiovascular studies	-55.5	-0.0
204	**Level I** nerve injections	-46.7	-0.0
15	**Level III** debridement and destruction	-45.9	-9.2
440	**Level V** drug administration	-31.1	-6.2
20	**Level II** excision/biopsy	-30.0	-6.0
74	**Level IV** endoscopy upper airway	-28.1	-0.0
160	**Level I** cystourethroscopy and other genitourinary procedures	-25.6	-5.1

Note: APC (ambulatory payment classification), EEG (electroencephalography), IMRT (intensity-modulated radiation therapy). We modeled cost-sharing changes based on current law: Copayments for APCs that are currently higher than 20 percent of the total payment rate would stay the same even if the total payment rate declines. APCs with copayments that equal 20 percent of the total payment rate would stay at 20 percent, but the copayment amount would be smaller if the total payment rate declines.

Source: MedPAC analysis of 100 percent Standard Analytic Claims files from 2010. MedPAC analysis of payment rates in the 2010 physician fee schedule and outpatient prospective payment system (OPPS) trended forward to 2012 using updates to the physician fee schedule and OPPS.

PCMH STANDARDS TO CHANGE, NCQA SAYS

The National Committee for Quality Assurance (NCQA) wants to better integrate behavioral healthcare with primary care.

In fact, the change is spelled out in new proposed standards for its Patient-Centered Medical Home (PCMH) program.

The changes are necessary to reflect current trends in healthcare and to place greater emphasis on outcome measures and reduced costs of care, NCQA explains.

"The proposed fifth iteration of the PCMH recognition program emphasizes outcome measures, resource stewardship like avoiding unnecessary/duplicative testing, and a focused approach to targeting resources to patients based on need.

Other revisions include:

- applicability of standards to pediatric practices, and
- continued alignment with the government's meaningful use Stage 2 requirements.

The five draft standards up for review include:

1. ***Enhance access and continuity***
2. ***Identify and manage patient populations***
3. ***Plan and manage care (includes self-management support)***
4. ***Track and coordinate care***
5. ***Performance measurement and quality improvement.***

NCQA has opened up the draft to collect comments through July 22, and plans to launch the program update by March 2014.

HUMANA LEADS TELEHEALTH PILOT TARGETING CHF PATIENTS

A nine-month telehealth pilot program was launched by Humana and AMC Health to evaluate clinical and financial outcomes of home-based monitoring for congestive heart failure (CHF) patients.

The program will equip 450 Humana Medicare Advantage members suffering from CHF with blue-tooth enabled scales and blood pressure monitors all linked to a cellular modem and voice response technology, the company reports.

The goal: To help patients better manage their conditions and adhere to their care plans.

The Humana Cares Heart Failure Remote Monitoring Program aims to evaluate how telehealth technology will transform clinical and financial outcomes.

CHF reportedly affects about 5.7 million people, according to the Centers for Disease Control and Prevention. Nearly 25% of Medicare patients admitted for heart failure were readmitted within 30 days after discharge. Poor care transitions, exercise activity, diet and adherence to treatment plan are the leading causes of those readmissions, Humana reports.

Rising operating costs continue to hinder practices, MGMA says

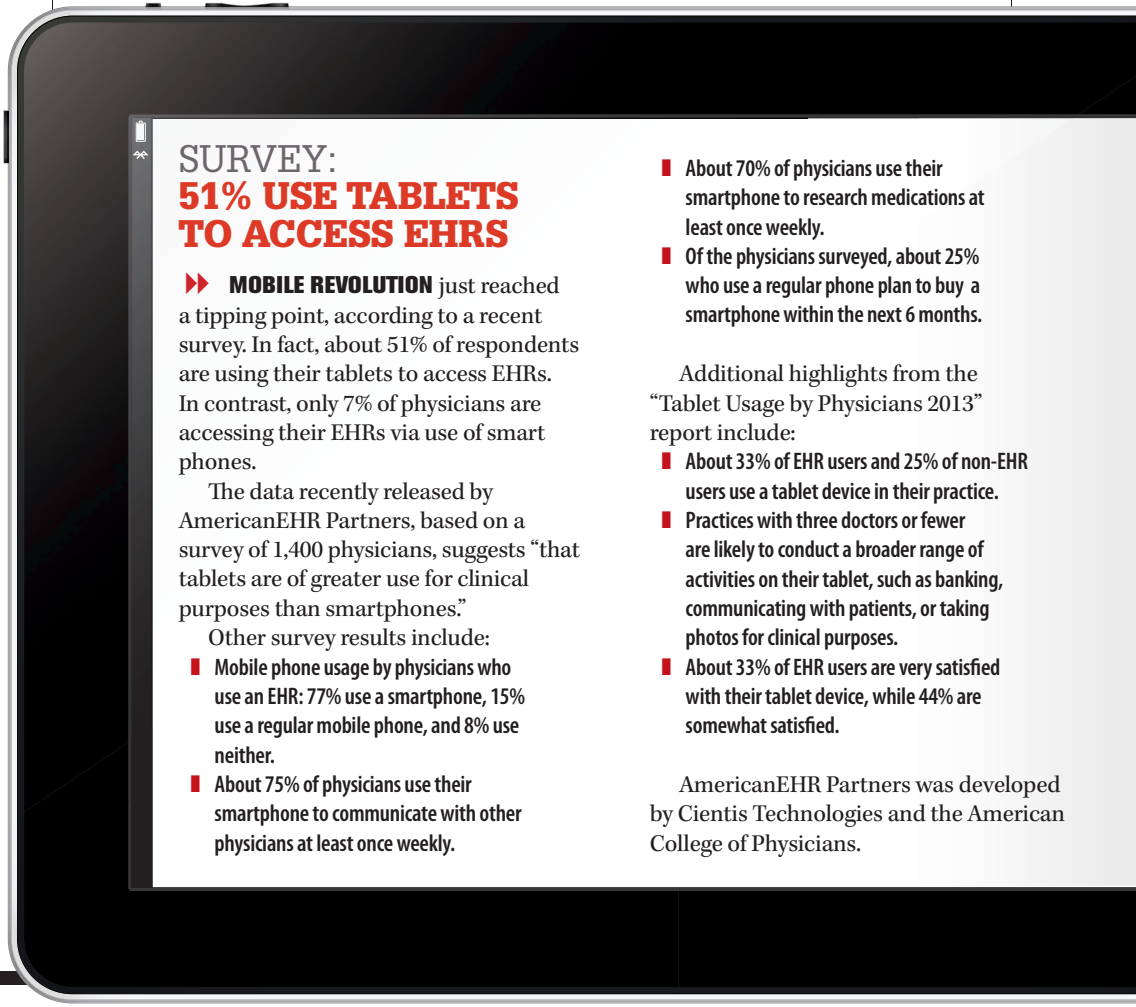
ADAPTING TO RAPID CHANGES, legislative pressures and fiscal uncertainty rank as the top challenges facing practice business leaders.

According to MGMA-ACMPE's recently released survey, the top five most applicable challenges of running a group practice are:

1. ***Dealing with rising operating costs***
2. ***Preparing for reimbursement models that place a greater share of financial risk on the practice***
3. ***Managing finances with the uncertainty of Medicare reimbursement rates***
4. ***Collecting from self-pay, high-deductible, and/or health savings account patients***
5. ***Understanding the total cost of an episode of care.***

"Physician practices are doing more and more to innovate and respond to our rapidly changing environment to meet the needs of their patients, but with fewer resources," says Susan L. Turney, MD, MS, FACMPE, FACP, MGMA-ACMPE president and chief executive officer. "They are working diligently to manage rising operating costs and prepare for potential cuts to reimbursement rates."

Other challenges cited by medical practice executives include collaborating with payers to implement new payment models, and using systems to better manage and evaluate population health.



SURVEY: 51% USE TABLETS TO ACCESS EHRS

MOBILE REVOLUTION just reached a tipping point, according to a recent survey. In fact, about 51% of respondents are using their tablets to access EHRs. In contrast, only 7% of physicians are accessing their EHRs via use of smart phones.

The data recently released by AmericanEHR Partners, based on a survey of 1,400 physicians, suggests "that tablets are of greater use for clinical purposes than smartphones."

Other survey results include:

- Mobile phone usage by physicians who use an EHR: 77% use a smartphone, 15% use a regular mobile phone, and 8% use neither.
- About 75% of physicians use their smartphone to communicate with other physicians at least once weekly.
- About 70% of physicians use their smartphone to research medications at least once weekly.
- Of the physicians surveyed, about 25% who use a regular phone plan to buy a smartphone within the next 6 months.

Additional highlights from the "Tablet Usage by Physicians 2013" report include:

- About 33% of EHR users and 25% of non-EHR users use a tablet device in their practice.
- Practices with three doctors or fewer are likely to conduct a broader range of activities on their tablet, such as banking, communicating with patients, or taking photos for clinical purposes.
- About 33% of EHR users are very satisfied with their tablet device, while 44% are somewhat satisfied.

AmericanEHR Partners was developed by Cientis Technologies and the American College of Physicians.

WILL AN EHR 'CODE OF CONDUCT' BENEFIT USERS?

More than 40 electronic health records (EHR) developers have pledged adherence to a new "EHR Developer Code of Conduct" that includes plans for enhancing patient safety, data portability, system interoperability, and security.

THE 9-PAGE code is a "reflection of our industry's ongoing commitment to collaborate as trusted partners with all stakeholders," says Mickey McGlynn, chair of the Electronic Health Record Association (EHRA), the group behind the pledge.

The code represents "an important milestone in the maturation of the healthcare information technology industry," says Siemens Chief Executive Officer John Glaser, an early supporter of the pledge. It's simply "the right way to treat our customers," says Farzad Mostashari, MD, chief of the Office of the National Coordinator for Health Information Technology (IT).

The code has its share of critics. "It's telling about the business practices of our industry that this is a new development," says Dave Chase, chief executive officer of Avado, a patient relationship management software provider. "Why this wouldn't be a standard practice is rather shocking."

Nonetheless, Chase acknowledges that the code represents a "step in the right direction" for doctors and patients—provided that the developers abide by it.

Brian Ahier, president of the health IT exchange company Gorge Health Connect, suggests that EHR developers may have other motivations for announcing the code, given widespread reports about growing physician and government dissatisfaction with existing EHR technology.

"To some degree, there probably is some sense of 'We need to do something to sort of calm down the regulatory bodies and the provider community as far as their complaints,'" Ahier says.

Ahier also takes issue with some of the code's patient safety pledges, calling them "too vague." For example, the EHR developers promise to participate with at least one patient safety organization in reporting, reviewing, and analyzing "health IT-related patient safety events." But the "nature, extent, and timing" of the companies' participation depends on many factors, including the outcome of "current industry and policy discussions," regulatory changes, the availability of "appropriate recognized organizations," and the development of "standardized definitions of safety events."

"That leaves an awful lot of wiggle room," Ahier points out, such as the "policy discussions" the developers refer to. Health IT policy discussions are ongoing, so who's to say when—or if—those discussions will produce a definitive outcome, he asks.

Some critics also argue that the EHR developers have attached conditions that don't necessarily promote transparency or inspire confidence that the companies are fully behind the code. The EHRA won't levy any charges or fees against a company that says it will abide by the code but fails to, *Modern Healthcare* reported. Nor will the EHRA keep a running tally of companies that have promised to abide by the pledge.

Michael Barr, MD, a senior vice president with the American College of Physicians, has embraced the code after some initial skepticism, praising it as "significant" and its intent as "genuine."

"I can go back to our members and point to [the code's] principles that are very responsive to the issues physicians would like addressed as they try to select, implement, optimize, and potentially change EHR solutions," he writes on the American EHR blog.

So while it may be too early to say whether the EHR Developer Code of Conduct will result in anything besides good public relations for the industry, EHR vendors have given doctors and patients several reasons to be both optimistic and pessimistic about the code's effects in the future.

Doctor's Bag

The latest in drugs, devices, technology, and more

FLUZONE QUADRIVALENT VACCINE APPROVED BY FDA

The FDA has approved the supplemental biologics license application (sBLA) for licensure of its 4-strain influenza vaccine, Fluzone Quadrivalent vaccine (Sanofi Pasteur). Fluzone Quadrivalent vaccine is the first and only 4-strain influenza vaccine option for patients as young as six months of age, as well as adolescents and adults.

There is now a way to have broader coverage against more strains of influenza vaccine with the seasonal flu shot, which helps protect patients from influenza and its resulting complications. In order to help protect patients, steps must be taken now to order the vaccine for the upcoming season and to put the necessary formulary and reimbursement processes in place.

Sanofi Pasteur is currently accepting orders for the vaccine; providers can order online or by calling the company's order center. Only a limited number is being manufactured for the 2013-2014 influenza season due to the timing of its licensure, and doses will be available first-come, first-serve.

A high demand is expected and there are no guarantees doses will remain for order in-season.

There are 2 new CPT codes for the vaccine. CPT 90685 when administered to children 6-35 months of age (0.25-mL dose) and CPT 90686 when administered to patients 3 years and older (0.5-mL dose). Providers must also remember to bill for vaccine administration.

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APPS OFFER CONTENT FROM CDC, AHRQ, NCCN

Epocrates, Inc., an athenahealth company and provider of the top medical app for U.S. physicians, has expanded collaborations with the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the National Comprehensive Cancer Network (NCCN). The goal of the collaboration is to deliver valuable content to clinicians on their mobile devices at the point of care.

CDC will work with Epocrates to provide information on imunization updates, emerging resistant bacteria, local disease outbreaks, and more. Epocrates has the ability to microtarget mobile alerts to clinicians by region or specialty to ensure relevant content is being received in mobile format.

For the Epocrates online product, CDC has hand-selected patient education handouts on topics such as weight management and STIs for clinicians to print out or email to patients.

AHRQ will provide up-to-date information through the National Guideline Clearinghouse as well as issue comparative effectiveness reports that provide a basis for clinical decision-making. Epocrates has selected more than 35 AHRQ guidelines for its targeted DocAlert messaging system. Timely and convenient delivery of these guidelines has helped impact treatment for GERD, drug allergy, and cancer screening.

The AHRQ electronic preventive services selector tool (EPSS) is also available in the free Epocrates app.

The company also recently expanded its free app based on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). The four-star-rated iPhone app provides quick access to NCCN Guidelines, such as those on prostate, breast, and colon cancers (with additional tumor types forthcoming.)

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The ENDOEYE FLEX 5 was one of 14 medical innovations displayed at the Premier healthcare alliance's 2013 Breakthroughs Conference and Exhibition.

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SPECIAL REPORT

Remembering BOSTON

Nearly 3 months after the Boston Marathon bombing, physicians say the tragedy taught lessons that will forever influence the care of and response to patients

by **DEBRA BEAULIEU**

For more than 6 weeks, the bloody pants Pierre Rouzier, MD, had worn on April 15, 2013, rested at the bottom of his closet. He'd looked at them two to three times a day, every day, since the bombings; but Rouzier, a family and primary care sports medicine physician at the University of Massachusetts in Amherst couldn't bring himself to touch them.

FINALLY, IN late May—about a week before the last of the injured victims would be released from Boston-area hospitals—Rouzier picked the pants up and looked at them, trying to decide whether to clean or throw them away. "My left knee was the bloodiest because that's what I was kneeling on [to help victims]," Rouzier says. "And there was splattered blood everywhere else, so I decided to throw them away."

But while the material reminders of that day could be removed, Rouzier and other volunteer physicians working in and around the medical tent during the 117th running of the Boston Marathon will be forever changed by their experience.

CELEBRATED DAY TURNED DEADLY

Compared to 2012, when extreme heat caused thousands of runners to defer their race entry to the following year and scores who did compete suffered severe hyperthermia, physicians' workload during the race was manageable.

"It was a picture perfect day," recounts James Broadhurst, MD, a family physician at UMass Memorial Medical Center in Worcester, Massachusetts, of his ninth time volunteering at what many consider the most celebrated marathon in the world. With the temperature just right and a gentle sea breeze soothing runners as they pushed up Heartbreak Hill, the team of medical volunteers had a steady stream of patients to tend to, but no one was inundated.

All that changed at 2:50 p.m., when two shrapnel-filled pressure-cooker bombs exploded near the race finish line.

"It was the most surreal picture you'd ever imagine," Rouzier, 56, says of his fifth year staffing the marathon medical tent. "We ran down the 75 yards or so and came into an area of maybe 20 feet by 40 feet, and there were just bodies on bodies lying on the ground." These individuals included both the injured and those consoling them, Rouzier says, adding that he and his team ran past one man's severed foot and leg on their way to help.

"And everybody—all the victims—had that gray look," Rouzier says. "There was the smell of blood and the smell of burning clothes and flesh. And there were pools of blood everywhere."

That afternoon, the death toll was three, while 264 injured were treated at 27 local hospitals.

Broadhurst, who stayed in the tent to treat casualties, was convinced based on what he heard from

→22

MORE RESOURCES VIDEO

Words for the wounded

"We were actually having a pretty easy day, and then, at about 10 minutes to 3, there was a noise. It was unmistakably wrong."

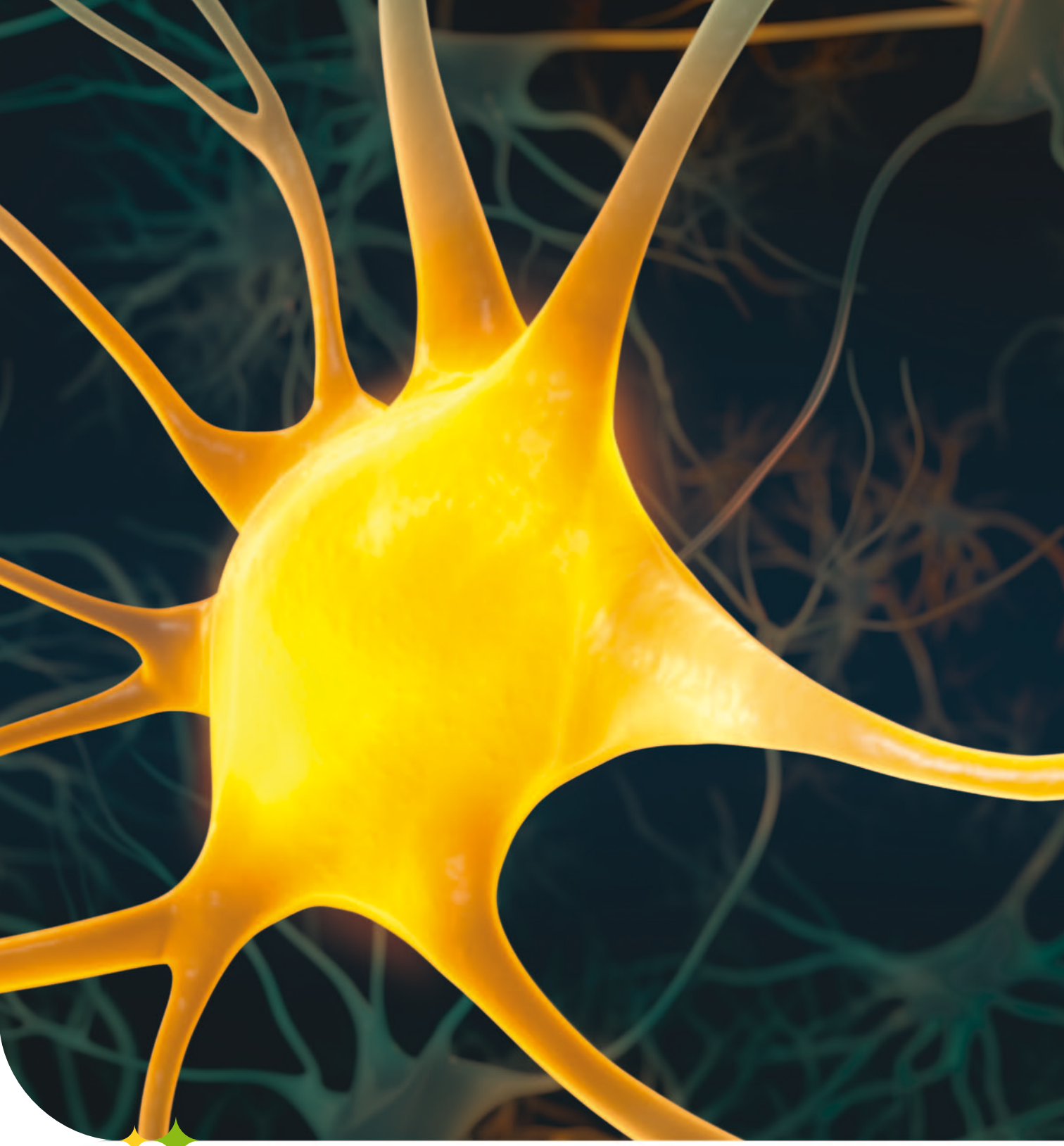
JAMES BROADHURST, MD
WORCESTER, MASSACHUSETTS

Visit www.youtube.com/watch?v=4gynR2xoqU4

Long road to recovery

14 University of Massachusetts Medical School personnel were stationed at the nearby Boston Marathon medical tent on Boylston Street when two bombs exploded, killing three people and injuring 264 more. This medal was left at the initial blast site on the day Boylston Street reopened to the public.

Pete Tschudy (opposite)



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

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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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> "There was the smell of blood and the smell of burning clothes and flesh. And there were pools of blood everywhere."
>
> PIERRE ROUZIER, MD
> AMHERST, MASSACHUSETTS

> "Everyone just became equals and found a role and did it regardless of their training."
>
> CHAD BEATTIE, MD
> DARTMOUTH, MASSACHUSETTS

19 colleagues that at least five people were killed by the blasts. "I was overjoyed to hear there were only three," he says. "But I fully expected to hear by Wednesday that that number would be five and by Friday it would be nine."

A TESTAMENT TO TEAMWORK

Broadhurst credits the survival and recovery of more than 200 injured victims to the outstanding performance of emergency medical services (EMS) personnel on the scene and dispatching patients to hospitals. "One of the things that I found extremely heartening was reporters standing in front of emergency rooms saying that emergency room personnel had noted how severe the injuries were that they were seeing but how remarkably stable the patients were who were showing up," he says.

"And that's a testament to the EMS folks and what we were able to achieve in the tent by stabilizing people as rapidly as we could and then transporting them as rapidly as we could in order to get them to sites of definitive care," Broadhurst says. "For that I'm incredibly grateful and feel very proud that I was able to be part of a much larger operation that succeeded so well in saving lives."

The teamwork displayed among all volunteers, medical personnel, and first responders throughout the disaster also made an impression on Chad Beattie, MD, a primary care sports medicine doctor in the Department of Orthopedics at Hawthorn Medical Associates in Dartmouth, Massachusetts.

"Everybody just became equals and found a role and did it regardless of their training," says Beattie, who graduated from his fellowship in July 2012 and was volunteering for his fifth Boston Marathon.

"Just by my proximity to where the bombs went off, I had to have been the first one from the medical tent there," he says, "and there was hardly anything for me to do because there were just so many other people there. Within 2 minutes after the bombs went off, the streets were just flooded with people helping."

Rouzier also found himself in awe of the fast and thorough response from personnel on the scene, recounting that every patient he checked to apply a tourniquet already had one. "Finally I rolled up my bloody belt and stuck it in my pocket because everybody had tourniquets put on," he says.

Having a full supply of willing and qualified personnel in the tent and at the finish line made it possible for Broadhurst to take on the important job of providing emotional support to individuals who weren't necessarily in medical danger.

"People need reassurance. They need to know they are safe. They need to know they are being cared for," Broadhurst says. "Given the number of personnel that we had, you had a doctor who could look after three or four or five patients, so you didn't have people lying off in a corner not receiving attention because they weren't terribly injured and there were so few providers that they had to concentrate on the most severe."

'EVERYONE THERE WAS A VICTIM'

After experiencing traumatic events such as this, the healers are not the least of those who need healing.

As Broadhurst notes, "everyone who was there was a victim of that disaster. And as a physician, I am no more immune to that than anybody else."

About a week after the attack, Broadhurst, Beattie, and Rouzier were among about 30 marathon-day medical volunteers who attended a debriefing session held at UMass in Worcester in which facilitators worked with providers to help process having experienced the disaster. "We were together for 4 to 5 hours and that was enormously helpful to me individually and for us collectively," Broadhurst says.

In the days immediately following the attack, Rouzier and Beattie attended a prescheduled professional meeting in California, and both credit having the other to talk to as being a critical part of the healing process.

"Probably I was lucky that I went to San Diego right afterwards because I could just be away from day-to-day work and I could be around people who were there," Beattie says, adding, "and Pierre [Rouzier] was especially the biggest help to me."

Nonetheless, going back to work had its challenges. For Beattie, having witnessed the most horrific injuries he had seen in his career so far made it difficult to listen to patients in his office complain about relatively minor problems.

"You don't want to take it out on them and you don't want to say, 'there are people who have it worse than you,' but that's what you're thinking inside," he says. "Before I went

Courtesy of James Broadhurst, MD

The medical team: During the Boston Marathon there were 14 personnel from the University of Massuchesetts Medical School on call. By day's end, emergency medical responders cared for more than 200 injured victims. James Broadhurst, MD, is second from the left (front row). Chad Beattie, MD, and Pierre Rouzier, MD, are in the back row (right).

in to see every patient, I had to sort of recheck myself and reset things a little bit. That was probably the hardest part."

For Beattie's colleague Rouzier, a major struggle was coping with feeling that his efforts to help patients on April 15 weren't enough. With the help of a therapist specializing in post-traumatic events, Rouzier recognized that his mentality was similar to a linebacker on a football team who had made 15 tackles lamenting the two that he had missed.

"Finally, the therapist asked me, 'What physical symptoms are you feeling?,'" Rouzier says. "I still get them, and I said, 'I'm getting this stabbing feeling over my heart.' And she just smiled and said, 'Oh, that's right over your heart. Consider you're sending love to the victims.'"

MOVING FORWARD

Despite the emotional wounds suffered by doctors from that tragic day, they came away with lessons that will influence the way they care for patients going forward.

For Beattie, the crash course he received in trauma care on April 15 may not come much into play during his office practice, but he expects it will make him better prepared to handle serious injuries he may one day encounter working on the sidelines of athletic events.

"I hated to be there," Beattie says of the 2013 Marathon, "but at the same time I'm kind of glad that I was there in the sense that it's just another life experience that will help me down the road."

Meanwhile, Broadhurst, with nearly 30 years more experience as a practicing physician than Beattie, says he came away from the disaster with a new appreciation for how significantly being part of a disaster can affect providers and patients alike.

"I now have an appreciation for how that can adversely affect folks and certainly a greater appreciation for the importance of intervention to try to prevent the disabling development of post-traumatic stress disorder in individuals," he says, adding that the resources provided at the UMass debriefing session helped set him on a path to healthy coping with his experience.

"And as a physician, it's given me a much better appreciation for how important it is for me to assist others who may have experienced a traumatic event," says Broadhurst, who also practices addiction medicine, "and not accept an explanation from the individual that they're okay, but spend a little additional time, and having a low threshold for referring patients for evaluation."

Happily, just as Broadhurst says he's learning to integrate this difficult experience into his life in a healthy way, so too do Beattie and Rouzier report that they are coping much better as of early June than during the first weeks after the bombing.

"I'm doing much better," Beattie says. "I think about it a lot less, and when I do think about it, it's not as emotional. I can think about it and not break down or freak out." Even months after the event, however, Beattie says he and many others who were onsite are still affected by loud bangs and the sound of sirens. "Everyone's still very jumpy," he says.

For Rouzier, intense emotions struck three weeks after the attack, while watching the Boston Celtics play the New York Knicks at Boston's TD Garden. Despite Rouzier's yearning to be around Boston sports fans and celebrate the "Boston Strong" mantra the city had adopted, hearing the Dropkick Murphys' 2005 song, "Shipping up to Boston [to find my wooden leg]," played in the stadium caused him to shake and cry, he says. After the game, Rouzier decided to walk back to the bomb site.

"There was the memorial where the tent was, and then there were flowers laid where the probable bomb went off, which is where I could imagine myself kneeling and working," he says. "That was a big deal for me to get that type of closure to that."

REGULATORY GUIDE
9 regulatory programs impacting practices [29]

MEDICAID PARITY
Reimbursement increases rolling out for PCPs [43]

Policy

Medicare abuse: Policies to help your practice fight back

How to protect legitimate patient needs and put unscrupulous DME companies on notice

by **JANIS COFFIN,** DO, FAAFP, **CARLA DUFFIE,** DNP, MHSA, RN, AND **ALLEN PELLETIER,** MD, FAAFP

HIGHLIGHTS

01 A policy that requires patients to initiate requests for DME can substantially cut down on Medicare fraud and abuse.

02 Though deterrence is difficult to quantify, there is empirical evidence that investigating and prosecuting healthcare fraud has resulted in reductions in improper claims to Medicare.

If you receive requests from durable medical equipment (DME) companies and you do not have a policy in place to deal with these requests, your practice could be at risk of committing Medicare fraud or abuse. ▸▸

▸▸ **WE ARE AN ACADEMIC PRACTICE** in the Georgia Health Sciences University, Augusta, with 26 interns and residents, and 21 full- and part-time faculty. About 32% of our patients are on Medicare. As such, we are an obvious target for companies engaged in systematic Medicare fraud and abuse. The following case is illustrative.

A 72-year-old patient complained to us about receiving harassing telephone calls to his home about purchasing DME and a mobility scooter. This patient walked up to 2 miles, four times a week, and was otherwise in excellent health. During further discussions with the patient, we determined this particular DME company requested that he submit paperwork to his primary care physician to complete. The patient did not need, nor want, this equipment and asked our advice on how to stop the telephone harassment.

Further investigation revealed our nurses and many of our physicians were bombarded daily with faxes and telephone calls from DME companies requesting power chairs, electric scooters, back braces, electric heated water pumps for back pain, and erectile dysfunction devices for patients. In many cases, these requests were bundled with legitimate-appearing requests for renewal of diabetic home glucose testing supplies. Multiple requests from ➔27

➔24 multiple companies came for the same patients. When we contacted patients by telephone, some admitted they had signed on with a DME company that promised to deliver diabetic supplies, but others were quite surprised and denied ever requesting any of the services we were being asked to authorize. We even discovered multiple requests for an air mattress for a deceased patient.

WHAT IS FRAUD?

Most Medicare payment errors are simple billing mistakes, not the result of a physician, provider, or supplier trying to take advantage of Medicare. Fraud occurs when someone intentionally falsifies information or deceives Medicare. A common example of fraud is purposely billing Medicare for services that were never provided or received by the patient.

Most physicians, providers, and suppliers are committed to providing high-quality care to patients and to billing Medicare only for the services provided. Unfortunately, a few individuals and companies are intent on defrauding or abusing Medicare.

Our experience, however, is unfortunately all too common. A recent *Journal of the American Medical Association* review estimates that outright fraud accounted for between $82 billion and $272 billion in wasteful healthcare spending in 2011, or potentially up to 21% of total national healthcare expenditures. [1]

Examples of Medicare fraud are the following:

- **A healthcare provider bills Medicare for services never received by a patient.**
- **A supplier bills Medicare for equipment never received by a patient.**
- **Someone uses another person's Medicare card to get medical care, supplies, or equipment.**
- **Someone bills Medicare for home medical equipment after it has been returned.**
- **A company offers a Medicare drug plan that is not approved by Medicare.**
- **A company uses false information to mislead someone into joining a particular Medicare plan.**

WHAT IS ABUSE?

Abuse occurs when doctors or suppliers do not follow established medical practices and procedures that result in unnecessary costs to Medicare. It is important to distinguish fraud from abuse: Fraud is action with deliberate intent to cheat or deceive Medicare for illegal gain. Abuse may be intentional and coupled with fraud, but is more often the result of systematically poor medical management or sloppy recordkeeping.

Abuse is not the occasional, accidental billing error, but a systematic practice pattern that leads to overbilling and waste of Medicare services. Abuse leads to improper payment, duplication of services, failing to discontinue services that are no longer medically necessary, or providing services or equipment that is not medically necessary.

A number of federal statutes define Medicare fraud and abuse. Penalties for violations can be severe, including exclusion from participation in all federally funded healthcare programs, fines, and even imprisonment. [2]

The Health Care and Fraud Prevention and Enforcement Action Team (HEAT) works in conjunction with local, state and federal agencies to combat Medicare fraud and abuse. HEAT Strike Forces have had a marked sentinel effect.[3]

Though deterrence is difficult to quantify, there is empirical evidence that investigating and prosecuting healthcare fraud has

Sample policy regarding DME requests

Goal: Meet legitimate need of patients, while insulating the practice from illegitimate DME companies engaged in Medicare fraud or abuse.

Here are key components to the policy:

- ☑ All DME requests must be initiated by the patient
- ☑ The practice no longer accepts faxed documents, without a patient first initiating the request
- ☑ Educate staff on policy and post it in visible locations throughout the practice
- ☑ Inform DME companies about your practice's policy.
- ☑ If DME company representatives continue to make repeated calls, inform them it is viewed as harassment and will be reported as Mediare abuse.
- ☑ Shred all faxed requests not initiated by patients.

OUTRIGHT FRAUD **accounted for an estimated** $82 BILLION TO $272 BILLION **in wasteful healthcare spending in 2011.**

Source: *Journal of the American Medical Association*

resulted in reductions in improper claims to Medicare. For example: a Miami resident pleaded guilty to submission of more than $200 million of fraudulent claims to Medicare; a Houston healthcare company owner and operator of a DME company was sentenced to 30 months in prison for Medicare fraud, and ordered to pay $471,022 in restitution;[4] and a Louisiana psychiatrist was indicted for Medicare fraud that spanned 5 years from 2004 to 2009 and included Medicare billings of $21 million.[5]

LEADS TO INTERNAL REVIEW

Could you or your practice be at risk of complicity in Medicare fraud or abuse? The answer is almost certainly, YES. The case of our 72-year-old patient led to an internal review of our practice and the realization that a systematic approach was needed to protect it and our patients. A policy was developed in open discussions with physicians, nurses, and medical records staff who were bearing the brunt of the paperwork deluge coming into the office. We recognized the need to meet legitimate patient needs and requests, while insulating our practice from inadvertent complicity with DME companies engaged in Medicare fraud or abuse.

We developed a standard operating procedure, which was communicated to all providers, nurses, medical records staff, and patients. Specifically, our policy states that, "All requests for durable medical equipment and supplies (diabetes testing, mobility scooters, heating pads, back braces, mattresses, knees/elbow/ankle sleeves, etc.) will need to be initiated by the patient. We will no longer sign faxed documents to our department that are from durable medical equipment companies, without the patient initiating the request first."

We educated all our staff on this policy and posted it on an electronic bulletin board that is clearly visible in our patient waiting area. This posting also includes the telephone number of the Medicare fraud and abuse hotline.

SERVE NOTICE ON SUPPLIERS

If a DME company calls our clinic with a request, we inform it of our policy, serve notice that repeated calls will be viewed as harassment, and such calls will be reported to the Medicare fraud and abuse hotline. We also immediately shred all faxes with requests for supplies or equipment that were not patient-initiated.

While we have not systematically tracked the results of our policy, we've substantially reduced the numbers of incoming faxes and telephone calls from DME companies. This has freed up our nurses and ancillary staff to concentrate on patient care. ■

MORE RESOURCES

Where to report fraud and abuse

We need to stand together as concerned physicians and stop continued fraud and abuse of the Medicare.. If you believe your practice or patients are victims of Medicare fraud or abuse, *the Office of the Inspector General (OIG) Medicare Fraud Hotline: 800-447-8477, or email at HHStips@oig.hhs.gov.*

Visit http://oig.hhs.gov/fraud/report-fraud/

REFERENCES

1. Berwick DM, Hackburth AD. Eliminating Waste in U.S. Health Care. JAMA 2012;307:1513-16.

2. Centers for Medicare and Medicaid, US Department of Health and Human Services. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads//Fraud_and_Abuse.pdf Oct. 2011). Accessed June 5, 2013

3. Statement by Lewis Morris, Chief Counsel, Office of the Inspector General, Testimony before the Ways and Means Committee, Subcommittee on Health, US House of Representatives, June 15, 2010. http://www.hhs.gov/asl/testify/2010/06/t20100615c.html. Accessed June 5, 2013

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Making sense of Obamacare

A guide to the government-led initiatives changing the delivery of medicine

by **JEFFREY BENDIX, MA, RACHAEL ZIMLICH, AND DANIEL R. VERDON** *editors*

There are thousands of pages of regulatory guidance on a slew of government-led mandates facing physicians this year and next. From sweeping revisions of the Affordable Care Act (ACA), to broad mandates of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to International Classification of Diseases, 10th revision's (ICD-10) colossal transition, *Medical Economics* is introducing this update to keep you informed about the many changes that will impact your practice.

INSIDE

The Affordable Care Act

ACA's sweeping reforms

ACA REPRESENTS vast changes in the way healthcare is financed in the United States. With a net cost estimated at $1.2 trillion between 2012 and 2021, with offsets due to cost cuts, savings, taxes, and other government-led initiatives, the overall theme is about improving quality and access to healthcare while lowering costs.

Opinions vary wildly on whether Obamacare will succeed, but there is little debate that ACA will forever change the delivery of healthcare in the United States. In 2013, 14 provisions were slated to go into effect including increased Medicaid payments to primary care physicians (PCPs), a push to improve preventive healthcare by providing new funding to state Medicaid programs that choose to cover preventive services for patients at little or no cost, Medicare bundled payment initiatives, open enrollment in the health insurance exchanges (Oct. 2013), and a Medicare tax increase. ACA will also provide bonus payments for PCPs in underserved areas and increase payments to rural healthcare providers.

Here are some of the key provisions that will impact every U.S. physician in 2014 and beyond. (This timeline was adapted from the Kaiser Family Foundation.)

Everyone must have insurance or face penalties

This provision mandates that U.S. citizens and legal residents have qualifying health coverage. For those people who opt out, there is a phased-in tax penalty. Some exceptions do apply. On January 30, the U.S. Department of Health and Human Services (HHS) released a proposed rule on minimum essential coverage. The Internal Revenue Service (IRS) will enforce this provision.

Implementation: January 1, 2014.

Health insurance exchanges

Creates state-based American Health Benefit Exchanges and Small Business Health Options Program (SHOP) Exchanges, administered by a governmental agency or nonprofit organization. Individuals and small businesses with up to 100 employees can purchase qualified coverage. Subsequent to its passage, HHS finalized two rules detailing how states must set up the exchanges and standards related to risk adjustment, risk corridors, and reinsurance provisions. The federally-facilitated exchanges will be run by HHS in states that have not established an exchange or have elected to run a partnership exchange.

Implementation: January 1, 2014

Expanded Medicaid coverage

Expands Medicaid to people not eligible for Medicare under age 65 (children, pregnant women, parents, and adults without dependent children) with incomes up to 133% of the federal poverty line and provides enhanced federal matching payments for new eligibles. (See page 37.) States may opt out of the increased income levels.

Implementation: January 1, 2014

Presumptive eligibility for Medicaid

Allows hospitals participating in Medicaid to make presumptive eligibility determinations for all Medicaid-eligible populations.

Implementation: January 1, 2014.

Health insurance premium, cost-sharing subsidies

Provides tax credits and cost sharing subsidies to eligible individuals. Premium subsidies are available to families with incomes between 133% and 400% of the federal poverty level to purchase insurance through the exchanges, while cost-sharing subsidies are available to those with incomes up to 250% of the poverty level.

Implementation: January 1, 2014

Note: On May 23, 2012, the Internal Revenue Service (IRS)

released final regulations related to the health insurance premium tax credits. Corrections to this regulation were published on July 17, 2012. Additionally, on January 30, 2013, the IRS released a final rule on the premium tax credit test for affordability of employer-sponsored insurance.

Guaranteed availability of insurance

Requires guarantee issue and renewability of health insurance regardless of health status and allows rating variation based only on age (limited to a 3 to 1 ratio), geographic area, family composition, and tobacco use (limited to 1.5 to 1 ratio) in the individual and the small group market and the exchanges.
Implementation: January 1, 2014

No annual limits on coverage

Prohibits annual limits on the dollar value of coverage.
Implementation: January 1, 2014

Essential health benefits

An essential health benefits package outlining a comprehensive set of services, limiting annual cost-sharing to Health Savings Accounts ($5,950/individual and $11,900/family). Creates four categories of plans that will be offered through the exchanges and in the individual and small group markets.
Implementation: January 1, 2014

Multi-state health plans

Requires the Office of Personnel Management to contract with insurers to offer at least two multi-state plans in each exchange. At least one plan must be offered by a non-profit entity and at least one plan must not provide coverage for abortions beyond those permitted by federal law.
Implementation: January 1, 2014

Temporary reinsurance program for health plans

A temporary reinsurance program will collect payments from health insurers in the individual and group markets to provide payments to plans in the individual market that cover high-risk individuals. On March 23, 2012, HHS issued a final rule implementing standards for states related to reinsurance and risk adjustment and for health insurance providers related to implementing reinsurance, risk corridors, and risk adjustment.
Implementation: January 1, 2014 through December 31, 2016

Basic health plan

Allows states to create a basic health plan for uninsured individuals with incomes between 133% and 200% of the federal poverty level.
Implementation: HHS delayed implementation of the Basic Health Plan program until 2015 due to the scope of coverage changes being implemented on January 1, 2014.

Employer requirements

Assesses a fee of $2,000 per full-time employee, excluding the first 30 employees, on employers with more than 50 employees that do not offer coverage and have at least one full-time employee who receives a premium tax credit. Last year, the Internal Revenue Service issued proposed regulations on the Employer Shared Responsibility provisions.
Implementation: January 1, 2014

Medicare Advantage plan loss ratios

Requires Medicare Advantage plans to have medical loss ratios not lower than 85%.
Implementation: January 1, 2014

Wellness programs

Permits employers to offer employees rewards of up to 30%, potentially increasing to 50%, of the cost of coverage for participating in a wellness program and meeting certain health-related standards; establishes 10 state pilot programs to permit participating states to apply similar rewards for participating in wellness programs in the individual market.
Implementation: Changes to employer wellness plans effective January 1, 2014; 10-state pilot programs established by July 1, 2014

Quality of care

An ACA provision will tie physician payments to the quality of care they provide. Physicians will see their payments modified so that those who provide higher-value care will receive higher payments than those who provide lower-quality care.
Implementation: January 2015

Experts advise you to prepare your practice for increased call volume, understand how your state will operate its exchange, get ready for new administrative challenges related to insurance claims, become familiar with the new insurance plans,and prepare to handle increases in copays. Also, practice owners should evaluate purchasing options for employees.
(Source for 2014 provisions: Kaiser Family Foundation)

For more coverage
ACA • bit.ly/13cXBXT RSS Available

Health Insurance Portability and Accountability Act

HIPAA's great risks

If you haven't done so already, consider circling September 23, 2013 on your calendar. That's the day that the federal government will start enforcing changes to the Health Insurance Portability and Accountability Act (HIPAA). The changes affect everything from how you secure your patients' protected health information to the contracts you sign with vendors to what you need to tell patients about their privacy rights. Although the new regulations officially took effect in March, physicians and other entities covered by HIPAA were given 6 months to comply. The U.S. Department of Health and Human Services, which developed the regulations, says the updates are needed to account for the widespread use of electronic health records and other changes in health information technology that have occurred since HIPAA was enacted in 1996.

Compliance with the updated regulations require medical practices to:

- conduct a risk analysis to determine the vulnerability of electronic protected health information (PHI) to loss or theft, and document that they have done so;
- encrypt patient PHI so that it can't be used if it's lost or stolen;
- review policies and procedures for what do if PHI is lost, stolen, or inappropriately disclosed;
- review contracts with vendors and other "business associates" that have access to PHI to ensure that the vendors have proper safeguards in place to secure patient PHI.

The penalty for unauthorized disclosure of PHI consists of fines that range from $100 to $50,000, depending on the circumstances of the disclosure and the size of the practice.

The new regulations also:

- allow patients to forbid disclosure of information about a test or treatment for which the patient has paid out-of-pocket, thus requiring practices to be able to identify and separate information a patient doesn't want disclosed so that it's not accidentally sent to an insurance provider;
- permit patients to request their health information in electronic form, and require practices to comply with the request within 30 days with one 30-day extension permitted; and
- require practices to update their notice of privacy practices to include all patients' rights, and send the updated notice to all patients and posting it in the practice's office and on its Web site.

The regulations will be enforced by the Office of Civil Rights, part of the U.S. Department of Justice. More information about the updated HIPAA regulations is available at www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/index.html.

To get ready, experts say, conduct a thorough evaluation of your practice operations to make certain you remain in compliance for data security, privacy, and reporting of breaches.

For more coverage

HIPAA • bit.ly/1aVs6SA RSS Available

Physician Quality Reporting System

It's about quality, not quantity

Your reimbursements will be tied to outcomes in the near future. Medicare's Physician Quality Reporting System (PQRS) currently offers .5% incentive to participate this year (1% with Maintenance of Certification); penalties will start in 2015 as a result of the Affordable Care Act (ACA).

The overall goal of the PQRS, according to CMS, is to collect meaningful data that can help lead to improved patient care. The program uses a series of measures—138 for 2013—developed by leading physician organizations to evaluate the level of care being provided by doctors. Measures consist of a denominator and numerator. PQRS denominators describe the eligible cases for each measure, such as the eligible patient population associated with a measure's numerator. The numerator describes the clinical action required by the measure for reporting and performance, according to CMS.

To qualify, a practice simply must meet CMS' criteria for satisfactory reporting for a particular reporting period. Groups, however, must self-nominate to submit data as a group rather than individually, CMS notes.

The quality measures for 2013 PQRS address areas such as preventive care, chronic- and acute-care management, procedure-related care, and care coordination. Review the 2013 PQRS Measures List (go to www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment- Instruments/PQRS/MeasuresCodes.html) for detailed guidance. CMS recommends considering typical clinical conditions treated, types of care provided, the setting the care, and quality improvement goals for 2013 when selecting measures to report.

When it comes to reporting, you can choose from several options, including reporting via paper claims or registry (each with multiple reporting options), reporting through an electronic health record (EHR) system, or reporting through the group practice reporting option.

For more coverage

PQRS • medicaleconomics.com/ehrwebseminars


Introducing a
NEW approach in
type 2 diabetes
treatment...

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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.

NOW AVAILABLE

In adults with type 2 diabetes,

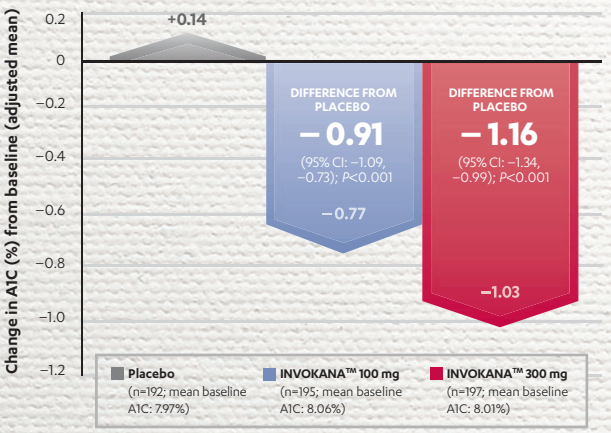
ENVISION NEW POSSIBILITIES

Introducing INVOKANA™—the first and only treatment option approved in the United States that reduces the reabsorption of glucose in the kidneys via sodium glucose co-transporter-2 (SGLT2) inhibition[1]

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

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION *(continued from first page)*

WARNINGS and PRECAUTIONS *(cont'd)*

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

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

OVERDOSAGE

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

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

ADVERSE REACTIONS

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

K02CAN13149

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

Invokana™
canagliflozin tablets

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

April 2013 K02CAN13075

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

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

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

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

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue *[see Adverse Reactions]*. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA.

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***** Week 26 in mITT LOCF population

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

INVOKANA™ (canagliflozin) tablets

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

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

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

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

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

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

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

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

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

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

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

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

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

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

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

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

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

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

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

DRUG INTERACTIONS

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

(Even) more MedEc

SEE WHAT YOU MAY HAVE BEEN MISSING IN OUR ENEWSLETTER

Keys to working with a staffing agency

NOT SURE if you should look for a job on your own or use a physician recruiting firm? Jim Stone, president and co-owner of physician recruitment organization The Medicus Firm, has some suggestions.

If you are open to working anywhere and have few restrictions, "a good recruiting firm will help provide counsel and insight as to what we're seeing in the market," Stone says.

On the other hand, physicians who know the type of job and location they want may not need any outside help. "I think for sure if you know exactly where you want to go and the facility you want to work at, it would be easy to place a call and find out if there's a position available," he says.

Small hospitals and practices, and/or those in rural locations face recruiting challenges in today's market, Stone adds. "Generally speaking, we know physicians' preferences are to live in a larger city [and] to make more money as opposed to less, and physicians tend to gravitate toward single specialty groups and hospital employment," Stone says. "If (an employer does) not fall into all of those categories, it will likely be harder to find candidates looking for those categories."

Insurance exchanges

Insurance exchanges: The clock is ticking

The months are winding down until the health insurance exchanges mandated under the Affordable Care Act (ACA) must be operational, and 17 states have declared their intent to open state-based exchanges, while seven have made plans for a partnership with the federal government, and another 27 have decided to let the feds take over their exchanges altogether.

Exchanges must be established by January 1, 2014, and are intended to allow individuals and small businesses to shop for health insurance. States had the option of establishing state-based exchanges, allowing the U.S. Department of Health and Human Services (HHS) to establish an exchange for the state, or forming a partnership with HHS.

HHS offered federal grants for states to create their own state-based exchanges, with nearly $4 billion in planning, establishment, and early innovator grants awarded so far. California received the most grant funding—more than $900 million, including $1 million in planning funds—for its exchange, which has an annual operating cost of $288 million. New York trailed California with $368.9 million in federal grants. States that have established their own exchanges are beginning to release rate information for their plans.

The next deadline for the program is October 1, 2013, when open enrollment must begin for coverage offered through the exchange in 2014. By January 1, 2014, all exchanges must be open, operational, and offering coverage in every state.

Even as the October enrollment date approaches, states scramble to get ready for the insurance exchange openings in January.

The marketplaces were created with the goal of increasing the availability of affordable insurance options for individuals who currently can't afford private insurance but don't quality for federal assistance programs, or who can't purchase insurance through their employer. Ideally, the program will decrease the amount of uncompensated care physicians currently provide.

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International Classification of Diseases, 10th Revision

ICD-10: It's really a numbers game

It's been several years since the federal government announced that healthcare providers would have to transition from the International Classification of Diseases, 9th revision (ICD-9) code sets to ICD-10—which contains roughly five times the number of codes as its predecessor. The transition is a costly one for physicians, who must often purchase new information technology systems and train staff on the new coding system.

Although practices have had time to plan for the October 1, 2014, deadline, the Medical Group Management Association (MGMA) announced in mid-June that practices are still moving very slowly toward compliance with the new coding requirements. There is a lack of communication and coordination between physician practices and their vendors regarding software updates and testing, and less than 5% of practices say they have made significant progress toward their overall readiness for ICD-10 implementation, MGMA says.

"The transition to ICD-10, with its substantial impact on documentation of clinical care, physician productivity and practice reimbursement, is unprecedented," says Susan L. Turney, MD, MS, FACMPE, FACP, MGMA president and chief executive officer. "It is proving to be one of the most complex and expensive changes our healthcare system has faced in decades.

Adding to the implementation challenge and clearly tax-

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ing all stakeholders, ICD-10 will arrive at the same time that several other transformative federal policies go into effect, such as health insurance exchanges and Stage 2 of the Centers for Medicare and Medicaid Services (CMS') Meaningful Use EHR (electronic health record) Incentive Program."

MGMA notes that roughly half of the physicians it recently surveyed had not heard from their practice management or EHR vendors about software updates, only about 5% had started internal testing of their programs, and almost 60% haven't heard from their clearinghouse regarding external testing dates. According to an implementation timeline created by CMS, practices should have begun testing their new coding systems as early as March 2013.

Uncertainty in their ability to transition to ICD-10 by the October deadline has many physicians wondering if they will be paid for the care they provide after October 1. In fact, 60% of physicians say they are "slightly" or "not at all confident" that they will meet the compliance date, according to MGMA. More than 80% are also concerned about the clinical impact of the changes, with nearly 88% expressing fears about loss of clinician productivity after implementation, and about 81% worried about the overall cost of the switch. Only about a third of the respondents said vendors covered their costs to upgrade or replace practice management systems.

According to MGMA, the cost for a 10-physician practice to upgrade or replace practice management and EHR software is about $200,000.

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Medicaid expansion

An answer to uncompensated care?

Medicaid expansion could save physicians and hospitals billions in uncompensated care costs. Yet fewer than half the states have agreed to increase their participation thresholds after challenging the expansion mandate before the Supreme Court last year.

A provision in the Affordable Care Act (ACA) expands Medicaid coverage for most low-income adults to 138% of the federal poverty level. Currently, states set the bar on who can qualify for Medicaid, and it varies widely from state to state, with thresholds ranging from about 50% of the federal poverty level to 100%.

The provision was included in the ACA as a compulsory change, but a legal challenge resulted in a 2012 Supreme Court ruling that left the decision on Medicaid coverage expansion to individual states. As of late June, 26 states had decided to participate in expansion, 13 were not participating, and the rest were undecided or pursuing alternative approaches.

The goal of the expansion, while it will likely increase the number of people who will qualify for Medicaid and therefore increase the burden on the already expensive program, is to reduce the number of uninsured Americans, which would in turn reduce the amount of uncompensated care that must be provided by physicians, and to create an even playing field in terms of who qualifies for Medicaid across the nation. Analysts like those at the Kaiser Family Foundation say overall state costs of implementing the Medicaid expansion would likely be less than the additional federal funds they would qualify for by participating in the expansion program. Some states, according to Kaiser, may actually see some savings.

However, studies indicate that Medicaid beneficiaries typically have higher rates of emergency department visits, which may reflect problems in accessing traditional care routes. Providers are less likely to accept patients with Medicaid compared to patients with private insurance—especially specialists, according to Kaiser. The ACA has attempted to increase the level of physician participation in Medicaid by temporarily offering increased payment rates to primary care physicians but, again, the increase is only temporary and does not apply to specialists. Moreover, payment rates are only one reason physicians may choose not to participate in Medicaid—participation in the program requires physicians to meet a number of additional benchmarks and regulations.

Medicaid expansion would increase overall state spending by more than $76 billion by 2022 (3%), while federal spending would increase by $952 billion (26%), according to a recent Kaiser report. The spending would be spread over an estimated 21.3 million new enrollees by 2022—a 41% jump compared to predictions in the ACA, says Kaiser, adding that Medicaid expansion coupled with other ACA provisions is expected to decrease the number of uninsured Americans by 48%. If no states were to agree to the expansion, Medicaid enrollment would rise by only 5.7 million, but the number of uninsured individuals would drop by only 28%, Kaiser notes. Kaiser estimates that physicians and other healthcare providers could save $183 billion between 2013 and 2022 if every state adopted the Medicaid expansion program.

For more coverage

MEDICAID EXPANSION • bit.ly/1cwS0tU RSS Available

Meaningful use

Make it meaningful

Meaningful use, the government program of financial rewards and penalties for encouraging doctors to use electronic health records (EHRs), has several important deadlines approaching. October 3, 2013, is the last day doctors and other eligible professionals (EPs) can begin the attestation process to qualify for the first stage of meaningful use (MU1) in 2013. (The reporting period for MU1 attestation is 90 days.)

February 28, 2014, is the final deadline for reporting attestation results for 2013 and qualifying for the Medicare MU financial bonus. The final 2013 deadline for Medicaid attestation varies from state to state, so EPs need to check with their state Medicaid agency to learn their state's deadline. EPs qualifying for the first time in 2013 under the Medicare program will receive $15,000, and those qualifying under Medicaid will receive $21,250.

In addition, EPs will be able to begin attesting to the second stage of meaningful use (MU2) on January 1, 2014. The MU2 attestation period for 2014 will be 90 days, but in 2015 and beyond will be for a full calendar year. That's because the MU certification requirements for EHR systems will change in 2014, says Robert Anthony, deputy director of the health information technology initiatives group in the Centers for Medicare and Medicaid Services. The briefer reporting period will give EPs additional time to acquire or upgrade to MU2-certified technology.

Medicaid EPs can choose any 90-day period in 2014 in which to attest, but Medicare EP attestation periods will start on January 1, April 1, July 1, or October 1.

Like MU1, qualifying for MU 2 requires meeting a series of core (required) and menu (optional) objectives. A complete list of MU2 objectives is available on the CMS Web site at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_MeaningfulUseSpecSheet_TableContents_EPs.pdf.

A self-directed timeline showing the length of time required to demonstrate meaningful use at each stage and the maximum incentive payment for each year of participation is available at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Participation-Timeline.html#.UcoEHOvgKS4.

For more coverage

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TCM codes

Transitional care management

Primary care physicians (PCPs) can, for the first time, get paid for transitional care management (TCM)—the time they spend coordinating care for patients transitioning from hospitals, nursing, or skilled nursing facilities back to the community.

Medicare began paying for TCM at the start of 2013, with the goal of encouraging PCPs to contact patients immediately after they are discharged from an inpatient facility, thereby reducing the mistakes in care coordination that frequently lead to rehospitalization. A 2007 Medicare Payment Commission Advisory Report to Congress found that 18% of Medicare patients discharged from the hospital were readmitted within 30 days of discharge, at a cost of $15 billion.

TCM is covered under the Current Procedural Terminology (CPT) codes 99495 and 99496. Required elements for CPT code 99495 are:

- communication (direct contact, telephone, or electronic) with the patient and/or caregiver within 2 business days of discharge;
- medical decision-making of high complexity during the service period; and
- a face-to-face visit within 14 calendar days of discharge.

For CPT code 99496 the requirements are:

- communication (direct contact, telephone, or electronic) with the patient and/or caregiver within 2 business days of discharge;
- medical decision-making of high complexity during the service period; and
- a face-to-face visit within 7 days of discharge. Both codes permit the face-to-face visit to take place in the patient's residence or somewhere other than the doctor's office.

Medicare requires that services performed under the codes be billed on the 30th day following discharge or later, although the rules for private payers may be different.

In addition to the codes covering transitional care management, the 2013 CPT list includes three new codes—CPT 99487, 99488, and 99489—for complex chronic care coordination (CCCC) services. CMS considers CCCC services to be bundled services covered by existing codes and thus does not pay for them separately, but is studying the new codes for future implementation. Its decision on whether to do so is expected later this summer.

For more coverage

CODES • bit.ly/14DpuE2 RSS Available

Higher Medicaid payments coming soon

Need to satisfy administrative requirements delays fee parity with Medicare promised under the ACA

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

Primary care physicians (PCPs) should soon see their Medicaid reimbursements rise to the level of those paid by Medicare —if they haven't already. The fee parity, funding for which was included in the Affordable Care Act (ACA), became effective January 1, 2013, and is scheduled to last through the end of 2014.

Increases in Medicaid fees are expected to average approximately 73%, according to a study by the Kaiser Family Foundation Commission on Medicaid and the Uninsured.

To qualify for the funds, however, states were required to amend their Medicaid plans. The deadline for submitting the amended plans to the Centers for Medicare and Medicaid Services (CMS) was April 30. CMS then had until July 1 to review and approve the amended plans. As of the third week of June CMS had approved 43 amended state plans. PCPs in Florida, Massachusetts, Michigan, and Nevada, were said to be receiving the higher payments, according to the National Association of Medicaid Directors.

An additional wrinkle is that about 60% of Medicaid patients nationwide are now in some form of managed care setting, and the ACA specifies that the payment increases must go directly to the provider. "So each state has to figure out a methodology for how to distribute the money, to crosswalk their capitated payments to their Resource-based Relative Value and Relative Value Units and apportion them appropriately," explains Stuart Cohen, MD, MPH, chairperson for the California chapter of the American Academy of Pediatrics.

MEDICAID EXPANSION COMING

In 2011 about 62 million people—including 47 million low-income adults and children—were getting health insurance through Medicaid, according to the Kaiser Family Foundation. The number of low-income persons covered by the program is expected to increase substantially next year, thanks to the higher income eligibility limits under the ACA. At the same time, however, slightly less than one-third of the nation's doctors are accepting new Medicaid patients, creating a potential scenario in which millions of newly-insured people remain unable to get healthcare from a PCP.

To try and head off that problem, the ACA included about $12 billion to bring states' Medicaid fees that were in effect as of July 1, 2009 up to the levels of Medicare fees during 2013 and 2014. "The thought was that as we increase the number of people insured by Medicaid, we want to make certain that there's enough PCPs to take care of them," says Jeffrey Cain, MD, FAAFP, president of the American Academy of Family Physicians. "It's not enough to just give more

Codes qualifying for higher Medicaid fees

Evaluation and management (E&M) and vaccine administration services qualify for the higher Medicaid fees. Qualifying codes are:

- ☐ **E&M:** *99201 through 99499*
- ☐ **Vaccine administration:** *90460, 90461, 90471, 90472, 90473, and 90474*

In addition, the following codes not covered by Medicare are eligible for the higher Medicaid payments:

- ☐ **new patient/initial comprehensive preventive medicine:** *99381 through 99387;*
- ☐ **established patient/periodic comprehensive preventive medicine:** *99391 through 99397;*
- ☐ **counseling risk factor reduction and behavior change intervention:** *99401 through 99404, 99408, 99409, 99411, 99412, 99420, and 99429;*
- ☐ **E&M/non face-to-face physician service:** *99441 through 99444;*
- ☐ **consultation services:** *9921 through 99245, 99251 through 99255;*
- ☐ **anticoagulant management:** *99363, 99364;*
- ☐ **medical team conference:** *99366 through 99368;*
- ☐ **care plan oversight:** *99399 through 99340, 99374 through 99380; and*
- ☐ **counseling services:** *99401-99420*

Source: American College of Physicians

State-by-state increases in Medicaid primary care fees

Medicaid fees for eligible primary care services are expected to increase by an average of 73% in 2013 and 2014 as a result of being raised to parity with Medicare fees. Because states differ in the amounts they currently pay for covered services, the fee increases will vary by state. Below is a state-by-state estimate of the increases.

State	Estimated 2013 fee hike	State	Estimated 2013 fee hike
Alabama	47%	Missouri	76%
Alaska	0%	Montana	7%
Arkansas	47%	Nebraska	38%
Arizona	33%	Nevada	52%
California	136%	New Hampshire	71%
Colorado	32%	New Jersey	109%
Connecticut	41%	New Mexico	22%
Delaware	2%	New York	156%
District of Columbia	25%	North Carolina	18%
Florida	105%	North Dakota	0%
Georgia	48%	Ohio	76%
Hawaii	79%	Oklahoma	3%
Idaho	13%	Oregon	39%
Illinois	93%	Pennsylvania	96%
Indiana	87%	Rhode Island	198%
Iowa	34%	South Carolina	35%
Kansas	29%	South Dakota	49%
Kentucky	44%	Texas	66%
Louisiana	34%	Utah	34%
Maine	61%	Vermont	22%
Maryland	45%	Virginia	36%
Massachusetts	47%	Washington	52%
Michigan	125%	West Virginia	34%
Minnesota	36%	Wisconsin	78%
Mississippi	11%	Wyoming	4%

Note: Tennessee has no Medicaid fee-for-service program.

Source: "How Much Will Medicaid Physician Fees for Primary Care Rise in 2013? Evidence from a 2012 Survey of Medicaid Physician Fees," Kaiser Commission on Medicaid and the Uninsured/Urban Institute.

people insurance. You have to make sure they have the ability to effectively use that insurance."

The authors of the ACA limited the Medicaid fee increases to 2 years as a way of holding down the overall price tag of the legislation, explains Neil Kirschner, PhD, senior associate for health policy and regulatory affairs for the American College of Physicians. Kirschner predicts that physicians' groups and many state governments will lobby Congress to extend the timeframe or even make the increases permanent.

"There are data showing that formerly uninsured people placed under Medicaid do better in terms of their healthcare benchmarks," Kirschner says. "One of the reasons provider groups wanted to get things started quickly was so that states could collect data further demonstrating the benefits (of Medicaid coverage) that would make it worthwhile for the government to extend these higher payments."

Although the Medicaid fee increases are expected to average 73% nationally, the actual increases will vary by state. (See table, "State-by state increases in Medicaid primary care rates,") The Kaiser Commission survey also found that Medicaid fees average about 66% those of Medicare, again depending on the state. Medicaid physician fees in 2012 ranged from 58% of the national average in Rhode Island to 242% in Alaska, and were more than 10% below the national average in some of the most populous states, including California, New York, Florida, and New Jersey.

"The fear we have is that the politics of Washington sometimes get in the way of good healthcare," says Cain. "So we want to make certain that the improved care that comes from this can go forward and not be hindered by politics."

WHO IS ELIGIBLE

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

- physicians who self-attest to being board-certified in the specialties of family medicine, general internal medicine, or pediatric medicine;
- subspecialists related to the specialties as recognized by the American Board of Medical Specialties, the American Osteopathic Association, or the American Board of Physician Specialties, and can also self-attest

➔46

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]

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

Subspecialties qualifying for higher Medicaid fees

Subspecialists recognized by the American Board of Medical Specialties (ABMS), American Board of Physician Specialties (ABPS), or American Osteopathic Association (AOA) qualify for the higher payments. The subspecialty certifications within each specialty designation are:

ABMS

Family Medicine: Adolescent medicine, geriatric medicine, hospice and palliative medicine, sleep medicine, sports medicine

Internal Medicine: Adolescent medicine, advanced heart failure and transplant cardiology, cardiovascular disease, clinical cardiac electrophysiology, critical care medicine, endocrinology, diabetes and metabolism, gastroenterology, geriatric medicine, hematology, hospice and palliative medicine, infections disease, interventional cardiology, medical oncology, nephrology, pulmonary disease, rheumatology, sleep medicine, sports medicine, transplant hepatology

Pediatrics: Adolescent medicine, child abuse pediatrics, developmental-behavioral pediatrics, hospice and palliative medicine, medical toxicology, neonatal-perinatal medicine, neurodevelopmental disabilities, pediatric cardiology, pediatric critical care medicine, pediatric emergency medicine, pediatric endocrinology, pediatric gastroenterology, pediatric hematology-oncology, pediatric infectious diseases, pediatric nephrology, pediatric pulmonology, pediatric rheumatology, pediatric transplant hepatology, sleep medicine, sports medicine

AOA

Family medicine: No subspecialties

Internal medicine: Allergy/immunology, cardiology, endocrinology, gastroenterology, hematology, hematology/oncology, infectious disease, pulmonary diseases, nephrology, oncology, rheumatology

Pediatrics: Adolescent and young adult medicine, neonatology, pediatric allergy/immunology, pediatric endocrinology, pediatric pulmonology

ABPS

Eligible certifications are American Board of Family Medicine Obstetrics, Board of Certification in Family Practice, and Board of Certification in Internal Medicine. There is no board certification specific to pediatrics.

Source: www.Medicaid.gov

➔ 44 **that they are board-certified (See sidebar, "Qualifying subspecialties");**

- **physicians practicing family medicine, internal medicine, or pediatrics who self-attest that at least 60% of their Medicaid claims for the prior year were for the evaluation and management codes specified in the final regulation implementing the applicable section of the ACA. (See sidebar, "Eligible evaluation and management codes.")**

Midlevel providers such as physician assistants and nurse practitioners are also eligible to receive the higher payments, provided they are working under the direct supervision of a qualified physician. On the other hand, physicians working in Federally Qualified Health Centers and Rural Health Clinics are not eligible.

The methods and deadlines for self-attestation to qualify for the higher payments vary from state to state. In most cases the increases are retroactive to January 1 of this year. A useful state-by-state summary, with links to the relevant documents, is available on the Web site of the American Academy of Pediatrics at (www.aap.org/en-us/advocacy-and-policy/state-advocacy/Documents/State_Md_Payment_Increase.pdf). Information is also available through state medical societies and state Medicaid offices.

WILL IT WORK?

Because only a few states are receiving funding for the higher payments, it's too soon to know if equalizing Medicaid and Medicare fees will persuade PCPs to treat more Medicaid patients. Richard Dupee, a geriatric internal medicine practitioner in Wellesley, Massachusetts, and governor of the state's ACP chapter, says the response among his colleagues has broken down along generational lines.

"The senior physicians are not going to take any more Medicaid patients because the higher payments for a year or two are not worth it, and their practices are already full in any case," he says. "And some of the newer docs coming in under the auspices of a hospital-owned practice are not taking them either, because that's a decision made at the top from the beginning."

But the reaction is different among the younger physicians he mentors. "They're all very happy these rates will be increasing," he says.

e Cohen says he is hearing "a collective sigh of relief" from pediatricians regarding the higher fees. "A vast majority already accept Medicaid patients as a significant part of their practices, and are optimistic that they will be able to continue accepting new Medicaid patients," he says.

At the same time, "many are skeptical until they actually see any payment increase, and many are wary that the managed care health plans receiving the added dollars will be less than transparent in distributing the money directly to providers, as was the intent of the ACA," he adds.

The ACP's Kirschner calls the effectiveness of the Medicaid bump an "open question, given how early in the process we are, but it's certainly a step in the right direction, particularly given the historically low Medicaid payments in many states."

Beyond the issue of money, some physicians don't accept adult Medicaid patients due to concerns over time constraints—the fear that because of their socioeconomic status the patients will require more time and attention than the physician can afford to provide. However, the AAFP's Cain thinks that need not be a concern.

"Almost all family doctors see Medicare patients, and elderly people tend to be similarly complex," he says. "The hope is that by raising Medicaid to Medicare levels doctors can afford to take care of Medicaid patients in a way that can better manage chronic diseases. We know that if you can spend money in primary care instead of more expensive places like the emergency department you'll have better outcomes and lower the cost to the whole syste m."

DPC MODEL
Physicians talk about the transition and impact [54]

Money

Fix to Medicare sustainable growth rate in the works

Congress appears to be serious about developing new payment models

by **LISA ZAMOSKY**

HIGHLIGHTS

01 The price tag attached to fixing the SGR problem has dropped considerably.

02 Gaining agreement to increase primary care reimbursement while holding specialist pay steady could be an uphill battle.

The Medicare Sustainable Growth Rate (SGR) formula has long been a thorn in physicians' sides. Initially created to rein in the growth of Medicare spending by tying reimbursements to U.S. economic output, the formula is widely accepted by physicians as a failure.

For years there's been discussion in Congress about fixing the flawed SGR, but legislators have never been able to agree on a solution.

INSTEAD, EACH YEAR CONGRESS postpones the scheduled reduction in physician reimbursement to avoid draconian cuts only to face the same problem the following year. The last postponement was made in December 2012 to avoid a 27% reduction in physician reimbursement that was scheduled to take effect January 1, 2013.

But now, serious proposals are on the table to replace the SGR formula, with both Republicans and Democrats working together to reach a solution to this long-standing problem.

"It used to be you'd say 'SGR' and their eyeballs would roll," says Jeff Cain, MD, president of the American Academy of Family

Provisions of the Medicare Physician Payment Innovation Act of 2013

- ☐ Repeal the sustainable growth rate permanently
- ☐ Stabilize the current payment system
- ☐ Institute interim measures to ensure access to care coordination and primary care services
- ☐ Provide positive payment updates for all physicians
- ☐ Aggressively test and evaluate new payment and delivery models
- ☐ Identify best practices and develop a menu of delivery model options
- ☐ Provide alternative value-driven, fee-for-service system
- ☐ Establish a transition period
- ☐ Reward clinicians for high-quality, high-value care while disincentivizing volume-driven care
- ☐ Ensure long-term stability in the Medicare physician payment system

Source: Representatives Allyson Schwartz (D-PA) and Joe Heck, DO (R-NV)

Physicians (AAFP). "But right now, we are hearing bipartisan support in the House, and also in the Senate."

What's different this time around? For starters, the price tag attached to fixing the SGR problem has dropped considerably.

"A lot of people are calling it the SGR fire sale, because it's projected to be so much cheaper to fix now than it was in past years," says David A. Lipschutz, policy attorney with the Center for Medicare Advocacy, Inc. in Washington, DC.

At one point scored by the Congressional Budget Office (CBO) at nearly $300 billion over a 10-year period, the price tag for doing away with the SGR is now $139 billion.

"I think this has encouraged both parties to go forward and feel that this is their best opportunity," says Bob Doherty, senior vice president of the American College of Physicians (ACP) Division of Governmental Affairs and Public Policy.

The other big push to reach an agreement is that this "fire sale" is likely time-limited. The CBO is scheduled to update its cost estimate in the fall, putting pressure on Congress to act now before the price for fixing the SGR potentially goes up.

"The CBO scoring process is rather opaque even to the people ➔50

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➔48 on the Hill…nobody is quite sure that you can bank on the CBO keeping the score as low as it is now," Doherty says. "The price could remain the same, could go up, or could go down. We just don't know."

PLANS ON THE TABLE

Republicans in the House Energy and Commerce Committee recently released an update to a draft bill to repeal and replace the SGR. The proposed plan has three phases:

Phase 1. SGR is repealed. Payments are stabilized for a period of 3 to 5 years, and providers continue to be paid on a fee-for-service basis.

In addition, "peer cohorts" are established in which providers self-select into categories representing those who treat similar patient populations. A set of core competencies for each peer cohort is developed and measured.

"If you did well in achieving those competencies and the associated measures, you would get an incentive update above the baseline update," Doherty says. What that baseline would be has yet to be established.

Phase 2. Payments to physicians are based on their ability to meet quality measures. Understandably, physician groups are concerned about what those measures will look like, and that they will play a major role in determining the standards to which they'll be held accountable. "This is all in play right now," Cain says. Thus far, physician groups such as the AAFP, ACP and the American Medical Association (AMA) are helping to craft the bill.

Phase 3. Providers have the option of participating in alternative payment models, such as Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes (PCMHs), which foster better coordination of care between primary and specialty care providers.

"We think those models are ready to go, and we are pleased that they were referenced in the draft Energy and Commerce language," Doherty says. He adds that ACP would be happy if greater specificity was written into the legislation to enable physicians who have already adopted these models, which are consistent with provisions under the Affordable Care Act (ACA), qualify immediately for higher incentive updates.

What's not been spelled out in the House Energy and Commerce Committee's plan are details explaining how providers would move from one phase to another, or how the quality measurements would correspond with payment. Also unclear is how to incentivize alternate payment models.

Another proposal on the table is a re-evaluation of the current Relative Value Unit (RVU) system with an emphasis on increasing the value of primary care services. That would mean paying for things such as care coordination and care transitions, and more for time spent by primary care providers explaining treatment options—services that play a critical role in good patient care but are not currently reimbursed.

Understandably, Cain says the AAFP supports an increase in pay for primary care. "Recent studies have shown that the complexity of care at a primary care office has been undervalued when compared with other specialty work," he says. "That's because as our population ages and there are more chronic diseases, the kinds of things that family doctors and primary care internists are expected to treat in their office is more complex than is currently recognized. So we are also advocating for a separate set of codes for primary care that reflect that increased value."

Gaining agreement to increase primary care reimbursement while holding specialist pay steady could be an uphill battle, Lipschutz says. "Feedback that we've gotten from some staffers on the Hill is that it's going to be very difficult to get buy-in from specialists on this issue."

Also challenging will be getting buy-in from the Congressional Doctors' Caucus, Lipschutz says. "A lot of the folks on that caucus are looking at this effort as a means to introduce other things not related to Medicare payment, such as tort reform, instituting more private contracting in Medicare, and getting rid of prohibitions on balance billing individual beneficiaries," he says.

ALTERNATE PLANS

Pennsylvania Democrat Allyson Schwartz and Nevada Republican Joe Heck, DO, have also introduced a bill to repeal and replace the SGR. The Medicare Physician Payment Innovation Act of 2013 puts a greater emphasis on moving ➔53

➔50 physicians toward new payment and delivery models.

According to Lipshutz, Congresswoman Schwartz has been a long-time proponent of fixing the SGR, and has very recently been critical of the proposal that has come out of the House Energy and Commerce Committee, saying that it doesn't go far enough to move us away from the current fee-for-service system.

The Schwartz-Heck bill "lays out a very clear timeline from where we are right now, to a system where the SGR is completely gone, and that most physicians would be expected to be in a new alternative payment model," says Doherty.

Between 2014 and 2018 the Schwartz-Heck bill stabilizes payments to physicians. "During that period of stability, the Secretary of Health and Human Services would follow a process that's spelled out in the legislation to evaluate a variety of different payment models that would be suitable to physicians in all specialty areas, and at the end of that period of stability, those new models would be finalized," Doherty explains.

At that point, the expectation is that physicians would have adopted one or more of the new models. Those who decline to participate in any of the new care delivery and payment models would see reduced fee-for-service reimbursement.

Despite the differences in the bills, Doherty says there's more cooperation than dissention at this point. Both the Senate and the House seem to be working together across the aisle on a bipartisan basis to come up with a proposal, he says. And, in spots where the bills diverge, he sees opportunities to bridge the gaps.

PAYING FOR SGR

No doubt one reason cooperation has been high to this point is because discussions about how to pay for the SGR fix have yet to take place. "I think the tenor will change when the conversation moves to the 'pay-fors,' " Lipschutz says.

As Congress looks to plug a financial hole to pay for any new piece of legislation there's a tendency to go back to proposals that have already been scored by the CBO. The fear, Lipschutz says, is that Congress will pull something off the shelf to meet a budgetary number, without real regard to the impact that it's going to have. "Our huge concern is that in order to pay for this legislation, they're going to adopt policies that would just shift cost onto the beneficiaries," he says.

> "A LOT OF PEOPLE ARE CALLING IT THE SGR FIRE SALE, BECAUSE IT'S PROJECTED TO BE SO MUCH CHEAPER TO FIX NOW THAN IT WAS IN PAST YEARS."
>
> DAVID A. LIPSCHITZ, CENTER FOR MEDICARE ADVOCACY, INC.

The same committees that are working on the SGR fix have also held a series of hearings on bipartisan Medicare reform proposals that touch on things like adding a home health copayment where there currently is none, increasing the Part B deductible, further means-testing Medicare Parts B and D premiums, and altering Medigap plans. "They're not drawing the connection. They're having hearings on this, but they're not saying, we're going to use this to pay for SGR, but that's what everyone really thinks is likely to happen" Lipschutz says.

The bottom line, Doherty says, is "somebody's offset is somebody else's ox being gored, so once you start naming offsets, you're going to get opposition."

"The question is, do we have the political will to move it forward? We'll see," Cain says.

He's optimistic about the level of understanding that the SGR is a broken system and the apparent enthusiasm to fix it. Still, Cain says, "We are challenged by a House and Senate that have been having difficulty working together in the last couple of years. We agree it's broken, now let's get together. This is why we elected our leaders," he says.

Direct primary care model gains traction in practice

More people using insurance for catastrophic care could drive growth

by **RACHAEL ZIMLICH**

HIGHLIGHTS

01 DPC is a retainer-based model for primary care practices, but does not come with a standard set of rules like many other models.

02 Patients who do stay on with a practice following a transition report improved experiences of care, better clinical outcomes, and increased engagements.

As he was nearing the midpoint of his career in family medicine at the Mayo Clinic, David Usher, MD—like many primary care physicians—knew something was missing from his professional life, and his personal life.

He found his answer in 2010 after reading an article in *Medical Economics* about a direct-pay primary care practice in North Carolina.

"I was experiencing the same thing a lot of PCPs are. The system just over time ratcheting down what you get paid and forcing you to work harder and harder to get it," Usher says, adding there was too much hassle to get paid and patients couldn't afford the care he was recommending.

He showed the article to his wife, and that's when his life changed.

Nearly 2 years later, he built an independent family practice in Wisconsin to about 2,000 patients that he describes as "loyal and happy." Yet Usher says he is starting to feel some of the same old pressures. "You're continuously looking at the bottom line and how many patients you are seeing a day and counting the dollars," Usher says.

Squeezing as many patients as possible into a day and having to be more focused on which codes will result in the highest reimbursements isn't the kind of practice many physicians envision. For physicians whose ideal was simply hanging a shingle out, the outlook is even worse.

The number of independent physicians dropped from 57% in 2000 to 39% in 2012, and those that are left are looking to new practice models to hold their ground, according to the Accenture Physicians Alignment Survey.

Accenture estimates that one in three remaining independent physicians—their ranks decline by 5% each year—will look to adopt subscription-based practice models to achieve higher yields, and that trend will continue to increase by 100% annually over the next 3 years.

The survey also included some of the top reasons physicians give for leaving independent practices to be employed elsewhere. The cost and expense of running a business was cited as the main reason for leaving independent practice by 87% of physicians surveyed. Another 61% cited dealing with managed care, 53% cited electronic health record (EHR) problems, another 53% cite maintaining and managing staff, and 39% cite the volume of patients they have to see to break even on overhead.

Although there are many ideas on how to save primary care in the face of an onslaught of new patients created by the Affordable Care Act (ACA), burnout and declining reimbursements, there are no clear solutions. But direct primary care—a more affordable version of concierge medicine—is gaining traction.

WHAT IS A DIRECT PRIMARY CARE PRACTICE?

Direct primary care (DPC) is a retainer-based model for primary care practices, but does not come with a standard set of rules like many other models. Instead, there is a common set of goals or char-

acteristics, and DPC practices are making their own rules as they go.

For M. Samir Qamar, MD, founder of MedLion—the first DPC practice in California—that meant starting from the ground up, then showing others how to do the same.

Qamar started training under the traditional fee-for-service model during his residency in family medicine at Lancaster General Hospital in Pennsylvania. By the end of his intern year, he knew he didn't like where his career was heading.

"I realized I only had 10 minutes with these patients. I didn't have the time I needed to harness their trust," Qamar says.

At that time, concierge medicine was still relatively new, but gaining popularity. But Qamar couldn't find any companies that would help a new graduate start a concierge practice—they only worked with existing practices. So he started his own, and incorporated his concierge practice during his third year of residency. Soon after, he and his wife—also a family physician—headed to Monterey, California. There were no concierge practices in the area, so they decided it would be a good place for Qamar to get his practice started while his wife elected to start her own, traditional model practice.

Qamar became the first concierge physician in central California and was soon named the house doctor for a series of resorts in Pebble Beach. He worked as a concierge physician for 7 years. Meanwhile, his wife had amassed a panel of more than 3,000 patients at her practice—one of the largest family practices in the area. When they started to compare the two practices, some big differences stood out.

"[We saw] all the things we read in the magazines about how frustrated primary care physicians are. She had to see 30 patients a day, and people were fighting about claims over and over," Qamar says. "We also felt that our accounts receivable in the traditional medical office was always a bit high."

Still, Qamar's concierge fee of more than $1,000 per month wasn't for everyone. There had to be care for those who couldn't afford boutique care. Yet, Qamar says he was surprised when the economy took a nosedive in 2008 and it was his wife's traditional practice, not his, that suffered.

"She had about a 25% decline in visits in the last quarter of 2008. We did internal checks and found that, because of the reces-

Before embarking on a transition

The American Academy of Family Physicians (AAFP) released a new policy on direct primary care (DPC) in March, defining the model as "a contract between a patient and his/her physician provides for regular, recurring monthly revenue to practices which typically replaces traditional fee-for-service billing to third party insurance plan providers." The AAFP says the model can be successful in stabilizing practice finances while at the same time allowing the physician and practice staff to focus more attention on patient needs and health outcomes than coding and billing because contract fees cover all of the primary care costs. Many patients of DPC practices still opt to carry some insurance, usually a high-deductible plan for major health events that must be handled outside of primary care, AAFP notes.

AAFP's Board Chair Glen Stream, MD, MBI, says the number of AAFP members who have developed DPC practices is small but growing, adding, "there is more than one way to build a PCMH."

"The model eliminates the insurance middleman and provides revenue directly to the practice to innovate in both customer service and quality of care for the patients they serve," Stream says. "This is one option that is particularly well-suited for small family medicine practices that are struggling financially in environments not yet supporting PCMH with a viable payment model."

> "There is more than one way to build a PCMH."
>
> —GLEN STREAM, MD
> AAFP'S BOARD CHAIR

The AAFP suggests exploring the following steps before embarking on a transition to a DPC model:

- Conduct a practice evaluation to determine the benefits of transforming to a DPC practice. Consider whether physicians in the practice want to spend more time with patients and would be willing to see fewer patients. Gauge the current practice management environment and insurance carrier contracts, deciding which could be carried over to a DPC. Finally, assess whether the current patient base would be receptive to the transition to a DPC clinic and whether there would be enough interest to maintain a table patient panel.
- Meet with legal consultants for insight on state and local regulations governing retainer-based healthcare models.
- Contact national DPC/concierge franchise operators to explore opportunities to establish a DPC practice under a franchise contract. Franchises usually charge a percentage of the practice's retainer fee but offer proven business models and a host of practice resources such as manuals, marketing materials, legal staff and operating guidelines.
- Inform patients about the transition and remain as transparent as possible throughout the process. Work with patients who choose not to participate in the new model to find a new primary care physician.

When dealing with private insurers, most direct primary care practices can be more proactive when it comes to contract service rates and participate only in contracts that are mutually beneficial for both the patient and the physician.

sion, people were losing their jobs and their insurance," Qamar says. "That was sort of the waking up moment for my wife and I."

Most patients wouldn't afford the self-pay fee of $100, and his wife couldn't maintain seeing 30 patients per day just to break even with overhead. Patients started to end up in the emergency room for simple medications because they refused to come in to the office and pay for a visit. When Qamar and his wife started calling those patients, they found out many were in foreclosure or financial ruin. "We wanted to help them," he says.

So the Qamars took the existing traditional practice and decreased the fees to an economically sustainable level so that their patients could afford to come in for treatment. For a $49 per month membership fee, Qamar says he doesn't think there was enough perceived value. When the fee was raised to $59 per month, the practice found its "sweet spot."

They defined a list of services for patients and implemented a $10 fee for each physician visit, in addition to the membership fee. "It's not cost-prohibitive for patients to do that, but it doesn't lend toward overutilization of service," Qamar says.

He then found discounted drug plans and ways to save his patients money on lab testing and other diagnostics like imaging. Soon, the practice started to grow and was saving 30% on business overhead just from eliminating insurance billing and started seeing patients coming from out-of-town.

"We felt patients were happier because we were not incentivized by making them come in anymore," he says, adding the practice did more telemedicine than under the traditional model.

RUNNING A DIRECT-PAY PRACTICE

The most common element of DPC practices is the offering of a full range of primary care services for a recurring, regular fee, usually billed to patients monthly. Some practices add an enrollment fee, while others keep membership fees low with per-visit fees. Others even use fee-for-service billing, but as direct-pay, without the involvement of insurance companies or government programs like Medicare. Membership fees in DPC models have lower retainer fees than concierge medicine.

The American Academy of Family Physicians (AAFP) estimates that typical DPC membership fees run from about $50 to $150 per month, while the Accenture survey places the range at $60 to $30,000 per year. This payment ensures DPC physicians are paid adequately for the services they provide. In contrast, under traditional, fee-for-service models, AAFP says nearly half of a physician's workday is spent outside of patient visits and therefore uncompensated.

Direct care practices vary based on the level of coverage their retainer fee provides and the structure of those fees. Some practices have membership fees that cover all primary care services, including off-site diagnostic services. Others are more limited and may still even continue participating in fee-for-service contracts with insurance carriers and use the subscription-based patients to supplement their contracts.

One of the biggest benefits cited by DPC physicians is the ease of the payment system, says the AAFP. DPC practices don't need staff dedicated to organizing, reviewing, filing, and managing third-party payment claims. When dealing with private insurers, most DPC practices can be more proactive when it comes to contract service rates and participate only in contracts that are mutually beneficial for both the patient and the physician.

Aside from the financial benefits of a DPC practice, many physicians running subscription-based practices cite their job satisfaction and ability to spend more time with their patients as an immeasurable benefit.

MAKING THE TRANSITION

For existing practices looking to transition to a subscription-based model, the change will likely benefit most patients in terms of cost and satisfaction—but not all of them. While most traditional model practices have patient panels of between 2,000 and 3,000 patients, DPC practices typically limit that number to between 600 and 800 patients.

Some patients may elect not to stay on with a practice following a transition to a DPC model, but physicians may also have to take a more active role in limiting their contract patients. Those patients who do elect to remain with the practice have reported improved experiences of care, better clinical outcomes and increased engagements, says AAFP.

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"You can't think fee-for-service anymore. It's okay to not check your watch during the patient visits. It's okay to settle in and prepare for a nice half-hour long visit. These things just don't happen any more."

—M. SAMIR QAMAR, MD
LAS VEGAS, NEVADA

➔56

Physicians considering a transition to a DPC model must determine whether to forego insurance contracts or maintain a limited number. Immediately ending insurance contracts means the practice will automatically become out-of-network and may negatively affect any patients that continue to receive insurance coverage. Those patients may therefore end up paying more out-of-pocket for primary care.

To help decide whether to discontinue insurance contracts or continue accepting some, the AAFP recommends the following considerations:

- **What is the concentration of patients across contract insurance carriers?**
- **Are there favorable contract payment rates for primary care services?**
- **Is the plan timely when it comes to its ability to process and pay out on existing claims?**
- **Are there any value-added support services provided by the insurer that would be beneficial to the DPC practice?**

If a DPC practice continues to participate in insurance contracts, it needs to make it clear to patients which services are covered by the insurance contract and which are covered by the DPC retainer fee, the AAFP says. Medicare patients are another special consideration. DPC practices can keep seeing Medicare patients, notes the AAFP, as long as the membership fee doesn't cover services already covered under Medicare.

TRANSITION AID AVAILABLE

For those seriously considering transitioning to a DCP, there is help available. Qamar turned his success with the model into a business, helping others transition their traditional practices or start new DCP practices.

In 2009, there weren't many others doing DCP, Qamar says. The nearest practice was in Washington state, but it was financed by a venture capital group.

"That immediately validated our model and what we were doing with our patients," Qamar says.

As they continued to grow their practice, they soon had interest from others. Remembering how little help he had in starting his own concierge practice years before, Qamar decided that the more than 2,000 family medicine residents who graduate each year might have interest in his model, and might not have help starting a DCP practice. Instead, they are courted by hospitals and insurers.

"The whole idea of the shingle being hung outside your office is being lost very quickly," Qamar says. "We want to help the underinsured and the uninsured, but also to resuscitate primary care private practice."

Over the last 2 years, Qamar has left concierge medicine and started helping other practices like his wife's convert to the DCP model. So far, his company MedLion has or is now in talks to license practices in Arizona, California, Colorado, Florida, Indiana, Kansas, Maryland, Nevada, Pennsylvania and Washington. His family moved to Las Vegas last fall to better position the company for growth.

But even with all his experience in transitioning practices to the DCP model, Qamar is cautious. The transition can be expensive, particularly when it comes to legal fees to keep you off the radar of government institutions seeking to label the practice as an insurance company, he says.

"It's a thin line between selling an insurance product and being in direct primary care," Qamar says. In fact, he spent about $1 million to get his company's model just right.

A DIFFICULT SELL

"For doctors doing it on their own, it's not easy," Qamar says. First, it's difficult to sell a new concept, Qamar says. And not just to patients, but to companies that could send their employees to your practice. It took Qamar about 3 years of trial and error to find the best way to grow the DCP practices, he says.

Practices in large cities have faster growth, but it also depends on the number of uninsured and employers willing to send their employees to the practice. Qamar says his sales and marketing team now goes into new areas to get at least 300 to 400 new patients signed up by contracting with employers before even opening a new practice.

Also, at MedLion, physicians opt out of Medicare because of the prohibition on charging rates lower than Medicare rates to non-Medicare patients. And physicians

looking to transform shouldn't be nearing retirement so the practice can have longevity, Qamar says.

"You can't think fee-for-service anymore," he says of life as a DCP practice. "It's okay to not check your watch during the patient visits. It's okay to settle in and prepare for a nice half-hour long visit. These things just don't happen any more."

As far as his company's expansion, Qamar says he would like to add 1,000 DCP practices in 10 years. He's even working on a loan repayment program to help attract new graduates to the model, adding that DCP physicians earn two to three times more than physicians in traditional model practices without a lot of the headaches.

CHALLENGES REMAIN

Usher, who was "run down by the rat race," says he is happy with the new model, but admits that he still faces challenges. It's easier to count the dollars at the end of the day because he accepts only cash, credit cards, or checks, and sees no Medicare or Medicaid patients. But he still has a bottom line to consider, and without a retainer system in place, all Usher can do to predict his income is look to the prior month's collections and keep his fingers crossed.

Still, the more Usher learns about subscription-based models, the more he sees it as a viable alternative to strict direct pay for the long-term.

Many of his patients still carry high-deductible insurance for catastrophic events, and he supplies them with coded receipts if they want to try and seek reimbursement for any of his services, although that doesn't happen often since he's not in anyone's network.

And although he likes that his practice has a low overhead with no billing or collections staff, he says it is a risk. For example, when he started this venture only about 5% of his patients came with him from his old practice.

"It was a big investment," Usher recalls. "We lived on savings for quite a while. If you're in your own practice and you can transition your own practice, that might be simpler, because you don't have to move."

Fortunately, finding patients isn't difficult for Usher, who sees four or five new patients each day. Though he started by placing local cable and newspaper advertisements and literally pounding the pavement, word of mouth is the biggest driver of new patients to his practice these days.

Nevertheless he isn't quite clearing enough in income to bring on more help, and doesn't envision having a practice that had to turn people away.

"I've always thought I would get busy, but didn't want to get too busy to get people in," he says. "I don't want to turn people away based on access."

Even if he had the money for more help—Usher now employs some part-time physicians at his practice— few in his area want to take a chance on a direct pay model.

The upside of his practice, Usher says, is that he can keep his prices and overhead low and spend more time with patients. "We don't have to mill them through," he says. But he believes a retainer-based model, rather than strictly direct pay, may help him develop a more steady stream of income for his practice.

Usher admits he isn't yet making what he did at the Mayo Clinic, but hopes that will change in a few years, as his noncompete agreement expires and he eyes a move back to a bigger city. But even without making the same or more than when he was employed by the hospital system, Usher says he has no regrets.

"Even if it was a break-even deal, just the job satisfaction would make it so worth it," Usher says. "I didn't realize how burned out I was until I stepped out of that system."

Although newer models and reforms like the move to Patient-Centered Medical Homes (PCMH) aim to improve the practice of primary care, Usher says he still believes there is too much overhead in the current system for PCPs to ever get to a point where they can practice satisfactorily and be happy with where they are for the long term.

"For me, the time to change was now because I knew things were all going to be changing anyway. I would never go back to the insurance billing world," Usher says. "I think ultimately some blend of a direct pay/a-la-carte model with the membership fee may be desirable because that positions you to grow in a marketplace where people can come and test you out without having to throw out a whole year's worth of membership fees."

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Legally Speaking

EMERGENCIES: IS CONSENT REQUIRED?

by **LEE J. JOHNSON,** *JD*

Here is how a family physician described a recent case: "A 10-year-old was brought to my office for treatment of a dog bite of the hand. I diagnosed the child with compartment syndrome, R/O as cause of radial nerve palsy. After a call, a pediatric orthopedist at Hospital A felt the child should be seen right away. We decided to send the child to Hospital B to expedite a transfer by ambulance to Hospital A.

THE PARENTS did take the child to Hospital B's emergency department (ED). But they refused consent for the ambulance transfer. A follow-up call to the patient's home revealed that the child was taken instead to Hospital C's ED. A call to Hospital C confirmed that the child was treated and discharged with antibiotics for an infection of the hand. I disagreed with the treatment."

LEGAL ISSUES

If a patient does not have capacity, another person may be designated to consent on the patient's behalf. For a minor, the parents are usually the legal guardians and have the right to consent or refuse to give consent on behalf of the child.

Consent is not required in an emergency. If the family physician or specialists had thought the situation an emergency, they could have treated the child despite the parents' objections.

For a minor, the needed treatment does not have to rise to the level of an emergency for a doctor to be able to render treatment without consent. The state has the right to override the parents under the doctrine of "parens patriae," when the state may act as parent and give consent. Child protective services of most states can be called and will give consent, if needed.

For consent to be truly informed, a doctor must discuss with the patient or legal guardians not only the risks and benefits of the recommended treatment, but also the risks and benefits of the alternatives, including no treatment. Be sure to document the conversation in the medical record.

MALRPACTICE

In this case, whether a lawsuit is filed by the child's parents and how well the doctors would fare depends in large part on how the child responds to the antibiotics. The best defense in a malpractice case is a good result.

In any malpractice lawsuit, the standard to which you are held is that of a "reasonable physician," which is defined as what other physicians in your specialty would do in a similar situation.

In this case, there was a disagreement of medical opinion between the family physician and the specialist at Hospital C. If there is disagreement among physicians, they should explain their reasoning to one another and try to reach a compromise. They should document in the medical record their reasoning in a straightforward manner.

In the event of a lawsuit, expressed disagreements in the medical record can be used to advantage by a plaintiff's attorney. Don't malign your colleague's position. Physicians can foment lawsuits by being unduly critical of other treating physicians.

FOLLOW-UP

A doctor has some obligation to follow-up on a non-adherent patient. The level of diligence required depends on your index of suspicion, the seriousness of the injury, and the capacity of the patient to make appropriate decisions. Since a child does not have capacity, the doctor may have more of an obligation to follow-up.

The family physician did a good job by calling Hospitals B and C, and the child's parents. Remember to always document in the medical record any follow-up calls to a patient or a patient's guardians. ◻

The author is a health law attorney in Mount Kisco, New York, and a Medical Economics *editorial consultant. Send your legal questions to* **medec@advanstar.com**.

Financial Strategies

8 TIPS FOR REDUCING COLLECTION AGENCY REFERRALS

by **KEITH BORGLUM,** *CHBC*

Patients don't like having their accounts sent to collection agencies for non-payment of medical bills, and few practices like having to send them there. Unfortunately, most of the effort required to avoid sending an account to collection falls on the practice, not the patient. Here are eight tips to help you keep your patients' accounts out of collection:

1. Have a written financial and payment policy form that patients sign. Use examples found in books and online. Don't try to invent one yourself, because there are laws that apply.

2. Always make a copy of the patient's insurance benefit card at the time of visit. Verify that the name on the card matches the patient's driver's license information. Check to make certain the insurance card is valid and active. This also helps to avoid a growing trend — healthcare identity theft. In one case I encountered, an insurance company refused to pay for an obstetrical delivery because it appeared to be the patient's third full-term delivery within the past 12 months. It turned out that two sisters were sharing the same insurance card at two different offices.

3. Know the deductible and copay rules of your most-common insurance plans, and collect payment-due at time of service (PATOS). If the patient "forgot their wallet" or offers another excuse, offer to reschedule the appointment, unless there is an urgent clinical need for the patient to be seen immediately. Many times the patient will miraculously find the money rather than reschedule.

4. Collect any prior payments-due at the time of service. Multiple non-payments will make it more likely that you'll have to send the account to a collection agency.

5. If the patient does not pay at the time of service and you still keep the appointment, give the patient a stamped, self-addressed envelope, and write the amount due on the inside of the flap. When you hand it to the patient say, "Send the payment as soon as you get home, and we'll expect to receive it by [date]. I'll make a note of that in your file."

6. Follow up on past due accounts with a phone call within 1 week of the due date. Get a promise to pay, and tell the patient you will make a note of that promise and date in the file. Follow that up with a call or note weekly for up to 90 days. The longer it's overdue, the less likely you will be paid.

7. Bill the patient's insurance promptly. It is common for patients to use up their medical benefits when expecting termination of employment. If you bill after the patient has lost coverage, the insurance company won't pay, and the patient has probably lost his or her ability to pay.

8. If a patient truly has a financial hardship and you provide a discount or waive payment, have the patient fill out a hardship form and keep it in his or her file. Samples of these types of form are available online. Many patients asking for an up-front discount decide they would rather pay than fill out such a form. It's important for all physicians to do some charity work from time to time, but that doesn't mean you have to allow patients to take advantage of the practice. ◻

The author is a medical practice management consultant in Santa Rosa, California, and a Medical Economics *editorial consultant. Send your practice management questions to* medec@advanstar.com.

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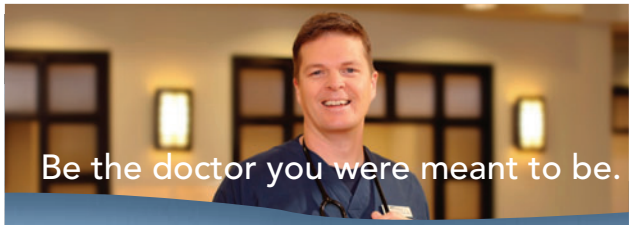

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Perspective

IS THE UNEQUAL DISTRIBUTION OF PCPs WORSE THAN THE SHORTAGE?

BY BRANDON GLENN

The perceived current and future shortage of primary care physicians (PCPs) has been attracting lots of attention from U.S. health policymakers, but a recent study suggests that the United States is facing a bigger primary care problem: an uneven distribution of physicians.

That uneven PCP distribution is felt most acutely in poor and rural communities, according to the policy brief from the Robert Graham Center for Policy Studies in Family Medicine and Primary Care, an affiliate of the American Academy of Family Physicians.

For example, there are 68 PCPs per 100,000 people in rural areas, compared with 84 per 100,000 in urban areas, according to data from the Agency for Healthcare Research and Quality that's cited in the brief.

"An unequal distribution implies that many areas have relative primary care shortages, especially rural communities and areas of measurable social deprivation," the brief states.

To hit the goal set by the Health Resources and Services Administration of a 2,000-to-1 population-to-physician ratio, the supply of physicians would need to be increased by 2,670 in rural areas and by 3,970 in urban areas, according to the brief.

Further, as more people gain insurance under the Affordable Care Act, the unequal distribution problem is likely to become exacerbated.

The obvious question, then, is what to do about the nation's unequal distribution of PCPs. That's where the brief falls short (though admittedly it's only a brief) by offering only a generic statement that lacks any hint of a detailed policy prescription.

"New incentives and policies for distributing primary care physicians to areas of greatest need, as well as a larger absolute number of these physicians, will be needed to ensure access for the newly insured," is as far as the authors are willing to go.

But the federal government has already established programs designed to funnel PCPs to areas of need. For example, the National Health Service Corps (NHSC) and Title VII of the Public Health Services Act are two of the most important federal programs designed to not only increase the number of PCPs across the nation but also boost primary care in underserved areas.

Established in 1972, the NHSC provides scholarships and loan repayment for PCPs to work in areas of the United States in which residents have limited access to healthcare. More than 2,400 PCPs served in the program in 2011, up 67% from 2008.

But while such programs may be having an impact on the PCP distribution problem, they've hardly solved it.

A recent study in the journal *Academic Medicine* drew the issue into sharper focus with its conclusion that a lack of accountability among publicly-funded graduate medical education (GME) institutions is a key reason why younger physicians are failing to plug the holes created by unequal physician distribution.

GME institutions receive about $13 billion in public funds annually through Medicare and Medicaid, yet they produce PCPs at an "abysmally low" rate, HealthLeaders media reported in an article about the study.

"Right now with the Medicare money that goes for GME there is very little requirement around that money other than that you train and report that you train 'X' number of residents," says Candice Chen, MD, a lead author of the study. "There is nothing in the payment that says you need to produce these kinds of doctors or produce doctors who are going into certain areas to serve the need that America has."

@ Want to weigh in on the debate about the distribution and shortage of primary care physicians? We want to know. Write us at medec@advanstar.com. Your comments could be in the next issue of *Medical Economics*.