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Medical Economics®

MAY 25, 2013

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CRACKING THE CODE

PAGE 20

TOP STRATEGIES

- Selecting appropriate E/M levels
- Documenting patient care

PLUS
Tips when using TCM codes

ADVANSTAR MEDICAL COMMUNICATIONS GROUP VOL. 90 NO. 10

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Volume 90
Issue 10

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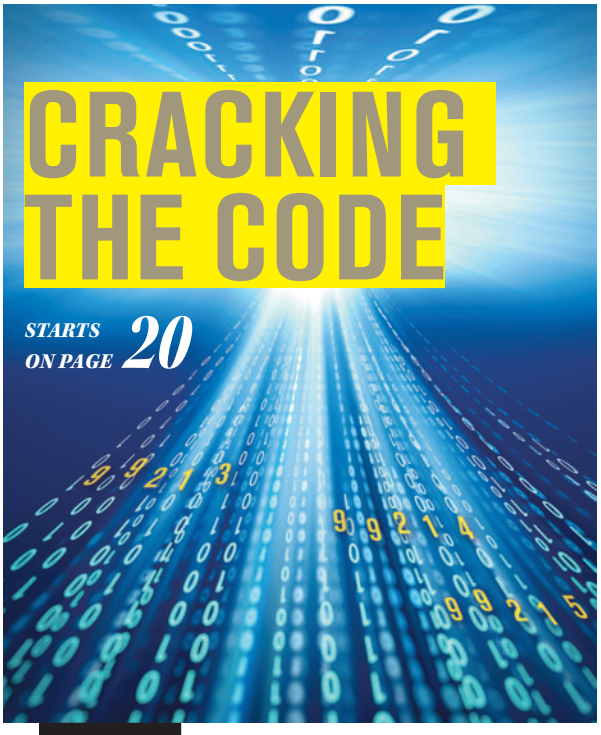

COVER STORY | OPERATIONS

Top strategies for selecting appropriate E/M levels and documenting patient care.

STARTS ON PAGE 20

- Coding for an outpatient visit of a returning patient
- Is EHR cloning ever acceptable?
- About those transitional care management codes

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FINANCIAL STRATEGIES

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How long-term disability insurance can protect income

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TECH TALK

Tony Consoli
Why your practice needs cyber insurance

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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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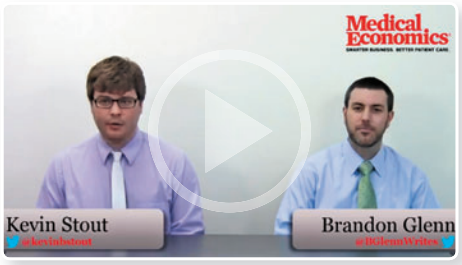

In our second Webcast of *Medical Economics* Weekly, Digital Content Manager Brandon Glenn and Social Media Manager Kevin Stout discuss how doctors may change their behavior if they are made aware of test costs, a new search engine for rare diseases, why healthcare cost growth has slowed recently, and more.

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"Repeated claim denials from a payer can sometimes be a warning of a coding problem."

—Lawrence Vernaglia, JD, MPH

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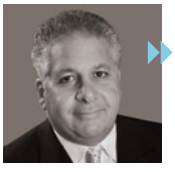

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from the Trenches

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

MY NEW AND IMPROVED DESK

This is my "new and improved," "meaningful use," "electronic health record-enabled," "paperless desk." The funny thing is, it's more littered with paper and more disorganized than my old, reliable "paper chart" desk.

I keep the cycling sign above it all to remind me of proper perspective on philosophy and practice of all healthcare work and personal interest and motivation.

> "THE FUNNY THING IS, [MY NEW DESK] IS MORE LITTERED WITH PAPER AND MORE DISORGANIZED THAN MY OLD...'PAPER CHART' DESK."

ABOUT THE AUTHOR

The author practices family medicine in Mullica Hill, New Jersey.

MOC PROGRAM FAILS IN ITS MISSION

I have never submitted correspondence to a magazine before. However, after reading the article "Get involved to help end MOC" (Talk Back, January 25) and then the article by Lois Nora, MD (Viewpoint, October 25, 2012), I felt it necessary to provide a counterpoint.

As a physician who has participated in the MOC program, I am not against its continuation. I both understand and agree with the need to "remain knowledgeable and skillful in our disciplines and care about providing safe, evidence-based, and compassionate care to patients" (as Nora stated). What continues to gall me (as well as most physicians who are required to participate in the MOC program) is that this program, in its present iteration, has completely failed in bringing its mission to fruition.

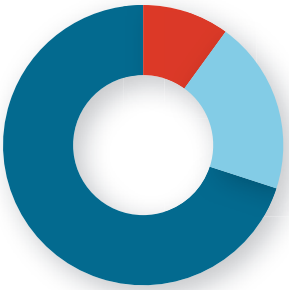
We have all been witness to physicians who have their board certificates proudly displayed in their offices, as well as claiming board certification as part of their credentials. I know for a fact that very few [patients] will inquire further to determine the date of the certification, nor even the veracity of the certification (as long as the physician states he or she is certified).

Whatever the reasons or excuses given by those who have been "grandfathered" into permanent board status, the fact is that all physicians should be required to participate in the MOC program; anything less is a mockery of the principles that the American Board of Medical Specialties expounds and thus a travesty that has continued far too long.

Since we are all physicians in the end, we should all be held to the same standards. Anything less invites the question of what the point is at all.

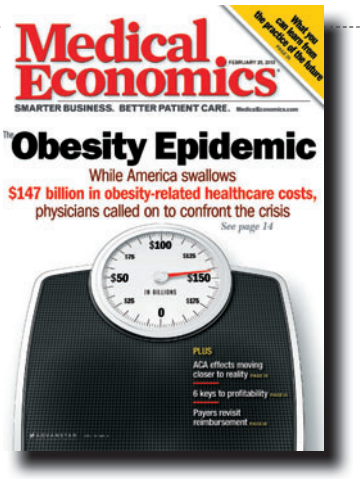
Robert M. Kleinhaus, MD
ABILENE, TEXAS

Are you part of an accountable care organization?



- ***Yes***
- ***No,*** but I plan to join one
- ***No,*** and I do not plan to join one

View comments and take our survey at www.facebook.com/MedicalEconomics



INDIVIDUAL NOT SEPARATE FROM SOCIETY

> "To try to separate the individual from society is...an argument that has been dispensed with in most of the developed world. The basic tenets of Plato and Hippocrates have been dissected, argued over, and revamped, and there are any number of more applicable philosophical approaches to the problems inherent in our healthcare system."

I am surprised by the naiveté expressed by Craig Wax, DO ("Plato versus Hippocrates," From the Board, February 25, 2013). To try to separate the individual from society is a long-held myth in America and an argument that has been dispensed with in most of the developed world. The basic tenets of Plato and Hippocrates have been dissected, argued over, and revamped, and there are any number of more applicable philosophical approaches to the problems inherent in our healthcare system.

Rationing of healthcare in America is not a new concept, or don't you have to deal with prior authorizations, denial of coverage for procedures or drugs, or patients who cannot afford COBRA, let alone basic insurance? Do you also deny that it has been public health, occupational health and safety, and immunization programs that could only be done with organized societal infrastructure that have had such an impact on our health as a country in the past 100 years?

Please go to a developed country and explain why the basics of clean water and proper sewage disposal (which are only tenable with an organized—dare I say government—infrastructure) are less important than one person's right to have a magnetic resonance imaging scan of the lower back that he or she injured yesterday.

I have lived and worked in the United Kingdom and in Canada. I have found the ethical relationships of the doctors there identical to ours here. Contrary to your assertion of "minimal health maintenance...and destruction of the doctor-patient relationship," the opposite is the truth. I have found from experience, and I think all studies have shown, closer relationships with a patient's primary care doctor, more cost-effective care, better population-based health outcomes, and better coverage. Granted, not every patient or doctor gets to do what he or she wants, but as I tell my patients, just because we *can* does not mean we *should*.

I do think, however, that the administration of healthcare in those countries could learn a lot from our system in terms of putting the patient first and how to separate the politics from good medical care. On the other hand, I find in unbelievable that we will provide legal aid for anyone as a right but not medical or dental care, that we require drivers to have proof of insurance before they can license a car, but parents do not have to have health insurance before they have a baby... and the list goes on.

Please join us in a constructive debate by looking at the other systems in the world and what works well for them and what might help us guide our system to provide better care for our patients, and stop the fear-mongering by perpetuating the myth that we as individuals should not try to live as a society. It's never been the case.

Bruce W. Young, MD, PhD
BROOKLYN PARK, MINNESOTA

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Or mail to:
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COSTS TO PATIENTS CONTINUE TO RISE

Out-of-pocket expenditures for patients increased while benefits of employer healthcare coverage became "less generous" from 2007 to 2011.

The results from a recent Harvard Medical School study (Chernew, et al.) in *Health Affairs* examining 10 million enrollees from large firms suggests that although the recession played a role in reducing healthcare growth overall, more factors are at work.

In fact, the study concludes that benefit design changes caused about one-fifth of the growth slowdown during this time period. And increasing out-of-pocket payments played a major role in the overall decline of healthcare spending growth, accounting for approximately 20% of the observed slowdown.

The study concludes that the declines in healthcare spending may be a long-term trend—not short-term as some research has postulated—and driven solely by the recession.

"Healthcare reform, changes in payment methodologies, such as the use of more global payments, and the transformation of the delivery system's organization could all have long-lasting effects," the authors state.

U.S. HOUSE: DOES HIPAA HINDER PATIENT CARE?

Mental health problems and suicide risks have lawmakers questioning whether new rules surrounding the Health Insurance Portability and Accountability Act of 1996 (HIPAA) ultimately "interfere with patient care and public safety."

In fact, the U.S. House Energy and Commerce Subcommittee recently put the topic on the docket in an attempt to better understand the scope of HIPAA's privacy laws and the way they could potentially interfere with a physician's ability to report information among other healthcare providers, patients, and families.

Rep. Tim Murphy (R-PA), a clinical psychologist, adds, "To be sure, HIPAA's obstruction of health information-sharing between provider and family in no way is limited to mental health. Some of our witnesses will testify that a widespread misunderstanding of what HIPAA says can prevent individuals with serious long-term medical conditions from obtaining appropriate care."

Of utmost importance, according to Murphy, is the law's impact as it relates to the care of mentally ill or severely depressed adolescents and HIPAA's effect on parental involvement as these individuals become young adults.

In testimony from Mark A. Rothstein, holder of the Herbert F. Boehl Chair of Law and Medicine and director of the Institute for Bioethics, Health Policy, and Law at the University of Louisville School of Medicine in Kentucky, each year more than 38,000 suicides and more than 700,000 emergency department visits are caused by self-inflicted harms. HIPPA's law considers the public health threat.

In fact, Rothstein outlines 12 types of health information covered entities are permitted to disclose without the need for patient consent or authorization:

1/ **required by law;**
2/ **for public health activities;**
3/ **about victims of abuse, neglect, or domestic violence;**
4/ **to avert a serious threat to health or safety;**
5/ **workers' compensation;**
6/ **for health oversight activities;**
7/ **for judicial and administrative proceedings;**
8/ **for law enforcement;**
9/ **about decedents to coroners, medical examiners, and funeral directors;**
10/ **for cadaveric organ, eye, or tissue donation;**
11/ **for research purposes pursuant to a waiver of authorization; and**
12/ **for military and veterans' affairs, national security and intelligence.**

PHASE OUT SGR WITH VALUE-BASED MODELS, ACP SAYS

Although the Congressional Budget Office recently downgraded the 10-year cost of repealing the sustainable growth rate (SGR) to $138 billion, the American College of Physicians (ACP) took to the Hill advocating a phased approach to repealing it and moving to value-based models.

In testimony before the U.S. House Ways and Means Subcommittee, **Charles Cutler, MD, FACP, chairman of the ACP Board of Regents**, said that a proposal developed by Ways and Means Committee Chairman Dave Camp (R-MI) and Energy and Commerce Committee Chairman Fred Upton (R-MI) is a "bold plan for Medicare payment reform that holds the promise of breaking a decade-long impasse on repeal of the Medicare SGR."

Some of the other ACP recommendations:

- **Establish positive baseline updates, with an increase for evaluation and management services, for 5 years.**
- **Starting in 2014, allow physicians to qualify for more value-based payment allowances.**
- **PCMH-recognized practices should qualify for a graduated incentive program.**

COALITION TARGETS POOR MEDICATION ADHERENCE RATES

TWO OUT OF THREE PATIENTS do not adhere to their care plans. In fact, adherence problems related to prescription medications is so widespread, they are costing the United States $100 billion a year in medication-related hospital admissions.

That's the message from a newly formed coalition of medical, pharmacy, pharmaceutical, and other stakeholders resolved to reverse the trend.

The coalition, Prescriptions for a Healthy America, has enlisted multiple industry stakeholders to ramp up legislative and educational remedies to improve medication adherence rates.

Among groups and organizations jumping on board are the American Academy of Family Physicians (AAFP), the American Heart Association, the American Academy of Ophthalmologists, Easter Seals, the National Association of Chain Drug Stores, the National Consumers League, PhMRA, Merck, Astra-Zeneca, GlaxoSmithKline, and CVS/Caremark.

Coalition activities will target elected officials and other key players to develop policies to help health plans, patients, employers, doctors, pharmacies, and other healthcare practitioners support patients' medication adherence as a critical part of the treatment plan.

Specifically, the coalition is looking at care coordination and comprehensive medication management, quality measurement, and performance improvement, health information technology, patient/provider education and engagement, and research.

AAFP board member Rebecca Jaffe, MD, MPH, is a believer.

"I see the negative impact nonadherence has on patients each day. I also see the positive impact that adherence to treatment protocols has an the improved quality of life many individuals experience as a result."

THE TOP 4 REASONS patients fail to adhere to medication treatment plans:

1/ **They forget to take the medication.**

2/ **They believe it is inconvenient.**

3/ **They start to feel better.**

4/ **They are confused about the treatment plan.**

Source: Greenberg Quinlan Rosner/ Public Opinion Strategies

EHR incentive program enrollment climbs to 73%

NEARLY THREE-FOURTHS of eligible professionals have registered for the government's electronic health record (EHR) incentive programs, according to a recent report from the Centers for Medicare and Medicaid Services.

To date, some 230,000 providers, or 44% of eligible professionals, are said to be "meaningfully using" EHR technology.

At the end of March, the federal government had paid about $13.7 billion to providers since 2011.

Little doubt exists that most physicians are pleased to receive payments to help them defray the costs of EHRs, but to what extent they're pleased with their EHR systems is another matter.

A survey of 17,000 active EHR users earlier this year found that 23% of physician practices are frustrated enough with the software to consider switching vendors.

Separately, another survey this year found that user satisfaction with EHRs is in decline, down 12 percentage points from 2010 to 2012.

At the same, time, the percentage of users who classified themselves as "very dissatisfied" with their EHRs increased 10 percentage points.

WASHINGTON BUDGET BATTLE FOCUSES ON ACA

REPUBLICANS SHARPLY criticized U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius in trying to jump start fundraising efforts to non-profits to implement the Affordable Care Act (ACA). The action follows repeated congressional budget denials for the healthcare law, now estimated at $1.3 trillion over 10 years, according a recent report in the *Washington Post*. Sen. Orrin Hatch (R-UT) called the effort "absurd" and demanded an inquiry.

The report suggests that Sebelius made multiple telephone calls to pharmaceutical industry executives and other community organizations in an effort to improve fundraising efforts to implement the ACA.

HHS argues that provisions allow the secretary to "encourage" support of non-profit groups.

The most recent action comes as the rhetoric toward ACA intensifies. This year, 14 ACA provisions will be implemented, and in 2014, the controversial health insurance exchanges will open to Americans.

Also, this month, the House Energy and Commerce, Ways and Means, and Education and the Workforce Committee released an updated "Obamacare Burden Tracker." It is described as a real-time, online resource of all of the new government mandates, rules, and red tape resulting from the ACA. Currently, the tracker estimates that the law adds nearly 190 million hours in compliance for healthcare providers, employers, and patients.

"Given the new demands of complying with the law, it is not surprising that over 70% of small businesses cite the healthcare law as a major obstacle to job creation," the committee states.

BUDGET CUTS SIGNAL TROUBLE FOR MEDICAL EDUCATION

Although the American Academy of Family Physicians threw support to President Obama's initiative for Medicaid expansion and Medicare payment reform, across-the-board cuts to graduate medical education (GME) threaten family medicine residency programs.

"Such broad and untargeted cuts would jeopardize family medicine residency programs at a time when they require critical investment to sustain the growing interest in training primary care physicians," says Glen Stream, MD, MBI, AAFP board chairman. "The evidence shows that improving quality and reining in costs depend on a strong primary care foundation. We have just begun to see a turnaround in the number of students looking for family medicine residency training, but without adequate support for training these physicians, that turnaround could quickly fade."

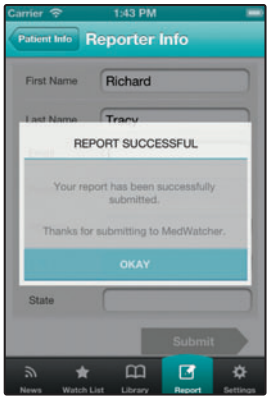
Between 2000 and 2013, medical academia closed 71 family medicine programs, Stream says. "The trend reversed last year, when no family medicine programs closed and seven new family medicine residency programs were accredited." If GME funding must be reduced, the AAFP wants Congress to preserve explicit support for primary care residency programs.

Doctor's Bag

The latest in drugs, devices, technology, and more

APP LETS YOU SUBMIT DEVICE REPORTS TO FDA

The MedWatcher mobile app allows physicians and other users to submit voluntary reports of serious medical device problems to the Food and Drug Administration using a smartphone or tablet. Although not intended to fulfill mandatory reporting requirements, the app is designed to improve patient safety more quickly by speeding the reporting process compared with traditional reporting done via mail, telephone, or Web.



Users can:

- **report serious adverse events, therapeutic failures, use errors, and product quality issues;**
- **upload photos to help identify visible problems; and**
- **receive safety alerts ,safety communications, recall information, and more.**

A built-in firewall means that information is not vulnerable after it has been received, according to the agency. The app does not store personal information from a user's mobile device, nor does it store reports once they are submitted.

MedWatcher is available for download in the iTunes and Google Play stores.

HealthMap (800) 463-6332 | www.medwatcher.org

BRACELET STORES MEDICAL HISTORY

Your patients may find the CARE Medical History Bracelet useful. They can store personal health history data on this portable, waterproof memory device preloaded with CARE e-Manager software. The device is designed to expedite care, reduce medical errors, and potentially save lives; emergency medical staff can view the medical records via USB.

The patient controls the information and works with his or her provider to keep it updated.

The devices are $29.99, come in seven colors and five sizes, and can be found in national drug store chains and other retailers. The bracelet is being used by the Muhammad Ali Parkinson Center, the Epilepsy Foundation, and the Special Olympics, according to the manufacturer.

GC Publishers LLC (866) 798-4531 | www.medicalhistorybracelet.com

APP LETS YOU CHECK ADHERENCE

You and your patients also may find the MediSafe Project pillbox app helpful. It uses cloud-sync technology to send alerts to caretakers, family, and friends when users miss a medication dose. The newly launched version 2.0 allows users to email a personalized list of medication adherence statistics to their physicians, giving doctors the ability to extend care into the home between visits. Adherence rates are color-coded to help users understand how well they are adhering to their prescribed medication regimens.

Other new features allow users to:

- **adjust medication refill reminders according to preference and**
- **separate medications into different user profiles when overseeing regimens for multiple people.**

To protect privacy, no patient identity information is included; users can add it if they choose to do so.

The app can be downloaded at not cost in Google Play and iTunes app stores, but the 2.0 update currently is available only for Android devices. An iOS update will be available in iTunes in June.

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- Low incidence of side effects[1]
  - — Discontinuation rate due to adverse events was 2.8% for BYSTOLIC vs 2.2% for placebo[1]

Important information about the cardiovascular benefits of lowering blood pressure

- The Food and Drug Administration (FDA) issued a guidance to explicitly make the connection between lowering blood pressure and improved cardiovascular outcomes in antihypertensive class labeling to address the public health concern of inadequate treatment of hypertension[8]
- The BYSTOLIC Prescribing Information has been updated based on this guidance
  - — BYSTOLIC reduces blood pressure[1]
  - — Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions[1]
  - — There are no controlled trials demonstrating risk reduction with BYSTOLIC, but at least one pharmacologically similar drug has demonstrated such benefits[1]
  - — Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake[1]
  - — Many patients will require more than one drug to achieve blood pressure goals[1]

Important Safety Information

Contraindications

- BYSTOLIC is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

Warnings and Precautions

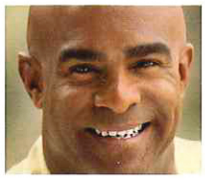
- Do not abruptly discontinue BYSTOLIC therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction, and ventricular arrhythmias have been reported following the abrupt discontinuation of therapy with beta blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Caution patients without overt coronary artery disease against interruption or abrupt discontinuation of therapy. As with other beta blockers, when discontinuation of BYSTOLIC is planned, carefully observe and advise patients to minimize physical activity. Taper BYSTOLIC over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, restart BYSTOLIC promptly, at least temporarily.

Adverse Reactions

- The most common adverse events with BYSTOLIC versus placebo (approximately ≥1% and greater than placebo) were headache, fatigue, dizziness, diarrhea, nausea, insomnia, chest pain, bradycardia, dyspnea, rash, and peripheral edema. The most common adverse events that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%), and bradycardia (0.2%).

Please see full indication and additional Important Safety Information on the following page and brief summary of the full Prescribing Information on the last page of this advertisement.

Bystolic®
(nebivolol) tablets
2.5 mg • 5 mg • 10 mg • 20 mg
Effective treatment for hypertension




BYSTOLIC is widely available on commercial and Medicare Part D formularies.

85% unrestricted access on commercial formularies[9]

84% unrestricted access on Medicare Part D formularies[9]

Indication

- BYSTOLIC is indicated for the treatment of hypertension, to lower blood pressure. BYSTOLIC may be used alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. There are no controlled trials demonstrating risk reduction with BYSTOLIC, but at least one pharmacologically similar drug has demonstrated such benefits.
- Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.

Important Safety Information (continued)

Warnings and Precautions

- BYSTOLIC was not studied in patients with angina pectoris or who had a recent MI.
- In general, patients with bronchospastic diseases should not receive beta blockers.
- Because beta blocker withdrawal has been associated with an increased risk of MI and chest pain, patients already on beta blockers should generally continue treatment throughout the perioperative period. If BYSTOLIC is to be continued perioperatively, monitor patients closely when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene are used. If beta-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.
  The beta-blocking effects of BYSTOLIC can be reversed by beta agonists, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Additionally, difficulty in restarting and maintaining the heartbeat has been reported with beta blockers.
- Beta blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Advise patients subject to spontaneous hypoglycemia and diabetic patients receiving insulin or oral hypoglycemic agents about these possibilities.
- Beta blockers may mask clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of beta blockers in these patients may be followed by an exacerbation of symptoms or may precipitate a thyroid storm.
- Beta blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease.
- Because of significant negative inotropic and chronotropic effects in patients treated with beta blockers and calcium channel blockers of the verapamil and diltiazem type, monitor the ECG and blood pressure of patients treated concomitantly with these agents.
- Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc). When BYSTOLIC is co-administered with an inhibitor or an inducer of CYP2D6, monitor patients closely and adjust the nebivolol dose according to blood pressure response. The dose of BYSTOLIC may need to be reduced. When BYSTOLIC is administered with fluoxetine, significant increases in d-nebivolol may be observed (ie, an 8-fold increase in AUC and a 3-fold increase in C_{max} for d-nebivolol).
- Renal clearance of nebivolol is decreased in patients with severe renal impairment. In patients with severe renal impairment (ClCr less than 30 mL/min) the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. BYSTOLIC has not been studied in patients receiving dialysis.
- Metabolism of nebivolol is decreased in patients with moderate hepatic impairment. In patients with moderate hepatic impairment, the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. BYSTOLIC has not been studied in patients with severe hepatic impairment and therefore it is not recommended in that population.
- Patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated challenge and may be unresponsive to the usual doses of epinephrine while taking beta blockers.
- In patients with known or suspected pheochromocytoma, initiate an alpha blocker prior to the use of any beta blocker.

Drug Interactions

- Do not use BYSTOLIC with other beta blockers.
- Both digitalis glycosides and beta blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.
- BYSTOLIC can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide.

Use in Specific Populations

- Use BYSTOLIC during pregnancy only if the potential benefit justifies the potential risk to the fetus. BYSTOLIC is not recommended during nursing.
- The safety and effectiveness of BYSTOLIC have not been established in pediatric patients.
- In a placebo-controlled trial of 2128 patients (1067 BYSTOLIC, 1061 placebo) over 70 years of age with chronic heart failure receiving a maximum dose of 10 mg per day for a median of 20 months, no worsening of heart failure was reported with nebivolol compared to placebo. However, if heart failure worsens, consider discontinuation of BYSTOLIC.

Please see brief summary of the full Prescribing Information on the following page of this advertisement.

References: 1. BYSTOLIC [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2011. **2.** Germino FW. Efficacy and tolerability of nebivolol monotherapy by baseline systolic blood pressure: a retrospective analysis of pooled data from two multicenter, 12-week, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging studies in patients with mild to moderate essential hypertension. *Clin Ther.* 2009;31:1946-1956. **3.** Data on file. Forest Laboratories, Inc. **4.** Lacourcière Y, Lefebvre J, Poirier L, Archambault F, Arnott W. Treatment of ambulatory hypertensives with nebivolol or hydrochlorothiazide alone and in combination: a randomized, double-blind, placebo-controlled, factorial-design trial. *Am J Hypertens.* 1994;7:137-145. **5.** Saunders E, Smith WB, DeSalvo KB, Sullivan WA. The efficacy and tolerability of nebivolol in hypertensive African American patients. *J Clin Hypertens.* 2007;9:866-875. **6.** Weber MA, Basile J, Stapff M, Khan B, Zhou D. Blood pressure effects of combined β-blocker and angiotensin-converting enzyme inhibitor therapy compared with the individual agents: a placebo-controlled study with nebivolol and lisinopril [published online ahead of print June 4, 2012]. *J Clin Hypertens.* doi:10.1111/j.1751-7176.2012.00666.x. **7.** Neutel JM, Smith DHG, Gradman AH. Adding nebivolol to ongoing antihypertensive therapy improves blood pressure and response rates in patients with uncontrolled stage I-II hypertension. *J Hum Hypertens.* 2010;24:64-73. **8.** U.S. Department of Health and Human Services Food and Drug Administration. Guidance for Industry Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims. March 2011. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075072.pdf. **9.** Fingertip Formulary® database, a registered trademark of Fingertip Formulary, LLC, as of July 2012. Data are subject to change.

Bystolic®
(nebivolol) tablets
2.5 mg • 5 mg • 10 mg • 20 mg
Effective treatment for hypertension
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Forest Pharmaceuticals, Inc.
Subsidiary of Forest Laboratories, Inc.
St. Louis, Missouri 63045

 044-13000071 08/12

BYSTOLIC® (nebivolol) tablets **Rx Only**
Brief Summary of full Prescribing Information
Initial U.S. Approval: 2007

INDICATIONS AND USAGE: Hypertension - BYSTOLIC is indicated for the treatment of hypertension, to lower blood pressure. BYSTOLIC may be used alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes, including the class to which this drug principally belongs. There are no controlled trials demonstrating risk reduction with BYSTOLIC. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC). Numerous antihypertensive drugs, from a variety of pharmacologic classes and with different mechanisms of action, have been shown in randomized controlled trials to reduce cardiovascular morbidity and mortality, and it can be concluded that it is blood pressure reduction, and not some other pharmacologic property of the drugs, that is largely responsible for those benefits. The largest and most consistent cardiovascular outcome benefit has been a reduction in the risk of stroke, but reductions in myocardial infarction and cardiovascular mortality also have been seen regularly. Elevated systolic or diastolic pressure causes increased cardiovascular risk, and the absolute risk increase per mmHg is greater at higher blood pressures, so that even modest reductions of severe hypertension can provide substantial benefit. Relative risk reduction from blood pressure reduction is similar across populations with varying absolute risk, so the absolute benefit is greater in patients who are at higher risk independent of their hypertension (for example, patients with diabetes or hyperlipidemia), and such patients would be expected to benefit from more aggressive treatment to a lower blood pressure goal. Some antihypertensive drugs have smaller blood pressure effects (as monotherapy) in black patients, and many antihypertensive drugs have additional approved indications and effects (e.g., on angina, heart failure, or diabetic kidney disease). These considerations may guide selection of therapy.

CONTRAINDICATIONS: BYSTOLIC is contraindicated in the following conditions: Severe bradycardia; Heart block greater than first degree; Patients with cardiogenic shock; Decompensated cardiac failure; Sick sinus syndrome (unless a permanent pacemaker is in place); Patients with severe hepatic impairment (Child-Pugh >B); Patients who are hypersensitive to any component of this product.

WARNINGS AND PRECAUTIONS: Abrupt Cessation of Therapy - Do not abruptly discontinue BYSTOLIC therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with β-blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Caution patients without overt coronary artery disease against interruption or abrupt discontinuation of therapy. As with other β-blockers, when discontinuation of BYSTOLIC is planned, carefully observe and advise patients to minimize physical activity. Taper BYSTOLIC over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, re-start BYSTOLIC promptly, at least temporarily. **Angina and Acute Myocardial Infarction -** BYSTOLIC was not studied in patients with angina pectoris or who had a recent MI. **Bronchospastic Diseases -** In general, patients with bronchospastic diseases should not receive β-blockers. **Anesthesia and Major Surgery -** Because beta-blocker withdrawal has been associated with an increased risk of MI and chest pain, patients already on beta-blockers should generally continue treatment throughout the perioperative period. If BYSTOLIC is to be continued perioperatively, monitor patients closely when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used. If β-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures. The β-blocking effects of BYSTOLIC can be reversed by β-agonists, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Additionally, difficulty in restarting and maintaining the heartbeat has been reported with β-blockers. **Diabetes and Hypoglycemia -** β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nonselective β-blockers may potentiate insulin-induced hypoglycemia and delay recovery of serum glucose levels. It is not known whether nebivolol has these effects. Advise patients subject to spontaneous hypoglycemia and diabetic patients receiving insulin or oral hypoglycemic agents about these possibilities. **Thyrotoxicosis -** β-blockers may mask clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of β-blockers may be followed by an exacerbation of the symptoms of hyperthyroidism or may precipitate a thyroid storm. **Peripheral Vascular Disease -** β-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. **Non-dihydropyridine Calcium Channel Blockers -** Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, monitor the ECG and blood pressure in patients treated concomitantly with these agents. **Use with CYP2D6 Inhibitors -** Nebivolol exposure increases with inhibition of CYP2D6. The dose of BYSTOLIC may need to be reduced. **Impaired Renal Function -** Renal clearance of nebivolol is decreased in patients with severe renal impairment. BYSTOLIC has not been studied in patients receiving dialysis. **Impaired Hepatic Function -** Metabolism of nebivolol is decreased in patients with moderate hepatic impairment. BYSTOLIC has not been studied in patients with severe hepatic impairment. **Risk of Anaphylactic Reactions -** While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. **Pheochromocytoma -** In patients with known or suspected pheochromocytoma, initiate an α-blocker prior to the use of any β-blocker.

ADVERSE REACTIONS: Clinical Studies Experience - BYSTOLIC has been evaluated for safety in patients with hypertension and in patients with heart failure. The observed adverse reaction profile was consistent with the pharmacology of the drug and the health status of the patients in the clinical trials. Adverse reactions reported for each of these patient populations are provided below. Excluded are adverse reactions considered too general to be informative and those not reasonably associated with the use of the drug because they were associated with the condition being treated or are very common in the treated population. The data described below reflect worldwide clinical trial exposure to BYSTOLIC in 6545 patients, including 5038 patients treated for hypertension and the remaining 1507 subjects treated for other cardiovascular diseases. Doses ranged from 0.5 mg to 40 mg. Patients received BYSTOLIC for up to 24 months, with over 1900 patients treated for at least 6 months, and approximately 1300 patients for more than one year. HYPERTENSION: In placebo-controlled clinical trials comparing BYSTOLIC with placebo, discontinuation of therapy due to adverse reactions was reported in 2.8% of patients treated with nebivolol and 2.2% of patients given placebo. The most common adverse reactions that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%) and bradycardia (0.2%). **Table 1** lists treatment-emergent adverse reactions that were reported in three 12-week, placebo-controlled monotherapy trials involving 1597 hypertensive patients treated with either 5 mg, 10 mg, or 20-40 mg of BYSTOLIC and 205 patients given placebo and for which the rate of occurrence was at least 1% of patients treated with nebivolol and greater than the rate for those treated with placebo in at least one dose group. **Table 1.** Treatment-Emergent Adverse Reactions with an Incidence (over 6 weeks) ≥1% in BYSTOLIC-Treated Patients and at a Higher Frequency than Placebo-Treated Patients are listed below in the following order: System Organ Class Preferred Term [Placebo (n = 205), Nebivolol 5 mg (n = 459), Nebivolol 10 mg (n = 461), Nebivolol 20-40 mg (n = 677)] **Cardiac Disorders:** Bradycardia (0, 0, 0, 1); **Gastrointestinal Disorders:** Diarrhea (2, 2, 2, 3); Nausea (0, 1, 3, 2); **General Disorders:** Fatigue (1, 2, 2, 5); Chest pain (0, 0, 1, 1); Peripheral edema (0, 1, 1, 1); **Nervous System Disorders:** Headache (6, 9, 6, 7); Dizziness (2, 2, 3, 4); **Psychiatric Disorders:** Insomnia (0, 1, 1, 1); **Respiratory Disorders:** Dyspnea (0, 0, 1, 1); **Skin and subcutaneous Tissue Disorders:** Rash (0, 0, 1, 1). Listed below are other reported adverse reactions with an incidence of at least 1% in the more than 4300 patients treated with BYSTOLIC in controlled or open-label trials except for those already appearing in **Table 1**, terms too general to be informative, minor symptoms, or adverse reactions unlikely to be attributable to drug because they are common in the population. These adverse reactions were in most cases observed at a similar frequency in placebo-treated patients in the controlled studies. **Body as a Whole:** asthenia. **Gastrointestinal System Disorders:** abdominal pain. **Metabolic and Nutritional Disorders:** hypercholesterolemia. **Nervous System Disorders:** paraesthesia. **Laboratory Abnormalities -** In controlled monotherapy trials of hypertensive patients, BYSTOLIC was associated with an increase in BUN, uric acid, triglycerides and a decrease in HDL cholesterol and platelet count. **Postmarketing Experience -** The following adverse reactions have been identified from spontaneous reports of BYSTOLIC received worldwide and have not been listed elsewhere. These adverse reactions have been chosen for inclusion due to a combination of seriousness, frequency of reporting or potential causal connection to BYSTOLIC. Adverse reactions common in the population have generally been omitted. Because these adverse reactions were reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency or establish a causal relationship to BYSTOLIC exposure: abnormal hepatic function (including increased AST, ALT and bilirubin), acute pulmonary edema, acute renal failure, atrioventricular block (both second and third degree), bronchospasm, erectile dysfunction, hypersensitivity (including urticaria, allergic vasculitis and rare reports of angioedema), myocardial infarction, pruritus, psoriasis, Raynaud's phenomenon, peripheral ischemia/claudication, somnolence, syncope, thrombocytopenia, various rashes and skin disorders, vertigo, and vomiting.

DRUG INTERACTIONS: CYP2D6 Inhibitors - Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.). **Hypotensive Agents -** Do not use BYSTOLIC with other β-blockers. Closely monitor patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, because the added β-blocking action of BYSTOLIC may produce excessive reduction of sympathetic activity. In patients who are receiving BYSTOLIC and clonidine, discontinue BYSTOLIC for several days before the gradual tapering of clonidine. **Digitalis Glycosides -** Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia. **Calcium Channel Blockers -** BYSTOLIC can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide.

USE IN SPECIFIC POPULATIONS: Pregnancy: Teratogenic Effects, Category C - Decreased pup body weights occurred at 1.25 and 2.5 mg/kg in rats, when exposed during the perinatal period (late gestation, parturition and lactation). At 5 mg/kg and higher doses (1.2 times the MRHD), prolonged gestation, dystocia and reduced maternal care were produced with corresponding increases in late fetal deaths and stillbirths and decreased birth weight, live litter size and pup survival. Insufficient numbers of pups survived at 5 mg/kg to evaluate the offspring for reproductive performance. In studies in which pregnant rats were given nebivolol during organogenesis, reduced fetal body weights were observed at maternally toxic doses of 20 and 40 mg/kg/day (5 and 10 times the MRHD), and small reversible delays in sternal and thoracic ossification associated with the reduced fetal body weights and a small increase in resorption occurred at 40 mg/kg/day (10 times the MRHD). No adverse effects on embryo-fetal viability, sex, weight or morphology were observed in studies in which nebivolol was given to pregnant rabbits at doses as high as 20 mg/kg/day (10 times the MRHD). **Labor and Delivery -** Nebivolol caused prolonged gestation and dystocia at doses ≥5 mg/kg in rats (1.2 times the MRHD). These effects were associated with increased fetal deaths and stillborn pups, and decreased birth weight, live litter size and pup survival rate, events that occurred only when nebivolol was given during the perinatal period (late gestation, parturition and lactation). No studies of nebivolol were conducted in pregnant women. Use BYSTOLIC during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers -** Studies in rats have shown that nebivolol or its metabolites cross the placental barrier and are excreted in breast milk. It is not known whether this drug is excreted in human milk. Because of the potential for β-blockers to produce serious adverse reactions in nursing infants, especially bradycardia, BYSTOLIC is not recommended during nursing. **Pediatric Use -** Safety and effectiveness in pediatric patients have not been established. Pediatric studies in ages newborn to 18 years old have not been conducted because of incomplete characterization of developmental toxicity and possible adverse effects on long-term fertility. **Geriatric Use -** Of the 2800 patients in the U.S. sponsored placebo-controlled clinical hypertension studies, 478 patients were 65 years of age or older. No overall differences in efficacy or in the incidence of adverse events were observed between older and younger patients. **Heart Failure -** In a placebo-controlled trial of 2128 patients (1067 BYSTOLIC, 1061 placebo) over 70 years of age with chronic heart failure receiving a maximum dose of 10 mg per day for a median of 20 months, no worsening of heart failure was reported with nebivolol compared to placebo. However, if heart failure worsens consider discontinuation of BYSTOLIC.

OVERDOSAGE: In clinical trials and worldwide postmarketing experience there were reports of BYSTOLIC overdose. The most common signs and symptoms associated with BYSTOLIC overdosage are bradycardia and hypotension. Other important adverse reactions reported with BYSTOLIC overdose include cardiac failure, dizziness, hypoglycemia, fatigue and vomiting. Other adverse reactions associated with β-blocker overdose include bronchospasm and heart block. The largest known ingestion of BYSTOLIC worldwide involved a patient who ingested up to 500 mg of BYSTOLIC along with several 100 mg tablets of acetylsalicylic acid in a suicide attempt. The patient experienced hyperhidrosis, pallor, depressed level of consciousness, hypokinesia, hypotension, sinus bradycardia, hypoglycemia, hypokalemia, respiratory failure, and vomiting. The patient recovered. Because of extensive drug binding to plasma proteins, hemodialysis is not expected to enhance nebivolol clearance. If overdose occurs, provide general supportive and specific symptomatic treatment. Based on expected pharmacologic actions and recommendations for other β-blockers, consider the following general measures, including stopping BYSTOLIC, when clinically warranted: *Bradycardia:* Administer IV atropine. If the response is inadequate, isoproterenol or another agent with positive chronotropic properties may be given cautiously. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary. *Hypotension:* Administer IV fluids and vasopressors. Intravenous glucagon may be useful. *Heart Block (second or third degree):* Monitor and treat with isoproterenol infusion. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary. *Congestive Heart Failure:* Initiate therapy with digitalis glycosides and diuretics. In certain cases, consider the use of inotropic and vasodilating agents. *Bronchospasm:* Administer bronchodilator therapy such as a short-acting inhaled β_2-agonist and/or aminophylline. *Hypoglycemia:* Administer IV glucose. Repeated doses of IV glucose or possibly glucagon may be required. Supportive measures should continue until clinical stability is achieved. The half-life of low doses of nebivolol is 12-19 hours. Call the National Poison Control Center (800-222-1222) for the most current information on β-blocker overdose treatment.

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Cracking the code

Top strategies for selecting appropriate E/M levels and documenting patient care

by **JEFFREY BENDIX, MA,** *Senior Editor*

HIGHLIGHTS

01 When documenting evaluation and management visits, be sure to note all the work you do and services you provide, both to obtain the proper level of reimbursement and to successfully defend yourself if you are audited.

02 Customizing the templates and prompts in your electronic health record system can help improve your coding and documentation.

03 Have an employee or someone outside the practice audit your charts periodically to make sure your documentation supports your coding.

You can obtain reimbursement at a higher level and overcome your fears of being audited by thoroughly and correctly documenting the care you provide to your patients. ▸▸

▸▸ **ALTHOUGH** this advice may seem self-evident, coding experts and practice management consultants say that a surprising number of doctors, especially primary care physicians (PCPs), are either unable or unwilling to follow it. Instead, they say, many routinely "downcode" when reporting their evaluation and management (E/M) services—that is, they code at a lower level than the level of service they actually provide—with the result being that they are not reimbursed commensurate with the complexity of the care provided for a patient's disease or condition.

A review of 60,000 audits of physician billing records conducted by the American Academy of Professional Coders (AAPC) client services division in 2012 found that 37% of the records either were undercoded or underdocumented, equating to an average of $64,000 in foregone or at-risk revenue per physician.

The reasons for doctors' unwillingness to use the appropriate E/M codes generally fall into two categories, experts say:

- **lack of understanding of the coding system and the accompanying importance of providing accurate and precise documentation, and**
- **fear of being audited.**

Jeannine Z.P. Engel, MD, FACP, is a physician adviser to the healthcare compliance office for the University of Utah, Salt Lake City. She frequently lectures on coding issues at American College of Physicians meetings and to other physician groups.

"My anecdotal observation is that the people who come to my coding talks consistently tell me that they're afraid to bill at the highest level because they're afraid they're going to get audited," she says.

Although the details of coding sometimes can feel overwhelming, Engel maintains that physicians can learn the basics and will benefit by doing so. She recalls starting her career

Coding for an outpatient visit of a returning patient

The grid below was developed by Jeannine Z.P. Engel, MD, FACP, as part of an instructional presentation on coding for physicians. The column on the left contains the three elements that make up an evaluation and management outpatient visit for a returning patient. The numbers across the top row are the Current Procedural Terminology (CPT) codes. The boxes beneath each CPT code display the minimum level of complexity or thoroughness required to bill for each code.

PF=problem-focused **EPF**=expanded problem-focused **DET**=detailed **COMP**=comprehensive

		99211	99212	99213	99214	99215
1*	History of present illness	Reserved for non-hospital-based practice	☐ 1**(PF)	☐ 1 (EPF)	☐ 4	☐ 4
	Review of systems			☐ 1	☐ 2 (DET)	☐ 10 (COMP)
	Personal, family, social history				☐ 1	☐ 2
2	Physical exam		☐ 1 (PF)	☐ 2 (EPF)	☐ 5 (DET)	☐ 8 (COMP)
3	Medical decision-making		☐ Straightforward	☐ Low	☐ Moderate	☐ High
	Time		10 minutes	15 minutes	25 minutes	40 minutes

Source: Jeannine Z.P. Engel, MD, FACP
*History of present illness; review of systems; and personal, family, social history comprise the "history" element.
**Numbers represent the minimum number of elements required for the documentation by the insurance carrier used in this example only and may differ slightly among carriers.

in an academic practice in which neither she nor her partners knew much about coding. She volunteered to learn more about it and teach her partners. "In doing that we figured out we were consistently billing at lower codes than what we were documenting in the services we were providing," she says.

The main Current Procedural Terminology (CPT) codes used by PCPs to bill for E/M service in an outpatient setting are 99201 through 99205 for new patients—those who have not been seen by your practice for the last 3 years—and 99211 through 99215 for returning patients. A new patient is defined as one that neither you nor anyone in your practice has seen in the past 3 years. A patient returning after more than 3 years is defined as new.

(Two important exceptions to the E/M codes are Medicare's "Welcome to Medicare" visit and the annual wellness visit. The wellness visit is billed using either code G0438 or G0439, depending on whether it is a first or subsequent visit. The "Welcome to Medicare" visit is billed using either G0402, G0403, G0404, or G0405.)

When documenting and coding a patient E/M office visit, Engel advises doctors to consider three questions:

- **Is the patient new or established?**
- **What level of history, physical examination, and medical decision-making (the three elements of documentation) will be recorded? What is the appropriate CPT code for the care documented?**

Each of the three elements of documentation, in turn, has various levels of complexity and sub-components:

History: Elements include history of present illness (HPI), review of systems (ROS), and past, family, and social history (PFSH). Levels of complexity include "problem focused" (PF), "expanded problem-focused" (EPF), "detailed," and "comprehensive."

Exam: The exam has the same four levels of complexity as history—PF, EPF, detailed, and comprehensive.

Medical decision-making (MDM): This element can be "straightforward" or of low, medium, or high complexity.

In general, CPT code numbers corre-

"WHAT I TRY TO PREACH IS THAT I WANT DOCTORS TO GET CREDIT FOR THE WORK THEY'RE ALREADY DOING."

JEANNINE Z.P. ENGEL, MD, FACP

spond to the level of service required to diagnose and treat the condition. The higher the level of service, the higher the code number used to bill the visit, and the greater the reimbursement.

IMPORTANCE OF THOROUGH DOCUMENTATION

No formula exists for producing E/M documentation that guarantees that a patient visit is coded and billed at the correct level, but Raemarie Jimenez, CPC, CPMA, director of product development for the AAPC, advises that good documentation should include answers to the following questions:

- **Why is the patient there that day?**
- **What is the patient describing?**
- **What type of exam(s) is/are being performed on the patient?**
- **What tests are being ordered, and why?**
- **If the patient has any chronic illnesses, what is your assessment of them?**
- **Are the patient's laboratory test results within the acceptable ranges for managing those diseases?**
- **Since the last visit, how has the patient been adhering to his or her medication regimen?**

"It's really just the patient's story of what's going on with him or her, the physician's observations, and the assessment and plan of treatment for that patient," Jimenez says.

The problem for many physicians, Engel says, is that they don't thoroughly document all the work they do during a patient visit and thus wind up coding at levels that don't reflect the services they actually provide. This shortcoming occurs most commonly in the MDM component.

"What I try to preach is that I want doctors to get credit for the work they're already doing, which they can do by making some small changes in the way they document," Engel says.

She cites as an example reviewing and acting on the result of a test such as a chest x-ray or electrocardiogram—something many PCPs routinely do. Documenting "chest x-ray-personally reviewed" rather than just "chest x-ray" and the result is enough to raise the level of medical decision-making—which may be sufficient to bill the visit at a higher code. "So if they're already doing the work, the just need to learn to document that it's actually being done," she says.

Without the proper documentation, Engel adds, an auditor reviewing the chart has no way of knowing how much work the physician did and the basis for the coding selection.

The level of MDM also can be increased by noting when someone other than the ➔24

Is EHR cloning ever acceptable?

By Renee Stantz

Although Medicare is encouraging the implementation and use of electronic health record (EHR) systems, the Office of Inspector General continues to focus on "identical notes" as an area of concern. So be sure to use your EHR effectively and not take too many shortcuts.

You can bring forward from a previous date of service some areas of evaluation and management (E/M) services documentation. According to the 1995 and 1997 E/M documentation guidelines, "A [review of systems (ROS)] and/or a [past medical, family, and social history (PFSH)] obtained during an earlier encounter does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information." This may occur when a physician updates his or her own record or in an institutional setting or group practice where many physicians use the same record.

You can document the review and update of the previous information by:

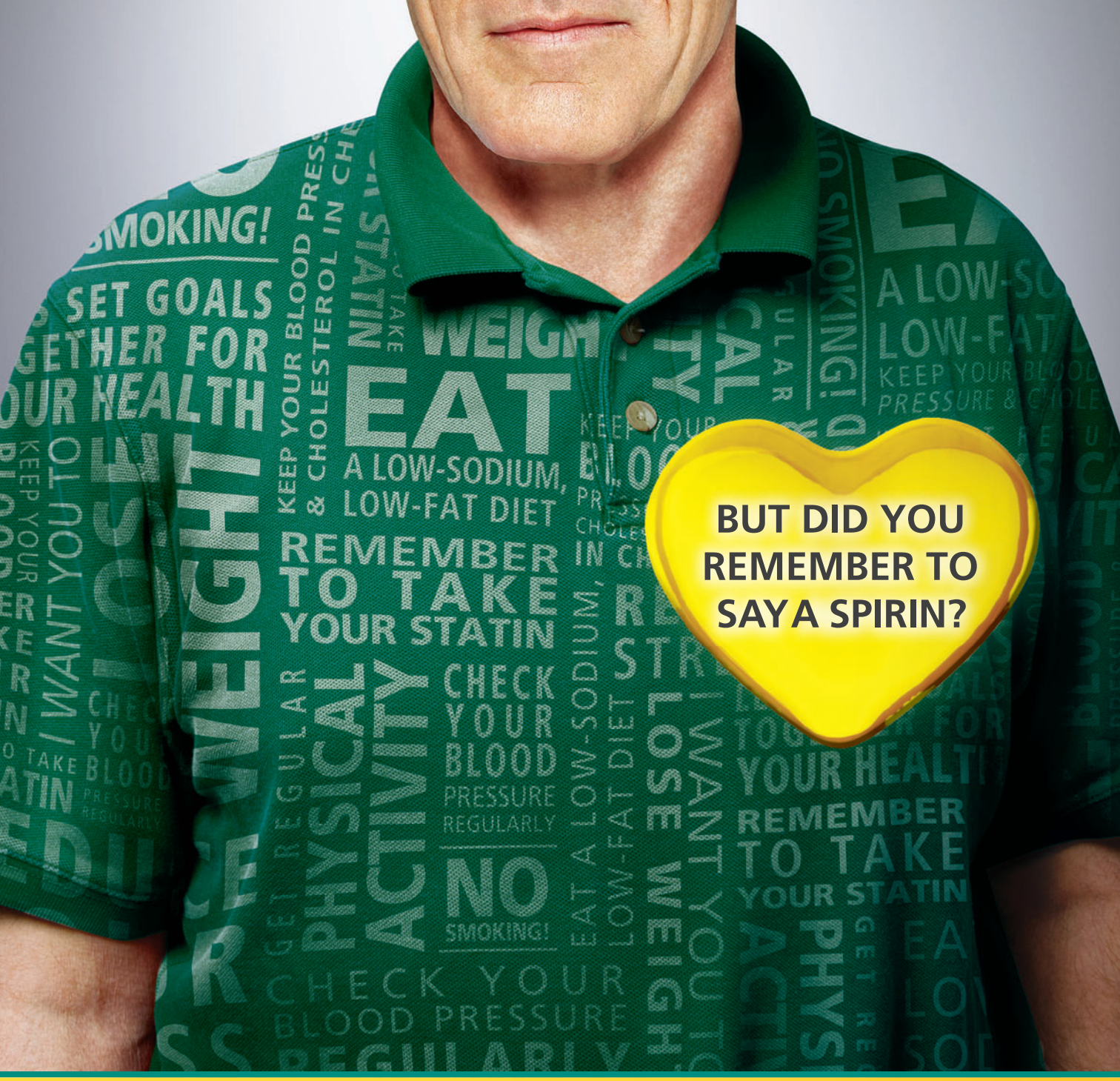
- **describing any new ROS and/or PFSH information or noting that no change in the information has occurred; and**
- **noting the date and location of the earlier ROS and/or PFSH.**

As emphasized, physicians and non-physician providers (NPPs) need to make sure they not only review the information but update it. Doing so leaves no doubt in an auditor's mind that the physician or NPP is aware of the information that the patient provided.

How can you benefit from EHR shortcuts while avoiding the pitfalls of cloned or identical notes? Here are some important tips:

- **Always document the history of present illness based on the patient's description that day. Never copy it from a previous visit.**
- **Only document those ROS elements that are relevant to that day's visit. ROS elements are intended to describe the patient's answers to the practitioner's questions regarding that day's chief complaint.**
- **Only use PFSH from a previous day of service if it is reviewed with the patient and relevant to that day's visit.**
- **Double-check that the diagnoses in your assessment are only those addressed at that visit. Some EHRs allow the copying of all diagnoses listed in the problem list, even those that have been resolved or aren't the reason for that day's patient visit.**
- **Use templates with care, editing them thoroughly, including medication and diagnosis "favorites" that you have set up previously.**
- **Be careful with information you copy and paste from a previous visit or another physician's visit. The documentation must be medically necessary, and you must have performed the work. Remember, the volume of documentation does not determine the level of care at which you bill.**
- **When your EHR vendor offers a way to duplicate another practitioner's documentation (for instance, copying another physician's interpretation or consultation), remember that he or she already has billed for this work, and understand that your review is just that, a review of this information.**

The author is a medical consultant based in Indianapolis, Indiana.



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References: 1. Antithrombotic Trialists' (ATT) Collaboration. Aspirin in the primary and secondary prevention of vascular disease: collaborative meta-analysis of individual participant data from randomised trials. *Lancet.* 2009;373:1849-1860. **2.** Cannon CP, Rhee KE, Califf RM, et al. Current use of aspirin and antithrombotic agents in the United States among outpatients with atherothrombotic disease (from the REduction of Atherothrombosis for Continued Health [REACH] Registry). *Am J Cardiol.* 2010;105:445-452. **3.** Heart disease and stroke statistics—2012 update: a report from the American Heart Association. *Circulation.* 2012;125:e2-e220.

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"AUDITS ARE AN OPPORTUNITY TO IMPROVE YOUR OPERATIONS AND FIND OUT WHERE THERE ARE PROBLEMS."

KATHY DEVAULT, RHIA, CCS, AMERICAN HEALTH INFORMATION MANAGEMENT ASSOCIATION

About those transitional care management codes

Transitional care management (TCM) codes, which Medicare introduced at the start of this year, have become a source of confusion for primary care physicians, as evidenced by anecdotal but widespread reports of claims submitted under the codes being rejected.

Current Procedural Terminology (CPT) codes 99495 and 99496 are designed to allow doctors and their staffs to be reimbursed for the time spent following up with patients after they are discharged from an inpatient setting or nursing or skilled nursing facility and coordinating the patient's care as he or she transitions back to the community. The codes require direct, telephone, or electronic communication with the patient, moderate- or high-complexity medical decision-making during the service period, and a face-to-face visit within 7 days of discharge under code 99495 or within 14 days of discharge under code 99496.

Unlike most other fee-for-service CPT codes, however, Medicare requires a waiting period before providers can submit bills for TCM. According to the American Medical Assocation Web site, bills can only be submitted beginning on the 30th day after the patient is discharged. Coding experts think this difference may be the reason behind many of the rejections.

"The way we're accustomed to billing things is, as soon as we provide the service, we send the bill in. I can easily envision providers submitting claims as soon as that patient comes in for that face-to-face encounter," says Raemarie Jimenez, CPC, CPMA, director of product development for the American Academy of Professional Coders and a former billing and coding manager. She adds, however, that "Medicare wants to see a continuum of care, not just that first face-to-face encounter with the patient."

Another possible cause of rejection could be that the facility from which the patient was discharged has not submitted the patient's discharge paperwork, according to Maxine Lewis, CMM, CPC, president of Medical Coding Reimbursement Management in Cincinnati, Ohio. "If the Medicare carrier hasn't received the hospital's billing, and here comes the physician sending in the TCM code, [the carrier] will reject it," she says.

➔22 patient provides information about the patient's disease or condition. "Again, this is something we do all the time," Engel says. "We often have the peanut gallery of spouses, children, and other relatives giving information. Some of it's useful and some isn't, but the important thing is to note somewhere in the record that you obtained information from someone else, because it bumps up the level of MDM."

THE ROLE OF EHRs

Electronic health record (EHR) systems can help doctors improve their documentation and coding, especially through the use of templates and prompts, says Kathy DeVault, RHIA, CCS, director of health information management practice excellence for the American Health Information Management Association (AHIMA). Moreover, many EHR systems allow physicians to customize their prompts to the most common diseases and conditions they see in their practices. For example, she says, a template for a cough might include questions about severity and duration and whether the cough is productive.

A pitfall of using EHRs, however, is the ease of copying (cloning) documentation or bringing forward a patient's entire past medical history, regardless of what you're treating the patient for during a particular visit.

"A lot of EHR systems will look at [those] data [that are pulled forward] and automatically start assigning higher coding levels," DeVault says. "I've also heard providers say that if their MDM is high, if they're treating a lot of diagnoses, then they can bill at a higher level. But that's not true, because it's not just MDM that drives your E/M coding." (For more on EHRs and documentation cloning, see "Is EHR cloning ever acceptable?" on page 22.)

RED FLAGS

Targets of coding and billing audits are chosen largely at random by both public (Medi-

care and Medicaid) and commercial payers. Nevertheless, physicians can somewhat lower the risk of being audited by avoiding several practices. Chief among those practices is billing the same level of service—usually the "middle" E/M code, 99213—too frequently.

"Sometimes a provider will say, 'I'll just pick the middle level, because then I won't be the target of an audit. But it's impossible for every patient to require the same level of care, so that's a big red flag," says the AAPC's Jimenez.

Consistently coding at higher levels than other PCPs in your geographic area also is likely to attract the attention of auditors. Maxine Lewis, CMM, CPC, president of Medical Coding Reimbursement Management in Cincinnati, Ohio, notes that computers enable auditors to analyze billing data at a more granular level than before, making it easier to compare physicians with peers in their region, or even their practice, and identify "outliers."

PHYSICIAN, AUDIT THYSELF

Although the range of options for avoiding an audit is fairly limited, you can minimize the chances of a negative outcome by ensuring that your documentation supports your coding. "Even if you see complex patients and bill for higher levels of service, as long as your documentation supports your level of service, then the outcome should be in your favor," Engel says. "The best thing you can do is document well."

The most effective way for physicians to document well, experts advise, is by conducting their own audits. "One of the things we recommend to our physician clients, in addition to training and educating staff [in coding], is to have a periodic outside review of their charts to see that they are coding appropriately and have a strong compliance posture," says Lawrence Vernaglia, JD, MPH, chairman of the healthcare industry team of the law firm Foley & Lardner LLP in Boston, Massachusetts, and a *Medical Economics* editorial consultant. "Even looking at as few as 10 charts per quarter is a good way to see if there are any outliers in a practice. There might only be one individual who's a problem, while everyone else is fine," he says.

Repeated claim denials from a payer sometimes can be a warning of a coding or documentation problem, Vernaglia adds. "Don't just ignore it. Follow up and treat it as an indicator that you might have a problem in that area."

An additional benefit of conducting self-audits is finding overpayments made to the practice. The stakes involved in finding those overpayments soon may become a great deal higher, Vernaglia notes: a provision in the Affordable Care Act says if a provider does not return a Medicare overpayment within 60 days of becoming aware of it, then he or she could be subject to a False Claims Act allegation, which carries a penalty of up to $11,000 per claim, treble damages, and program exclusion.

Although the law technically is in effect, the Centers for Medicare and Medicaid Services has not yet published final regulations to define certain key provisions of it. "This leaves physicians to make their own judgments as to their responsibilities with respect to potential overpayments they see in their practices," Vernaglia says.

RESPONDING TO AN AUDIT NOTICE

But suppose, despite of your best efforts, you receive notice that you're going to be audited. What should you do?

First, take a deep breath and try not to panic, Engel advises. "We physicians are always quick to assume we've done something wrong, but an audit doesn't necessarily mean that," she says. "Then contact your compliance group or your legal representative to understand exactly what your responsibilities are."

It also is important to find out who is conducting the audit, and why, Vernaglia says. "Are you being checked at random or because of a specific complaint? Is it conceivable there's a whistleblower lurking around? If so, you'd need the involvement of lawyers more than if it were just a routine periodic audit."

In addition, he suggests finding out how much information the auditor is requesting, because you may not be required to submit it all. For example, your contracts with a commercial payer might have limits on how much information you have to provide for an audit, and Medicare recovery audit contractors are limited in how many charts they can pull at any one time as well as how far back they can look, Vernaglia says.

Other recommendations from the experts to whom we spoke:

- **Don't make any changes to the charts, records, or other documents you are submitting for the audit. If you believe you must add some information, Lewis says, then date and initial the addendum.**
- **Provide *all* the requested documentation. "I've seen charts sent without an x-ray report, without labs, without the personal history form the patient filled out," Lewis says. "Everything done on that day must be sent in. Otherwise, there's no record of what you did." Also check that you've signed all the charts.**
- **Neatness counts. "The more orderly, organized, and thorough the information you provide the auditor, the better your chance of a successful outcome," advises the AAPC's Jimenez. "Give them all the pertinent information. Don't make them look for a needle in a haystack."**
- **Ask about the auditor's qualifications. "Every environment for coding is different," notes AHIMA's DeVault. "If the auditor has only worked on hospitals, [then he or she] shouldn't be auditing a small practice, because there's a big difference. So I think it's appropriate to ask who's doing the auditing? What are their credentials? What is their experience?"**

DeVault advises doctors to try to view an audit as a learning experience. Admittedly, doing so is not easy under the circumstances, she says, but "audits are an opportunity to improve your operations and documentation and find out where there are problems. And if you're spot on in your documentation, you should be fine." ◘

Coding Insights

CLARIFYING NEW PLACE OF SERVICE RULES

Q For years, we have billed our physician's lab interpretations with the place of service (POS) of 11, office, even when a hospital or an outside lab performs the test. We've never received a denial when we bill this way, but we heard this situation could be changing. Is this correct, and if so, can you tell us how it will change?

THE CENTERS for Medicare and Medicaid Services (CMS) clarified the POS rules in the recent *MLN Matters* number MM7631. They became effective April 1.

The Office of Inspector General found that from 2002 to 2007, doctors and other suppliers frequently reported incorrect POS codes when they furnished services, specifically when the services were billed with the technical component (modifier TC) and professional component (modifier 26). This occurrence was particularly problematic when the POS for the technical component was furnished in an ambulatory surgical center (ASC) or hospital and the professional component was billed with POS 11 because the physician performed the interpretation in an office.

CMS determines whether a Medicare physician fee schedule (MPFS) facility or non-facility payment rate is appropriate for a specific setting when a POS code is developed. The POS code determines the reimbursement rate for each service and is based on where the patient received face-to-face services. The CMS professional component MPFS reimbursement for laboratory services is higher when billed as performed at a non-facility (for instance, a physician office) as opposed to at a facility (for instance, a hospital, POS 22, or an ASC, POS 24).

CMS, therefore, has clarified that, in situations when a physician is interpreting a diagnostic test from a site other than where the patient received the technical component of the test, the doctor should assign the same POS code as the technical component of the service.

TWO EXCEPTIONS

The face-to-face rule has two exceptions:

- **When a patient receives care as a hospital inpatient or outpatient (POS 21 and 22, respectively), regardless of where he or she receives the face-to-face services, placing POS 21 or 22 on the claim triggers the facility payment under the MPFS.**
- **If the physician maintains separate office space in the hospital or on the hospital campus, and that physician office space is not considered a provider-based department of the hospital as defined in section 413.65 of Title 42 of the Code of Federal Regulations, then the physician should use POS 11 (office).**

ASC (POS 24)

When a provider is rendering services in a Medicare-participating ASC, POS 24 should be used. According to the *MLN Matters* article, providers are not to use POS 11 for ASC-based services unless the physician has an office at the same physical location of the ASC that meets all requirements, including meeting the "distinct entity" criteria defined in the ASC State Operations Manual, which preclude the ASC and an adjacent physician office from being open at the same time—and provided that the physician service actually was performed in the office suite portion of the facility. ◘

The answer to this question was provided by Renee Stantz, a billing and coding consultant for VEI Consulting Services, Indianapolis, Indiana. For more on this topic, see www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_1_ambulatory.pdf on the CMS Web site. Send your coding questions to us at ***medec@advanstar.com****.*

Money

Rewarding for value

Value-based payment models healthier for patients and economically viable for PCPs, groups report

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

HIGHLIGHTS

01 Payment rates under the Medicare physician fee schedule for practices with 100 or more physicians will be subject to a value-based payment modifier (VBPM) starting in 2015. The requirement will extend to all physicians, regardless of practice size, by 2017.

02 The VBPM is based on performance from the previous 2 years, meaning the 2017 VBPM will be judged using 2015 performance.

03 Those who don't buy in to the value-based payment model will lose out on additional income their practice could be earning.

Although value-based payment models are built on the concept of reducing healthcare costs, the ultimate goal is to improve care—and that focus could deliver a needed boost to the economics of primary care.

THAT'S THE MESSAGE leading physicians' organizations are sending when it comes to transitioning to value-based payment models. Is a lot still uncertain about these new systems? Yes. Will it take time and lots of adjustment to get them to work? Of course. But in the face of the current state of the healthcare system, with its unsustainable fee-for-service model and skyrocketing costs, does another choice exist?

"[The Centers for Medicare and Medicaid Services] is trying to move away from the basic fee-for-service payment system that rewards you for doing more and more complex stuff but doesn't have any component in it that recognizes quality or value. If you talk to doctors who are savvy about the system, they will tell you about times they tried to do things for their patients and they get punished under the current payment system for that," says Stuart Guterman, vice president of the Commonwealth Fund. Doctors and hospitals usually end up hurting themselves financially when they try to do best by patients under the current system, he adds. And that's bad for everyone all around.

Recognizing value "is one of the initiatives that Medicare is undertaking, and many private insurers are doing similar things to reward good care so doctors who do best for their patients actually get rewarded instead of punished," Guterman continues.

The plan is to save money long term by

> We pay for performance now; we just pay for the wrong performance. We pay people for increasing volume, and we're willing to pay more for the wrong things. If we're spending this much on healthcare, shouldn't we be paying for the things we want to have happen?" STUART GUTERMAN, VICE PRESIDENT, COMMONWEALTH FUND

keeping patients healthier through quality care, Guterman adds.

"So you get that doctor off that treadmill where [he or she] just [has] to see more and more patients to make a living, instead of allowing the doctors to focus on the care they would like to be providing," he says. "The challenge is to make sure that it actually encourages the kind of behavior that doctors want to be pursing and the kind of care that doctors want to be giving."

Healthcare costs will only continue to spiral out of control unless the nation moves from a volume-based to value-based purchasing system, according to a recent study released by the National Commission on Physician Payment Reform.

Value-based payment models reward quality of care though payment incentives and transparency. Providers are held accountable for the quality and cost of their services through a system of rewards and incentives. The incentives are set up to discourage inappropriate, unnecessary, and costly care.

U.S. healthcare spending totals about $8,000 per person annually, the group says, adding that, as a proportion of the federal budget, Medicare costs have increased from 3.5% in 1975 to 15.1% in 2010—with a predicted jump to 17% by 2020.

"This enormous investment has not produced a commensurate improvement in the nation's health," the report authors note. "In fact, the health status of Americans pales in comparison to other nations, with the United States ranking 37th in health status."

The Affordable Care Act references the word "value" more than 200 times, so it's not surprising that this new method of measuring success is on the way. Healthcare costs now consume 23% of the federal budget, and Medicare costs are expected to increase from the 16% of the federal budget they take up today to 20% by 2016, according to data from the Deloitte Center for Health Solutions. Meanwhile, value-based payments are expected to reduce Medicare spending by about $214 billion over the next decade.

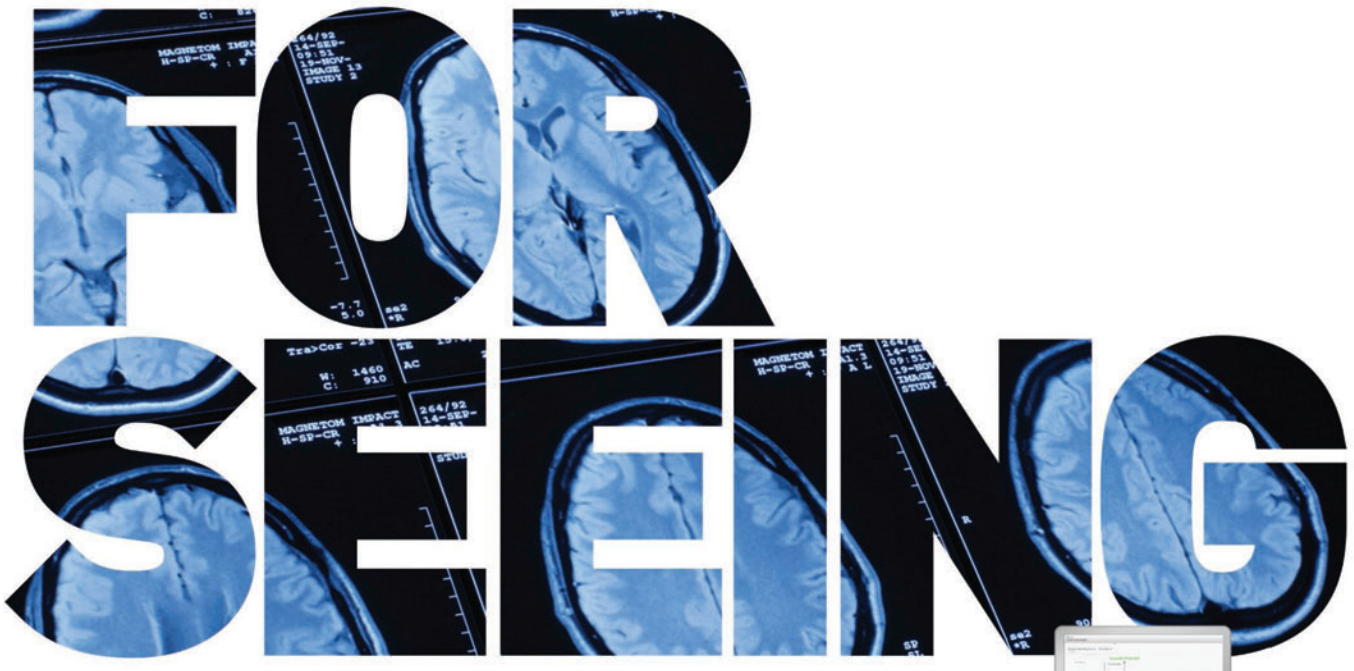
The National Commission on Physician Payment Reform study blames factors such as fee-for-service reimbursement for healthcare spending problems, along with too much reliance on technology and expensive care and using too many high-cost specialists.

"Our nation cannot control runaway medical spending without fundamentally changing how physicians are paid, including the inherent incentives built into the current fee-for-service pay system," the report authors continue.

The study report made a total of 12 recommendations on health spending reform, including the elimination of the sustainable growth rate and big changes to the current fee-for-service system. The report authors also call for a 5-year transition to any value-based system.

The report's additional recommendations for transitioning to value-based payment models include increasing payment for evaluation and management services, reducing pay disparities between primary care physicians (PCPs) and specialists or for the same service provided in different treatment settings, and promoting bundled payments.

The American Academy of Family Physicians (AAFP) says the report's findings are largely in line with its own position statements on value-based payment models and reiterates its call for the re-evaluation of primary care.



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JEFFREY J. CAIN, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

The American College of Physicians (ACP) suggests that physicians implement new Medicare initiatives in 2013 if they have not done so already. The ACP says that a three-physician practice that has $1.425 million in total annual revenue and a 20% Medicare/payer mix could save more than $19,000 per physician in the practice by doing so. Early adoption allows a practice to capture every possible bonus payment while avoiding costly penalties, according to the organization.

For value-based payments, that means starting to think about them now if you haven't already.

Payment rates under the Medicare physician fee schedule for larger group practices with 100 or more physicians will be subject to a value-based payment modifier (VBPM) starting in 2015. The requirement will extend to all physicians, regardless of practice size, by 2017. If you think that's a long way off, remember that the VBPM is based on performance from the previous 2 years, meaning the 2017 VBPM will be judged using 2015 performance.

MEETING THE REQUIREMENTS

Medicare is working toward putting more focus on the PCP as the center of the healthcare system, Guterman explains. And every PCP should be aware of the many new programs coming into effect, such as increases in PCP payments from Medicare and Medicaid.

"There's a strong desire to change what we pay for, from more and more complicated to better and more appropriate," Guterman says. "The question is, how do you do that? The doctor has to decide what's better, but [the system] can take steps to help make sure you are rewarding doctors for the care their patients should be getting."

To be certain that it is making payments for the aspect of care it wants to reward, Medicare first must have a way to measure physician success.

The first way to do this is through process measures, Guterman says. More emphasis is placed on the doctor's process up front, because it's much easier to tell what a physician did rather than to tell whether what he or she did improved the patient's outcome, he explains.

Secondly, patient satisfaction will be measured. "Patients need to be able to say they were able to communicate with their doctors," Guterman says.

Third, Medicare will examine how much it spends on the doctor's patients.

Because all of these measures will be used to determine whether the physician is providing value, Guterman says, doctors obviously will need to report a lot of information. But physicians who are on board—or will be soon—with associated programs such as the Physician Quality Reporting System (PQRS), meaningful use of electronic health records, and Patient-Centered Medical Homes will be ahead of the game, Guterman says.

Cost information easily can be found in Medicare claims, but quality data are more difficult to come by, he adds. PQRS participation is one of the requirements that must be met to earn performance rewards in the value-based payment model. It allows Medicare to get all the data it needs to see whether additional payment is warranted, Guterman says.

"It's difficult, but it really needs to be done. But it's heartening to know a lot of doctors are adopting these programs," he adds.

THE CARROT OR THE STICK?

Guterman says that clear penalties do not exist, unlike some other federal initiatives that levy fines after a certain period of noncompliance. Instead, those who don't buy in to the value-based payment model simply will lose out on additional income their practice could be earning, he says.

"It's certainly important to improve care and make sure doctors are rewarded for providing good care, but there's also great alarm about the rate of [healthcare] spending and rate of increase in this country," Guterman says.

Many ways to approach increasing costs exist, but the most productive way is to improve care, he adds.

"It's a combination of 'We're not going to pay for stuff that's not going to help people' and 'We're going to more if you help more," Guterman explains. "The thing is that, unfortunately, negative feedback sometimes is more effective, but you have to have a combination because you want to have this be not a punishment but a reward for doing something right."

How big that reward will be depends on the physician, says Jeffrey Cain, MD, FAAFP, president of the AAFP.

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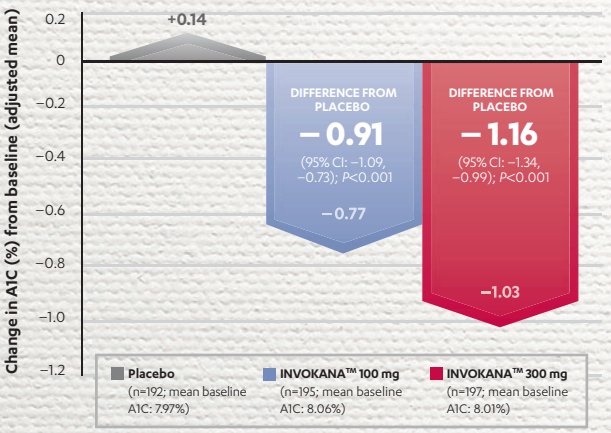

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» Difference from sitagliptin†: −0.37%

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.

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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

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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

Report data this year to avoid PQRS penalty

PHYSICIANS who don't report quality data this year through the federal government's Physician Quality Reporting System (PQRS) program will be docked 1.5% of their Medicare reimbursements in 2015.

The Center for Medicare and Medicaid Services' (CMS') PQRS program provides four reporting options: claims-based, registry-based, qualified electronic heath record (EHR), or the group practice reporting option.

October 15, 2013, is a key date for administrative claims-based reporting. CMS will analyze every claim from an individual or group practice to determine whether those providers have met PQRS requirements. Providers submit data to CMS via a Web portal that's expected to be available in July. Physicians who choose the administrative claims-based reporting option will not be eligible for bonus payments but could avoid penalties.

PQRS' goal is to collect data that can help improve patient care. The program uses a series of measures developed by leading physician organizations to evaluate the level of care being provided by doctors.

Find more information at:

- **www.MedicalEconomics.com/PQRSreportingoptions**
- **www.MedicalEconomics.com/PQRSperiodoptions**

➔34 is increasingly expensive because it encourages procedures. It rewards for outputs of units, and the system no longer can afford to contain this, Cain says.

"Payers, including the government and employers, find that [model] unsustainable for their ability to offer healthcare," he adds, explaining why the move is in the direction of a model that pays for outcomes and details instead.

Physician offices that already have moved to team-based care models will increase their percentage of reimbursement under a value-based payment model. The shared savings approach to payment has limited life, Cain cautions. The plan is to pay for a broad package of services that will include hospitals, PCPs, specialists, and more. How the value will come down to providers has yet to be determined because it will be divided up among all the providers in the package, he says.

Pay-for-performance, or value-based payment models, all involve moving away from getting paid for what you do to getting paid for a whole package of care, Cain says.

Guterman says: "There's a lot of debate about pay-for-performance and value-based purchasing and whether it's effective. We pay for performance now; we just pay for the wrong performance. We pay people for increasing volume, and we're willing to pay more for the wrong things. If we're spending this much on healthcare, shouldn't we be paying for the things we want to have happen?

"We do need to find the best way to do these things," he adds. "I don't think there needs to be a case made that it's better to pay for things you don't want. We just have to figure out the best approach.

Cain says: "This is a new model, and the details are going to matter a lot, [but] the details are yet to be determined. And that's the challenge," considering value-based purchasing will begin for practices with 100 or more physicians by 2015 and for all by 2017.

But physicians have been through a lot of reforms already—many that didn't work. And the difficult part in all of this will be to gain the trust of doctors "so they know this isn't just another effort to take money out of their pockets, but a way to help get the flexibility to allow them to do what they are trained to do," Guterman says.

On the bright side, more data will be available within the physician's office, and doctors will have a better understanding of costs for equipment.

"If the quality is the same but the price varies two- or three- or four-fold, value-based purchasing will give you the tools to choose the highest quality and lowest cost for your patient," Cain says.

The new model will result in better preventive and chronic care because value-based purchasing will be able to incent the things that PCPs already do or want to do but can't get rewarded for.

Many physicians fear this model will mean additional work on top of seeing patients, but they should look at as a way of being rewarded for the things they are already doing or want to be doing in their practice, Cain says. Incentives will exist for communicating with hospitals, coordinating care for specialists, managing diabetes in patients between visits, and more.

"It does mean letting go of an old model, but in the old model, they're frustrated," he says.

Doctors see more patients per day and per week now, but the incentive will be to make sure patients are staying healthier and out of the hospital.

"Instead of seeing how many people can be moved through your office per day, it will be about how you can best manage the patients in your practice," Cain says.

The new system has risks, too, Cain adds. It needs to involve transparency for improved quality of care and utilization of performance measures using evidence-based guidelines, he says. Some ethical and legal questions certainly will arise, too. For instance, how does a physician profile or risk-adjust? How is increased value determined? How do you incent for having a healthy population versus one with more chronic disease?

These questions have yet to be answered, but Cain says they won't hold value-based payments back.

"It's coming. This is coming our way. It does seem risky because it's moving away [from the current system]. But it's moving away from a dysfunctional model," Cain says. "It is incenting and valuing where there is added value, and the [AAFP] believes that will be a benefit to practices, patients, and the country." ◘

PART OF A CONTINUING SERIES

The costs of becoming patient-centered

Cost estimates based on practice size elusive, but technology still biggest expense

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

HIGHLIGHTS

01 Transitioning to a Patient-Centered Medical Home (PCMH) model ranges in price but may cost you about $15 per patient. Technology costs are variable; if you're already using an electronic health record system and registries, you're ahead of the game.

02 Personnel costs can be the biggest expense during a transition; the team-based approach of a PCMH means that you may need to hire additional staff members. You may be able to address personnel needs by changing the roles of existing staff members, however.

Becoming a Patient-Centered Medical Home (PCMH) can be an expensive proposition—costing $23,000 to $90,000 per physician, including technology, according to recent estimates.

Although the biggest challenge in the transition to a PCMH is changing the cultural mindset of the practice, David N. Gans, MSHA, FACMPE, senior fellow for industry affairs at the Medical Group Management Association (MGMA)–American College of Medical Practice Executives, says costs can be a barrier. He advises that practices undertake a detailed cost-benefit analysis before making this transition.

Some of the most recent estimates place the cost of becoming a PCMH at $15 per patient. Information technology spending represents the largest variable cost, with spending estimated from $5,000 to $11,000 per physician, according to a report by the Commonwealth Fund. (To view the entire report, see www.commonwealthfund.org/Publications/Fund-Reports/2009/Oct/Incremental-Cost-Estimates-For-The-Patient-Centered-Medical-Home.aspx.)

But Gans says it's difficult to get a handle on the true costs of implementation.

"To my knowledge, there is very little updated [cost] information. That is because it is so dang hard to get," he says.

Gans recently partnered on a research grant project with the Agency for Healthcare Research and Quality (AHRQ) to look at the cost of transitioning to and maintaining a PCMH. He couldn't reveal much, because the study is pending publication, but Gans says the biggest obstacles to pinning down costs are that every practice has a different starting point, and the final cost depends on what type of PCMH the practice will become.

Sarah Scholle, vice president of research and analysis for the National Committee for Quality Assurance (NCQA), who worked with Gans on the grant project to study PCMH implementation costs, agreed that a practice's starting point is a major factor in how much a transition will cost a practice. Obviously, becoming a PCMH will be more expensive for a practice using paper records than one already fully equipped with the latest health information technology (HIT).

Biggest isn't necessarily better. Scholle says electronic health record (EHR) systems and registries can be simple and cheap as long as they get the job done.

Many primary care practices already have EHR systems, and some have registries. Others already use care coordination is some way in their practices. But they aren't all PCMHs.

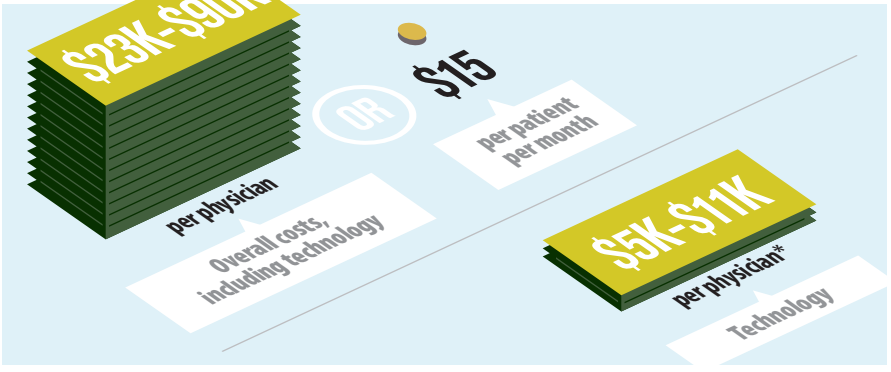
Gans shares a story about one clinician he met on a site visit in upstate New York. The solo practitioner was ranked "PCMH zero," and his practice located in the same building where he grew up. His father owned the building and ran a shoe store on the main floor.

"TO MY KNOWLEDGE, THERE IS VERY LITTLE UPDATED [COST] INFORMATION. THAT IS BECAUSE IT IS SO DANG HARD TO GET."

DAVID N. GANS, MSHA, FACMPE, SENIOR FELLOW FOR INDUSTRY AFFAIRS, MGMA–ACMPE

PCMH costs

Expense isn't necessarily the most important factor when making the transition to a Patient-Centered Medical Home, but it's important. Here are some of the most recent cost estimates:



Transition costs compared with current spending

+27.3%	CLINICAL FACILITIES	+24.4%	MEDICAL EQUIPMENT
+24.6%	MEDICAL SUPPLIES	+69.5%	HIT

*Source: The Commonwealth Fund
Source: Various studies analyzed by David N. Gans, MSHA, FACMPE, Medical Group Management Association–American College of Medical Practice Executives.

The older neighborhood gave the physician a base of roughly 2,000 patients—many of whom he had known for 20 years. He maintained manual health records, and when asked how he managed the needs of his diabetic patients, he pulled out his own style of registry on a spreadsheet.

"He's running a manual registry. He tracks patients and his own performance and keeps track of their foot exams and eye exams," Gans says, adding the doctor often would check in with patients when he ran into them around town, even advising them on grocery purchases. "He is really a PCMH, even though he's [ranked] a 'zero.' He was walking the walk but didn't have any of the 'stuff.' "

Gans says he saw many other practices that had all the "stuff" one would need to become a PCMH but didn't embrace the culture.

The key takeaway, Gans says, is that the transition to PCMH isn't solely about the costs involved.

Gans co-presented a talk about the costs of implementing and maintaining a PCMH in late April, revealing new information he gleaned from a study he did last year with MGMA members whose practices had earned PCMH recognition. Most organizations talked about the increase in cost during the transition as a major element on their journey, he says.

Although little hard data exist about transition costs available, Gans revealed that recent results gleaned from several studies put the range from $23,000 to $90,000 per physician—and that's mostly costs associated with technology. Low-, mid- and high-scoring PCMHs have reported different cost ranges, although ➔41

➔38 they typically spend about the same in every area except technology, Gans says.

In his research among MGMA members, Gans found that practices that had transitioned to PCMH status reporting spending increases in the following areas:

- 69.5% more on HIT,
- 27.3% more on clinical facilities,
- 24.6% more on medical supplies, and
- 24.4% more on medical equipment.

Changes to staffing also were documented, with practices that had transitioned to PCMH status reporting:

- a 55% increase in clinical staff,
- a 44.6% increase in administrative staff,
- a 43.2% increase in non-physician providers,
- a 40.8% increase in registered nurses, and
- a 19.3% increase in physicians.

Gans also discusses how roles change after a practice becomes a PCMH. The MGMA study revealed that in non-PCMH primary care practices, internal staff members perform about 91.6% of patient education, 42.2% of nutrition counseling, 84.9% of care coordination, and 29.2% of behavioral health. In a PCMH, internal staff members perform 95.2% of patient education, 53% of nutrition counseling, 90.6% of care coordination, and 44.5% of behavioral health.

The AHRQ has asked for proposals to find researchers already working with practices that transformed to PCMHs that can go back and see what it cost those practices to transition to and operate under the new model, says David Meyers, MD, director of the Center for Primary Care for the AHRQ.

The funding announcement was made because not enough evidence on cost existed, and the AHRQ recognized that not having the answer to the cost question might be part of what is keeping many practices from making the leap. Meyers says that the AHRQ hopes to have more data over the next few years.

THE BIGGEST COSTS—TECHNOLOGY AND STAFFING

If your practice is considering becoming a PCMH, the first element to consider in terms of technology needs is having a good EHR system and knowing how to use it.

In a PCMH, the EHR system is not just used for medical records, Gans says; it's used as a quality assessment tool and to schedule preventive services. Patient registries add function by tracking populations, and practice hours are expanded to offer greater patient access. Electronic communications with patients are common, and patient education and engagement are key elements. And you have to use your EHR in the context of a PCMH and look at it in terms of managing a population, Gans says. You must have a registry function, and if your EHR doesn't include that capability, you may need to purchase an add-on or a separate registry program plus an interface for your EHR system so the data can go back and forth between the two systems. (For more information on registries, see www.MedicalEconomics.com/registries.)

Optional ways exist to spend money and gain patient benefit when it comes to HIT as well. Many PCMHs are expanding telemedicine functions with items such as medical devices that can be given to the patient that report data back to the physician.

"There are all these new technology devices you wear on your wrist and tell you how many calories you burned today, record blood pressure, record heart beat—and it's reported back to the doctor," Gans says. "Very few do that, but that's the type of tech expenditure that practices are looking at because they are patient-centered."

That type of technology may be especially helpful when it comes to patient buy-in, Gans says. Patient portals are another expensive yet very helpful HIT tool, he says. (For more on patient portals, see www.MedicalEconomics.com/portals.)

You also will want to look into ways to communicate more effectively with colleagues—not just patients—when transitioning to a PCMH so you can share information such as laboratory test results, tests ordered, and a summary of an office visit. "Ideally, you want double sharing of information," Gans says.

He suggests that practices make sure their EHRs interface with other EHRs. The same advice holds true for programs that deal with medication reconciliation and clinical appointments.

Much technology might be tempting to invest in, but Meyers cautions against being caught up in it all.

Changes to your practice in becoming a PCMH

Staffing changes

Clinical staff

55% increase

Administrative staff

44.6% increase

Non-physician providers

43.2% increase

Registered nurses

40.8% increase

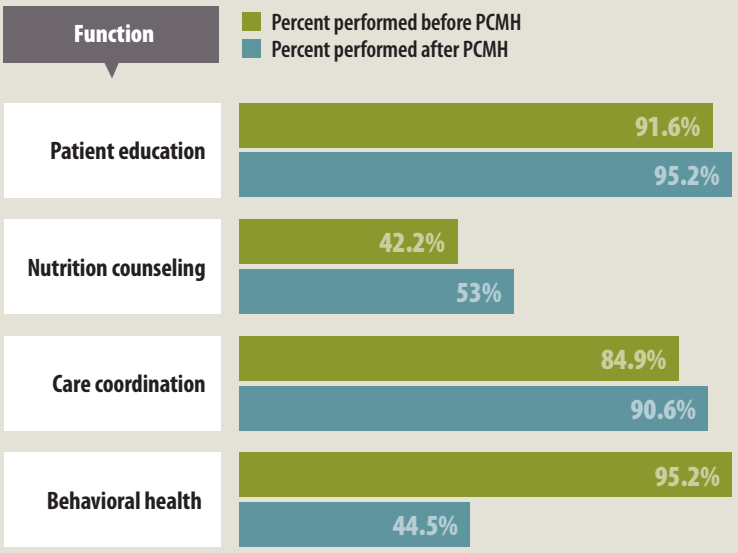
Physicians

19.3% increase

Source: Medical Group Management Association–American College of Medical Practice Executives

Time considerations

Internal staff roles



Source: Medical Group Management Association–American College of Medical Practice Executives

"While I'm really excited by what all sort of innovators are doing with technology, that's all bells and whistles. The basics are what folks are needing to concentrate on," he says. "A good EHR [is one] that's not just a billing machine but about making information available to doctors and patients."

The scoring systems used for PCMHs award higher scores for higher levels of HIT use, but that criterion doesn't necessarily indicate that those practices are better than others, Meyers says.

"PCMHs are still about relationships," he adds. "Technology can help us enhance relationships, but that's not required. You can still have high-quality care that's personal, that's coordinated, that's safe, with basic level investments in technology."

But even with the best HIT systems in place, a practice needs to be diligent about inputting data, Gans says. For a primary care physician (PCP) who has a new patient or an existing patient who develops diabetes, if the doctor wants to add the patient to a registry, manually adding that information comes with a cost. Practices need to remember that, aside from the HIT cost, human time associated with inputting data will have to be compensated as well.

Staffing is the single biggest expense during the transition to a PCMH, in Meyers' opinion, because the move to a team-based model could require a lot of additional people.

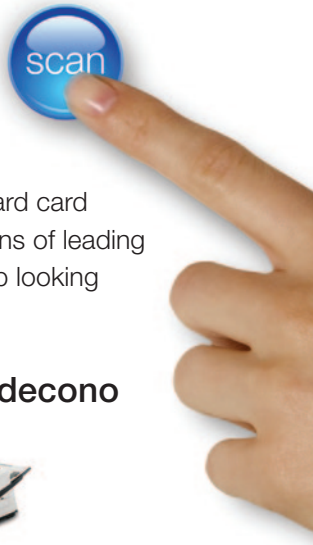
"Most [practices] recognize that these added team members are what really makes a practice patient-centered and improves the level of care," Meyers says, adding that in a PCMH or not, almost every patient needs a care coordinator at some point. "Some practices already have a team in place to do that well, but most don't. What I've seen is that in many of the demonstrations and pilot programs, those who have been successful are the ones that really reinforce or build in their care coordination." (For more on care coordination in a PCMH, see www.MedicalEconomics.com/PCMHcare.)

But it isn't always necessary to add staff, Scholle says, explaining that many of the practices she surveyed changed the functions of their current staff members rather than hire additional ones. Medical assistants who used to measure vital signs and guide patients to examination rooms can be given standing orders for patients with diabetes or to manage processes associated with specific tests. The questions to consider, she says, are whether you have staff members who can take on additional responsibilities and whether you can rearrange their roles to fit the practice's needs.

"If you don't have a care coordinator, it's a make-versus-buy situation," Gans says. Increases to clinical staffing levels often are a major part of the cost to transition to a PCMH. More clinical staff members are required to record data and coordinate care, in addition to offering the extended access to the practice that is central to the PCMH ideology.

Additional staff members also are helpful in providing the education and engagement functions required for PCMH recognition. Many PCMHs use

Find documents faster



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The cost of recognition

Costs to be recognized as a Patient-Centered Medical Home vary depending on the agency performing the certification, the size of the practice, and the type of practice. The costs presented below are general estimates. Contact individual recognition organizations for specific information pertaining to your practice based on the extensiveness of the particular certification process and your practice arrangement.

Cost	Organization
$2,500	**Accreditation Association for Ambulatory Health Care (AAAHC)** estimated cost for a **medical home on-site certification** (1 day and one surveyor) involving the principles of a medical home for a primary care practice with two providers and six exam rooms. An additional $775 survey application fee also applies.
$6,400 – $8,000	**AAAHC** estimated cost for the same practice listed above seeking **full AAAHC accreditation**, including information in Chapter 25 (medical home) of its accreditation handbook, a more comprehensive review of an entire practice operation (1.5 to 2 days with one surveyor). An additional $775 survey application fee also applies.
$2,500 – $6,000	**URAC PCHCH** (Patient Centered Health Care Home) **Achievement program** cost, depending on size and organization type as well as the length of the onsite audit
$600 – $4,000	**National Committee for Quality Assurance certification** fee, based on the number of physicians in a practice

group visits effectively, and those visits help with patient engagement and allow a practice to educate and assist several patients in a subgroup within the same time frame. The physician doesn't have to duplicate efforts, and group visits are "batch work" for staff, he says.

GETTING RECOGNIZED

Even practices that have the technology and the staff benchmarks met, Gans says, may not achieve PCMH recognition simply because they never applied. For example, Gans says he doesn't know whether any Kaiser practices are PCMHs, yet they have all of the features.

"To my knowledge, none of the Kaiser groups are PCMHs because they don't have to be. They already are. They just never sought certification because they don't need it," he says.

On choosing to apply, those practices fulfilling all those elements would immediately be recognized because they are already doing everything they need to do.

Cost certainly is a factor when looking at certification.

Costs vary depending on the agency performing the certification, the size of the practices, and the type of practice.

The Accreditation Association for Ambulatory Health Care (AAAHC) and Joint Commission have two programs—full accreditation with medical home and medical home on-site certification. Pricing for each is based on the size and scope of services of the practice applying. A small primary care practice might anticipate a total cost of about $2,500 for medical home on-site certification. A similar practice seeking full AAAHC accreditation, including its Chapter 25 on medical homes, might anticipate a cost of $6,400 to $8,000. A $775 application for survey fee is added to either option.

The URAC PCHCH (Patient Centered Health Care Home) Achievement program cost varies depending on size and organization type, as well as the length of the onsite audit, Gans says, adding that it ranges from $2,500 to $6,000.

The NCQA bases its certification fee on the number of physicians in a practice. Cost can range from about $600 for a solo practice to more than $4,000 for a practice with eight or more doctors.

WILL REIMBURSEMENTS BE WAITING?

Payment for achieving PCMH status can come in many forms, Gans adds:

- enhanced fee-for-service for office visits,
- reimbursement for PCMH-related services, and
- fee-for-service with pay-for-performance bonuses for meeting goals.

The most common reimbursement method for commercial payers to PCMHs is a standard fee-for-service for all services plus an additional payment based on the number of enrolled patients. Pay-for-performance bonuses are offered for meeting predetermined goals.

But some practices start transitioning to a PCMH and stall at some point, usually for financial reasons.

"There are people who can make steps toward the journey but then can't go any further," Meyers says. Many practices are engaged in demonstrations, and the Centers for Medicare and Medicaid Services is one of the entities paying a lot of primary care practices to participate in its coordinated care demonstrations, he adds.

"For many people, looking around to find out what incentives and resources [are available] in your area—this is the kind of journey you don't want to have to go on alone if you don't have to," Meyers says.

A wide range of financial support is available to practices that want to transition to PCMHs, Scholle says. In some parts of the country, numerous resources exist, but others have virtually nothing. The American College of Physicians and the American Academy of Family Physicians both have resources—or at least guides to help you find them—available, and practices interested in making the switch should check community resources, too. Local medical societies, state organizations, and other local medical groups often offer resources and guidance on affordability and any programs available to aid the transition to PCMH, Scholle says.

But the fact is, not everyone will be able to find an assistance program that fits his or her practice, Meyers cautions. If you're in such a situation, take some time to learn more about the PCMH model, and move toward it gradually. Most physicians already want to be there anyway, Meyers says.

"Most doctors will say, 'This is the way I'd like to practice.' They want to provide care coordination, and they want to get information about their patients so they stay out of the hospital," Meyers adds. "For many people in [a PCMH], they would never go back. They say, 'This is why I went into the healing practice.' If you deliver care the way it needs to be delivered, most people have found ways to get it covered."

"YOU CAN STILL HAVE HIGH-QUALITY CARE THAT'S PERSONAL, THAT'S COORDINATED, THAT'S SAFE, WITH BASIC LEVEL INVESTMENTS IN TECHNOLOGY."

DAVID MEYERS, MD, DIRECTOR, AHRQ CENTER FOR PRIMARY CARE

One trend to watch for down the road will be the possible partnership of accountable care organizations (ACOs) and PCMHs. Meyers says healthcare professionals have asked him whether they should join an ACO or become a PCMH. He says they should do both.

"A good primary care practice is the foundation of a good ACO. It can invest in helping primary care make the change [to a PCMH]," he says.

The most difficult part of the transition is getting out of the fee-for-service cycle. Physicians in traditional models don't have time to build relationships with patients or put data into registries, Meyers says. They need new funding to support care coordination, and Meyers says the transition to pay-for-performance models will be the impetus that gets more practices on the path to the PCMH.

But healthcare reform and the millions of new patients it will bring to primary care, coupled with PCP shortages, make it difficult to slow down and spend more time with fewer patients. Meyers says the profession needs to move past the idea that the physician is the center of the practice.

"[In a PCMH, it] is a team that cares for you, not just that one doctor," Meyers says. This arrangement means a physician might spend 30 minutes talking to the patient about his or her symptoms and what is going on in his or her life, but then a team member takes over to help the patient better understand medications or medical devices.

"The team can take of more people, and at the right time. Doctors shouldn't spend time finding printouts or checking on lab results; that way, they can spend more time talking about what's going on in the patient's life. That's what you want your doctor doing, not chasing down the paper. It's better use of doctors. It lets them do their best when the team does [more]."

The most exciting part about new models such as the PCMH is that ideas discussed several years ago are finally starting to come to fruition, Meyers says. "It's nice to have a real vision of what we want in our healthcare system and now to make it happen."

Financial Strategies

A LONG-TERM DISABILITY POLICY CAN PROTECT YOUR INCOME

by **ELI J. HJERMSTED**

Achieving your personal and professional goals depends on your ability to earn an income. A disabling accident or illness, however, can prevent you from practicing medicine for a long period of time.

ABOUT ONE in five Americans will become disabled for 1 year or more before age 65, with the average disability lasting 30 months. Few physicians are prepared to rely solely on their savings to carry them through an extended recovery period. Long-term disability policies can provide you with income if you are injured or become ill. But before you start shopping for a policy, you need to know the features to look for, and the language the insurance industry uses to describe them.

Total disability coverage

Two types of policies are written for total disability: "own occupation" and "modified own-occupation." An own occupation policy will continue to pay your disability insurance claim even if you are employed in another occupation. Currently, six companies offer own occupation policies: the Standard, Guardian Insurance, MetLife, the Principal Financial Group, Ameritas Life Insurance Corp., and MassMutual.

A modified own occupation policy, by contrast, will pay a claim only if you are unable to perform the substantial and material duties of your occupation and you are not working. In other words, it will not pay you if you work in a field other than your medical specialty—either medical or non-medical—when you are able to resume working.

To avoid the possibility of losing your coverage just when you need it most, choose a policy that's non-cancellable and guaranteed renewable to age 65. Such a policy also will guarantee premiums until age 65.

Riders to consider

By adding a rider to your policy, you can ensure that you obtain benefits if you suffer a loss of income as a result of partial (residual) disability. This is an important feature because most disability claims are for less than total disability.

An annual future increase options rider is especially important for younger physicians, because it allows you to increase your base benefit as your income grows without having to go through medical underwriting.

Costs

The cost of a long-term disability policy usually is about 2% of the gross income you are trying to protect. So to protect $100,000 of income, you should plan on spending about $2,000 annually. This amount is similar to the cost of policies to protect homes and vehicles, which typically range between 2% and 4% of the asset's value.

Although no one likes to contemplate the possibility of severe injury or illness, such occurrences are a part of life. You need to protect yourself, your family, and your business if something should happen to you.

Additional information regarding long-term care policies is available through the Council for Disability Awareness at www.disabilitycanhappen.org.

Companies selling own occupation disability insurance policies:

- The Standard
- Guardian Insurance
- MetLife
- Principal Financial Group
- Ameritas Life Insurance Corp
- MassMutual

The author is a financial adviser with North Star Resource Group in MInneapolis, Minnesota. Send your practice-related financial questions to ***medec@advanstar.com****.*

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Trends

GERD: Rising healthcare costs spark new debate, guidelines

Revised standards designed to save system money, prevent overuse of diagnostics

by **LISA ZAMOSKY**

HIGHLIGHTS

01 Outpatient gastrointestinal (GI) endoscopy exams, which are used to diagnose gastroesophageal reflux disease and rule out related illness, cost the healthcare system $32.4 billion every year.

02 The literature shows that 10% to 40% of upper endoscopies performed for GI concerns do not conform to clinical guidelines.

03 New guidelines from the American College of Physicians say that upper endoscopy should not be routinely performed in a woman of any age or in men aged fewer than 50 years who have heartburn.

The overuse of medical tests and procedures has become a major issue of concern in the United States as awareness grows about the fact that *more* medicine isn't necessarily *better* medicine and concerns over ever-rising healthcare costs reach a fevered pitch.

THE NONPROFIT Institute of Medicine estimates $765 billion worth of waste in the U.S. healthcare system annually, $210 billion of which is comprised of unnecessary medical services. And although physicians tell *Medical Economics* that reducing bloated healthcare costs is healthy, defensive medicine sometimes is necessary to protect against litigation and should be factored into any discussion focused on the merits, use, and cost/value proposition associated with certain diagnostic tests. (See "Addressing patient concerns," page 49.)

Gastrointestinal (GI) disorders, including conditions such as gastroesophageal reflux disease (GERD), are no exception. In fact, GERD, a chronic digestive disease marked by acid reflux, is the most common GI-related diagnosis, representing 8.9 million patient visits. And outpatient GI endoscopy exams alone, which are commonly used to diagnose GERD and rule out related illness, cost the healthcare system $32.4 billion annually, according to the Centers for Disease Control and Prevention (CDC).

"I see people daily who are treated for GERD. It may not be why they are there in my clinic, but I am definitely seeing them every day," says Dean Seehusen, MD, MPH, an American Academy of Family Physicians (AAFP) member and co-author of the AAFP paper "Managing chronic gastroesophageal reflux disease."

Both the frequency of the ailment and

Addressing patient demands

In an era in which patients often read about conditions and treatments before visiting a physician's office, how can you reassure a patient who insists on a particular treatment when current guidelines and your judgment determine that is not warranted?

Medical guidelines such as those related to upper endoscopy can serve as a good starting point for a discussion, and the American College of Physicians has created a video (see www.MedicalEconomics.BOHGERD) and patient materials (www.acponline.org/clinical_information/gerd_patient_brochure.pdf) to help you explain current medical thinking about appropriate and necessary treatment and the evidence behind that thinking. Viewing these materials can help your patients understand the approach you are recommending—which you should arrive at after considering guidelines, applying medical knowledge and skill, and exercising reasonable care and best judgment. A strong physician-patient relationship can build trust.

If patient education is not successful and you're worried that you could be sued for malpractice if you don't acquiesce to patient demands, following the standard of care—and documenting in the medical record that you have done so—can be protective, according to Lee J. Johnson, JD, a health law attorney in Mount Kisco, New York, and a Medical Economics editorial consultant. You meet the standard of care if you:

- Did something a "reasonably prudent" physician would do under similar circumstances.
- Didn't do something a reasonably prudent doctor would not have done under similar circumstances.
- Demonstrate the knowledge and ability that is expected of doctors who provide the service in question.

the high cost of testing associated with it are particularly relevant to internal and family medicine physicians, given how common it is for patients to present with heartburn and GERD in the primary care setting.

THE TESTING CONUNDRUM

Also relevant, but often overlooked, is the evidence demonstrating that upper GI endoscopy to diagnose GERD and/or rule out other related illnesses is performed unnecessarily in many cases.

According to Nicholas Shaheen, MD, MPH, director of Center for Esophageal Diseases and Swallowing at the University of North Carolina School of Medicine, Chapel Hill, the literature shows that 10% to 40% of upper endoscopies performed for GI concerns do not conform to clinical guidelines.

What's more, the rate at which upper endoscopy is used is increasing. Nationwide, a 40% increase has occurred in its use in the past decade among Medicare patients. On average, upper endoscopy costs more than $800 per examination, according to the American College of Physicians (ACP).

"We're spending a lot of money," Shaheen adds.

Much of that money is spent with scant evidence to support the use of endoscopy in diagnosing GERD, experts say.

According to Seehusen, if the clinical picture fits GERD with no other complications, such as a patient who is coughing up blood, has difficulty swallowing, or is losing weight, then it is easy and relatively inexpensive to perform a trial of treatment, including lifestyle modification and medications. "If you do a trial of treatment and it helps, then you pretty much have your diagnosis," Seehusen says.

Still, the pressure to test can be great, particularly in patients whose conditions don't improve over time.

"All of us want to do right by our patients but are often not sure of what's useful and what will be helpful. There is just so much to keep up with," says Molly Cooke, MD, president of the ACP.

When the condition is long-standing, many physicians understandably worry about the possibility of missing something more serious, such as esophageal cancer or Barrett's esophagus.

"Heartburn is extremely common, and all physicians appreciate that some patients with chronic heartburn end up with esopha-

"WE AS A FIELD HAVE DONE A GOOD JOB OF CONFUSING GENERALISTS ABOUT WHEN TO DO THIS TEST. PART OF WHAT WE SEE IN TERMS OF INAPPROPRIATE UTILIZATION IS OUR OWN FAULT FOR NOT GIVING PEOPLE UNAMBIGUOUS GUIDANCE."

NICHOLAS SHAHEEN, MD, MPH, A GASTROENTEROLOGIST AND LEAD AUTHOR OF THE ACP'S NEW GUIDELINES

"FROM MY PERSPECTIVE AS A CLINICIAN, I DIDN'T APPRECIATE HOW VANISHINGLY LOW THE RISK OF ESOPHAGEAL CANCER IS IN WOMEN."

MOLLY COOKE, MD, PRESIDENT, AMERICAN COLLEGE OF PHYSICIANS

8.9 MILLION

Annual gastroesophageal reflux disease-related patient visits

$32.4 BILLION

Annual total cost for outpatient gastrointestinal endoscopy exams

geal cancer," Cooke says. "It's a little like the headache and brain tumor situation. The vast majority of people with a headache don't develop a brain tumor, but many patients with tumors have headaches. To decide is hard."

GUIDELINES CAN BE TOUGH TO FOLLOW

A lack of clarity in the professional guidelines is another major cause of endoscopy overuse.

"We as a field have done a good job of confusing generalists about when to do this test. Part of what we see in terms of inappropriate utilization is our own fault for not giving people unambiguous guidance," says Shaheen, a gastroenterologist and lead author of the ACP's new guidelines, which indicate that endoscopy should not be used to screen for GERD in the general population. The guidelines were developed for internal medicine and family physicians as well as other clinicians who diagnose and treat GERD.

The ACP clinical guidelines, published in the December 2012 edition of the *Annals of Internal Medicine* (see http://annals.org/article.aspx?articleid=1470281), outline the confusion caused by competing guidelines among three major U.S. gastroenterologic professional societies.

"The American Society of Gastrointestinal Endoscopy recommends that screening upper endoscopy be considered 'in selected patients with chronic, longstanding GERD.' They identify frequent GERD symptoms (several times per week), chronic GERD symptoms (symptoms for >5 years), age older than 50 years, white race, male sex, and nocturnal reflux symptoms as risk factors.

American Gastroenterological Association guidelines recommend against screening the general population with GERD for Barrett esophagus and esophageal adenocarcinoma but say that it should be considered in patients with GERD who have several risk factors associated with esophageal adenocarcinoma, including age 50 years or older, male sex, white race, hiatal hernia, elevated body mass index, and intra-abdominal distribution of fat. Neither the relative importance of these risk factors nor the number of risk factors necessary to trigger screening is stated.

"Lastly, the American College of Gastroenterology guidelines note that 'screening for Barrett's esophagus in the general population cannot be recommended at this time. The use of screening in selective populations at higher risk remains to be established, and therefore should be individualized.' They, too, note GERD symptoms and body mass index as risk factors for Barrett esophagus. As acknowledged by the authors, formulation of these guidelines was hampered by the generally poor quality of data about the use of endoscopic screening and surveillance programs. In many cases, expert opinion formed the basis for specific recommendations."

Two particular aspects of the new ACP guidelines stand out among its previous guidelines and those of the other societies:

- **Upper endoscopy should not be routinely performed in a woman of any age.**
- **Men aged fewer than 50 years who have heartburn should not routinely be screened via upper endoscopy.**

The incidence of cancer in both these populations is very low.

"Before this guideline, people didn't make that much note of gender," Shaheen says.

In fact, a woman with heartburn has a lower risk of esophageal cancer than a man without heartburn. "It doesn't make a lot of sense to be scoping the women with heartburn but not the men without heartburn if you want to stop the cancer," Shaheen says.

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ACP VIDEO

Video for you, your patients

The American College of Physicians has produced a video explaining the new guidelines for upper endoscopy for gastroesophageal reflux disease. It resides on a part of the society's Web site that is not password-protected, so in addition to viewing the video yourself, you can share this link with your patients as well. See www.MedicalEconomics.com/BOHGERD.

Visit www.MedicalEconomics.com/BOHGERD

"LIMITING YOUR DIAGNOSIS TO ONLY THOSE PATIENTS WHOM YOU HAVE A HIGH INDEX OF SUSPICION FOR UNDERLYING BARRETT'S OR MALIGNANCY IS THE RIGHT ANSWER."

DEAN SEEHUSEN, MD, MPH, CO-AUTHOR OF THE AAFP PAPER "MANAGING CHRONIC GASTROESOPHAGEAL REFLUX DISEASE"

➔50

In the end, heartburn, it seems, is not a very useful marker of cancer risk. In fact, esophageal cancer in heartburn sufferers affects only about one in 2,500 patients aged more than 50 each year, according to a 2012 report by *Consumer Reports*, the ACP, and the *Annals*. Even among people with Barrett's esophagus, the risk of cancer is quite low.

The new aspects of the ACP guidelines that address upper endoscopy use in women and men aged fewer than 50 years are impactful, Cooke says. "From my perspective as a clinician, I didn't appreciate how vanishingly low the risk of esophageal cancer is in women."

OTHER PRESSURES THAT PUSH DOCTORS TO SCOPE

Another possible reason cited for the use of endoscopy ties in with physicians' concern over missing a diagnosis of cancer. People with unexplored symptoms could be viewed by their doctors as having a higher medical-legal risk.

Then there's the culture of expectation among some groups of patients that their symptoms be fully explored. Americans have become accustomed to being repeatedly checked for a medical problem. In some cases, that approach is clinically advisable, but not so in the case of GERD.

Of course, the economics of testing and its benefit to endoscopists' business cannot be overlooked as another possible cause of overuse.

As new budget-based payment models associated with accountable care organizations, medical homes, and shared savings programs increase in prominence compared with traditional fee-for-service models, those incentives likewise will shift.

HELPING TO REDUCE UNNECESSARY TESTING

Physicians can examine the use of tests for patients with GERD in several ways:

- A patient with chronic heartburn for 5 years who has had a single endoscopy that was clear does not need to be tested again unless other troublesome symptoms, such as anemia, weight loss, or difficulty swallowing, arise. Most cancers show up early on in a patient experiencing symptoms. If it didn't show in the initial test, therefore, it's unlikely to be an issue, Shaheen says. "That's an easy one to get rid of."
- Eliminate endoscopy testing for women without red-flag symptoms and men aged fewer than 50 years.
- Use your electronic health record (EHR) system to support effective testing. "The holy grail would be the integration of guidelines into the medical record," Cooke says. EHRs can be used as a powerful education tool for patients with GERD.
- Consider step therapy, in which the least expensive treatment to manage GERD is used as a first step, Seehusen of the AAFP suggests.
- Helping patients make lifestyle changes also could help reduce short- and long-term costs.

"Limiting your diagnostics to only those patients who you have a high index of suspicion for underlying Barrett's or underlying malignancy is the right answer," Seehusen adds. ■

40%
Of U.S. population with at least one monthly episode of heartburn

10 to 40%
Of upper endoscopies performed for GI concerns that do not conform to clinical guidelines

40
Percent by which the use of upper endoscopy has increased in Medicare patients in the past decade

$800
Average cost of upper endoscopy per examination

@ For resource centers related to gastroesophageal reflux disease and other topics in our Business of Health series, including hypertension, obesity, immunization, pain management, and circulatory disorders, as well as collections of articles related to our EHR Best Practices Study, Patient-Centered Medical Homes, and accountable care organizations, see www.MedicalEconomics.com/ResourceCenterIndex.

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Technology

The art of medicine: It's still personal

Medical Economics EHR Best Practices Study participant talks about technology and how to maintain a connection with patients

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

HIGHLIGHTS

01 When using your electronic health record system during an encounter, invite patients to become active participants in helping you document the encounter and discuss an appropriate treatment plan.

02 One solo, office-based family practice implemented and went live in 1 week, with a modest $3,000 investment in hardware.

"We have to be invested in our patients." It's our chance to connect in meaningful ways, says Martin McClintock, MD, a family physician in the St. Louis, Missouri, suburb of Ballwin. After 30 years of practice, McClintock knows. He describes his role as family physician as part educator, part confidante, part actor to help patients change behavior, and part healer.

DEVELOPING AND STRENGTHENING this bond with patients is truly the art of medicine. It's built by listening, by communicating, and by caring.

And not one of those roles, McClintock adds, has anything to do with typing notes into a computer.

For McClintock, maintaining a very personal connection with patients during an encounter has been an ethos guiding his career, and it simply was not negotiable when his solo practice made the decision to adopt the practice's first electronic health record (EHR) system using Amazing Charts.

His first decision regarding implementation of the EHR system was one of the easiest, he says: he did not want to work on a computer during a patient encounter.

And his patients agreed.

→59

"The months before imple-

➔56 menting, I was going to try to bring the computer into the exam room. One of my patients said, 'I can't stand talking to my doctor while he is typing into the computer. He spends more time with computer than he does with me.' " For McClintock, it was enough said. And although the computer lock-out is contrary to what many practice management consultants advise for many office-based practices, McClintock and his staff of two nursing aides have found a way to make it work.

In just 1 year, his practice not only achieved meaningful use; it also improved revenue by 5% last year, excluding government incentives.

As a participant in the *Medical Economics* EHR Best Practices Study, McClintock talked about how he and his staff organized the practice, as well as his approach to implementation and use of the EHR system.

ANATOMY OF THE PRACTICE

Ballwin is considered a second-ring suburb of St. Louis, with a population of about 30,000. From the surrounding area, McClintock has a patient base of 10,000, but far fewer appointments are scheduled every year. His client base is about 35% to 40% Medicare in an area that has grown with urban sprawl around the St. Louis area.

Although McClintock says his caseload has not increased, patients are calling and coming into the practice with multiple complaints—more so today than in the past. On average, McClintock schedules 30-minute appointments to address those problems. The family physician deals with everything from bronchitis to manic depression—sometimes during the same appointment. His patients are newborns to grandparents and every age in between.

The complexity of the cases, McClintock says, is another challenge in documenting the encounter. He believes it confounds working in an EHR during the information gathering stage of a patient encounter.

"I may get about 1% of the necessary information, and the patient jumps to the next problem and offers about 10% of that information and then skips to problem three, etc.," he explains.

The result, he says, does not necessitate a smooth experience when using the pick list fields within an EHR. McClintock, on the other hand, simply broke rank with the advice of many of ex-

Breaking down barriers

Some electronic health record (EHR) system features are so distracting they can prevent the physician and patient from having a meaningful personal interaction.

In fact, multiple surveys have shown the shortcomings of EHR systems as they relate to the many ways physicians interact with patients and use a system during an encounter, according to a report from the Office of the National Coordinator for Health Information Technology (ONC).

The problem, the ONC reports, is that the physician becomes so focused on filling out check boxes and navigating within the system that he or she fails to communicate effectively or ask pertinent open-ended follow-up questions to patients during an encounter.

So what is the solution? Consider strategic placement of an EHR workstation so the physician can maintain eye contact and work in collaboration with the patient.

David Judge, MD, of the Ambulatory Practice of the Future at Massachusetts General Hospital in Boston, told Medical Economics that he invites patients to sit at a shared computer station so they can work on the document together. Not only does it break down barriers, it lets the patient become an active participant in his or her care by helping to document the accuracy of the information and build a treatment plan.

The ONC also outlines these patient engagement activities:

- **viewing medical records and key medical data;**
- **conducting transactions with providers, such as secure messaging, refilling prescriptions, and scheduling appointments;**
- **accessing medical knowledge and health information materials;**
- **managing personal health information (for example, blood pressure, weight, etc.); and**
- **receiving decision support for healthcare and health management decisions by participating in health-related online social networks.**

> "I have read the stories about loss of productivity and all the problems associated with go live. We didn't have any of those issues. I am the furthest thing from a computer geek, and we got this up and running very quickly. Go live was not a big thing."
>
> MARTIN McCLINTOCK, MD

perts on the subject of actively using the EHR during an encounter to document the patient visit as it is occurring. He handwrites his encounter notes and simply transfers them to one of his nursing aides to type into the templates that he and his staff designed. He reviews the accuracy of the note at a later time.

In relation to other business processes, invoices mostly are generated by the office and mailed to patients for remittance. The practice does not accept credit cards, simply because the charges associated with credit card fees are too expensive for a small practice to absorb, he says. Like many small solo, office-based practices, McClintock remains self sufficient, and the staff members all share responsibility for the front-office and back-office functions.

IMPLEMENTATION

When it came to the implementation of the EHR system, the practice began using the software December 5 and went live a week later.

As part of the *Medical Economics* EHR Best Practices Study, McClintock received the software for use for 2 years. Associated costs of the implementation, however, ran about $3,000 in hardware and some information technology support. The dreaded go-live date was anything but dreaded, McClintock says. He describes the implementation as quite simple.

"I have read the stories about loss of productivity and all the problems associated with go live. We didn't have any of those issues," he says. "I am the furthest thing from a computer geek, and we got this up and running very quickly. Go live was not a big thing," he adds.

Although McClintock and his team did not scan his patient records, they still maintain paper charts.

The system boasts of broad capabilities for charting, scheduling, messaging, e-prescribing, billing, creating templates and working off site, but McClintock says that combining the technology with a traditional paper-based approach remains an acceptable and efficient way for the practice to operate.

He is not working off a dedicated server, but the vendor does recommend doing so for practices with three or more physicians.

McClintock jumped into the digital age on a shoestring budget. And he didn't do it for the efficiency gains, but because of the government's incentives and penalties for not using EHR systems.

The practice's success, however, shows that even a very small practice on a tight budget can make implementation work, he says. And he couldn't have done it without the help of his two longtime nurse aides, McClintock says. In fact, after reaching meaningful use, McClintock shared the bonus with them.

"I might see the patients, but we run this practice as a group, and I think that is why we have worked so well together for 28 years. It is because they have a lot of responsibility around here, and we work together."

McClintock and his staff have found the balance between adopting technology and applying it in ways to protect the bond he has built with his patients over decades of practice. And EHRs have advantages, the key is adapting the technology to work within the parameters of the practice, McClintock says.

And although many of the EHR systems are expanding features that include clinical guidelines and decision support, McClintock cautions physicians to never lose sight of their instinct and the art of medicine.

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Tech Talk

CYBER INSURANCE NOW A MUST FOR MEDICAL PRACTICES

by **TONY CONSOLI**

Increasing regulation and a growing number of cases involving releases of protected health information (PHI) highlight the need for your practice to purchase data security and privacy liability—or cyber—insurance.

Even if you don't yet use an electronic health record system, the reality is that paper records, portable devices such as smartphones, and employee error all put you and your practice at risk. In the healthcare setting, cases involving medical identity theft are escalating. According to the Ponemon Institute, a leading independent research organization, more than 1.5 million Americans have been affected by medical identity theft at a cost more than $30.9 billion. Ponemon also found in its annual benchmarking report that 52% of healthcare organizations say they experienced one or more incidents of medical identity theft.

LOSS PREVENTION

As with most other areas of risk management, an organization's ability to prevent adverse events is based on its people, processes, and technology. Organizations with dedicated information security personnel and those that screen prospective employees will have an edge in preventing unauthorized access to and accidental releases of PHI. Performing background security checks and drug screenings on prospective employees who will have access to health information technology (HIT) systems and infrastructure will help find applicants with criminal records and substance abuse issues. Equally important, these actions will set the tone for the rest of the organization and help create a culture of safety and accountability.

INSURANCE AND LIABILITY

Even with the most technologically advanced systems and the most robust risk management program, it is impossible to achieve 100% prevention. Therefore, a growing number of organizations are purchasing "cyber liability" coverage. Towers Watson reports in its 2013 survey of risk and finance managers that the number of organizations purchasing this coverage increased by 11% compared with the previous year.

Insurers such as Axis Insurance, ACE Group, AIG, Beazley, Chubb Group, C.N.A., Ironshore, OneBeacon Insurance Group, and Travelers offer these policies. All of these insurers offer highly customizable policies that can be tailored to focus on those key risks identified in the assessment process. Key coverage considerations:

- **Investigation expenses;**
- **notification and credit monitoring;**
- **legal liability;**
- **public relations expenses;**
- **cyber extortion;** and
- **regulatory actions** (these typically carry a sublimit for covering defense of fines and penalties associated with regulatory actions such as the Health Insurance Portability and Accountability Act (HIPAA).

Most insurers offer a sublimit of coverage to their physician customers. Key national insurers such as the Doctors Company, Medical Protective, Medicus, ProAssurance, and others routinely provide coverage extension, but all practices should investigate the costs and benefits of purchasing a standalone policy to address their unique organization and risk profile.

Under the recently adopted update to HIPAA rules, the fines for PHI violations are high enough to potentially put a small medical practice out of business. That fact alone should make it worthwhile for you to investigate purchasing a cyber insurance policy for your practice.

The author is president of the mid-Atlantic region and the national healthcare practice leader at CBIZ Risk Management and Insurance Services Inc. Send your healthcare technology-related questions to ***medec@advanstar.com.***

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WILL EPIC STIFLE INFORMATION TECHNOLOGY INNOVATION?

Epic is the nearly undisputed leader of the electronic health record (EHR) world. About 40% of the U.S. population has its medical information stored in an Epic EHR system, and the company often sits atop research firm KLAS' rankings of best-available EHR systems.

EPIC HAS many big-name clients who have spent a great deal of money on its systems: $700 million from Duke University Health System; $700 million from Boston's Partners Healthcare; $150 million from the University of California, San Francisco; and $80 lion from Dartmouth–Hitchcock Medical Center in New Hampshire, *Forbes* magazine reported last year.

So it's not surprising that such a high-profile company has attracted critics who warn that its market dominance could have harmful effects on the future of health information technology, EHRs, and even patient care. Worse, those critics warn, Epic has achieved much of its market dominance on the backs of taxpayers—courtesy of $35 billion in federal subsidies paid to hospitals and doctors to purchase EHR systems.

"As a country, we get nervous when any company in any sector has a market share in the range of 40% because we know that companies will use their market dominance to limit consumer options and hold back technological advancement," wrote Paul Levy, former chief executive officer of Beth Israel Deaconess Medical Center in Boston, Massachusetts, on his "Not Running a Hospital" blog.

Levy made waves in health information technology (HIT) circles recently when he compared the Epic customer experience to the Stockholm syndrome, which occurs when hostages begin to empathize with and have positive feelings for their captors.

Aside from the taxpayer subsidies Epic has indirectly received, what really rankles the company's critics is that Epic's is a "closed" system, meaning that it doesn't share patient data well with doctors or hospitals who don't use Epic's software.

"If Epic decides to maintain an essentially closed system and to drive all innovation internally, this could prove stultifying, limiting the development of novel ideas and forcing the many high-profile adopters of Epic to accept stagnation or pay the staggering costs of switching," David Shaywitz, MD, PhD, an adjunct scholar at the American Enterprise Institute, wrote in *Forbes*.

In other words, the "closed" nature of Epic's systems—coupled with its dominant market position—could mean that Epic ends up setting the *de facto* standards for EHR systems, effectively stifling innovations that its competitors might develop in the EHR market. That situation, in turn, could lead to Epic's big hospital customers—and those hospitals' patients—being frozen out from advances in EHR technology.

HIT analyst John Moore of Chilmark Research predicts that's exactly what will happen. Writing at the Health Care Blog, Moore said that Epic is operating on a model that "will ultimately hinder healthcare organizations' ability to rapidly innovate and respond to market changes. Epic simply will not be able to move fast enough, and their customers will struggle as a result."

Then there's the question of to what extent American taxpayers are subsidizing Epic's market dominance as a result of EHR incentive payments. The privately held company's sales have been skyrocketing in recent years, up to $1.2 billion in 2011, double what they were 4 years earlier, according to *Forbes*. That doesn't sit well with Levy.

"We need to consider whether it is appropriate that an EHR company that is making its money in great measure on contracts paid directly or indirectly by federal funds should be able to engage in practices that support long-term market dominance," he wrote.

Q&A

➔74 The data are compelling that the healthcare industry is pulling the larger U.S. economy off a cliff. The industry's most powerful tool has been the capture of law and regulation through lobbying. A recent Rand study showed that more than four-fifths of household income growth is now siphoned off by healthcare. We pay double for healthcare what other developed nations do, because the system has been structurally steered to get that result, with benefit that accrues to healthcare interests. This is the greatest current threat to our national economic security.

What steps potentially could allow primary care to recapture its value to the American health system?

All primary care professionals must galvanize and mobilize to begin to serve as a counterweight to rest of the healthcare industry's influence. It's important to systematically promote primary care's economic impact and value and to convey the role that primary care must play as a solution to the healthcare cost crisis and the U.S. budget crisis. To leverage your value, though, you must align with the nation's largest and most influential group—non-healthcare business leaders—to ensure that they understand that a system that subverts primary care cannot become more efficient. Develop the organizational capacity to manage clinical and financial healthcare risks that are beyond the capabilities of primary care. And advocate, in policy and the market, for approaches that promote value in healthcare.

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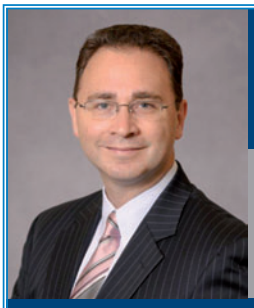

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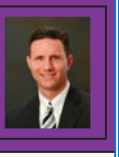

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Q&A

HOW THE RUC HARMS PCPs —AND WHAT YOU CAN DO ABOUT IT

If primary care physicians (PCPs) have a bigger enemy than the American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee (RUC), Brian Klepper, PhD, hasn't heard about it. Medical Economics *recently spoke with the healthcare analyst, author of the Replace the RUC blog, and chief development officer of Florida-based We Care TLC, a company that operates primary care clinics for employers and health plan sponsors.*

Why do you think more PCPs aren't angry about the RUC?

They are demoralized as a group. PCPs have their heads down and are running as fast as they can to care for their patients. Most probably have never heard of the RUC, are unaware of how the system came to be stacked against them, and doubt that they can do anything about it.

How do you believe the RUC has most harmed PCPs?

First, the RUC's greatest harms have fallen most on patients, then purchasers, then PCPs. The RUC, effectively an AMA lobbying group that, with the complicity of [the Centers for Medicare and Medicaid Services], controls a key element of reimbursement policy, has over-valued specialty services and dramatically undervalued primary care, so much so that an ophthalmologist extracting cataracts and inserting an intraocular lens—arguably less complicated care than figuring out what's going on with moderately complex primary care patients—earns 12.5 times a PCP's hourly rate. But most importantly, by driving down primary care's reimbursement, it has forced shorter primary care visits, which makes managing complexity more difficult, severely compromising primary care practice and opening a more direct patient pathway to lucrative downstream services. Primary care-to-specialist referrals have more than doubled in the past decade, distorting practice patterns and fueling an explosive systemic cost increase.

You've called for the creation of a new primary care society. Why do you believe the existing societies...don't adequately represent the interests of PCPs?

Primary care societies' leaders are political animals who, certainly in the case of the RUC, demonstrated greater interest in placating the AMA than representing the interests of their members. PCPs comprise more than one-third of all doctors, but they're fragmented into seven different societies, most of which also represent subspecialists and so have conflicted loyalties. So part of primary care's ineffectiveness on the stage of power is due to its insistence on a diluted power structure. They could enhance their influence by having all primary care professionals—including non-physicians—and their current societies come together into a larger congress. They also should recognize that their strongest potential ally is the business community that pays for more than half of healthcare and seeks greater value.

At Medical Economics, we often hear from doctors who are frustrated with the government for intruding on the practice of medicine. Your writing suggests that that anger would be more appropriately directed toward specialty societies, drug and device firms, and hospitals that grab a bigger share of healthcare dollars. Is that a fair reading of your work?

➔65

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