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Medical Economics®

JUNE 25, 2013

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# EHR DIVORCE

## WHAT'S DRIVING DISSATISFACTION?

- ☐ Examining true costs
- ☐ A closer look at usability and certification

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EXCLUSIVE
EHR BEST PRACTICES CASE STUDY PAGE 30

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ADVANSTAR MEDICAL COMMUNICATIONS GROUP VOL. 90 NO. 12

# Twitter Talk

*Other people and organizations tweeting about issues that matter to you*

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**@MILLER7**
*There is limited alignment between a patient's real-life, heartfelt goals, and the goals in traditional medical model.*

**MARK HYMAN**
**@MARKHYMANMD**
*"Food is information and it controls your gene expression, hormones, and metabolism."- The Blood Sugar Solution*

**RICH DUSZAK**
**@RICH DUSZAK**
*So much for evidence based practice? MT @medskep: Majority of Clinical Trials Don't Provide Meaningful Evidence bit.ly/17F04Lh*

**DARRYL FEARS**
**@BYDARRELFEARS**
*In 1900, there were about 2 million chimps. Now, maybe 300K. Should they be used for med research? My story: wapo.st/1707s4B*

**STEPHEN WILKINS**
**@HEALTHMESSAGING**
*Just because you build a "medical house" to @NCQA specs doesn't mean it's a pt-centered "medical home" wp.me/pGXmn-SF #primarycare*

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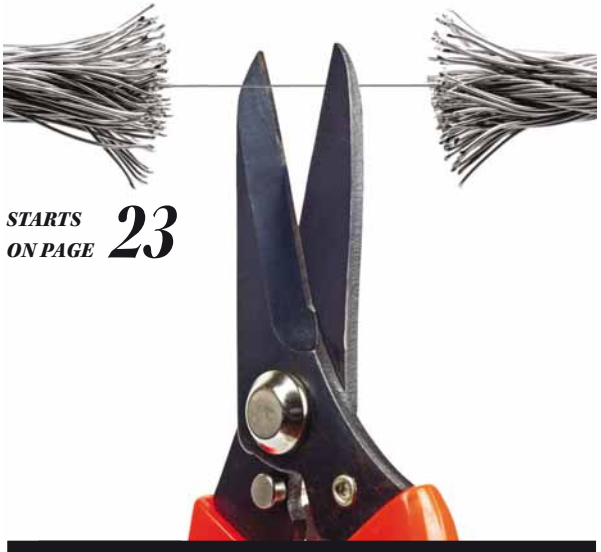
# EHR DIVORCE: WHAT'S DRIVING DISSATISFACTION?



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COVER STORY | TECH

While multiple surveys depict growing dissatisfaction with EHRs, experts talk about the drivers and offer solutions on how to ease your frustration.

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- How to examine true costs
- A look at certification
- Transitioning vendors

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*Calculating the ROI of equipment*

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CODING INSIGHTS

**Maxine Lewis**
*7 compliance measures for new HIPAA rules*



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

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ONLINE EXCLUSIVE

# MEDICAL ECONOMICS WEEKLY, EPISODE 5

In the fifth in *Medical Economics*' series of weekly Webcasts, we examine the impact of the growing shortage of skilled health information technology workers, discuss a study revealing that a majority of physicians in independent practice do not want to sell their practice, and looks at the potential for the new Microsoft Xbox to help patients monitor and improve many aspects of their health.

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**#2 OBAMACARE TO MEAN MORE JOBS FOR PHYSICIANS**
The law is expected to bring more people into the healthcare system, increasing the demand for doctors.
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**#3 CRACK THE CODE**
Learn how to increase revenues by accurately coding for the services you provide.
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## Twitter Talk

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**HEALTHCARE DATA**
*Get ready for a more data-driven approach to #healthcare, says @Sebelius. http://ow.ly/IHAbx via @HillHealthWatch*

**MEDICARE CLAIMS**
*Physicians' #Medicare claims data could be made public after court ruling http://ow.ly/IGUa1*

**INTEROPERABILITY**
*Reasons for optimism around #EHR interoperability: 'Direct' is coming. http://ow.ly/IF6gk via @THCBstaff #HealthIT*

**NEW PAYMENT MODELS**
*How value-based payment models could reduce #healthcare costs & boost #PrimaryCare http://ow.ly/IA1nQ #familymedicine*

**EHR TRANSITION**
*4 common unanticipated issues when transitioning from paper to #EHR. http://ow.ly/IAIRO via @hitnewstweet #HealthIT*

**HEALTH EXCHANGES**
*A look at the challenges California faces getting young adults to enroll in its #ObamaCare exchange. http://ow.ly/IEjpG via @latimes*

**HEALTHCARE COSTS**
*"The U.S. just pays providers of #healthcare much more for everything." http://ow.ly/IEhUs via @nytimes*

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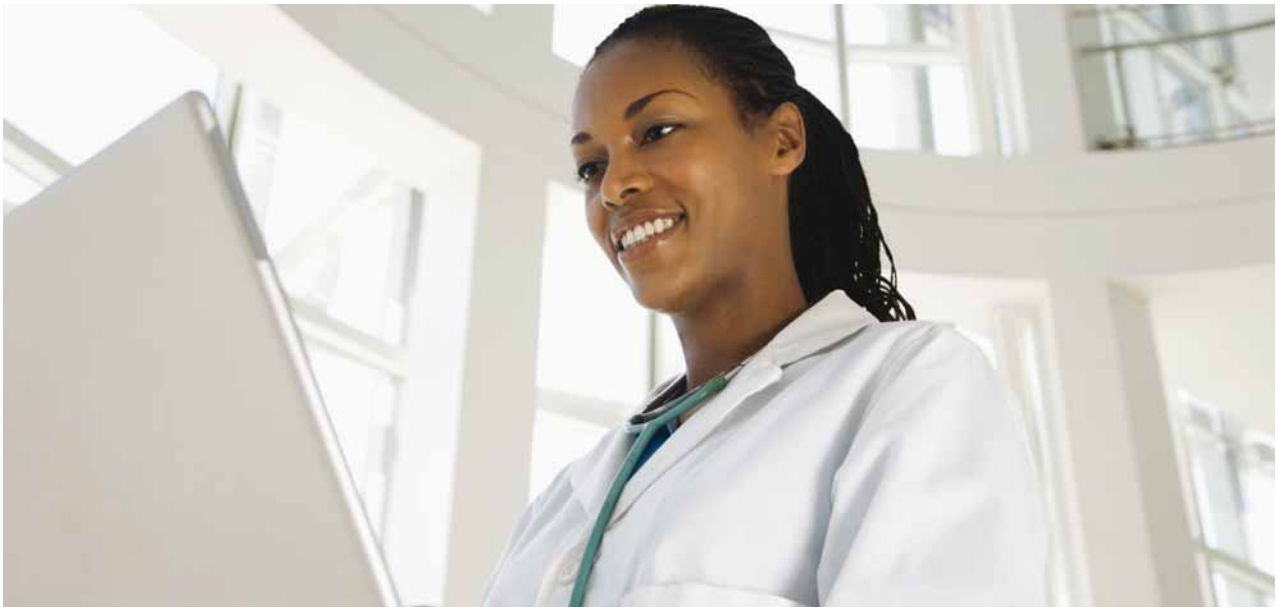

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Together we'll go far

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Before acquiring costly new equipment for your practice, calculate your likely return on the investment.

**—Reed Tinsley,** CPA

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# *from the* Trenches

> The evidence...points to prejudice, substandard treatment, and unacceptable experiences for the obese population. All patients deserve sensitive, compassionate, and competent care, regardless of their weight.
>
> **Joan Temmerman, MD, MS** CONNERSVILLE, INDIANA

## OBESITY RESULTS FROM MANY COMPLEX FACTORS

I am writing this in response to "Obesity Not An Epidemic" *(Medical Economics*, May 10, 2013) by Michael Moffat, MD, which I found highly offensive as well as erroneous. Obesity is a chronic, complex disease with a multifactorial etiology. Genetic, environmental, neuroendocrine, perinatal, dietary, and psychosocial factors all contribute to the development of obesity. In addition, many commonly prescribed medications, such as psychotropic and anti-diabetic medicines, are associated with significant weight gain, so iatrogenic factors cannot be overlooked.

Energy imbalance is the core cause of obesity. Our modern environment is characterized by the avoidance of physical activity and the constant temptation to eat. The lack of fixed-meal patterns at home, abundant food availability outside the home (fast food, vending machines, ready-to-eat foods), increased portion sizes and fewer opportunities to expend energy via physical work produce a net energy excess.

Genetics, activity patterns, medications, and the food environment all influence energy and weight regulation. Obesity affects all ages and socioeconomic groups. It threatens to overwhelm both developed and developing countries, according to the World Health Organization. Obesity is not only an epidemic, it is a pandemic.

It is quite unfortunate that obesity is heavily stigmatized by society as well as the medical profession. Obese individuals are not only condemned for their appearance, but blamed for it as well. Weight discrimination has increased by 66% over the past decade and is prevalent even among health professionals.

Patients consistently report disrespectful treatment because of their weight, and weight is blamed for most medical problems. Weight bias negatively affects health outcomes. Obese patients often delay or forgo preventative care because of unsatisfactory experiences, discrimination, embarrassment or discomfort.

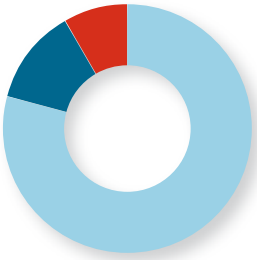
Weight discrimination is associated with low self-esteem, depression, maladaptive eating patterns, avoidance of exercise, and impaired ability to engage in healthy lifestyle behaviors. The evidence overwhelmingly points to prejudice, substandard treatment, and unacceptable experiences for the obese population. All patients deserve sensitive, compassionate and competent care, regardless of their weight.

Blaming the victim for obesity is archaic and should be obsolete by now. Haven't we had enough of this from the food and beverage industries?

Discrimination in any form is unacceptable and should not be tolerated. Weight bias is especially unworthy of the medical profession.

***Joan Temmerman, MD, MS***
CONNORSVILLE, INDIANA

***In your opinion, how will ACOs fare?***



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

***Visit our Resource Center to view a video discussion on the pros and cons of using bariatric surgery as early intervention in morbid obesity at bit.ly/15Xv8SD***


> Wolfson ... argues that intensive performance monitoring, testing, and patient data-sharing is inevitable and necessary, and doesn't violate privacy. His opinion, although widely held by the government and the electronic health records industry, is not supported by data.
>
> **Craig M. Wax, DO,** MULLICA HILL, NEW JERSEY

## ATTORNEY HAS 'DISTURBING' VIEW OF MEDICAL SYSTEM

This letter expresses concern over the opinion presented by Jay Wolfson, DrPh, JD, in "Costs, control, data access remain top EHR concerns," (*Medical Economics*, January 25, 2013.) His view of the medical system is disturbing.

Wolfson says physicians must install electronic health records (EHRs) for the good of medicine. He further argues that intensive performance monitoring, testing, and patient data-sharing is inevitable and necessary, and doesn't violate privacy. His opinion, although widely held by the government and the EHR industry, is not supported by data.

The last and final straw is the view that it is reasonable for the federal government to say, "Since we're paying you with Medicare and Medicaid, we need to know as much about what you do as possible so that we can help you ensure that quality outcomes meet reasonable standards. If you don't, we're not going to pay."

Wolfson says that the U.S. Department of Veterans Affairs' (VA) EHR system is efficient and interoperable. My colleagues at the VA tell me, however, that due to the complexity and technical problems with their EHR system they can see only 15 patients a day at most. On the interoperability question, did you ever try to get the VA to communicate with your private practice office? They cannot and will not communicate with other physicians.

Wolfson's dystopian medical vision if realized would destroy quality care and any semblance of the doctor-patient relationship necessary for healthcare to function.

***Craig M. Wax, DO***
MULLICA HILL, NEW JERSEY

## CHILDREN SHOULD BEAR SOME COLLEGE COSTS

Joel Greenwald, MD, CFP's answer to the question about how to pay for a child's college education ("Financial Strategies—Advice From the Experts," April 10, 2013) had some glaring omissions. His advice wrongly puts all the burden on the parents.

I submit that in most cases it is not appropriate for parents to cover the entire cost of college for their children. My wife and I are in the process of helping three of our children get through higher education through a combination of efforts. All of them worked very hard to excel in high school. They also took preparatory tutoring for these exams, and their resulting high scores netted large scholarship rewards.

Furthermore, all our children worked through college, including holding research assistant positions, student teaching, tutoring, and summer jobs.

As Greenwald suggested, we started 529 plans for each of our children when they were toddlers, but I think all parents should encourage their college-age children to take an active role in funding their own educations..

***Jay W. Grosse, MD***
CLYDE, NORTH CAROLINA

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## GEORGIA'S 'PHYSICIAN SHIELD ACT' PRAISED BY AMA

Access to high-quality healthcare cannot be used to "invent new legal actions against physicians," according to a new Georgia law.

The American Medical Association's (AMA) Patrice A. Harris, MD, board member, explains, "This first-of-its-kind legislation reinforces the concept that medical decisions are made based on a patient's unique medical needs."

"The decisive action of Georgia lawmakers holds the line against medical liability abuse and helps avert more civil actions against physicians, which increase medical liability insurance premiums and reduce access to health care for Georgia's patients.

AMA reports working in collaboration with the Medical Association of Georgia to get the legislation passed.

# COALITION AIMS TO QUASH EXPANDED ROLE OF NPs IN CALIFORNIA

Broadening the duties of nurse practitioners has drawn sharp criticism from a coalition of medical societies.

Despite recent revisions to proposed California legislation, the California Medical Association (CMA) contends this legislation does not address the problems associated with the primary care shortage and the influx of newly insured patients next year as a result of the Affordable Care Act (ACA.)

"Allowing practitioners to perform procedures they simply aren't trained to do can only lead to unpredictable outcomes, higher costs and greater fragmentation of care," CMA cites in a position paper.

"As health care delivery becomes more complex, expanding the team of health care professionals that serves patients makes sense. However, it is not in the best interest of patients to abandon the current physician-led team approach to health care."

Specifically, the legislation seeks to:

- remove certain requirements that require physician and/or surgeon consultation.
- allow a nurse practitioner to establish a "physical diagnosis and prescribe drugs and devices"
- set up rules related to referrals to physicians and licensed healthcare providers.

"Rather than expanding the scope of practice of allied health practitioners," CMA contends, "California should be looking toward an integrated team-based care led by physicians. These teams will streamline care, maintain and improve patient safety and decrease the costs of care."

Other members of the coalition include the California Academy of Family Physicians, Osteopathic Physicians and Surgeons of California, California Academy of Eye Physicians & Surgeons, California Society of Anesthesiologists, Canvasback Missions Inc., Diabetes Coalition of California, Lighthouse for Christ Mission Eye Center, Union of American Physicians and Dentists – AFSCME Local 206, California Psychiatric Association and the American College of Emergency Physicians – California Chapter.

### WHAT'S DRIVING THE DEBATE?

**16** of **58 California counties** have recommended ratio of physicians to residents.

ACA will bring **5 million more** Californians into the healthcare delivery system.

Legislation seeks to **remove physician signature** related to treatment.

**We want your opinion about the scope of practice and its ramifications for healthcare delivery. Share on facebook.com/MedicalEconomics or send them via e-mail to medec@advanstar.com.**

## E-PRESCRIBE DEADLINE JUNE 30

If you have not enrolled in Medicare's e-prescribe program, you have until June 30 to do so or face a 2% penalty next year.

According to the Centers for Medicare and Medicaid Services (CMS), physicians will need to electronically transmit 10 prescriptions (G8553 code) for billable Medicare Part B services provided between Jan. 1, 2013 to June 30, 2013 to avoid the 2014 penalty.

To capture the .05% Medicare e-prescribe incentive (and avoid a 2015 penalty), participating practices will need to document 25 "unique e-prescribing encounters in 2013."

If you plan to apply for the Medicare electronic health record (EHR) incentive in 2013, note that you can't receive the e-prescribing incentive in the same payment year, CMS says. Physicians applying for the Medicaid EHR incentive are still eligible for e-prescribing incentive payments.

*For more information, go to cms.gov/eprescribing.*

### Medicare penalties/ incentives for e-prescribing

| | Incentive | Penalty |
|---|---|---|
| 2012: | 1% | 1% |
| 2013: | 0.5% | 1.5% |
| 2014: | None | 2% |
| Beyond: | None | 2% |

# Draft legislation unveiled to eliminate SGR formula

**A CONGRESSIONAL** committee wants to reform the Medicare payment system by first repealing the controversial sustainable growth rate (SGR).

In fact, in recent weeks the House Energy and Commerce Committee released a plan to replace the SGR formula with a system of stable payment updates with a fee-for-service payment option.

The committee has reportedly been working on the plan since January 2013.

"The policy would repeal SGR and, in return, replace it with an improved fee-for-service system in which providers—working with the Secretary of Health and Human Services (HHS)—develop quality measures that will lead to better care in a more efficient manner," the committee said in prepared comments.

"Unveiling our committee's draft legislation is an important milestone in our thoughtful, collaborative efforts to repeal SGR. We are working to restore certainty, fiscal sanity, and we will responsibly pay for these reforms," said committee chairman Fred Upton (R-MI).

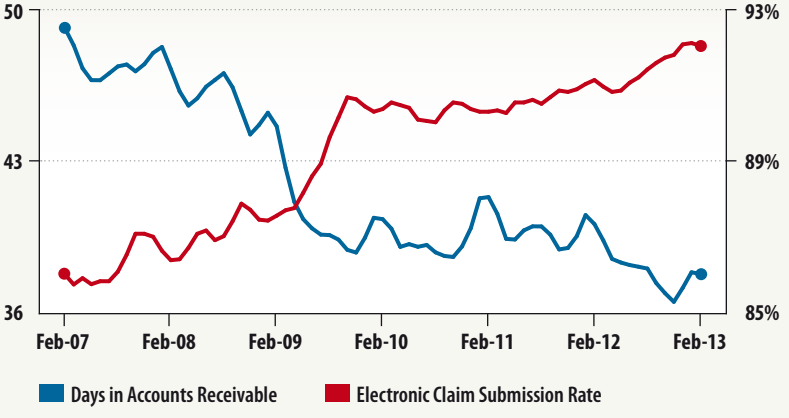
While the legislation does not specify terms of payments, it does call for HHS to incorporate quality metrics and alternative payment models that reward for quality care.

The draft reflects many of the principles for transitioning to a higher-performing Medicare system that the American Medical Association, California Medical Association (CMA), and more than 100 state and specialty medical societies submitted to Congress last fall, officials say.

"While the draft doesn't specify what quality measures would be used, it does say that the measures would be physician developed and Medicare reimbursements would be based on quality scores relative to their peers, improvements in scores from previous years and clinical improvement activities," CMA officials say. "It also states that quality measures would be risk adjusted so that providers are not penalized for treating sicker or more complicated patients.

### Days in Accounts Receivable vs. Percent Electronic Claim Submission

**The time it takes for a doctor to get paid (days in accounts receivable) significantly decreased when claims were submitted electronically. This data was generated from 40,000 providers and 29 million claims.**




Source: athenahealth

# Doctor's Bag

*The latest in drugs, devices, technology, and more*

## HBA1c DIABETES TEST CLEARED FOR DIAGNOSING DIABETES

The U.S. Food and Drug Administration (FDA) recently announced that the Cobas Integra 800 Tina-quant HbA1cDx assay can now be used by healthcare professionals as an aid to diagnose diabetes. HbA1c is the first test the FDA has allowed to be marketed for diabetes diagnosis. Other HbA1c tests on the market are cleared for monitoring blood glucose control but not for diagnosing diabetes.

The laboratory-based test can be used to diagnose both, providing physicians with another way to identify undiagnosed cases of diabetes and treat patients before problems develop or worsen.

Investigators analyzed 141 blood samples and found less than 6% difference in the accuracy of test results from the new assay compared with results from the standard reference for hemoglobin analysis, according to the FDA.

The assay is available by prescription for use in clinical laboratories. Over-the-counter HbA1c tests should not be used by patients, and only a qualified healthcare professional should make a diagnosis of diabetes.

An estimated 25.8 million people in the United States have diabetes—including 7 million who remain undiagnosed.

**Roche** www.roche.com www.rocheusa.com

### ONLINE PROGRAM HELPS MANAGE PATIENT LIFESTYLE


Virtual Lifestyle Management is an online weight management program that can help physicians manage their overweight adult patients. With 24/7 online access to summaries and graphs of each patient's progress, physicians can treat numerous people in less time and at lower staffing levels.

Over the 12-month program, patients will learn and adopt healthy behaviors by taking lessons, completing workbooks, and tracking their physical activities and nutritional intake. VLM can enroll users in 6 weeks using existing staff within a practice or DPS Health's trained coaches.

Funded by the U.S. Department of Defense, VLM is based on the Diabetes Prevention Program's (DPP) lifestyle intervention, an in-person weight management approach developed by the University of Pittsburgh and funded by the National Institutes of Health.

**DPS Health** (310) 444-0636 | www.dpshealth.com

### ELECTRONICALLY IDENTIFY THREATS TO PATIENT SAFETY

Truven Health Analytics has introduced enhanced flexibility and new functionality in reporting for its Pharmacy Intervention and Infection Prevention products, part of the Micromedex 360 Care Insights Suite.

Enhancements allow physicians to demonstrate improved care quality and better patient outcomes, as well as provide operational efficiencies and cost savings to a practice. Reporting capabilities provide greater visibility into clinical quality and financial tracking.

Real-time clinical surveillance solutions can electronically identify patients at risk for adverse events as well as other threats to patient safety. By providing a comprehensive view of the patient, timely and informed treatment decisions can be carried out. Clinical profiles are built with evidence-based rules and clinical decision support.

**Truven Health Analytics**
1 (800) 525-9083
www.truvenhealth.com

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Trends

# MOC: Debate intensifies as Medicare penalties loom

## Experts offer advice on how physicians can team up to make the process more palatable, valuable

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

### HIGHLIGHTS

**01** While maintenance of certification has spurred seemingly continuous debate among physicians, groups are making online study modules more accessible for physicians to complete Part II MOC assessments.

**02** Experts say that group study, online tutorials, education modules and online dashboards becoming available will make the process easier and more transparent.

If you want to spark a debate, just ask a physician about maintenance of certification (MOC) requirements. The reaction often is visceral. The rules are designed to create a culture of continuous improvement in practice, but they can be confusing, costly, and time-consuming. In 2015, Medicare penalties are on the way for not participating.

**TODAY, MANY** physicians are fighting the requirements, with one medical group going so far as to file a federal lawsuit (see sidebar: Maintenance of Certification spurs federal lawsuit), while many others are trying to make the best of it, looking for ways to make the experience easier and more valuable to them. *Medical Economics* recently asked a variety of experts on the subject for their advice on how physicians can make that goal a reality.

Working with your medical society, partnering with colleagues when appropriate, looking for ways to piggyback data collection onto projects you are already doing, and taking the time to really understand the requirements associated with MOC were among the top suggestions.

### STRENGTH IN NUMBERS

Eric Holmboe, MD, chief medical officer for the American Board of Internal Medicine (ABIM), suggests that in addition to availing themselves of the many ABIM online modules, physicians take advantage of the numerous opportunities offered by their medical societies to complete Part II assessments. Organizations such as the American College of Physicians and the American College of Cardiology are incorporating modules that meet Part II requirements at their annual meetings.

"Physicians can often complete questions online right after attending one of these sessions," he says.

Some societies present the ABIM modules in a setting in which a group goes over the materials with an expert and they discuss the questions together, then go on the ABIM portal to enter them, he says. Similarly, the members of a group practice can work on the modules together, he adds.

Robert Phillips, MD, MSPH, vice presi-

# Maintenance of Certification spurs federal lawsuit

Many physicians dislike maintenance of certification (MOC) requirements, but one group has made its objections more official, suing in federal court.

The Association of American Physicians and Surgeons (AAPS) filed a lawsuit in Trenton, New Jersey, on April 26 against the American Board of Medical Specialties (ABMS), claiming that ABMS and its 24 member boards violate antitrust laws and misrepresent the medical skills of physicians who decline to purchase and spend time on their program.

"The boards invite patients to go online to see if their physicians are enrolled in MOC, as if they can prove that this has any bearing on their clinical skills or ability to care for their patients," AAPS says.

"These boards regulate themselves with no outside oversight. Physicians cannot see where they made mistakes on the test and have no way to appeal or to verify the accuracy of the grading. The tests are pass-fail and designed to have a certain failure rate, which could be 20% or more, depending on the board. Many a physician has lost his ability to practice medicine in his current location because of MOC – even though he has been doing an excellent job for his patients," the AAPS says in a statement.

AAPS President Alieta Eck, MD, told *Medical Economics* that her group's goal is to get ABMS to "stop requiring MOC and stop misrepresenting the idea that MOC makes for better physicians."

ABMS, she says, has convinced medical insurance plans and hospitals that participation in its programs is necessary to ensure they are offering quality care, and many are now requiring their physicians to enroll in MOC programs.

"What was once considered a mark of excellence, board certification, has turned into a mark of competence, something that has never been proven," she says.

"We believe in maintenance of knowledge and want to keep up with our field. CME classes are already required in most states. But you can't measure things like clinical judgment or bedside manner with a test," she says. "The best way we continue to learn is by reading, consulting with our colleagues, and actually caring for our patients. Each patient we see is a test of our skills."

Certification by a group that is monopolistic, that is possessive of its questions, and that strongly pushes physicians to take its classes all go against the concept of learning, she says. AAPS instead advocates for shared information and open book tests, which it says more accurately replicates life in practice.

Eck also says that predetermined fail rates have led to some good physicians being forced off a staff. "Patients are losing access to their physician at a time when we are hiring more nurse practitioners to see patients," she says.

AAPS asserts that the boards are primarily motivated by the profit they earn from MOC testing and classes, pointing out that some board executives have compensation packages nearing $1 million.

Eck believes AAPS will prevail in its legal action. "We will diminish the power of these huge groups," she predicts. "No other profession is as over-regulated and, frankly, exploited as the medical profession."

dent of research and policy at the American Board of Family Medicine (ABFM), says ABFM is working closely with state family medicine chapters, supporting their efforts to help members work together on self-assessment modules and quality improvement measures, at annual meetings and throughout the year.

"Physicians in these pilot programs have enjoyed it a lot more and do not feel so alone," he says. "This also draws more attendees to the state meetings, which is an added bonus."

## STUDY UP ON THE EXAM

For Part III, the exam, Holmboe suggests physicians avail themselves of the board preparation materials that makes the most sense for their learning style and needs.

He also recommends that physicians review the "blueprints" of the exams that are posted on the ABIM Web site for each specialty. These blueprints show how much of each content area

➔ 20

# The components of maintaining certification

### American Board of Medical Specialties

**☑ PART I:**
**Licensure and Professional Standings:**
Medical specialists must hold a valid, unrestricted medical license in at least one state or jurisdiction in the United States, its territories, or Canada.

**☑ PART II:**
**Lifelong learning and self assessments**
Physicians participate in educational and self-assessment programs that meet specialty-specific standards that are set by their member board.

**☑ PART III:**
**Cognitive Expertise**
Physicians demonstrate, through formalized examination, that they have the fundamental, practice-related and practice environment-related knowledge to provide quality care in their specialty.

**☑ PART IV:**
**Practice Performance Assessment**
Physicians are evaluated in their clinical practice according to specialty-specific standards for patient care. They are asked to demonstrate that they can assess the quality of care they provide compared to peers and national benchmarks and then apply the best evidence or consensus recommendations to improve that care using follow-up assessments.

### Osteopathic continuous certification

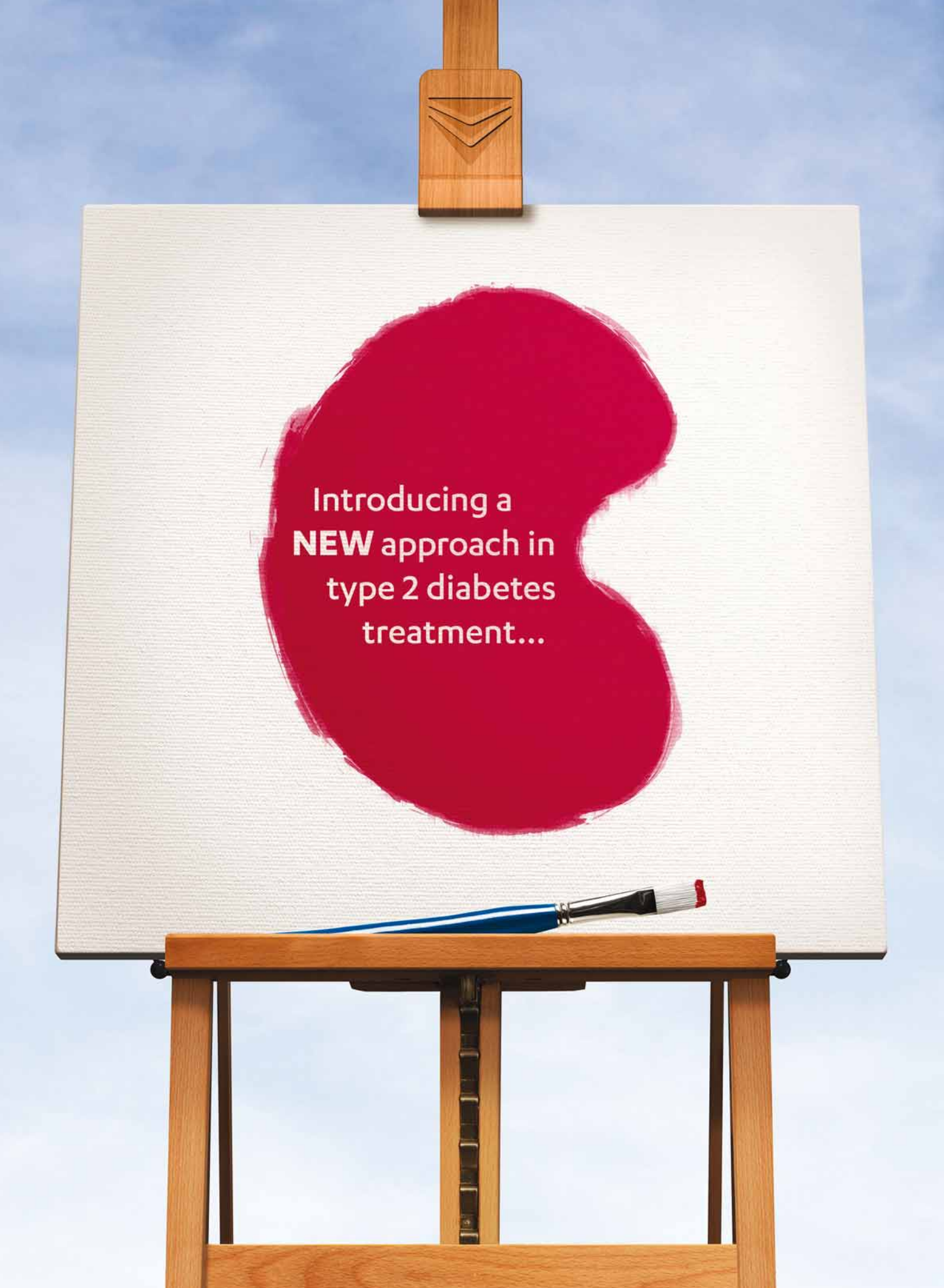
**☑ COMPONENT 1:**
**Unrestricted Licensure**
Requires that osteopathic physicians who are board-certified by the American Osteopathic Association (AOA) hold a valid, unrestricted license to practice medicine in one of the 50 states. In addition, these physicians are required to adhere to the AOA's Code of Ethics.

**☑ COMPONENT 2:**
**Lifelong Learning/Continuing Medical Education**
Requires all recertifying physicians to fulfill a minimum of 120 hours of continuing medical education (CME) credit during each 3-year CME cycle–though some certifying boards have higher requirements. Of these 120+ CME credit hours, a minimum of 50 credit hours must be in the specialty area of certification. Self-assessment activities will be designated by the specialty certifying boards.

**☑ COMPONENT 3:**
**Cognitive Assessment**
Requires provision of one (or more) psychometrically valid and proctored examinations that assess a physician's specialty medical knowledge, as well as core competencies in the provision of healthcare.

**☑ COMPONENT 4:**
**Practice Performance Assessment and Improvement**
Requires physicians to engage in continuous quality improvement through comparison of personal practice performance measured against national standards for the medical specialty.

**☑ COMPONENT 5:**
**Continuous AOA Membership**
Membership in good standing through the AOA serves to establish your foundation of commitment to lifelong learning through basic CME requirements. In addition, certified members participate in relevant specialty-specific educational activities. Membership also demonstrates your dedication to the ethical practice of osteopathic medicine through adherence to the AOA's Code of Ethics.


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,*

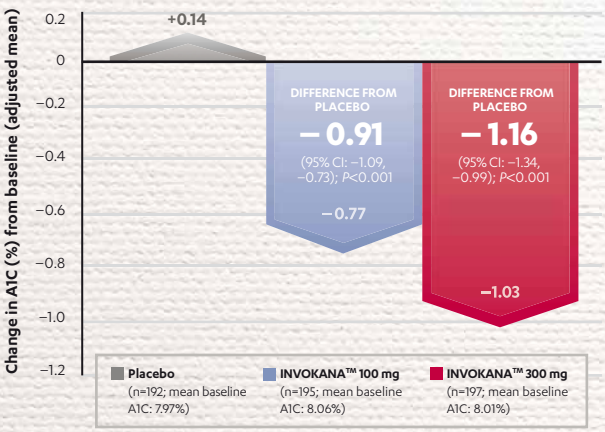
# ENVISION NEW POSSIBILITIES

**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

# New Web site aids ICD-10 transition

Worried about making the transition to the International Classification of Diseases, Tenth Revision (ICD-10)? A new Web site (www.lussierlab.org/transition-to-ICD10CM ) designed by researchers at the University of Illinois-Chicago (UIC) may ease the process by letting you input your currently used codes to find the appropriate new ones.

The complex translations related to ICD-10 are organized into clusters of two or more somewhat related codes, explains Yves A. Lussier, MD, principal investigator of the work. "Many ICD-9 clusters map to many ICD-10 codes, and many ICD-10 codes map back to a significantly different cluster of ICD-9 codes."

Healthcare providers have until October 2014 to switch to the new coding system, used to classify every disease or condition and in every aspect of healthcare. The American Medical Association estimates that the administrative costs associated with ICD-10 implementation will be $87,000 to $2.7 million per practice, plus potential losses in reimbursement due to incorrect coding.. The UIC researchers, however, found that the transition could be more costly than expected, so the tool was designed to enable practices to make the change without hiring outside experts.

➔18 is represented on the exam. Having this information may help a physician decide where to focus his or her studying efforts.

### MAKE IT A TEAM EFFORT

For Part IV, practice performance assessments, Holmboe says the principle of working with others applies here as well when using the ABIM's Web-based practice improvement modules (PIMs).

"There is no reason a physician has to enter all of the data," he says. "Staff members can do it too. Most questions collect primary data, such as blood pressure readings, so it is not too complicated to enter much of the data into the PIMs, but it does take time."

He also recommends working with colleagues if you are in a group practice. "This

## Practice performance added to Osteopathic Continuous Certification

According to Stephen Scheinthal, DO, chair of the Bureau of Osteopathic Specialists, the Osteopathic Continuous Certification (OCC) requirements are not a major change from the previous osteopathic recertification process. The only difference is the addition of a practice performance assessment, he says.

"Osteopathic physicians have always needed to hold an unrestricted license to practice medicine, to complete 50 hours of specialty continuing medical education (CME) credits, to take a cognitive test, and to maintain membership in the (American Osteopathic Association [AOA])," he says.

"OCC added a practice performance module, making a four-step process into a five-step process," Scheinthal says. "The idea is for the physicians to compare how they are performing against national benchmarks."

There are a variety of ways a physician can do this, he says, and options are available for osteopathic physicians who work primarily in a specific, limited area, such as research or administrative roles. "They can pick and choose the content that best is most relevant to them," he says.

For example, he is a geriatric psychiatrist, so he notifies the board that all of his patients are over 55, and he only completes modules relating to that patient population.

He notes that OCC is a fluid concept, and it is constantly monitored and modified based on feedback from members. It was developed over a 6-year period, and implemented January 1 by all 18 osteopathic boards. It is not mandatory for all osteopathic physicians, just the ones who have time-limited certificates. It is hoped that osteopathic physicians on non-time-limited certificates will voluntarily participate in OCC, he says.

Many osteopathic physicians are under the mistaken impression that they have to submit their charts as part of completing this new fifth step. In fact, he says, they only have to submit data off the charts and it is entirely up to the physician to decide which patients he or she wants to use.

He stresses that data gathered in this way is owned entirely by the AOA and is used only to improve physician performance. It is not shared or published.

For greater success on the exam component, he suggests that osteopathic physicians attend their specialty meetings whenever possible as many of the osteopathic boards select questions from information presented at recent meetings.

Also, each osteopathic board has a great deal of information about OCC on its individual Web site that can help demystify the process, he adds.

"There is naturally some apprehension about anything that is new and unknown but the feedback we are getting is that the process is really quite smooth. We are hearing that it takes a little more time, but the feedback it provides is valuable and is helping the OCC process evolve."

Unlike the American Board of Internal Medicine (ABIM) and the American Board of Family Medicine (ABFM), which recommend physicians work together on maintenance of certification (MOC), Scheinthal says the AOA does not recommend a group approach to OCC.

"We want to gather non-aggregated data to create a helpful, unique experience for each physician," he says.

makes it easier for the practice to incorporate the practice improvements that are discussed," Holmboe says. "Quality improvement really is a team sport."

Doing the performance improvement modules as a group also cuts down on the number of charts required per physician, he adds.

Interpreting data received from the module can be overwhelming at first, Holmboe says. Again, working with an experienced peer who can coach you through the process can be a big help.

Mark Malangoni, MD, associate executive director of the American Board of Surgery, agrees.

"If patient care activities are provided by a team, it may make sense to look at outcomes as a group," he says. "It is not about assigning blame, but about finding ways to improve patient care."

## DON'T BE REPETITIVE

Holmboe notes that Part IV isn't limited to practice improvement modules. If your practice already receives performance data from a health plan or other validated source, it can be used to meet MOC requirements and trigger a quality improvement metric as well.

"If you have already gathered data like this in the past 2 years, you can leverage it to complete your project more efficiently," Holmboe says.

Accepted Quality Improvement Pathways are another option. If your institution has submitted an approved project, a physician can attest that he or she was involved in it and get MOC credit. This is most commonly seen in a large practice or hospital setting, he says.

Many societies also offer registries that physicians can join to make the process easier, Holmboe says.

"Our goal is to align activities and reduce redundancy and let physicians do things that are meaningful and relevant to their practice," he says.

## HELP IS COMING

Holmboe notes that in 2014 the ABIM is changing its MOC program to make it easier for physicians to know what they need to do to be current at any time. Starting in January, each physician will have a customized Web portal available that clearly explains his or her status.

"This portal will know you and will lead you to ways to complete MOC in your discipline," he says.

Phillips says ABFM is working to align MOC requirements with other programs so that physicians face less repetition in reporting.

"ABMS (the American Board of Medical Specialties) is a Physician Quality Reporting System (PQRS)-certified registry, and we are trying to let MOC efforts qualify physicians for the PQRS bonus payments. This means reviewing 30 charts instead of 10, because Medicare requires 30 and the Board requires 10 for the quality improvement (Part IV) MOC requirement. This helps physicians meet both reporting needs with one effort and makes quality improvement easier," he says.

> "We are working to give [our members] a way to identify the patients they need to work with. It's not just about giving data to the board or Medicare; it's about helping unlock their EHR data for their own use. We are trying to find a way to help doctors that will be low or no cost to them."
>
> —ROBERT PHILLIPS, MD, MSPH, VICE PRESIDENT OF RESEARCH AND POLICY, AMERICAN BOARD OF INTERNAL MEDICINE

## ASSISTANCE WITH ACHIEVING MEANINGFUL USE

Phillips also says ABFM is trying to help members achieve meaningful use by identifying ways to gather the data they need from their electronic health records (EHRs) so that they do not need to extract and report it multiple ways, multiple times, for multiple reasons. ABFM has set aside $2 million to build and find tools to help physicians turn their EHR data into information that helps them improve patient care and can reduce their quality reporting burdens.

"We are working to give them a way to identify the patients they need to work with," he says. "It's not just about giving data to the board or Medicare; it is about helping unlock their EHR data for their use. Even meaningful-use certified EHRs don't always have the tools to do this. We are trying to find a way to help the doctors that will be low or no cost to them."

## THINK OF THE MONEY AND OUTCOMES

Malangoni encourages physicians to view MOC as a fact of life, especially as it has become increasingly tied to financial incentives, he says. The Centers for Medicare and Medicaid Services (CMS) is paying bonuses to physicians who participate in MOC in 2013. Those reverse and become penalties for failure to participate in 2015.

"This makes participation exceedingly

"The idea isn't just to enter information. It is to get this information back and analyze ways to improve your practice, make changes, and re-analyze the updated data. It becomes a continuous quality improvement loop that is extremely important."

—MARK MALANGONI, MD, ASSOCIATE EXECUTIVE DIRECTOR, AMERICAN BOARD OF SURGERY

important," he says. "It is affecting multiple disciplines, from MDs to DOs, as well as podiatrists."

He adds that physicians who are board-certified perform better in practice and are less likely to be involved in a malpractice lawsuit. MOC is simply changing certification from being a "snapshot in time" to being an ongoing process, he says.

"Physicians now need to document in four areas that they have stayed involved in learning activities between examinations," Malangoni says. "All you are doing is documenting that you have met your board requirements for lifelong learning and practice performance improvement, nothing more."

## KNOW THE SPECIFICS OF WHAT'S REQUIRED

Malangoni encourages physicians who are feeling overwhelmed about MOC to thoroughly educate themselves about their boards' requirements. "Much of the anxiety about this relates to misinformation and confusion. Familiarizing yourself with the specifics is one of the most important things you can do," he says.

"Often when we are frustrated, we spend a lot of time and energy figuring out how to get out of doing what we will end up having to do anyway. Don't risk letting your certification lapse. Learn the requirements. Ask your colleagues what they do," he says.

All of the boards have help available, via phone or email, or on their Web sites, as do many specialty organizations, he adds.

Each board has its own approach to the Part IV requirements (practice performance improvement), he says. For example, many surgical boards have registries into which physicians can enter their data and get comparative results back.

"The idea isn't just to enter information. It is to get this information back and analyze ways to improve your practice, make changes, and re-analyze the updated data," Malangoni says. "It becomes a continuous quality improvement loop that is extremely important.

"The real principle is that by doing these types of activities, physicians will better stay abreast of changes in care that can be slow to reach them. It also links lifelong learning to practice improvement," he says.

It is important to customize your MOC experiences, he says, particularly continuing medical education attendance, to match what you do in your practice. Don't waste your time at classes that cover an area in which you do not practice, he says.


ADDITIONAL RESOURCES

**Go to ModernMedicine.com** and type "maintenance of certification" into the search box.

**In the article headlined "Viewpoint: Maintenance of certification has value for physicians and their patients," the president of the American Board of Medical Specialties defends the MOC process.**

**In the article headlined "Author's view of MOC unrealistic," a few *Medical Economics* readers share their frustrations with MOC.**

**The article "Where do you stand on maintenance of certification?" examines both sides of the controversy around MOC, with one disillusioned physician incredulously asking, "I have to spend time and money being told to wash my hands?"**

FIRST IN A SERIES

# EHR divorce

## What's driving dissatisfaction?

### While surveys document dissatisfaction among physicians, experts advise on the costs of implementing or making a switch

Getty Images/E+/Thomas Vogel (wire); Thinkstock/iStockphoto (scissors)

*by* **DANIEL R. VERDON** *Group Editor, Primary Care*

One in five physicians may be filing for divorce from their electronic health record (EHR) system. While it's a sobering statistic that is being validated by multiple market surveys – from Black Book to AmericanEHR Partners [a group developed by Cientis Technologies and the American College of Physicians (ACP)], it signals a new era in the adoption and acceptance of health information technology.

**"THIS IS AN ODD** point in history," explains MGMA Healthcare Consulting Group's Derek Kosiorek, "where we have asked physicians to take processes they have done their entire professional career and change them. We are taking the paper chart and every piece of information in that paper chart and we are shuffling it up like a deck of cards and putting it on a computer screen in different places."

How could that not influence attitudes, especially when you factor in an increasing economic pressure to build new efficiencies, adhere to a throng of government compliance mandates, nurture and coach your staff, and maintain a daunting pace to see

### HIGHLIGHTS

**01** While multiple surveys have documented physician dissatisfaction with EHRs this year, some data suggest improvement.

**02** If you are considering a switch thoroughly evaluate the cost structure and base it on: hardware, software, support, training, ongoing network fees and associated fees to access or transfer your data.

# 7 REASONS driving the dissatisfaction

1/ **Overall dissatisfaction with performance**

2/ **Poor vender support**

3/ **Lack of technology skill/expertise by doctor**

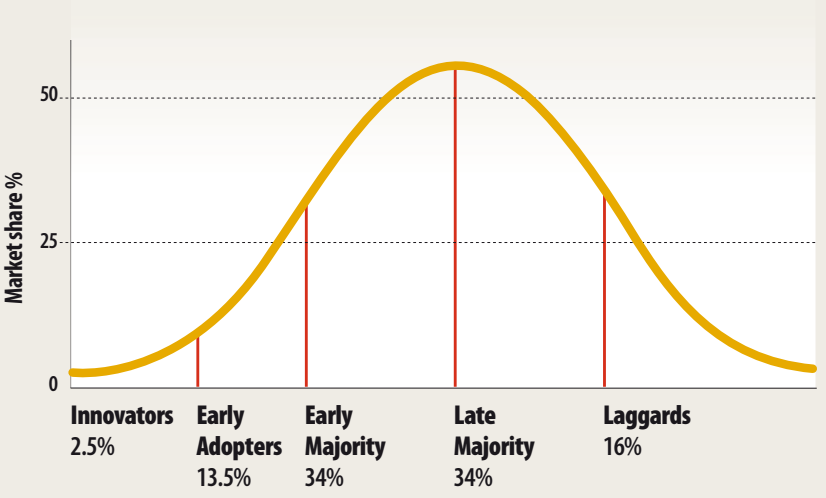
4/ **Cost**

5/ **Server vs. web/cloud**

6/ **Complicated, not physician friendly software**

7/ **Lack of ability to reach MU2**

## Diffusion of Innovation




Source: Wikimedia

more patients in order stay ahead of tighter public and private reimbursements?

Dissatisfaction is as diverse as the user's expectations in the first place, experts say, and to truly understand the reasons for it might be based on a litany of factors like computer competency, practice size, organizational structure, clinical and business processes, hardware, speed of system, access points within the practice and attitudes about technology in the first place. Despite the U.S. government dishing out $3.3 billion to MDs and DOs for its EHR adoption incentive program, satisfaction could likely be translated into one simple premise: help users find information when they need it.

"The bottom line is a physician needs this information available to help them make important healthcare decisions," says Kosiorek. "And if they have to hunt to find the information, it is an extremely frustrating proposition."

This angst has been captured in AmericanEHR's survey from 2010 to 2012 showing very dissatisfied users increased 10% for the same time period. The percentage of clinicians who would not recommednd their EHR to a colleague increased from 24% in 2010 to 39% in 2012, reports Alan Brookstone, MD, chairman of Cientis and co-founder of AmericanEHR Partners.

Some other results from the survey include:

- 34% were very dissatisfied with the ability of their EHR to decrease workload
- 32% of respondents had not "returned to normal productivity" compared to 20% in 2010.
- 37% in 2012 were dissatisfied with the EHR's ease of use

So, why the apparent disconnect between vendor and physician?

### THE BELL CURVE

Jacob Reider, MD, a family physician and director of the Office of the Chief Medical Officer of the Office of the National Coordinator (ONC) for Health Information Technology in Washington, says it is a multifactorial issue that is influenced by the 2012 class of EHR adopters.

In fact, consider that a traditional adoption curve is made up of the early adopters, fast followers, early majority, etc. In the physician market, health information technology adoption is at the 50% mark. Early adopters are

Getty Images/ Paul Garnier

far more tolerant of slightly challenging technical solutions," Reider says. "When they succeed, typically the enthusiasm generated may leave false impressions about the capabilities of the technology. When the next group that adopts the technology are not necessarily as skilled or proficient and have very high expectations. Well, they become dissatisfied.

The market, Reider says, realizes that "when you plug these things in, they are not purring like a BMW right away."

## IS IT TIME FOR COUNSELING?

EHR usability is solely based on the experience of the user. Some of the perceptions about a system could be based on cost, usability, design, functionality and the skill of the operator.

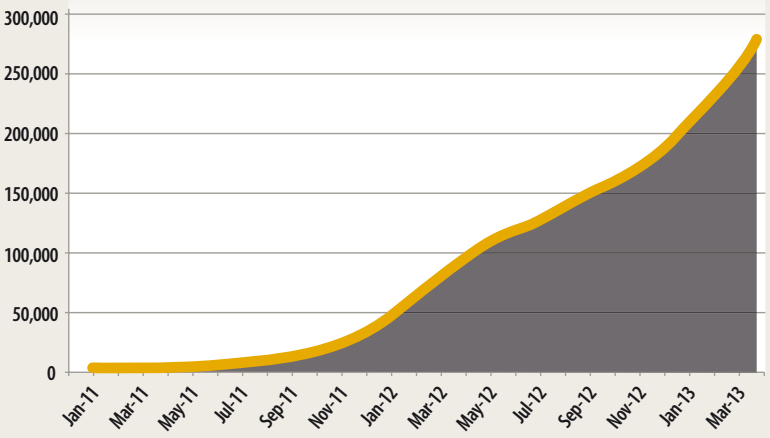
So, if you find yourself wanting to split up with your EHR system, take time to identify the cause of your frustration. Is it the speed of the network? How long is it taking to access information? Is your system able to interface with laboratories? How are the claims processing features? Is the dashboard simply not intuitive? Are there too many repetitive functions?

Also, clearly differentiate your evaluation of an EHR based on its competencies "to deliver on the business needs of the practice compared to the EHR's ability to assist in improvements in quality of care," Brookstone says.

Remember that most physicians' practices have limited capacity. "Adding technology to the practice is also adding new responsibilities.

"Normally, in a product development cycle, you would expect to see the technology and software, and maybe the hardware, adapting to the user because there is usually more time for feedback for usability and functionality testing," Brookstone says. The speed at which meaningful use was implemented is another consideration. "The vendors were under a lot of pressure to meet meaningful use requirements, he says, "and the systems have not often kept up with the usability requirements of the clinicians. Some process-

## Physicians and other providers obtaining EHR incentives




Source: Office of National Coordinator

## Medicare incentive payments for EHR program

| | Numbers of providers paid | Payments to date |
|---|---|---|
| **Doctors of Medicine and Osteopathy** | 209,727 | $3.3 billion |
| **Top 10 specialties** | | |
| **Family practice** | 42,451 | $665 million |
| **Internal medicine** | 38,514 | $622 million |
| **Cardiology** | 14,752 | $246 million |
| **Orthopedic surgery** | 10,482 | $176 million |
| **Gastroenterology** | 8,634 | $143 million |
| **General surgery** | 7,951 | $132 million |
| **Ophthalmology** | 6,258 | $106 million |
| **Neurology** | 6,362 | $102 million |
| **Urology** | 5,984 | $99 million |
| **Obstetrics/gynecology** | 9,439 | $98 million |

Source: Centers for Medicare and Medicaid Services

es that might have taken one or two clicks might have taken 2, 4 or 10 clicks under the new process to get it done. As a result, the systems have not been optimized."

Many of the efficiencies built into EHRs are achieved in front-office operations, Kosierek adds. "Those efficiencies do not necessarily translate to the doctor in the examination room. And since the doctor pay the bills, they also want to see benefits from it."

## EXAMINE THE TRUE COSTS

Experts also want physicians to analyze all of the costs associated with a new system if they are implementing for the first time or changing vendors. The analysis should include:

- Hardware: desktop computers, tablets/laptops, database servers, printers, and scanners
- EHR software: Potential costs include EHR application, interface modules, and EHR upgrades.
- IT support: Implementation assistance costs could include IT contractor, attorney, electrician, and/or consultant support; chart conversion; hardware/network installation; and workflow redesign support.
- Training in how to use the EHR and associated hardware, and how the EHR will create new workflows.
- Ongoing network fees and maintenance: Potential ongoing costs include hardware and software license maintenance agreements, ongoing staff education, telecom fees, and IT support fees. Some practices may need to hire IT operations staff, clinical data analysts, or application analysts.
- Associated fees to access or transfer your data.

# Understanding the EHR certification process

Five organizations, commissioned by the federal government, have been charged with certifying the thousands of electronic health record products making their way to market.

When it comes to certifying an EHR for meaningful use for Stage 1 and Stage 2, the government mandates a set of functional criteria required for each system.

Those 26 functional criteria mirror the expectations or tasks required for physicians to reach meaningful use in Stage 1 or Stage 2.

"In other words," Reider explains, "if meaningful use says you have to build and maintain a problem list, then the EHR has to be able to technologically perform that task as well," says Jacob Reider, MD, director of the Office of the Chief Medical Officer of the Office of the National Coordinator for Health Information Technology.

Please note EHR products are being certified for Stage 2 meaningful use (see chart), and certification criteria differ from those mandated for Stage 1 meaningful use.

It's important for a physician in evaluating a system to understand these criteria and ask the prospective vendors about the system's capabilities now and in the future.

In certifying the technology, the government evaluates some 26 functional expectations. Once they meet the criteria, a surveillance program is in place to re-evaluate these systems.

While it was widely reported in May that the certification of 2 EHR systems were revoked for the first time after a subsequent review, Reider says, the system is built on surveillance and testing.

If complaints are filed with ONC, the government and its certifying agencies will review the merits of the complaints. If a system fails it's tests, the EHR is de-certified.

It's an extremely important for a physician in evaluating a system to understand these criteria and ask the prospective vendors about the system's capabilities now and in the future.

While EHR-related costs vary widely based on geographical location, size of practice and type of system, ONC offers these estimates:

**In-office system:**
- Upfront cost: $33,000
- Yearly cost: $4,000
- 5-year total cost of ownership: $48,000

**SaaS/Web-based systems**
- Upfront cost: $26,000
- Yearly cost: $8,000
- 5-year total cost of ownership: $58,000

In *Medical Economics* 2-year EHR Best Practices Study, 29 reporting physicians estimate implementation costs (outside of the costs associated with purchase of the system) at $7,610 in February 2013.

## REVIEW THE END-USER LICENCE AGREEMENT

While the end-user license agreement is typically created to benefit the vendor, Kosiorek says, most contracts can bend.

"I have not encountered a vendor who is not willing to negotiate terms of the contract," he says.

Look at payment terms closely, and schedule them according to task completed.

While training might go faster the second time around, factor in time to customize the system and train. This process should take six months, Kosiorek says.

## WORDS OF CAUTION

For most physicians, the goal when implementing an EHR system is to marry the system with your processes. Don't speed date. Do your homework and take a thoughtful approach to system selection that can come the closest to meeting your processes.

"I think speed would be your enemy," ONC's Reider says. "It is important to act deliberately as you implement healthcare information technology. Build insights from others. Don't step in the same puddles," Reider says. "Use this as an opportunity to think very carefully about what your current workflow is and how information technology can be optimized to leverage your work processes.

"If you do that and leverage health IT toward practice transformation, that is doing it right. If you plug in a computer and think that will solve it, you are going to have problems."

## The mobile revolution?

In a recent Black Book Rankings poll, most physicians want EHR applications for mobile devices too. According to the survey, **89%** of primary care and internal medicine are using smart phones to communicate with staff, yet only **1%** say "they are maximizing use of their mobile clinical and business applications."

Another **83%** of the respondents said they would immediately use mobile EHR functionalities to update patient charts, check labs and order medications immediately if available to them via their current EHR. The most popular mobile devices included iPhones (**68%**), iPads and Tablets (**59%**), and Smart/Android phones/other (**31%**).

## EHR vendors with certified products for meaningful use stage 2, June 2013

- ☑ Orion Healthcare
- ☑ athenahealth
- ☑ Epic Systems Corp.
- ☑ GE Healthcare
- ☑ ChartLogic, Inc.
- ☑ Dynamic Health IT, Inc.
- ☑ Corepoint Health
- ☑ Henry Schein Practice Solutions
- ☑ FairWarning Technologies, Inc.
- ☑ Cerner Corp.
- ☑ Greenway Medical Technologies
- ☑ Healthcare Management Systems, Inc.
- ☑ CareEvolution, Inc.
- ☑ McKesson
- ☑ Get Real Health
- ☑ InteliChart LLC
- ☑ LDM Group, LLC
- ☑ Logicare, Corp.
- ☑ MEDHOST, Inc.
- ☑ LSS Data Systems
- ☑ Medical Information Technology, Inc.
- ☑ HealthFusion
- ☑ NextGen Healthcare
- ☑ IGI Health
- ☑ PEPID, LLC
- ☑ Iatric Systems, Inc.
- ☑ Montrue Technologies
- ☑ Sunquest Information Systems, Inc.
- ☑ Vitera Healthcare Solutions, LLC

Source: Health and Human Services

@ Go to medicaleconomics.com/ehrbestpractices for a comprehensive look at EHR best practices.

***Coming in the next issue:***
*How to get an EHR divorce*

# The economics of change

## While future challenges require EHRs, changing business dynamics require us to plan and act now

*by* **DANIEL WEGG, MD**

### HIGHLIGHTS

**01** Important changes in healthcare and practice economics are happening this year. While this practice went digital with an electronic health record system implementation, it facilitated cost-cutting measures and additional revenue possibilities.

**02** Look at bundling services as a way to reduce practice costs. Bundling the communications services (telephone, data) saved this practice $9,000.

With the rapid economic changes taking place and still to come in primary care, standing still is not an option if our practices are to survive. Any discussion involving the economics of private practice in 2013 must begin with the relative merits of the switch to an electronic health record (EHR) system.

Our two-physician practice has successfully made the move and received the government's financial bonus for doing so. To the plus side went $45,000, but that's not so impressive when weighed against the expense of the conversion.

Let's look at where the dollars are flowing. We are Web-based and pay for our system at an annual cost of $14,000. In addition, our information technology support person seems to have taken up almost permanent residency in our office, and I count his monthly check as a fixed expense. Still, there are positives to the experience.

The embedded billing system in the EHR is more efficient than my previous system, and we have been able to reduce staffing in the billing department by one full-time employee (who left to work for the EHR firm) at an annual savings of $30,000.

Additionally, we now have little use for dictation services and this brings an annual savings of around $9,000. In all, bonuses aside, the switch to the EHR probably will result in an annual $15,000 improvement in our bottom line.

### EFFECTIVE USE OF STAFF

Aside from the EHR, the economic climate has forced further change on us. One midlevel has left to work for a local hospital and this did present a challenge. We decided not to lay off any clinical staff, but rather to find ways to use them more effectively. This has worked quite well and allows me to see 30 patients per day and my remaining midlevel to see 25 patients, with two clinical support staff to each do intake histories and reviews of systems, as well as all the previously delegated duties of medication refills, etc.

Obviously, there has been a decline in productivity, but savings on the payroll side offsets this. Whether these changes will be positive or negative remains to be seen, but so far after 7 months we are seeing a positive trend.

Further analysis of the expense side revealed that we were losing money providing phlebotomy services. In order to limit this loss, we initially discontinued this service—with a net annual savings of $20,000—but found that to be a very unpopular solution with our patients. However, we made arrangements with a local lab to staff our office lab so long as patient volumes remained strong. Thus we retained the savings without serious inconvenience to our patients.

Our efforts to limit costs did not stop there. For example, we bundled our telephone service with our Internet provider and could potentially save $9,000 annually. In addition, we are reaping the rewards of renegotiating

our hazardous waste disposal contract at an annual savings of $10,000.

## CAN'T CONTINUE TO CUT THE FAT

We can't continue to "cut the fat" forever, so we have made some initiatives on the revenue side. Our practice does a good deal of pain medicine and we perform drug screenings partially in- house with just the confirmation going to the reference lab. This returns between $100 and $180 for each test with a cost of $5 to $10 for materials plus minimal labor costs. Net revenue for this service is about $15,000 a year.

Our in-house pharmacy looks promising. Revenue gains so far are not robust, but we net a yearly profit of $5000 to $10,000 when combined with our efforts to provide patients with dietary supplements and vitamins. One reason for the modest return lies in our commitment to provide medications at a cost that our rural patient base can afford. However, we are seeing solid growth potential with each passing month.

## MORE CURVE BALLS

No doubt the future will throw to us more curve balls and challenges. Still, we remain committed to improvement. Each challenge seems to bring with it an opportunity to be better in some way and the trick seems to lie in being open minded and flexible enough to make it through.

In the final analysis, it has been a year of change not brought on by a desire for more, but a desire for survival. Adapting to this brave new world has led me on a personal journey of discovery. I have found that my reward comes in that 15-minute time spent with the patient. God put that inside of me and I seem to need that. Everything else is just business.

*Wegg specializes in general practice in Ridgeville, Indiana.*

OUR INTENSE EFFORTS TO LIMIT COSTS DID NOT STOP THERE. WE BUNDLED OUR TELEPHONE SERVICE WITH OUR INTERNET PROVIDER AND COULD POTENTIALLY SAVE $9,000 ANNUALLY.

# The EHR project

## How this rural practice took consistent steps to implement an EHR without loss of patient volume

*by* **DANIEL R. VERDON** *Group Editor, Primary Care*

### HIGHLIGHTS

**01** This rural practice made the decision to convert two patients a day to the EHR system and slowly, methodically retire its paper charts. The strategy helped the practice maintain its volume during the implementation.

**02** A spreadsheet to document the problems and solutions was maintained as a way to track and communicate with the EHR vendor and the staff.

Editor's note: As part of our continuing coverage of *Medical Economics* EHR Best Practices Study, we spoke with Melissa Lucarelli, MD of Randolph Community Clinic. A graduate of the Massachusetts Institute of Technology with an MD from the University of Illinois, she operates a rural solo practice in Randolph, Wisconsin. She is working with McKesson to implement an EHR system.

**Q: Tell me about your practice?**

**Lucarelli:** We are the only medical practice in the town of Randolph, Wisconsin and Randolph is a town of under 2,000 residents. I am a solo practice family doctor. I have a lot of staff members who are part of our team including a physician assistant and a nurse practitioner. Randolph, Wisconsin is sort of in the middle of everything but near nothing, and we are about an hour from both Milwaukee and Madison.

**Q: How many staff members do you have in total?**

**Lucarelli:** Virtually no one on the support staff is full-time. The three providers are full-time, but we are using a kind of 0.5 to 0.8 model for the other staff members. We have 12 employees.

**Q: Is it a management challenge?**

**Lucarelli:** It's really important, when you are in a solo practice, to have a lot of flexibility. So when you have folks who are part-time, then you have the flexibility of expanding them temporarily in order to meet a need. So, if somebody is on a medical leave or somebody is on prolonged vacation, we have a deep pool of temps we can utilize. I think it actually works better for us, and it's a good fit for our employees. Right now, not by design, the staff is comprised of all females and most of us are also parents. It gives us the ability to be able to focus on our families and contribute to the clinic.

**Q: Tell us about your involvement with the Medical Economics EHR Best Practices Study. Is this your first electronic health record system?**

**Lucarelli:** Yes.

**Q: How did you and your staff approach this project?**

**Lucarelli:** The process started back in about 2004, actually. We had a couple of vendors come in and do presentations then, and we even had one come back a second time so that we could kind of test drive the system. At the time, I didn't feel like I could financially afford an EHR. The price tag then was higher than it is now -- just the start-up costs. I am so glad I waited. The company I would have been jumping in with is now defunct. It's now out of business. The product that we would have been with is no longer supported, and for sure it is of no meaningful use. I put implementation on the back burner. Then, we started

to do some government programs like the Physician Quality Reporting System (PQRS) through a dashboard. We were manually entering data in order to qualify.

We qualified for PQRS the first year it was available, but it seemed awkward. Meaningful use came along and opened up incentives to financially make it possible for us to adopt an EHR system. That was right about the time the study opened.

**Q: Could you talk about how your practice organized internally when you started talking to McKesson to implement this system?**

**Lucarelli:** First, we wanted to decide what workflow we were going to change when we moved to an EHR. Before we went live, we tried to look at the transition and tried to figure out how we could do it without cutting back on the numbers of patient visits.

That strategy doesn't work for everybody, and it doesn't work for every practice. We operate on such a narrow margin in this practice that we are really hand-to-mouth for our paychecks. We are in the black, and we always have been, but I don't have the ability to just cut our visits in half. So, we had to figure out a transition to maintain our same production. It wasn't 100% percent successful, but it was the goal.

We also had a regional extension center in our area, and we decided to sign up early on to have them assist us with our EHR implementation. They helped us with not only workflow analysis and bringing in vendors, but to understand where the priorities are during an implementation. They are still helping us with Health Insurance Portability and Accountability Act risk analysis assessments as part of our annual meaningful use attestation.

After that we organized as a group and split into small teams. We did a lot of whole clinic meetings too. We have been doing more staff meetings than we have ever done before to talk about all the details of retiring charts, for example. To make the transition, we decided that each of our three providers would be responsible for two new EHR patients a day. That's how we rolled it out when we went live. Over time all of our patients were entered into the system.

> "BEFORE WE WENT LIVE [WITH THE EHR], WE TRIED TO LOOK AT THE TRANSITION AND FIGURE OUT HOW WE COULD DO IT WITHOUT CUTTING BACK ON...PATIENT VISITS."
>
> —MELISSA LUCARELLI, MD

Narayan Mahon

We were running two back-end systems too. We were running our old billing system, and we were running the new billing system. That way when we were having difficulty testing certain claims and certain payers with the EHR, we still had our back-end system running for the majority of our charts. Because of it, we didn't see a huge drop in our collections because we were catching things as we were going. It really worked well, because you have to transition your old medical management system over at least 90 days because there are collections in various states of payment. So you can't just shut off your old system and switch to the new anyway.

We actually continued generating claims on the old system at the same time as we were generating 6, 8, or 10 new claims a day on the new system. I had my clinic manager pick which patients were be going to be arrived in the EHR, so that we had a mix of payers as well. We would actually track the time to collections and see where the system was hanging up.

**Q: Did it work?**

**Lucarelli:** Yes, and then we got to a point where we ended up closing the back-end billing system and that didn't really impact the practice.

After we attested for meaningful use, and we had enough of our patients populated in the EHR, we just made the decision to convert everyone into the digital format.

We learned that you have to be organized; otherwise it really slows you down.

As a team, we talk all the time about how we are going to do things differently. We still have little pieces of the puzzle that aren't functioning yet, like our lab interface. We actually were part of another research study sponsored by the Wisconsin Research Education Network. They accepted us in a

study having to do with workflow analysis. It gave us an opportunity to look at our workflow around labs. We were having problems because some people were populated in the EHR, some people were in the paper charts, some lab reports were coming by fax, and some were coming electronically.

So, now we have a staged plan for the labs too that we are rolling out.

**Q: When you first started implementing, did you really take a look at the current workflow and did you adapt it all?**

**Lucarelli:** We did. Actually a full year before I even selected a vendor, we switched our paper charts to a different system. We started with templated notes. Before that we were straight dictation. We dictated SOAP notes for almost everything. Transcription gradually was fading away before switching to the EHR. Otherwise our charts were really handwritten, which is plus and minus.

Before the EHR, the practice created paper forms or templates. In other words, if a patient was coming in with an upper respiratory problem, we made a form just for upper respiratory. It was filled out and went into the paper chart. It was sort of a baby step towards using templates in an EHR. We wanted an EHR that had templates, because we were already used to using them. We already knew what we wanted included in our templates.

**Q: Was it easy to create templates within the EHR?**

**Lucarelli:** I would say no.

**Q: But it is important, right?**

**Lucarelli:** It's important. Because we don't have a designated information technology department, we had champions for different projects. My physician assistant is our expert template writer. She actually took a couple of paper templates and made them into EHR templates. Then, we tweaked them as we used them. It's not hard to do; it's just takes extra training and time. In a way, I think it's nice to have a designated person who works on templates. We made the decision that all of us would use the same basic templates, and that's what we were doing when using paper templates. You could do it the other way where each provider does their own templates and tweak them themselves, but I feel like the model works better if we all are used to looking in the same place for the same thing.

**Q: As far as using the EHR, have you seen benefits or efficiency?**

**Lucarelli:** The obvious one that really has made a difference is e-prescribing. We were faxing the majority of our prescriptions. Our refills are so much easier now, and I think safer. There is less interpretation, and there are no handwriting problems.

If a patient is taking five medications, I can click five boxes, and boom, it gets refilled. The patients are amazed too. We used to have piles of charts. At the end of the day, the nurses would get to those refill requests. Now that comes up automatically during the day, and it's just so much smoother.

Another thing, although I didn't think about until it started happening, is we spent a lot of time looking for charts. With the paper chart, that's the medical record, and it moves around the office. I can't even estimate how much of my lead receptionist's time was spent looking for charts. In fact, I am looking at my desk right now, and while it's not a pretty sight, there are no charts on it. That means my front desk staff is spending more time doing EHR-related activities and a lot less time chasing charts.

**Q: How did your practice track other problems?**

**Lucarelli:** When we started implementing, we found that our EHR wasn't able to consistently do all the things that we were expecting it to do.

When we started doing this, we started logging the problems, status, date and who was responsible for the fix. All of those things, from the minute to the really big project-oriented issues were on this master spreadsheet. As we addressed the issues, they would be crossed off. We shared the spreadsheet with our vendor and that's when I learned there is actually a process for this in business, they call it creating tickets. We had over 100 open tickets for a while, and now I think we are in the 20s. So we are on our way. ◘

# Tech News

## HALF OF ALL ELIGIBLE PROVIDERS HAVE RECEIVED EHR INCENTIVES: HHS

More than 291,000 physicians and other eligible professionals have received incentive payments through Medicare and Medicaid EHR Incentive Programs for adopting or meaningfully using electronic health record (EHR) systems, the U.S. Department of Health and Human Services (HHS) announced recently.

**"WE HAVE** reached a tipping point in adoption of EHRs," HHS Secretary Kathleen Sebelius says, adding that the technology is "critical to modernizing our healthcare system."

The American Recovery and Reinvestment Act of 2009 included incentives for physicians, hospitals, and other eligible providers to adopt EHRs as part of an effort to improve healthcare quality and efficiency. The programs began in 2011 and are administered by the Centers for Medicare and Medicaid Services and the Office of the National Coordinator of Health Information Technology.

The payments seem to be accomplishing their intended goal. Doctors' and hospitals' use of health information technology (IT) has more than doubled since 2012, according to HHS. As of 2008, 17% of eligible professionals and 9% of hospitals had adopted advanced EHR systems, a 2012 Centers for Disease Control and Prevention survey found. Now, more than 50% of eligible providers and about 80% of eligible hospitals (3,800) and critical access hospitals in the United States have received incentive payments for adopting, implementing, upgrading, or meaningfully using EHRs.

The federal government maintains that EHR adoption also is critical to meeting broader goals initiated under the Affordable Care Act. These goals—improving care coordination, reducing duplicative tests and procedures, and rewarding hospitals for keeping patients healthier—are facilitated by the widespread use of EHRs, according to HHS, in part because they lead to fewer errors and hospital readmissions.

"Health IT helps providers better coordinate care, which can improve patients' health and save money at the same time," Sebelius says.

In turn, HHS says, efforts to improve care coordination and efficiency create additional incentives for providers to adopt technology.

### ONE-THIRD OF MEDICAL PRACTICES CHANGING EHRs

About 31% of medical practices in a recent survey say they're replacing their old electronic health records (EHRs) systems with new ones. Respondents cited dissatisfaction most frequently as the reason for the switch.

The 31% figure represents a jump of 10 percentage points from a similar survey from 2010, according to Software Advice, a company that aims to match software buyers with the right systems for them.

The sample size from the Software Advice survey is small—just 385 practices in each year. Its results are somewhat close to what a much larger survey of 17,000 EHR users from Black Book Market Research found earlier this year, however.

The Black Book survey showed that 23% of practices were frustrated enough with their EHRs to consider changing vendors. Dissatisfied users reported problems interfacing with other software, overly complex connectivity and networking schemes, and concerns related to integration with mobile devices.

Software Advice says its latest survey also shows mounting dissatisfaction with EHR vendors. Half of the survey's dissatisfied respondents cited unwillingness to pay the associated costs of forced upgrades. Respondents also complained of being "nickeled and dimed," and not being made fully aware of what to expect on the final invoice, according to the survey.

# Money

# Know what your practice is worth

An accurate valuation of the business remains vital for financial and retirement planning, but remember that methods vary widely

*by* **TRACEY WALKER** *contributing editor*

## HIGHLIGHTS

**01** The unique nature of the medical business makes it difficult to apply standard valuation methods to most practices.

**02** Estimating the value of goodwill is frequently the most difficult and contentious aspect of setting a practice's sale price.

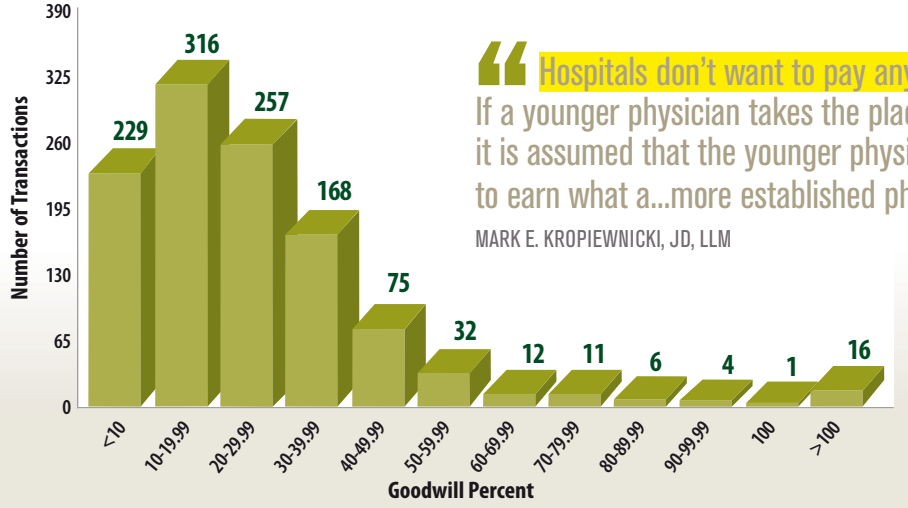
**Practice valuation: They are the two most important business terms a practice owner needs to know.** For a young physician venturing into private practice, they could determine his or her largest financial transaction. And to a retiring physician, practice valuation may decide the amount of sweat equity built over a career.

**"A PHYSICIAN** has worked for a long time and made a living, but when the time is appropriate, they want to receive value for the practice they've built up," says Mark E. Kropiewnicki, JD, LLM, president of Health Care Law Associates, P.C. and a principal consultant with and president of The Health Care Group, Inc., Plymouth, Pennsylvania. "The seller has a ready-made income stream to sell. The buyer is looking for a ready-made income stream to buy. In business, that's what value is all about." While practice valuation is a necessity when a hospital buys or leases a practice, it can also protect buyers and sellers from Stark laws, affect the distribution of property after a divorce, and impact taxes. This report chronicles some of the most important considerations in determining a practice's value.

## BREAKING DOWN VALUE

Determining the value of a physician practice requires addressing a variety of issues: referral patterns; the age of the seller and whether he or she is staying with the practice for an extended period of time; the practice's insurance mix; the reimbursement and economic climate at the time, and the practice specialty, says David H. Glusman, CPA, CFS, partner-in-charge, Philadelphia region for the accounting and consulting firm Marcum LLP, in Bala Cynwyd, Pennsylvania. "The single largest →37

## All Medical Records Goodwill Percent




1127 out of 1397 records reported GOODWILL PERCENT and were used

> "Hospitals don't want to pay anything for goodwill. If a younger physician takes the place of a senior physician, it is assumed that the younger physician won't be able to earn what a...more established physician earns."
>
> MARK E. KROPIEWNICKI, JD, LLM

34 driving factor in the value of a practice is the cash flow available for the buyer after taking into account a fair market value compensation for the seller or replacement physician," he says. "Especially in this age of the Stark Laws and anti-kickback legislation, it's important for any transaction that involves a buyer and seller where there is the potential for actual or implied referrals of business to establish fair market value."

### DETERMINING FAIR MARKET VALUE

In performing fair market value analysis of physician practices, as well as other relationships that physicians may enter into, instead of an outright sale of a practice, a variety of factors are taken into account, according to Glusman.

"Two physicians in the same geography in the same specialty may not have the same fair market value compensation," he explains. "The relative efficiency in the practice is certainly one criterion. The other issues that relate to the practice, how it is operating and its profitability also are carefully evaluated. At the end of the day, selling a medical practice has become a lot more like selling any other business; the buyer is looking for a return on their investment in the form of cash flow and potential growth.

"The combination of art and science in preparing a business valuation for a medical practice is understanding the relative risks which go into the capitalization rate to be used in the economic environment that allows for the determination of the likely cash flow stream. The seller is looking for the sale price to reflect the past efforts to build the practice, its reputation, and the revenue it will continue to provide to the new owner," Glusman adds.

Tangible and financial assets, patient accounts receivable, office building, goodwill, and intangible assets are all factors that determine a practice's value. Tangible and financial assets include the practice's equipment and furniture, cash, prepaid insurance [unexpired insurance premiums], and other assets less liabilities, including payroll taxes, loans, and retirement plan contributions, DeMuth says.

Because most medical practices are cash basis taxpayers, patient accounts receivable do not normally show up on their financial statements, according to DeMuth. "The amount of the receivables should be based upon the amount charged, which is expected to be collected," he says. "There are several ways this could be calculated depending upon the information available."

### A WORD ABOUT GOODWILL

Practice goodwill is generally the most subjective and variable asset in valuing a medical practice. Valuing the intangible assets and goodwill of a medical practice can be a contentious issue.

"Hospitals don't want to pay anything for goodwill. If a younger physician takes the place of a senior physician, it is assumed that the younger physician won't be able to earn what a seasoned, more established senior physician earns," Kropiewnicki says. "A hospital buys a practice because they want the physician, for example, a surgeon because the hospital wants to make sure there are enough surgeons to meet patient needs in the hospital's catchment area."

With the expected proliferation of ACOs established by hospitals, purchases of physician practices by hospitals may increase dramatically, so that there will be enough physicians to take care of all the patients contracted to the ACO, Kropiewnicki adds.

If the practice or related entity owns the office building, a commercial real-estate appraiser normally appraises the structure. If the office is leased, the leasehold may have a value depending upon the number of years remaining, amount paid for rent compared to going market rent, and the ability to renew the lease, DeMuth explains.

# FACTORS AND FORMULAS FOR DETERMINING A PRACTICE'S VALUE

Vincent M. Brinly, director of valuation services at Practice Valuation Group, Washington, D.C., offers the following factors to determine a practice's value:

- ☑ **Macroeconomic Risk Factors**
  - CMS Fee Schedule
  - Maldistribution of doctors in catchment area
- ☑ **Practice Specific Risk Factors**
  - Payer Profile
  - Expense Ratios vs. Medical Group Management Association (MGMA) Benchmarks
  - Active Patient Population
  - Referent Network
  - Doctor Productivity
- ☑ **Amount and Quality of Normalized Adjusted Net Cash Flow**
- ☑ **Certainty of Future Earnings**
  - Reliability and continuity of future earning capacity
  - Amount and quality of current earning capacity
- ☑ **Transfer Risk**
  - Reflects the amount of professional goodwill that can be transferred from one doctor to another.

## PRACTICE VALUATION GROUP, LLC DEBT-CAPACITY METHOD©

**value = (adjusted net cash flow) x amortization factor**
**(debt service coverage ratio)**

Source: The Practice Valuation Group LLC

**DEFINITIONS:**

### ADJUSTED NET CASH FLOW

Adjusted net cash flow is the cash flow available for debt amortization before income taxes but after fixed and variable expenses and professional compensation are paid. Non-recurring or extraordinary expenses as well as excess professional wages and discretionary fringe benefits are eliminated to normalize practice earnings.

### DEBT SERVICE COVERAGE RATIO

The debt service coverage ratio (DSCR) reflects the risk peculiar to a specific subject practice as well as the general economic outlook and the outlook for the health-care industry. The DSCR indicates the transfer risk or potential erosion of professional goodwill. The lower the risk, the lower the capitalization rate, the higher the value of the practice.

### AMORTIZATION FACTOR

The amortization factor, which is the statistical summation of the terms and conditions of a credit accommodation, reflects the principal ratio and term of the loan.

Office location and profitability are also important, according to Kropiewnicki. "If a practice is in the middle of nowhere, rural versus suburban Pennsylvania or New Jersey, then the rural practice will almost certainly be worth less than the suburban practice, all else being equal," he says. "Also, profitability is a major factor, so if you have two practices in the same geographic area each grossing $1 million, and one physician is making $300,000 and the other physician is netting out $500,000, a buyer should be willing to pay more for the more profitable practice."

"While there are numerous factors which could affect it, the value of goodwill is generally dependent upon the ability of the purchaser to be able to earn a superior return from the practice compared with what could normally be expected to be earned by physicians in the specialties represented in the practice," DeMuth says.

The Health Care Group publishes the Goodwill Registry, a large database of healthcare practice transactions from all over the country and source of actual goodwill values paid. It lists goodwill as a percentage of a practice's gross income and has other financial information about the practices reported to them by specialty.

"When buying a home, comparables exist—you can compare homes in different neighborhoods," Kropiewnicki says. "No neighborhood level comparables exist like that when it comes to medical practices. The Goodwill Registry comes closest to providing healthcare practice comparables, but on a wider geographic scale."

Although it's usually inappropriate to solely apply rules-of-thumb in valuing medical practices, especially goodwill and intangible assets, the Goodwill Registry can be used to support or confirm the valuation results achieved using other valuation methods.

"Even when using a database of sales data, significant thought needs to go into understanding similarities and differences in published data, such as the Goodwill Registry. Some data is based on matrimonial disputes, some are arm's-length sales, some are based on

internal sales transactions which may have other, tax driven components to them. Failure to fully take these issues into account is likely to lead to erroneous conclusions," Glusman says.

## OLD FORMULAS MAY NO LONGER APPLY

The value of a practice will always be based on the specifics of that practice as a business. "With that said, the old formulas and multipliers of revenue that were rules of thumb for the value of a practice hold true less and less today than they did 15 or 20 years ago," Glusman notes. "There was a time when primary care practices routinely sold for between 1 and 1.25 times annual gross revenue. To the extent there are generalities today, the multiplier on gross revenue has tended to come down." (See sidebar, "Factors and formulas for determining a practice's value.")

Glusman cites the example of a retiring solo practitioner in a rural area who may not be able to sell the practice for a significant sum. "The buyer will weigh the price to be paid to the retiring physician against the cost and time necessary to start a practice in a similar area from scratch. Since it can take several years to start a new practice to reach a reasonable level of profitability, the buying physician will look at the alternative cost and revenue stream."

In a larger practice or one with some additional specialty there may be more opportunity to improve efficiencies or reduce costs, says Glusman. In these cases the physician may be able to obtain a value at or above .75 times gross revenue, a figure that people think of today as one rule of thumb," Glusman explains.

In DeMuth's opinion, there are no appropriate formulas to plug into gross or net incomes to determine the value of a medical practice. "Whenever we see claims to the contrary, we can typically make examples of two practices, one of which is particularly valuable and the other is not, and conclude that the formula values them identically," he says.

"A medical practice possesses unique characteristics that a non-medical business does not possess," notes Vincent M. Brinly, director of valuation services at Practice Valuation Group, Washington, D.C. "Consequently, certain methods of appraisal are not appropriate and should not be used to value medical practices. For example, since few medical practices are comparable, the market method has severe limitations and should only be used in conjunction with another appraisal method. The cost method disregards professional goodwill and concentrates on the value of the tangible assets," he says.

"In my opinion, debt-capacity is the most appropriate method to use to value a medical practice" Brinly adds. "The capitalization-of-earnings method and the debt-capacity method are similar; both capitalize adjusted net cash flow to determine fair market value. In a professional practice, the emphasis is on the value of professional goodwill. Since the focus of the debt-capacity method is on the transfer risk or value of the patient records that can be transferred from one doctor to another, it is the most fitting method of appraisal to value a professional practice," he explains.

## LEGAL CONSIDERATIONS

Numerous legal considerations are part of establishing fair market value opinions for physician practices, according to Glusman. "A full understanding of the Stark Law and related regulations and anti-kickback rules is an important issue when hospitals are buying or leasing practices," he says. "For a physician who is, literally, selling the practice walking out the door and leaving town, not practicing medicine in any way and with no ability to make a referral to the buyer, the Stark rules and anti-kickback regulations may not even come into play."

On the other hand, a cardiologist who is selling his or her practice to a hospital, becoming a full-time employee of the hospital, as well as the medical director for the cardiology department, and being in a position to admit patients and refer patients to other hospital-based cardiac facilities, has an extraordinarily high level of likelihood of making referrals and the full weight of the Stark and anti-kickback regulations come into play, according to Glusman.

In connection with hospital purchases of medical practices, both the physician and the hospital need to follow IRS and other governmental guidelines for valuing the practice. For example, the IRS prefers the discounted cash flow method in medical practice valuations involving tax-exempt entities, such as not-for-profit hospitals.

"In addition to legal issues, tax issues need to be taken into consideration such as the tax impact of earnings in S corporations, partnerships and other flow through entities that commonly exist for physician practices," says Glusman.

Taxation is affected by the legal form in which the practice seller conducts business, be it a proprietorship, general partnership, limited liability company or partnership, or a C or an S corporation, DeMuth explains.

"For example, are the assets of the medical practice being sold to a hospital or related entity or is a new doctor buying stock in a professional corporation?" he says. "When a hospital is buying the assets of a practice, it may be attractive from the tax standpoint for it to acquire personal goodwill from the doctors who own the practice, individually as opposed to buying the entity's goodwill, which could cause either a potential additional layer of tax or tax at a higher rate than if personal goodwill was utilized."

"The deal has to take into consideration the legal structure and the tax implications that carries," Glusman agrees. "Nonetheless, the net price paid for the assets, including any goodwill, must be fully justified as fair market value to avoid governmental allegations at a later date."

The purchase or sale of a medical practice or of an ownership interest can be one of the biggest financial transactions in a doctor's life. "The physician's financial interest in his medical practice may be more than his home," DeMuth says. "To assure that the doctor is paid or pays appropriately for what has been or will be his life's work, its incumbent upon him or her to see that the practice's value is appropriately determined and legally sound."

# Financial Strategies

## BE CONSERVATIVE IN CALCULATING EQUIPMENT ROI

*I am in a three-physician family practice, and my partners and I are debating whether to acquire laser equipment to offer certain cosmetic procedures to our patients. How do we calculate the return on our investment for acquiring the equipment? And are we better off purchasing or leasing?*

**THE "LEASE** or buy" question is one that medical practices often confront. Unfortunately, it does not have a clear-cut answer. Many banks are offering very low interest rates to physician practices for use in capital purchases, and equipment lease contracts tend to have higher interest rates and additional fees. Also, most medical equipment purchases can take advantage of accelerated depreciation schedules that offer a tax advantage. A Section 179 expense deduction allows medical practices to deduct up to $500,00 of the purchase price of certain equipment during the tax year in which it was bought and placed in service, rather than depreciating the purchase over an extended period of time.

On the other hand, purchasing equipment requires predicting how long it can be used before it wears out or becomes obsolete. If you are predicting a short lifetime because of technology advances, a lease option may be attractive because they can upgrade or replace the equipment more easily.

What I find is that financially stable practices generally prefer to purchase equipment, and practices that are just getting by prefer to lease. I also find the practices that like the newest and greatest technologies often lease more often than they buy.

Calculating return on investment (ROI) means answering the question, "Am I making a profit on the services being rendered with the new piece of equipment?" Here is the typical ROI formulary:

### The ROI Calculation

**Gross revenues collected**

**Less:** Financing costs (loan payments)

**Less:** Direct costs of operating the equipment

**Less:** Indirect costs of operating the equipment

**Equals:** Net profit (or loss)

I assume you've done your due diligence on potential utilization of this particular capital equipment. I find that most practices are overly optimistic in their revenue projections, so I suggest being very cautious in yours. Remember also that arriving at an accurate ROI requires determining the true cost of providing the additional service. This includes direct costs, such as disposables, maintenance, technical support, rent (if additional space is required to house the equipment, etc.) and the indirect costs of rendering the service (allocated receptionist time, billing staff time, etc.)

In summary, make sure there is a market for whatever piece of equipment you intend to purchase or lease. Will there be sufficient patient volume to justify the acquisition and make a profit? If the answer is yes, prepare a financial proforma to get an idea of profit that can be generated by the new service(s). Due diligence is the difference between a good decision and financial trouble. ◻

*The answer to our reader's question was provided by Reed Tinsley, CPA, an accountant and certified healthcare business consultant based in Houston, Texas. Send your practice management questions to* ***medec@advanstar.com****.*

# Coding Insights

## 7 COMPLIANCE MEASURES FOR NEW HIPAA RULES

*How will the new Health Insurance Portability and Accountability Act (HIPAA) regulations pertaining to audits affect me in private practice?*

**IN THE PAST,** audits conducted by the Office for Civil Rights (OCR) related to compliance with the Health Insurance Portability and Accountability Act (HIPAA) were initiated by complaints and self-reported breaches in the provider environment. That is no longer the case. Provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act require the U.S. Department of Health and Human Services (HHS) to undertake periodic audits of covered entities and business associates for compliance with the HIPAA privacy rule, security rule, and breach notification.

A covered entity is considered to be one of the following:

- **physicians,**
- **clinics,**
- **psychologists,**
- **dentists,**
- **chiropractors,**
- **nursing homes,**
- **pharmacies, and**
- **information transmitted in an electronic form with a transaction for which HHS has adopted a standard.**

The type of functions of a business associate may include claims processing, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, and practice management The services may be legal, accounting, consulting, data aggregation, management, administrative accreditation, and financial.

The preliminary results from an OCR pilot program showed that the majority of protected health information (PHI), which refers to individually identifiable health information, is that which can be linked to a particular person. These identifiers include:

- **names;**
- **geographic identifiers;**
- **dates directly related to an individual;**
- **phone and fax numbers;**
- **email addresses;**
- **Social Security numbers;**
- **medical record numbers;**
- **health insurance beneficiary numbers;**
- **patient account numbers;**
- **vehicle identifiers and serial numbers, including license plate numbers, device identifiers, and serial numbers;**
- **URLs and IP address numbers;**
- **biometric identifiers including finger, retina, and voice prints;**
- **full face images, and any comparable identifiers.**

It is important to prepare your practice for such an audit. Covered entities and business associates should ensure that they take the following compliance measures:

1. ***Provide the Notice of Privacy with the appropriate changes to patients.***
2. ***Have written and signed business associate agreements with all entities considered a business associate.***
3. ***Conduct a thorough assessment of the risk to electronic protected electronic health information (ePHI).***
4. ***Implement required technical and administrative safeguards to protect ePHI.***
5. ***Update the formal policies and procedures for the privacy and security of PHI to reflect the changes resulting from the omnibus final rule.***
6. ***Train all employees whose duties are***

# Coding Insights

***affected on privacy and security policies, even those with previous training, to bring them up-to-date with the additional changes.***

7. ***Maintain documentation of all employee training, disclosure logs, breach analyses, and sanctions against employees for violations of security and privacy. This can be done either in written or electronic form.***

## HOW THE AUDIT PROCESS WORKS

These audits are likely to begin in September 2013. The audit process begins when the OCR sends a document request to the audit contractor and a request for required HIPAA documents, including copies of the privacy policies and procedures, training documentation, incident response plans, and risk analyses.

When a covered entity is selected for an audit, OCR will notify the covered entity in writing. The OCR notification letter introduces the audit contractor, explains the audit process and expectations in more detail, and describes initial document and information requests. It also specifies how and when to return the requested information to the auditor. OCR expects covered entities and business associates who are the subject of the audit to provide requested information within 10 business days of the request for information.

**ON-SITE VISITS MAY TAKE BETWEEN 3 AND 10 BUSINESS DAYS DEPENDING UPON THE COMPLEXITY OF THE ORGANIZATION AND THE AUDITOR'S NEED TO ACCESS MATERIALS AND STAFF.**

OCR expects to notify selected covered entities between 30 and 90 days prior to the anticipated on-site visit. On-site visits may take between 3 and 10 business days depending upon the complexity of the organization and the auditor's need to access materials and staff.

After completing fieldwork, the auditor will provide the covered entity with a draft report; a covered entity will have 10 business days to review and provide written comments back to the auditor. The auditor will complete a final audit report within 30 business days after the covered entity's response and submit it to OCR. If a complaint describes an action that could be a violation of the criminal provision of HIPAA (42 U.S.C. 1320d-6), OCR may refer the complaint to the Department of Justice for investigation.

OCR reviews the information, or evidence, that it gathers in each case. In some cases, it may determine that the covered entity did not violate the requirements of the privacy or security rule. If the evidence indicates that the covered entity was not in compliance, OCR will attempt to resolve the case with the covered entity by obtaining:

- **Voluntary compliance**
- **Corrective action**
- **Resolution agreement**

Most privacy and security rule investigations are concluded to the satisfaction of OCR through these types of resolutions. OCR notifies the person who filed the complaint and the covered entity in writing of the resolution result.

If the covered entity does not take action to resolve the matter in a way that is satisfactory, OCR may impose civil money penalties (CMPs) on the covered entity. If CMPs are imposed, the covered entity may request a hearing before an HHS administrative law judge who will decide if the penalties are supported by the evidence in the case. Complainants do not receive a portion of the CMPs collected. ◘

**@ Additional information on complying with the new HIPAA regulations and protecting patients' health information is available on the Modern Medicine Web site at: bit.ly/12sgjXo and bit.ly/15Xq28K**

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

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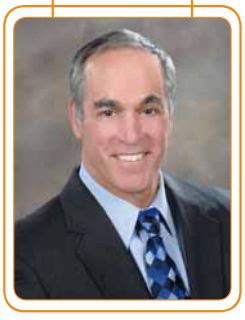

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Perspective

# PATIENTS OPEN TO EXPANDED ROLE OF PHYSICIAN ASSISTANTS, NPs

BY ALISON RITCHIE

The shortage of primary care physicians in the United States is expected to worsen next year, when many newly-insured patients enter the market under the Affordable Care Act. Some policy analysts have suggested expanding the roles of physician assistants (PA) and nurse practitioners (NP) as one potential way to help alleviate some of the burden on physicians, and a new study published in *Health Affairs* shows that consumers are open to that idea.

The study, which was part of the December 2011 – January 2012 Association of American Medical Colleges (AAMC) Consumer Survey, questioned 2,053 individuals who required medical care within the previous 12 months.

In the survey's first scenario, respondents said that when finding a new primary care provider, 50% preferred a physician, while 23% preferred a PA or NP and 26% indicated no preference.

But it was the second scenario that indicated timeliness likely influences a patient's decision. Respondents were given the option of seeing a PA or NP on the same day for a worsening cough or seeing a physician the next day. Nearly 60% preferred to see a PA or NP, while only 25% preferred to wait.

Clese Erikson, the director of the AAMC Center for Workforce Studies and a co-author of the study, says the survey results show that timeliness of care is an important factor for patients.

"[The results showed] those who had seen a physician assistant before were more willing to see one a second time, especially if it meant getting in to the office a day earlier," says Erikson. "It's consistent with what Americans are doing already. Many people have had that same experience when calling their physician's office to make an appointment. We saw that the time trade played a big role. That's going to be important avenue to ensuring access to care in future."

The survey also examined which respondents were more likely to seek treatment from a PA or NP based on their sex, age, race, annual income and insurance status.

But many primary care physicians are reluctant to see NPs expand their scope-of-practice, citing concerns over patient safety and discrepancies in education. (See "Coalition aims to quash expanded role of NPs in California," page 13.) A separate study released earlier this year by the *New England Journal of Medicine* showed that physicians see a difference in the quality of care that they provide. Nearly two-thirds of physicians in the study agreed with the statement that physicians provide a higher-quality examination and consultation than nurse practitioners during a primary care visit. In that same study, however, more than three-fourths of nurse practitioners disagreed with that same statement.

According to *Health Affairs*, 18 states and the District of Columbia allow NPs to practice without physician involvement, and that number could grow in the coming years as more state legislatures consider proposals.

The *Health Affairs* study concludes, "As scope-of-practice battles continue to be waged and new reforms for care delivery and reimbursement roll out, our findings provide early evidence that health care consumers in the United Stares are open to the idea of seeing physician assistants and nurse practitioners in the future – and in many cases prefer it."

**@ Want to weigh in on the debate about expanded role of NPs and PAs? We want to know. Write us at medec@advanstar.com. Your comments could be published in the next issue of *Medical Economics*.**

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