Medical Economics®

SMARTER BUSINESS. BETTER PATIENT CARE.

MedicalEconomics.com

JANUARY 25, 2014
VOL. 91 NO. 2

FAMILY MEDICINE'S REVIVAL

How one physician reinvented delivery of care

PAGE 20

ADVANSTAR MEDICAL COMMUNICATIONS GROUP

Medical Economics®

SMARTER BUSINESS. BETTER PATIENT CARE.

CONTACT US

CUSTOMER SERVICE	877-922-2022	BACK ISSUES	218-740-6477
EDITORIAL	800-225-4569	REPRINTS	877-652-5295, EXT. 121
ADVERTISING	732-596-0276	SUBSCRIPTION CORRESPONDENCE:	Medical Economics, *P.O. Box 6085, Duluth, MN 55806-6085*
CLASSIFIEDS	800-225-4569		

Twitter Talk

Other people and organizations tweeting about issues that matter to you

NATIONAL HEALTH SERVICE CORPS
@NHSC
Apply for #NHSC #loanrepayment between 1/7 and 3/20/2014 and watch your student debt decrease. #primarycare

ANDREW MORRIS-SINGER
@AMORRISSINGER
Calling ALL #primarycare advocates. READ THIS: http://primarycareprogress.org/blogs/16/329 AMAZING piece from the next generation @PCareProgress

CLINICAL ADVISOR
@CLINICALADVISOR
Primary-care #cancer screening practices vary widely http://cliniad.com/1dvWUHC #PrimaryCare

PRIMARYCARE PROGRESS
@PCAREPROGRESS
Med student breaks down how would-be #primarycare docs get lost in med school. A must-read! http://primarycareprogress.org/blogs/16/329

APHA
@PUBLICHEALTH
"More work to be done" on U.S. smoking: http://goo.gl/TOrH8N

join us online

facebook.com/MedicalEconomics
twitter.com/MedEconomics

PART OF THE ModernMedicine NETWORK

Medical Economics is part of the ModernMedicine Network, a Web-based portal for health professionals offering best-in-class content and tools in a rewarding and easy-to-use environment for knowledge-sharing among members of our community.

Referenced in MedLine®

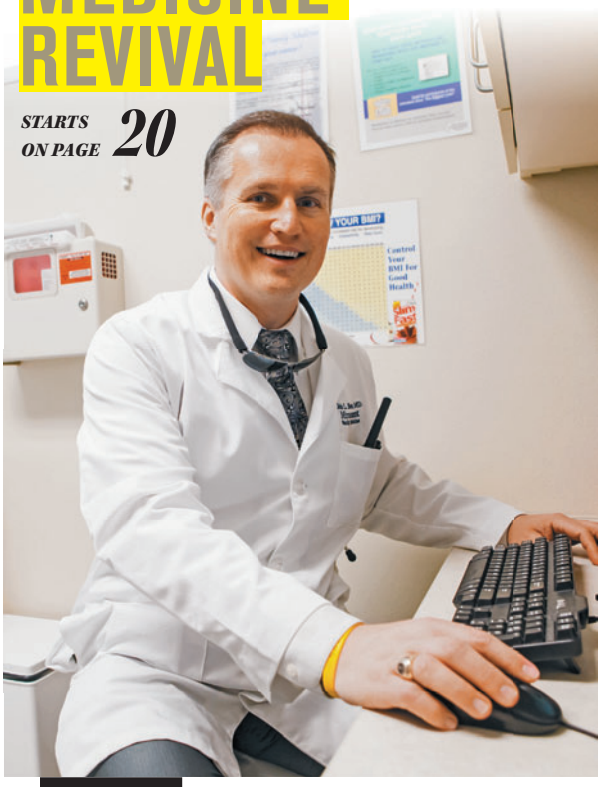
Medical Economics®
SMARTER BUSINESS. BETTER PATIENT CARE.

JANUARY 25, 2014

Volume 91
Issue 2

FAMILY MEDICINE REVIVAL

STARTS ON PAGE 20



COVER STORY | OPERATIONS

How John L. Bender, MD, and his practice reinvented the delivery of care

STARTS ON PAGE 20

- Bending the cost curve
- The value of metrics
- The price of efficiency

IN DEPTH

COLUMNS

MISSION STATEMENT

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

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

Cover: Steve Glass/Novus Select

We connect care.

So **care managers** can easily identify and focus on the sickest patients.
So **patients** can seamlessly access care in your health system.
So **in-network specialists** get referrals with the information needed to take action.
So **primary care physicians** get timely results and can follow their patients' care.

So health system leaders can ensure quality care and loyal patients and physicians.

---

athenahealth®
Cloud-based EHR, practice management and care coordination services

Find out how our Best in KLAS services can help your health system connect across the continuum of care. Visit us at **athenahealth.com/connectcare** or at **HIMSS booth #3528.**

ONLINE EXCLUSIVE

THE TOP MED EC FACEBOOK STORIES OF 2013

From the rollout of the problem-plagued healthcare.gov website to the legalization of medical marijuana in Colorado to United Healthcare's decision to drop thousands of physicians from its Medicare Advantage panels, 2013 was a year that healthcare professionals will remember for a long time to come. See which stories on *Medical Economics*' Facebook page drew the most reader interest at **MedicalEconomics.com/Facebook**

ME App. DOWNLOAD FREE TODAY.
Get access to all the benefits *Medical Economics* offers at your fingertips. The *Medical Economics* app for iPad and iPhone is now available for free in the iTunes store.
MedicalEconomics.com/app

Available on the App Store

Diabetes care and management resource center

Find information to help your patients control the effects of this rapidly-growing disease at **MedicalEconomics.com/diabetesmanagement**

Top Headlines Now @ME*online*

#1 PATIENTS WANT PCPs TO TREAT THEIR CHRONIC CONDITIONS
A new study shows patients' preference for primary care physicians over specialists. Learn more at **MedicalEconomics.com/preferPCP**

#2 PHYSICIAN VACANCY RATE AT HOSPITALS UP
It's nearing 18%, far higher than just a few years ago. Find details at **MedicalEconomics.com/vacancies**

#3 PATIENTS DON'T UNDERSTAND HEALTH INSURANCE TERMS
Fewer than 25% know the meaning of some basic concepts. Read more at **MedicalEconomics.com/insuranceterms**

PART OF THE ModernMedicine NETWORK

Medical Economics is part of the ModernMedicine Network, a Web-based portal for health professionals offering best-in-class content and tools in a rewarding and easy-to-use environment for knowledge-sharing among members of our community.

Twitter Talk

Follow us on Twitter to receive the latest news and participate in the discussion.

ICD-10
Only 25% of vendors say they are ready for #ICD10 http://ow.ly/sf3fK

AFFORDABLE CARE ACT
New #ACA and #Medicaid patients may mean more time spent on verification http://ow.ly/slMoM

MEANINGFUL USE INCENTIVE PAYMENTS
@harrygreenspun: #MU adoption incentives have totaled $17 billion! http://bit.ly/KkLPT0 Occ

FORMULARIES
Immunosuppressants could come off #Medicare Part D protected class http://bit.ly/K2cliT

INSURANCE PANELS
Docs say insurers dropping them in hopes their costly patients follow http://ow.ly/sf2TX via @CNN."

TELEMEDICINE
RT @ChrysalisVC: Why telemedicine is natural for next generation of docs: http://ow.ly/sdfBA @FierceHealthIT #healthIT

TOP CHALLENGES TO PHYSICIANS
It's 2014...what are the top challenged facing #physicians this year? http://ow.ly/sdt1t

join us online

facebook.com/MedicalEconomics
twitter.com/MedEconomics

PAGE 68

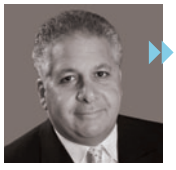
"Having a good transition plan sends the right message to your potential buyer."

—Robert C. Scroggins, CONSULTANT

EDITORIAL BOARD

Mary Ann Bauman, MD
Internal Medicine
Oklahoma City, OK

Patricia J. Roy, DO
Family Medicine
Muskegon, MI



George G. Ellis Jr., MD
Internal Medicine
Youngstown, OH

Joseph E. Scherger, MD
Family Medicine
La Quinta, CA

Gregory Hood, MD
Internal Medicine
Lexington, KY

Salvatore S. Volpe, MD
Internal Medicine-Pediatrics
Staten Island, NY

Jeffrey M. Kagan, MD
Internal Medicine
Newington, CT

Richard E. Waltman, MD
Family Medicine
Tacoma, WA

Jeffrey K. Pearson, DO
Family Medicine
San Marcos, CA

Craig M. Wax, DO
Family Medicine
Mullica Hill, NJ

Elizabeth A. Pector, MD
Family Medicine
Naperville, IL

ask us

Have a question for our advisers? Email your question to **medec@advanstar.com**.

EDITORIAL CONSULTANTS

PRACTICE MANAGEMENT

Judy Bee
www.ppgconsulting.com
La Jolla, CA

Keith Borglum, CHBC
Professional Management and Marketing
Santa Rosa, CA

Kenneth Bowden, CHBC
Berkshire Professional Management
Pittsfield, MA

Michael D. Brown, CHBC
Health Care Economics Indianapolis, IN

Frank Cohen, MPA
www.frankcohengroup.com
Clearwater, FL

Virginia Martin, CMA, CPC, CHCO, CHBC
Healthcare Consulting Associates
of N.W. Ohio Inc. Waterville, OH

Rosemarie Nelson
MGMA Healthcare Consultant Syracuse, NY

Mark D. Scroggins, CPA, CHBC
Clayton L. Scroggins Associates Inc.
Cincinnati, OH

Gray Tuttle Jr., CHBC
The Rehmann Group Lansing, MI

Michael J. Wiley, CHBC
Healthcare Management
and Consulting Services Bay Shore, NY

H. Christopher Zaenger, CHBC
Z Management Group Barrington, IL

Karen Zupko
Karen Zupko & Associates Chicago, IL

TAXES & PERSONAL FINANCE

Lewis J. Altfest, CFP, CPA
Altfest Personal Wealth Management
New York City

Robert G. Baldassari, CPA
Matthews, Carter and Boyce Fairfax, VA

Todd D. Bramson, CFP
North Star Resource Group Madison, WI

Glenn S. Daily, CFP
Insurance consultant New York City

Barry Oliver, CPA, PFS
Thomas, Wirig, Doll & Co.
Capital Performance Advisors
Walnut Creek, CA

Gary H. Schatsky, JD
IFC Personal Money Managers New York City

David J. Schiller, JD
Schiller Law Associates Norristown, PA

Edward A. Slott, CPA
E. Slott & Co. Rockville Centre, NY

HEALTH LAW & MALPRACTICE

Barry B. Cepelewicz, MD, JD
Garfunkel Wild, PC Stamford, CT

John M. Fitzpatrick, JD
Wheeler Trigg Kennedy, LLP Denver, CO

Alice G. Gosfield, JD
Alice G. Gosfield and Associates
Philadelphia, PA

James Lewis Griffith Sr., JD
Fox Rothschild Philadelphia, PA

Lee J. Johnson, JD
Mount Kisco, NY

Lawrence W. Vernaglia, JD, MPH
Foley & Lardner, LLP Boston, MA

Indication

BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes).

Limitations of Use

- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss, including prescription drugs (eg, phentermine), over-the-counter drugs, and herbal preparations, have not been established.
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

Important Safety Information

Contraindication

- BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.

Warnings and Precautions

- BELVIQ is a serotonergic drug. The development of potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors, and selective serotonin reuptake inhibitors, tricyclic antidepressants, bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists,

particularly when used in combination. Patients should be monitored for the emergence of serotonin syndrome symptoms or NMS-like reactions, including agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, nausea, vomiting, diarrhea, and muscle rigidity. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents should be discontinued immediately if the above events occur, and supportive symptomatic treatment should be initiated.

- Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (eg, cabergoline). In clinical trials, 2.4% of patients taking BELVIQ and 2.0% of patients taking placebo developed valvular regurgitation: none of these patients were symptomatic. BELVIQ should be used with caution in patients with congestive heart failure (CHF). Patients who develop signs and symptoms of valvular heart disease, including dyspnea, dependent edema, CHF, or a new cardiac murmur, should be evaluated and discontinuation of BELVIQ should be considered.
- Impairment in attention, memory, somnolence, confusion, and fatigue, have been reported in patients taking BELVIQ. Patients should not drive a car or operate heavy machinery until they know how BELVIQ affects them.
- The recommended dose of 10 mg twice daily should not be exceeded, as higher doses may cause euphoria, hallucination, and dissociation. Monitor patients for the development or worsening of depression, suicidal thoughts or behaviors, and/or any changes in mood. Discontinue BELVIQ in patients who develop suicidal thoughts or behaviors.
- Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus who are being treated with antidiabetic medications, so measurement of blood sugar levels before and during treatment with BELVIQ is recommended. Decreases in doses of antidiabetic medications or changes in medication regimen should be considered.
- Men who experience priapism should immediately discontinue BELVIQ and seek emergency medical attention. BELVIQ should be used with caution with erectile dysfunction medications. BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (eg, sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (eg, angulation, cavernosal fibrosis, or Peyronie's disease).
- Because BELVIQ may cause a slow heartbeat, it should be used with caution in patients with a history of bradycardia or heart block greater than first degree.
- Consider monitoring for CBC changes, prolactin excess, and pulmonary hypertension.

Most Common Adverse Reactions

- In patients without diabetes: headache (17%), dizziness (9%), fatigue (7%), nausea (8%), dry mouth (5%), and constipation (6%).
- In patients with diabetes: hypoglycemia (29%), headache (15%), back pain (12%), cough (8%), and fatigue (7%).

Nursing Mothers

- BELVIQ should not be taken by women who are nursing.

BELVIQ is a federally controlled substance (CIV) because it may be abused or lead to dependence.

Please see Brief Summary of Prescribing Information and references on adjacent pages.

BELVIQ® (lorcaserin HCl) CIV

BELVIQ®
(lorcaserin HCl) CIV

BRIEF SUMMARY:
For prescribing information, see package insert.

INDICATIONS AND USAGE
BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:
- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

Limitations of Use:
- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established

DOSAGE AND ADMINISTRATION
The recommended dose of BELVIQ is 10 mg administered orally twice daily. Do not exceed recommended dose. BELVIQ can be taken with or without food. Response to therapy should be evaluated by week 12. If a patient has not lost at least 5% of baseline body weight, discontinue BELVIQ, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

CONTRAINDICATION
- Pregnancy

WARNINGS AND PRECAUTIONS
Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions. BELVIQ is a serotonergic drug. The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors (SNRIs) and selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors [MAOIs]), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists, particularly when used in combination.
Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Serotonin syndrome, in its most severe form, can resemble neuroleptic malignant syndrome, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms.
The safety of BELVIQ when coadministered with other serotonergic or antidopaminergic agents, including antipsychotics, or drugs that impair metabolism of serotonin, including MAOIs, has not been systematically evaluated and has not been established.
If concomitant administration of BELVIQ with an agent that affects the serotonergic neurotransmitter system is clinically warranted, extreme caution and careful observation of the patient is advised, particularly during treatment initiation and dose increases. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.
Valvular Heart Disease. Regurgitant cardiac valvular disease, primarily affecting the mitral and/or aortic valves, has been reported in patients who took serotonergic drugs with 5-HT$_{2B}$ receptor agonist activity. The etiology of the regurgitant valvular disease is thought to be activation of 5-HT$_{2B}$ receptors on cardiac interstitial cells. At therapeutic concentrations, BELVIQ is selective for 5-HT$_{2C}$ receptors as compared to 5-HT$_{2B}$ receptors. In clinical trials of 1-year duration, 2.4% of patients receiving BELVIQ and 2.0% of patients receiving placebo developed echocardiographic criteria for valvular regurgitation at one year (mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation): none of these patients was symptomatic.
BELVIQ has not been studied in patients with congestive heart failure or hemodynamically-significant valvular heart disease. Preliminary data suggest that 5HT$_{2B}$ receptors may be overexpressed in congestive heart failure. Therefore, BELVIQ should be used with caution in patients with congestive heart failure.
BELVIQ should not be used in combination with serotonergic and dopaminergic drugs that are potent 5-HT$_{2B}$ receptor agonists and are known to increase the risk for cardiac valvulopathy (e.g., cabergoline).
Patients who develop signs or symptoms of valvular heart disease, including dyspnea, dependent edema, congestive heart failure, or a new cardiac murmur while being treated with BELVIQ should be evaluated and discontinuation of BELVIQ should be considered.
Cognitive Impairment. In clinical trials of at least one year in duration, impairments in attention and memory were reported adverse reactions associated with 1.9% of patients treated with BELVIQ and 0.5% of patients treated with placebo, and led to discontinuation in 0.3% and 0.1% of these patients, respectively. Other reported adverse reactions associated with BELVIQ in clinical trials included confusion, somnolence, and fatigue.
Since BELVIQ has the potential to impair cognitive function, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that BELVIQ therapy does not affect them adversely.
Psychiatric Disorders. Events of euphoria, hallucination, and dissociation were seen with BELVIQ at supratherapeutic doses in short-term studies. In clinical trials of at least 1-year in duration, 6 patients (0.2%) treated with BELVIQ developed euphoria, as compared with 1 patient (<0.1%) treated with placebo. Doses of BELVIQ should not exceed 10 mg twice a day.
Some drugs that target the central nervous system have been associated with depression or suicidal ideation. Patients treated with BELVIQ should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue BELVIQ in patients who experience suicidal thoughts or behaviors.
Potential Risk of Hypoglycemia in Patients with Type 2 Diabetes Mellitus on Anti-diabetic Therapy. Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus treated with insulin and/or insulin secretagogues (e.g., sulfonylureas); hypoglycemia was observed in clinical trials with BELVIQ. BELVIQ has not been studied in combination with insulin. Measurement of blood glucose levels prior to starting BELVIQ and during BELVIQ treatment is recommended in patients with type 2 diabetes. Decreases in medication doses for anti-diabetic medications which are non-glucose-dependent should be considered to mitigate the risk of hypoglycemia. If a patient develops hypoglycemia after starting BELVIQ, appropriate changes should be made to the anti-diabetic drug regimen.
Priapism. Priapism (painful erections greater than 6 hours in duration) is a potential effect of 5-HT$_{2C}$ receptor agonism.
If not treated promptly, priapism can result in irreversible damage to the erectile tissue. Men who have an erection lasting greater than 4 hours, whether painful or not, should immediately discontinue the drug and seek emergency medical attention.
BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease). There is limited experience with the combination of BELVIQ and medication indicated for erectile dysfunction (e.g., phosphodiesterase type 5 inhibitors). Therefore, the combination of BELVIQ and these medications should be used with caution.
Heart Rate Decreases. In clinical trials of at least 1-year in duration, the mean change in heart rate (HR) was -1.2 beats per minute (bpm) in BELVIQ and -0.4 bpm in placebo-treated patients without diabetes and -2.0 beats per minute (bpm) in BELVIQ and -0.4 bpm in placebo-treated patients with type 2 diabetes. The incidence of HR less than 50 bpm was 5.3% in BELVIQ and 3.2% in placebo-treated patients without diabetes and 3.6% in BELVIQ and 2.0% in placebo-treated patients with type 2 diabetes. In the combined population, adverse reactions of bradycardia occurred in 0.3% of BELVIQ and 0.1% of placebo-treated patients. Use with caution in patients with bradycardia or a history of heart block greater than first degree.
Hematological Changes. In clinical trials of at least one year in duration, adverse reactions of decreases in white blood cell count (including leukopenia, lymphopenia, neutropenia, and decreased white cell count) were reported in 0.4% of patients treated with BELVIQ as compared to 0.2% of patients treated with placebo. Adverse reactions of decreases in red blood cell count (including anemia and decreases in hemoglobin and hematocrit) were reported by 1.3% of patients treated with BELVIQ as compared to 1.2% treated with placebo. Consider periodic monitoring of complete blood count during treatment with BELVIQ.
Prolactin Elevation. Lorcaserin moderately elevates prolactin levels. In a subset of placebo-controlled clinical trials of at least one year in duration, elevations of prolactin greater than the upper limit of normal, two times the upper limit of normal, and five times the upper limit of normal, measured both before and 2 hours after dosing, occurred in 6.7%, 1.7%, and 0.1% of BELVIQ-treated patients and 4.8%, 0.8%, and 0.0% of placebo-treated patients, respectively. Prolactin should be measured when symptoms and signs of prolactin excess are suspected (e.g., galactorrhea, gynecomastia). There was one patient treated with BELVIQ who developed a prolactinoma during the trial. The relationship of BELVIQ to the prolactinoma in this patient is unknown.
Pulmonary Hypertension. Certain centrally-acting weight loss agents that act on the serotonin system have been associated with pulmonary hypertension, a rare but lethal disease. Because of the low incidence of this disease, the clinical trial experience with BELVIQ is inadequate to determine if BELVIQ increases the risk for pulmonary hypertension.

ADVERSE REACTIONS
Clinical Trials Experience. In the BELVIQ placebo-controlled clinical database of trials of at least one year in duration, of 6888 patients (3451 BELVIQ vs. 3437 placebo; age range 18-66 years, 79.3% women, 66.6% Caucasians, 19.2% Blacks, 11.8% Hispanics, 2.4% other, 7.4% type 2 diabetics), a total of 1969 patients were exposed to BELVIQ 10 mg twice daily for 1 year and 426 patients were exposed for 2 years.
In clinical trials of at least one year in duration, 8.6% of patients treated with BELVIQ prematurely discontinued treatment due to adverse reactions, compared with 6.7% of placebo-treated patients. The most common adverse reactions leading to discontinuation more often among BELVIQ treated patients than placebo were headache (1.3% vs. 0.8%), depression (0.9% vs. 0.5%) and dizziness (0.7% vs. 0.2%).

Most Common Adverse Reactions

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 rates in the clinical trials of another drug and may not reflect the rates observed in practice.
The most common adverse reactions for non-diabetic patients (greater than 5% and more commonly than placebo) treated with BELVIQ compared to placebo were headache, dizziness, fatigue, nausea, dry mouth, and constipation. The most common adverse reactions for diabetic patients were hypoglycemia, headache, back pain, cough, and fatigue. Adverse reactions that were reported by greater than or equal to 2% of patients and were more frequently reported by patients taking BELVIQ compared to placebo are summarized in Table 1 (non-diabetic subjects) and Table 2 (subjects with type 2 diabetes mellitus).

Table 1. Adverse Reactions Reported by Greater Than or Equal to 2% of BELVIQ Patients and More Commonly than with Placebo in Patients without Diabetes Mellitus

	Number of Patients (%)	
Adverse Reaction	**BELVIQ 10 mg BID N=3195**	**Placebo N=3185**
Gastrointestinal Disorders		
Nausea	264 (8.3)	170 (5.3)
Diarrhea	207 (6.5)	179 (5.6)
Constipation	186 (5.8)	125 (3.9)
Dry mouth	169 (5.3)	74 (2.3)
Vomiting	122 (3.8)	83 (2.6)
General Disorders And Administration Site Conditions		
Fatigue	229 (7.2)	114 (3.6)
Infections And Infestations		
Upper respiratory tract infection	439 (13.7)	391 (12.3)
Nasopharyngitis	414 (13.0)	381 (12.0)
Urinary tract infection	207 (6.5)	171 (5.4)
Musculoskeletal And Connective Tissue Disorders		
Back pain	201 (6.3)	178 (5.6)
Musculoskeletal pain	65 (2.0)	43 (1.4)
Nervous System Disorders		
Headache	537 (16.8)	321 (10.1)
Dizziness	270 (8.5)	122 (3.8)
Respiratory, Thoracic And Mediastinal Disorders		
Cough	136 (4.3)	109 (3.4)
Oropharyngeal pain	111 (3.5)	80 (2.5)
Sinus congestion	93 (2.9)	78 (2.4)
Skin And Subcutaneous Tissue Disorders		
Rash	67 (2.1)	58 (1.8)

Table 2. Adverse Reactions Reported by Greater Than or Equal to 2% of BELVIQ Patients and More Commonly than with Placebo in Patients with Type 2 Diabetes Mellitus

	Number of Patients (%)	
Adverse Reaction	**BELVIQ 10 mg BID N=256**	**Placebo N=252**
Gastrointestinal Disorders		
Nausea	24 (9.4)	20 (7.9)
Toothache	7 (2.7)	0

(Table continues)

Table 2. (cont'd.)

Adverse Reaction	Number of Patients (%)	
	BELVIQ 10 mg BID N=256	Placebo N=252
General Disorders And Administration Site Conditions		
Fatigue	19 (7.4)	10 (4.0)
Peripheral edema	12 (4.7)	6 (2.4)
Immune System Disorders		
Seasonal allergy	8 (3.1)	2 (0.8)
Infections And Infestations		
Nasopharyngitis	29 (11.3)	25 (9.9)
Urinary tract infection	23 (9.0)	15 (6.0)
Gastroenteritis	8 (3.1)	5 (2.0)
Metabolism And Nutrition Disorders		
Hypoglycemia	75 (29.3)	53 (21.0)
Worsening of diabetes mellitus	7 (2.7)	2 (0.8)
Decreased appetite	6 (2.3)	1 (0.4)
Musculoskeletal And Connective Tissue Disorders		
Back pain	30 (11.7)	20 (7.9)
Muscle spasms	12 (4.7)	9 (3.6)
Nervous System Disorders		
Headache	37 (14.5)	18 (7.1)
Dizziness	18 (7.0)	16 (6.3)
Psychiatric Disorders		
Anxiety	9 (3.5)	8 (3.2)
Insomnia	9 (3.5)	6 (2.4)
Stress	7 (2.7)	3 (1.2)
Depression	6 (2.3)	5 (2.0)
Respiratory, Thoracic And Mediastinal Disorders		
Cough	21 (8.2)	11 (4.4)
Vascular Disorders		
Hypertension	13 (5.1)	8 (3.2)

Other Adverse Reactions

Serotonin-associated Adverse Reactions. SSRIs, SNRIs, bupropion, tricyclic antidepressants, and MAOIs were excluded from the BELVIQ trials. Triptans and dextromethorphan were permitted: 2% and 15%, respectively, of patients without diabetes and 1% and 12%, respectively, of patients with type 2 diabetes experienced concomitant use at some point during the trials. Two patients treated with BELVIQ in the clinical program experienced a constellation of symptoms and signs consistent with serotonergic excess, including one patient on concomitant dextromethorphan who reported an event of serotonin syndrome. Some symptoms of possible serotonergic etiology that are included in the criteria for serotonin syndrome were reported by patients treated with BELVIQ and placebo during clinical trials of at least 1 year in duration. In both groups, chills were the most frequent of these events (1.0% vs. 0.2%, respectively), followed by tremor (0.3% vs. 0.2%), confusional state (0.2% vs. less than 0.1%), disorientation (0.1% vs. 0.1%) and hyperhidrosis (0.1% vs. 0.2%). Because serotonin syndrome has a very low incidence, an association between BELVIQ and serotonin syndrome cannot be excluded on the basis of clinical trial results.

Hypoglycemia in Patients with Type 2 Diabetes. In a clinical trial of patients with type 2 diabetes mellitus, hypoglycemia requiring the assistance of another person occurred in 4 (1.6%) of BELVIQ-treated patients and in 1 (0.4%) placebo-treated patient. Of these 4 BELVIQ-treated patients, all were concomitantly using a sulfonylurea (with or without metformin). BELVIQ has not been studied in patients taking insulin. Hypoglycemia defined as blood sugar less than or equal to 65 mg/dL and with symptoms occurred in 19 (7.4%) BELVIQ-treated patients and 16 (6.3%) placebo-treated patients.

Cognitive Impairment. In clinical trials of at least 1-year duration, adverse reactions related to cognitive impairment (e.g., difficulty with concentration/attention, difficulty with memory, and confusion) occurred in 2.3% of patients taking BELVIQ and 0.7% of patients taking placebo.

Psychiatric Disorders. Psychiatric disorders leading to hospitalization or drug withdrawal occurred more frequently in patients treated with BELVIQ (2.2%) as compared to placebo (1.1%) in non-diabetic patients.

Euphoria. In short-term studies with healthy individuals, the incidence of euphoric mood following supratherapeutic doses of BELVIQ (40 and 60 mg) was increased as compared to placebo. In clinical trials of at least 1-year duration in obese patients, euphoria was observed in 0.17% of patients taking BELVIQ and 0.03% taking placebo.

Depression and Suicidality. In trials of at least one year in duration, reports of depression/mood problems occurred in 2.6% BELVIQ-treated vs. 2.4% placebo-treated and suicidal ideation occurred in 0.6% BELVIQ-treated vs. 0.4% placebo-treated patients. 1.3% of BELVIQ patients vs. 0.6% of placebo patients discontinued drug due to depression-, mood-, or suicidal ideation-related events.

Laboratory Abnormalities. *Lymphocyte and Neutrophil Counts.* In clinical trials of at least 1-year duration, lymphocyte counts were below the lower limit of normal in 12.2% of patients taking BELVIQ and 9.0% taking placebo, and neutrophil counts were low in 5.6% and 4.3%, respectively. *Hemoglobin.* In clinical trials of at least 1-year duration, 10.4% of patients taking BELVIQ and 9.3% taking placebo had hemoglobin below the lower limit of normal at some point during the trials.

Prolactin. In clinical trials, elevations of prolactin greater than the upper limit of normal, two times the upper limit of normal, and five times the upper limit of normal, occurred in 6.7%, 1.7%, and 0.1% of BELVIQ-treated patients and 4.8%, 0.8%, and 0.0% of placebo-treated patients, respectively.

Eye Disorders. More patients on BELVIQ reported an eye disorder than patients on placebo in clinical trials of patients without diabetes (4.5% vs. 3.0%) and with type 2 diabetes (6.3% vs. 1.6%). In the population without diabetes, events of blurred vision, dry eye, and visual impairment occurred in BELVIQ-treated patients at an incidence greater than that of placebo. In the population with type 2 diabetes, visual disorders, conjunctival infections, irritations, and inflammations, ocular sensation disorders, and cataract conditions occurred in BELVIQ-treated patients at an incidence greater than placebo.

Echocardiographic Safety Assessments

The possible occurrence of regurgitant cardiac valve disease was prospectively evaluated in 7794 patients in three clinical trials of at least one year in duration, 3451 of whom took BELVIQ 10 mg twice daily. The primary echocardiographic safety parameter was the proportion of patients who developed echocardiographic criteria of mild or greater aortic insufficiency and/or moderate or greater mitral insufficiency from baseline to 1 year. At 1 year, 2.4% of patients who received BELVIQ and 2.0% of patients who received placebo developed valvular regurgitation. The relative risk for valvulopathy with BELVIQ is summarized in Table 3. BELVIQ was not studied in patients with congestive heart failure or hemodynamically-significant valvular heart disease.

Table 3. Incidence of FDA-Defined Valvulopathy at Week 52 by Treatment Group[1]

	Study 1		Study 2		Study 3	
	BELVIQ N=1278	Placebo N=1191	BELVIQ N=1208	Placebo N=1153	BELVIQ N=210	Placebo N=209
FDA-defined Valvulopathy, n (%)	34 (2.7)	28 (2.4)	24 (2.0)	23 (2.0)	6 (2.9)	1 (0.5)
Relative Risk (95% CI)	1.13 (0.69, 1.85)		1.00 (0.57, 1.75)		5.97 (0.73, 49.17)	
Pooled RR (95% CI)	**1.16 (0.81, 1.67)**					

[1] Patients without valvulopathy at baseline who received study medication and had a post-baseline echocardiogram; ITT-intention-to-treat; LOCF-last observation carried forward.

DRUG INTERACTIONS

Use with Other Agents that Affect Serotonin Pathways. Based on the mechanism of action of BELVIQ and the theoretical potential for serotonin syndrome, use with extreme caution in combination with other drugs that may affect the serotonergic neurotransmitter systems, including, but not limited to, triptans, monoamine oxidase inhibitors (MAOIs, including linezolid, an antibiotic which is a reversible non-selective MAOI), selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), dextromethorphan, tricyclic antidepressants (TCAs), bupropion, lithium, tramadol, tryptophan, and St. John's Wort.

Cytochrome P450 (2D6) substrates. Use caution when administering BELVIQ together with drugs that are CYP 2D6 substrates, as BELVIQ can increase exposure of these drugs.

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category X.

Risk Summary. BELVIQ is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. Maternal exposure to lorcaserin in late pregnancy in rats resulted in lower body weight in offspring which persisted to adulthood. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard of maternal weight loss to the fetus.

Clinical Considerations. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to the obligatory weight gain that occurs in maternal tissues during pregnancy.

Animal Data. Reproduction studies were performed in pregnant rats and rabbits that were administered lorcaserin during the period of embryofetal organogenesis. Plasma exposures up to 44 and 19 times human exposure in rats and rabbits, respectively, did not reveal evidence of teratogenicity or embryolethality with lorcaserin hydrochloride.

In a pre- and postnatal development study, maternal rats were dosed from gestation through post-natal day 21 at 5, 15, and 50mg/kg lorcaserin; pups were indirectly exposed in utero and throughout lactation. The highest dose (~44 times human exposure) resulted in stillborns and lower pup viability. All doses lowered pup body weight similarly at birth which persisted to adulthood; however, no developmental abnormalities were observed and reproductive performance was not affected at any dose.

Nursing Mothers. It is not known whether BELVIQ is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use. The safety and effectiveness of BELVIQ in pediatric patients below the age of 18 have not been established and the use of BELVIQ is not recommended in pediatric patients.

Geriatric Use. In the BELVIQ clinical trials, a total of 135 (2.5%) of the patients were 65 years of age and older. Clinical studies of BELVIQ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Since elderly patients have a higher incidence of renal impairment, use of BELVIQ in the elderly should be made on the basis of renal function. Elderly patients with normal renal function should require no dose adjustment.

Renal Impairment. No dose adjustment of BELVIQ is required in patients with mild renal impairment. Use BELVIQ with caution in patients with moderate renal impairment. Use of BELVIQ in patients with severe renal impairment or end stage renal disease is not recommended.

Hepatic Impairment. Dose adjustment is not required for patients with mild hepatic impairment (Child-Pugh score 5-6) to moderate hepatic impairment (Child-Pugh score 7-9). The effect of severe hepatic impairment on lorcaserin was not evaluated. Use lorcaserin with caution in patients with severe hepatic impairment.

DRUG ABUSE AND DEPENDENCE

Controlled Substance. BELVIQ is listed in Schedule IV of the Controlled Substances Act.

Abuse. In a human abuse potential study in recreational drug abusers, supratherapeutic oral doses of lorcaserin (40 and 60 mg) produced up to two- to six-fold increases on measures of "High", "Good Drug Effects", "Hallucinations" and "Sedation" compared to placebo. These responses were similar to those produced by oral administration of the positive control drugs, zolpidem (15 and 30 mg) and ketamine (100 mg). In this study, the incidence of the adverse reaction of euphoria following lorcaserin administration (40 and 60 mg; 19%) is similar to the incidence following zolpidem administration (13-16%), but less than the incidence following ketamine administration (50%). The duration of euphoria following lorcaserin administration persisted longer (> 9 hours) than that following zolpidem (1.5 hours) or ketamine (2.5 hours) administration.

Overall, in short-term studies with healthy individuals, the rate of euphoria following oral administration of lorcaserin was 16% following 40 mg (n = 11 of 70) and 19% following 60 mg (n = 6 of 31). However, in clinical studies with obese patients with durations of 4 weeks to 2 years, the incidence of euphoria and hallucinations following oral doses of lorcaserin up to 40 mg was low (< 1.0%).

Dependence. There are no data from well-conducted animal or human studies that evaluate whether lorcaserin can induce physical dependence, as evidenced by a withdrawal syndrome. However, the ability of lorcaserin to produce hallucinations, euphoria, and positive subjective responses at supratherapeutic doses suggests that lorcaserin may produce psychic dependence.

OVERDOSAGE

No experience with overdose of BELVIQ is available. In clinical studies that used doses that were higher than the recommended dose, the most frequent adverse reactions associated with BELVIQ were headache, nausea, abdominal discomfort, and dizziness. Single 40- and 60-mg doses of BELVIQ caused euphoria, altered mood, and hallucination in some subjects. Treatment of overdose should consist of BELVIQ discontinuation and general supportive measures in the management of overdosage. BELVIQ is not eliminated to a therapeutically significant degree by hemodialysis.

References: 1. BELVIQ [package insert]. Woodcliff Lake, NJ: Eisai Inc; 2012. **2.** Thomsen WJ, Grottick AJ, Menzaghi F, et al. Lorcaserin, a novel selective human 5-hydroxytryptamine$_{2C}$ agonist: in vitro and in vivo pharmacological characterization. *J Pharmacol Exp Ther.* 2008;325(2):577-587.

from the Trenches

> About the most galling aspect of medical malpractice lawsuits is that, no matter the outcome nor how trivial or asinine the complaint, the mere fact that anyone filed a malpractice lawsuit against you will likely require that you answer for it for the rest of your life.
>
> **Roderick T. Beaman, DO,** JACKSONVILLE, FLORIDA

SUGGESTED PAYMENT MODEL IS UNWORKABLE

KJ Lee, MD's payment ideas in his article "New payment models should reward quality" (November 25, 2013) are the worst since subprime mortgage loans. The concept that physicians should be paid 60% of their fee first and the remaining 40% be dispersed quarterly and based on "metrics and outcome measures" is ridiculous and insulting.

As a family practice doctor it is a constant struggle to get my maximum allowable fee (average $60--including copay!) from the insurance companies already. Now Lee wants me to get reimbursed 60% of that pittance and have to jump through hoops to get the remaining 40%? The billing procedure is burdensome enough, fraught with paperwork, denials, preexisting conditions forms, and more. Now add "metrics and outcome measures" as another reason for denial of payment to the stew of reasons to get that explanation of benefits without a check in it?

As a professor of surgery, Lee should test his theory by taking only 60% of his salary, forgoing the other 40% until his students have graduated, passed their surgical boards, had their surgeries discussed at grand rounds and the surgical patients outcomes followed quarterly. Now that is a great idea.

Lee Morgentaler, DO
OLD TAPPAN, NEW YORK

EFFECTS OF MALPRACTICE LAWSUITS LINGER

About the most galling aspect of medical malpractice lawsuits is that, no matter the outcome nor how trivial or asinine the complaint, the mere fact that anyone filed a malpractice lawsuit against you will likely require that you answer for it for the rest of your life. You will be questioned about each and possibly have to provide the most minute details of the suit on just about every license, hospital privilege, or insurance provider application. They never go away.

Roderick T. Beaman, DO
JACKSONVILLE, FLORIDA

DOCTOR-PATIENT RELATIONSHIP MUST ENDURE

I was born in the charity ward of Cook County, Illinois Hospital, and promptly hustled into the orphanage where my two brothers were already students, and where my mother worked in the laundry. Just over 14 years later I reported for football practice on the orphanage football team. The practice abruptly ended with the other members of the team carrying me to the hospital with a broken leg. It was a pretty bad break, both bones piercing the skin and digging into the dirt of the field. Since this was in the days before penicillin, the only treatment was to strap me in bed, keeping

> The criticism most often raised by those who oppose nurse practitioners being given the right to practice independently is that doctors have more training. This is misleading because within the limits of their training... nurse practitioners are capable of performing many primary care MD functions.
>
> **Edward Volpintesta, MD**, BETHEL, CONNECTICUT

the wound open so as to suppurate, and hope for the best.

In the hospital, the doctors and nurses seem to have made a point of stopping often, talking with me, asking if they could do something for me. In other words, taking a true, personal interest in me. For the first time in my life, people other than my mother paid attention to me. I was "somebody."

Jump forward 78 years, to when a copy of the December 10, 2013 issue of *Medical Economics* came into my hands. The cover article of that issue is entitled, "Can the doctor-patient relationship survive?" My answer to that question is, "It had better. Or the doctor-patient relationship has died of a lost heart."

Stuart Lyons
ST. JOHNS, ARIZONA

NURSE PRACTITIONERS CAN PERFORM MANY M.D. TASKS

Donna Marbury, MS discussed the major questions surrounding the nurses' scope of practice issue ("Scope of practice debate," September 10, 2013.)

The criticism most often raised by those who oppose nurse practitioners being given the right to practice independently is that doctors have more training. This is a misleading argument because within the limits of their training and education nurse practitioners are capable of performing many primary care MD functions. Sore throats, earaches, school physicals, house calls, monitoring glucose and cholesterol levels are just a few of the functions that nurse practitioners should be allowed to perform.

Although primary care doctors bristle when they hear that not everything they do needs to be done by an MD, the very broadness of primary care makes it so.

Furthermore, the hard life of a primary care doctor, made worse by the excessive amount of regulatory and administrative demands has brought on burnout and dissatisfaction for many of them. Is it any wonder that most medical students shun a career in primary care?

All things considered, the number of new patients soon to enter the health system under the Affordable Care Act makes it an urgent necessity to use every reasonable way to increase access to the health system.

Nurse practitioners are well-suited to help restore efficiency and job satisfaction to primary care doctors and to increase access to the health system. The best chances for achieving these goals are to encourage them to practice primary care collaboratively with MDs or to allow them to practice within the scope of their training independently. Both are valid entries into primary care.

Edward Volpintesta, MD
BETHEL, CONNECTICUT

TELL US

medec@advanstar.com

Or mail to:
Letters Editor, Medical Economics, 24950 Country Club Boulevard, Suite 200, North Olmsted, Ohio 44070. Include your address and daytime phone number.

Letters may be edited for length and style. Unless you specify otherwise, we'll assume your letter is for publication. Submission of a letter or e-mail constitutes permission for Medical Economics, its licensees, and its assignees to use it in the journal's various print and electronic publications and in collections, revisions, and any other form of media.

the Vitals

Examining the News Affecting the Business of Medicine

HEALTHCARE JOBS DECLINE, BUT AMBULATORY EMPLOYMENT SURGED IN 2013

The healthcare sector shed 6,000 jobs in December, marking only the second time in 23 years the sector has lost jobs. That short-term decline masked a strong hiring year in 2013 for the ambulatory care sector, which includes physician practices, according to employment data compiled by the U.S. Bureau of Labor Statistics.

While ambulatory care jobs dropped in December, the sector added 270,200 jobs last year, which represents growth of about 30%. Also included in the ambulatory care sector are outpatient care centers, diagnostic laboratories, and home health agencies.

Hospital hiring did not experience the same growth rate, adding only about 40,000 jobs in 2013. That's a 30% decrease when compared to the annual average over the last 23 years.

AAFP POLL: AMERICANS UNITED IN PREFERENCE FOR PHYSICIANS

Primary care physicians are more important than ever to the care patients demand.

Percentage of Americans who prefer to see a physician for their healthcare:

9 OUT OF 10

ADULTS WANT A PHYSICIAN TO LEAD THEIR MEDICAL TEAM

Americans say physicians possess the qualities that matter most to care delivery.

Americans want a healthcare provider who is knowledgeable, experienced, trustworthy, and up-to-date on the latest healthcare trends.

And they believe physicians exemplify these traits by more than 2:1 compared to non-physician counterparts:

Up-to-date on the latest medical advances and treatments **80%**	Experienced **77%**
Knowledgeable **77%**	Someone they trust **72%**

Methodology: Online survey of 1,00 adults conducted in November 2013. **Opinion Leaders:** Individuals who are registered to vote; have at least a college degree; are over age 25; make more than $75,000 annually unless they are between the ages of 25 and 29; are heavy news consumers; and are politically and/or socially engaged. **Source:** American Academy of Family Physicians

Getty Images/David Ake (left); Getty Images/Fuse (right).

U.S. healthcare spending growth slows to 50-year low; ACA impact minimal

HEALTHCARE SPENDING in the United States is still growing, but the rate of growth has reached its lowest level in more than 50 years.

A new report by the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS), published in *Health Affairs*, shows that healthcare spending was $2.79 trillion in 2012, making up more than 17% of the U.S. economy. The spending growth is mostly attributed to patients receiving more and more intensive healthcare services from office-based physicians and hospitals, and not from price growth. Medical prices actually grew at a lower rate in 2012.

While spending in 2012 grew by 3.7%, the rate of growth was the lowest since 1960, when the government began tracking that data. The dip in growth also marked the first time that healthcare costs grew slower than the gross domestic product (GDP) in 15 years.

The report has stirred debate over whether the Affordable Care Act, which was approved in 2010 and is rolling out its main provisions now, has impacted healthcare growth.

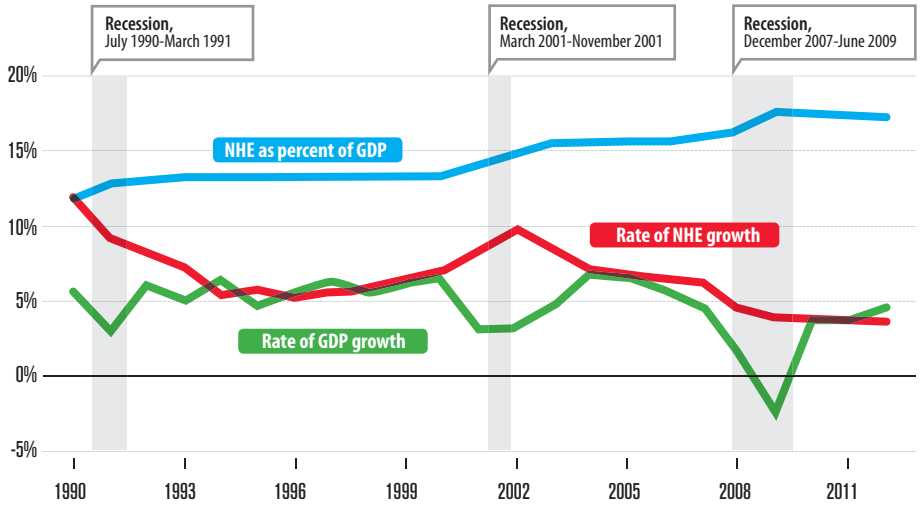
But officials from CMS' actuary office say the ACA has had minimal impact at best on the spending slowdown. At the same time, the ACA did not add to healthcare spending, contributing 0.1% of the growth from 2010 until 2012.

"While our historical data cannot parse out the spending that was directly the result of the ACA, the projections model showed that there was minimal impact from the ACA on aggregate national health expenditure trends," said Anne Martin, an economist with CMS, during a press briefing.

Healthcare costs will continue to grow as the ACA brings more patients into the healthcare market, according to CMS' actuary office.

Healthcare spending in 2013 is expected to remain below 4% of GDP, but spending is expected to speed up in future years as the ACA takes effect.

Growth In National Health Expenditures (NHE), Gross Domestic Product (GDP) and NHE as a Share of GDP, 1990-2012



Sources : Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group; US Department of Commerce, Bureau of Economic Analysis; and National Bureau of Economic Research.

U.S. SENATORS PUSH FOR EHR INTEROPERABILITY BY 2017

While members of Congress are expected to continue debating Sustainable Growth Rate reform this spring, a parallel effort is underway to require electronic health record (EHR) interoperability by 2017 in order for a provider to attest to meaningful use. Stage three of the meaningful use program is scheduled to begin in 2017.

That proposal, authored by Republican Senators John Thune and Mike Enzi, is not the only proposal. Senator John Cornyn, also a Republican, has proposed an amendment requiring the U.S. Department of Health and Human Services to adopt an interoperability standard by 2017.

Also, the U.S. House of Representatives Energy and Commerce Committee has published a report arguing that interoperability, healthcare quality improvement and cost reduction are connected.

"We must recognize that these technologies will be unable to truly transform our health system unless they can easily locate and exchange health information," the members wrote. "However, more must be done to bolster interoperability."

Doctor's Bag

The latest in drugs, devices, technology, and more

FDA APPROVES FIRST ONCE-DAILY BRONCHODILATOR TO TREAT COPD

FDA has approved Anoro Ellipta (umeclidinium and vilanterol inhalation powder) for the once-daily, long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

It is the only combination product approved in the U.S. that delivers two once-daily bronchodilators in a single inhaler.

Anoro Ellipta is a combination of umeclidinium—an inhaled anticholinergic that affects the muscles around the large airways and stops the muscles from tightening—and vilanterol, a long-acting beta2-adrenergic agonist (LABA) that improves breathing by relaxing the muscles of the airways to allow more air to flow into and out of the lungs. The safety and efficacy of Anoro Ellipta were evaluated in more than 2,400 patients with COPD. Those treated showed improved lung function compared to placebo.

The drug carries a boxed warning that LABAs can increase the risk of asthma-related death. A patient medication guide was approved with Anoro Ellipta. According to the National Heart, Lung, and Blood Institute, COPD is the third leading cause of death in the United States.

GlaxoSmithKline http://us.gsk.com/

NEW TREATMENT FOR PARTIAL-ONSET SEIZURES APPROVED

FYCOMPA (perampanel) CIII has been approved by the FDA as an adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy age 12 years and older. It is the first non-competitive AMPA glutamate receptor antagonist to be approved by the FDA.

Approval was based on three Phase III studies, which evaluated efficacy and safety compared to placebo. FYCOMPA significantly reduced seizure frequency in patients with partial-onset seizures with or without secondarily generalized seizures.

FYCOMPA has a boxed warning for causing serious psychiatric and behavioral reactions, and it has been designated by the U.S. Drug Enforcement Administration as a federally controlled substance.

FYCOMPA will be available in the United States to eligible patients by prescription beginning this year.

"Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking FYCOMPA."

Eisai Inc. (201) 692-1100 | us.eisai.com

MAYO CLINIC USES SOCIAL MEDIA TO REACH PHYSICIANS

Mayo Clinic has produced a series of expert-led presentations where physicians can learn from each other, ask questions, and engage in peer-to-peer dialogue on a variety of medical topics. The presentations are part of Quantia's social learning and collaboration platform, QuantiaMD.

QuantiaMD is designed to enhance physician collaboration and information sharing. According to Mayo Clinic, about 30% of physicians nationwide have visited QuantiaMD to learn from experts, share advice and help each other become better doctors. More than 25,000 physicians have already watched presentations or participated in discussions based on information from Mayo Clinic physicians.

Moving forward, Mayo Clinic physicians will be covering future topics such as liver and pancreas surgery to depression and adult congenital heart disease.

Mayo Clinic & Quantia, Inc.
www.mayoclinic.com
www.quantiamd.com

Q Do you have a favorite new product?
Tell us at www.facebook.com/MedicalEconomics

ICD-10 READINESS
Answers to questions about the ICD-10 transition [38]

FIRING A PATIENT
The right way to part from a problem patient [42]

Family medicine's revival

How one physician and his team reinvented care delivery to bend the cost curve and improve efficiency

by **DANIEL R. VERDON** *Group Content Director* | *Photos by* **STEVE GLASS**

Primary care is perfectly positioned to bend the cost curve. And that's precisely what is driving consistent 45% growth of Fort Collins, Colorado-based Miramont Family Medicine, says CEO John L. Bender, MD, FAAFP. The multi-specialty group, with a heavy focus on family medicine, has an entirely different notion.

HIGHLIGHTS

01 Independent primary care practices are poised to advance simply because they are delivering a far stronger value/quality proposition compared with hospital systems.

02 Lean principles, as used by manufacturing, can help you build a more efficient practice. Look for value, and try to trim the time it takes to perform certain procedures.

THEY WANT TO KEEP as much of the delivery of healthcare within its seven facilities to improve it and manage escalating costs.

And the practice has built a model to do just that with advanced technology and medical equipment, contracts with visiting specialists, a practice design built around saving steps for nurses and medical assistants, and a patient base that has swelled to 35,000 and growing.

While Miramont has been consistently expanding, independent family medicine practices in the area have been contracting. Nearly 30 primary care practices in this locale have either sold to the area's hospitals or, in eight cases, gone bankrupt.

While financial implosion is a grim reality on the eve of the full-scale implementation of Obamacare, according to Bender, it signals the need for great disruption in the way primary care delivers services to patients and how it is paid.

Most primary care practices struggle with cash-flow problems, Bender explains, and to improve it, practices have to become far more efficient and predictable in delivery and revenue collection.

"Practices that fail often are the one's that have not effectively managed labor costs," Bender says. "I cannot simply pay my staff less. If anything, I have to pay them more because we are in such a high-density of services and digitalization. What Miramont does differently is through Lean principles and leveraging information technology," he says. "We allow our staff to do things in 10 minutes what used to take 20, and that is the secret."

Lean principles, adopted and successfully used in manufacturing by Toyota, are a management tool to help identify value and eliminate waste in a process.

"We recognized that we could treat cases for $300, when the emergency room was charging $3,000. We have a better product than the emergency department for about 90% of what it is seeing."

And if you ask Bender, that is exactly why independent practices in family medicine and internal medicine are so vitally important and poised to succeed.

Hospital systems are embroiled in a kind of medical arms race that is not sustainable, Bender says. Neither is the buying spree of independent primary care and other specialist practices.

For example, the Fort Collins area has seen large-scale growth in emergency department (ED) utilization by almost 50%, according to latest estimates, he says.

"What this suggests to me is that if people don't have a family physician or a Patient-Centered Medical Home, they are going to the [ED] at a later stage at a higher cost," Bender says.

The EDs have been such a driver to hospital traffic that one of the area hospital's built a freestanding ED, the competing hospital responded with a freestanding emergency facility and the purchase of the county's emergency medical service. The other hospital escalated the race by buying a second air ambulance to service an area of fewer than 500,000 residents.

"Who is paying for this? We all are. It's raising everyone's premiums and moving at

Team power

John L. Bender, MD, FAAFP (left) of Miramont Family Medicine in Fort Collins, Colo. says that by empowering the team and closely examining patient metrics can improve outcomes. And they have data to prove it.

High quality, low cost

Miramont Family Medicine, now in seven locations, grew by 45% in 2013 and was named one of the fastest-growing businesses in northern Colorado. The vision is simple: Make the service accessible, affordable and deliver on quality. Miramont Family Practice CEO John Bender, MD (far right) constructed a practice aiming to incorporate technology and processes to trim the amount of time it takes to perform tasks.

"I HAVE STOPPED APOLOGIZING FOR OUR PRICES. OUR BILLS ARE HUNDREDS OF DOLLARS, BUT THEY ARE NOT THOUSANDS LIKE SPECIALTY CARE OR TENS OF THOUSANDS LIKE HOSPITALS."

JOHN L. BENDER, MD, FORT COLLINS, COLO.

an amazing rate," Bender says. In the past 2 years, 250 physicians in this area have become hospital employees.

"Having said that, the hospital medical group in 2010 lost $7 million," he adds. "In 2011, they lost $20 million. Last year, I don't know how much they lost, but they relieved their chief executive officer, chairman of the board and other executive leaders. It's not working for them. Hospitals cannot just buy up ambulatory practices that are failing and run them like hospitals. This truly is making our healthcare situation worse."

THE QUEST FOR EFFICIENCY

When Bender and his wife Teresa (the practice administrator) bought Miramont in 2002, it was one of the oldest family medicine practices in Fort Collins.

Looking back, "we really were producing a lousy product," he says. "Our test results were slow; our labor costs were high, and it would take three weeks to get into see me."

It took that realization, along with heart-to-heart discussions with his partners and staff, and a retreat to develop a renewed vision for the practice—one that was simple, practical, and focused on providing convenience, value, and quality medical care.

"As physicians and leaders of the practice, we know that we need to sustain profitability so that we can be here for years. And we wanted to eliminate as much waste as possible." It was a big step forward for everyone involved in the practice, and it takes courage to change, Bender says.

In 2005, Bender took out a second mortgage on his home for a 10% down payment on a $1.4-million facility. The practice developed a signature floor plan that would ultimately cost $160 per square foot. The dispensing pharmacy was placed in the lobby, while the labs for blood draw were conveniently placed near the nursing station. The idea was to trim as many steps from the system as possible, a key to Lean processes.

The practice rents space to visiting specialists for everything from general outpatient surgery to pain management to physical therapy. Bender wants to make it as convenient as possible for his patients to receive healthcare in his practice locale. It's easier for patients and physicians. It's strategic, and it's cost effective, he says. And he has created a patient-centered practice that delivers as much specialty care within the practice as possible while maintaining quality.

The practice has adopted an ethos of continuous quality improvement and applied other Lean processes to empower staff at all levels to improve the process to influence outcomes.

We have learned over and over again that if you go to your staff or ask your patients how you should fix this, 92% of the time the collective wisdom of the group will give you the right answer.

"A lot of this has to do with management instilling this kind of power to influence change in a system that needs it."

Checklists also help, Bender says. Pilots use them all the time, and they do improve outcomes without having to go through a lot of elaborate training. "Why are we satisfied with a defect rate of 30% to 40% in healthcare?"

Metrics are invaluable, he says. "Once you start measuring, you know where you stand. I promise you when you start, your numbers will be worse than what you imagined. But once you start measuring outcomes, patient populations or disease conditions; they begin to improve.

"It took us about one year to get our A1Cs up to goal, and we got there by measuring them," Bender says.

Miramont's healthcare delivery teams are built around each of the physicians in the practice, and the metrics are displayed for everyone to see.

Improved metrics not only help patients and healthcare teams, they put the practice in a far stronger position to negotiate with payers.

Anatomy of a practice

MIRAMONT FAMILY MEDICINE

Locations: 7

Communities served: 6 in the nearby Fort Collins and Denver, Colorado areas

Annual revenue: about $7 million

Practice certification: NCQA Level 3 PCMH

Practice efficiency project: Robert Woods Johnson Learning from Effective Ambulatory Practices (LEAP) program.

Patient panel: 35,000

Physicians: 12

Total providers: 22

Total employees: 80

Payers: Private health insurers, Medicare, Medicaid, and direct pay

Some services:
Family medicine
Internal medicine
Pediatric s
Ob/Gyn
Some general outpatient surgery
Wellness
Acupuncture
Physical therapy
Audiology
Behavioral health
Allergies
Hematology and chemistry laboratory
Dispensary
X-ray
Aesthetics
Laser treatments
Mammography
Insulin pumps
Nutrition

Exploring ancillaries

Cosmetic dermatology has grown to a $10,000 segment of the $7 million family practice. While it's not the mainstay, it is a very viable service that keeps patients engaged in their healthcare, says Miramont CEO John L. Bender, MD, FAAFP.

FINANCIAL MANAGEMENT

Controlling costs is one of the most important management disciplines, so too is transparency in pricing, Bender says. In fact, Miramont has taken it a few steps further, becoming one of the few practices that publishes its fee schedule.

"We want transparency in pricing, and we value price our services," Bender says. The practice established a value plan for those without insurance. Most visits in this plan are $64, and patients sign a contract with the practice, requiring them to pay at the time of service. That way there is no billing, no coding and no waiting for an explanation of benefits.

How does the practice work with payers?

"If a payer contacts us and tells us we want that price, we say okay, but here's the rub, you have to pay us by 5 p.m. the day of service. Payers have not built their systems to do instant adjudication," Bender says.

"Under the current system, I am an interest-free loan. I have receivables and tens of thousands of dollars in any given time, and they are given that money interest-free. They could save a lot of money if they paid their bills on time and renegotiated contracts with me."

There are also tremendous possibilities for direct pay, he says, especially as it relates to negotiating care directly with employers.

"I have six people on staff just to collect money. Just by not having to do that would drastically reduce our prices.

"But I have stopped apologizing for our prices. Our bills are hundreds of dollars, but they are not thousands like specialty care or tens of thousands like hospitals," he says.

EXPANSION PLANS

The practice, Bender says, sees a bright future, despite the economic uncertainty tied to the Affordable Care Act. According to Bender, this is all just part of operating a healthcare business in 2014. And it becomes part of Miramont's strategy to double in the next 2.3 years. As a result of ACA, he plans to grow his Medicaid base this year. In fact, five years ago 1% of his practice population consisted of Medicaid patients. The practice's Medicaid population has grown to 21% this year, and he plans to push it further to 30% next year, drawing patients from the Denver area.

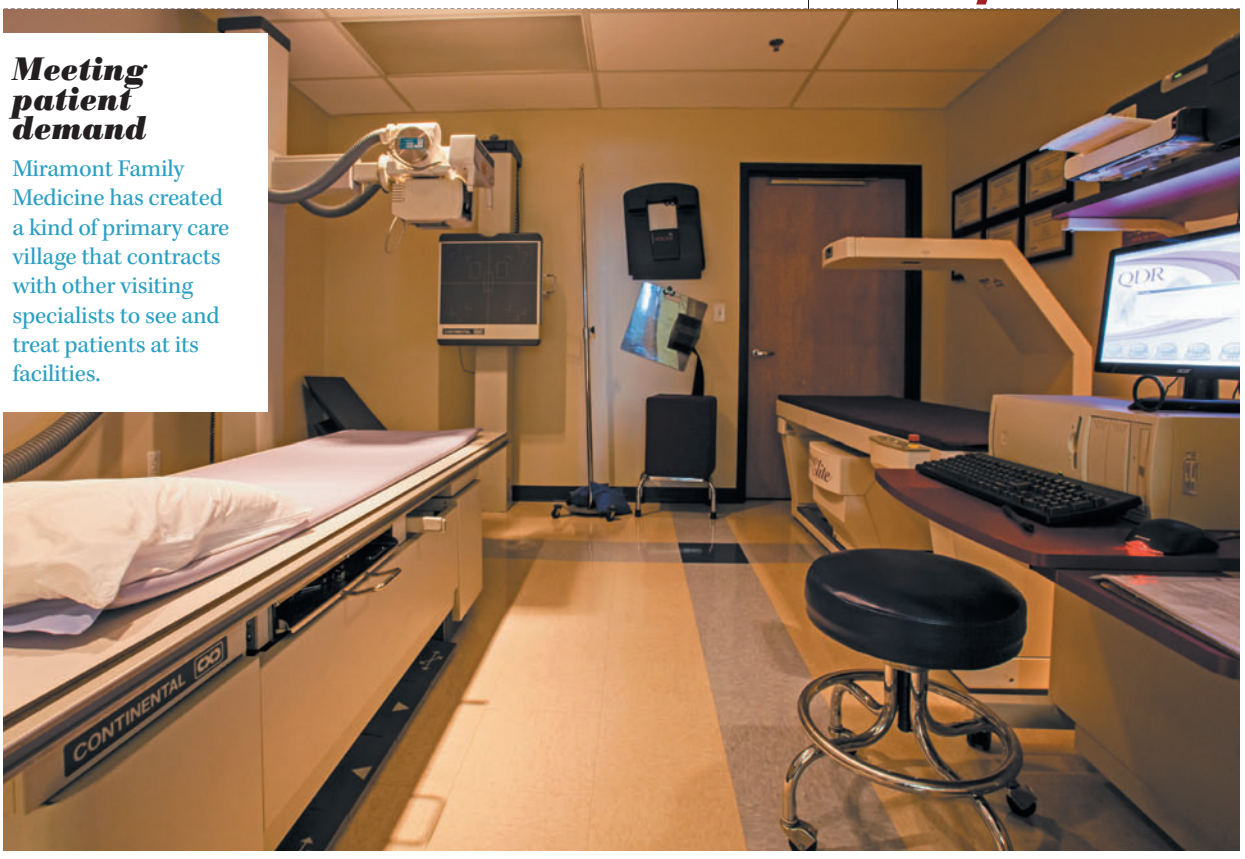
➔ 29

"A lot of it is because we

The 5 principles of Lean

1. Specify value to the customer.
2. Identify all the steps in the value stream, and eliminate those steps that do not provide value.
3. Make the value-creating steps occur in a tight sequence so the product flows smoothly toward the customer.
4. As this flow is introduced, let customers pull value from the next upstream activity.
5. As value is specified, value streams are identified, wasted steps are removed, and flow and pull are introduced, begin the process again and continue it until a state of perfection is reached in which perfect value is created with no waste.

Source: www. lean.org



Meeting patient demand

Miramont Family Medicine has created a kind of primary care village that contracts with other visiting specialists to see and treat patients at its facilities.

➔24 improved our efficiencies because our overhead was less and that is what created margin and allowed us to take care of Medicaid patients and allowed us to grow," he says.

The practice also opened three new facilities this year. And this growth has been driven by a broad service mix that combines family medicine, internal medicine, pediatrics, Ob/Gyn with a litany of specialty services. (See "Anatomy of a practice," page 23.)

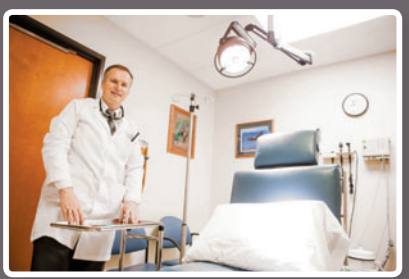
And that's the point: To combine service with convenience and keep healthcare affordable. Bender believes patients will ultimately vote with their feet and keep walking into Miramont Family Medicine.

Pricing transparency

To care for patients without insurance, the practice has set up the Miramont Value Plan contract that spells out costs for common encounters. Some of the prices include:

Bladder infection:	$69	Strep throat:	$84	Male physical exam:	$206
Bronchitis:	$64	Cholesterol screening:	$58	PSA:	$35
Ear infection:	$64	Diabetic screening:	$56	Chest X-ray:	$32
Pink Eye:	$64	Well woman exam:	$206	Mammogram:	$125

MORE RESOURCES SLIDESHOW



John L. Bender, MD, FAAFP, offers insight on how Miramont Family Medicine has bent the cost curve. He talks about the practice strategy and vision for success.

Visit MedicalEconomics.com/Miramont

Preparing for Obamacare

How your practice can meet the workflow and financial challenges that newly insured patients will present.

by **DONNA MARBURY, MS,** *and* **CHRIS MAZZOLINI, MS**

HIGHLIGHTS

01 The insurance verification process is different depending on whether the plan was purchased on a state or federal exchange.

02 Patients who do not pay their insurance premiums have a 90-day grace period, and insurers won't be required to pay for claims during the final 60 days.

03 Practices should be upfront about payment rules and options when dealing with patients with high deductible health plans.

With millions of newly insured patients entering the healthcare system in the first round of Affordable Care Act (ACA) enrollments, there will be patient confusion in the first months of implementation. Physicians should be prepared to deal with insurance eligibility questions from patients and, the consequences of the ACA premium grace period.

PRIMARY CARE physicians nre about to find out to what extent milions of newly insured ACA patients will impact the workflow of their practices, including new patients who have not been to an office visit in years, if ever, and don't understand how the process works.

Other ACA consequences could impact practice finances, including dealing with a large number of patients with high-deductible health plans and the 90-day grace period for patients who do not pay their premiums.

1/ Questions about insurance coverage

Many patients who signed up for coverage in December may not have insurance identification cards yet, but they still may be calling to make appointments.

But what options do physician-owned practices have when scheduling patients who say they have insurance but have yet to receive identification?

Experts say that practices should prepare to spend even more time verifying coverage, and must consider using cash reserves to

> A certain amount of people are not going to pay. Some physicians are going to have to repay insurance companies. It's going to sting, particularly when insurance companies start demanding repayments... It's another area for cautious preparation."
>
> —GRAY TUTTLE, CHBC, REHMANN HEALTHCARE ADVISORS, LANSING, MICHIGAN

float payments for the next few months.

"Make sure your practice credit line has money available and take cash or credit cards," says H. Christopher Zaenger, CHBC, a consultant with Z Management Group in Barrington, Illinois, and a *Medical Economics* editorial consultant. "Copy all the information on patients cards and for those who do not yet have cards, get their application paperwork and the plans they are joining by specific name and number, then go to the Qualified Health Plans website and verify the coverage and effective date."

Depending on whether your patient has a plan run by the state or federal government, the verification process will be different. If your state has a federal-run marketplace, it is best to call customer service for the plan to verify coverage. A database of health plan contact numbers is available online at **http://1.usa.gov/1lYOVqZ**. Find contact information for state run plans on the left side of the Healthcare.gov website.

It will also be up to practice staff to continually educate patients about their payment responsibilities.

"Remind your patients to keep all of their paperwork and receipts from all of their doctor's appointments and from the pharmacy as well," says Reed Tinsley, CPA, a healthcare consultant in Houston, Texas. "They may need them for their insurer. Remind them they should carry their card at all times. If they don't have a card, they can contact their plan to get a card."

National chain pharmacies, including Walgreens and CVS Caremark, have received media praise for offering patients with new or transitional insurance plans a 15- to 30-day supply of prescription drugs with no upfront cost.

2/ Dealing with the 90-day grace period

A provision in the ACA that could cause problems for primary care practices is that patients will be allowed to keep their health coverage for 90 days even if they don't pay their premiums.

While the ACA requires insurers to reimburse providers during the first 30 days of the 90-day grace period, insurers won't be required to pay for claims during the final 60 days. This means physicians may provide healthcare to patients in the next few months that they are never reimbursed for, thus requiring physicians to collect money from the patient directly.

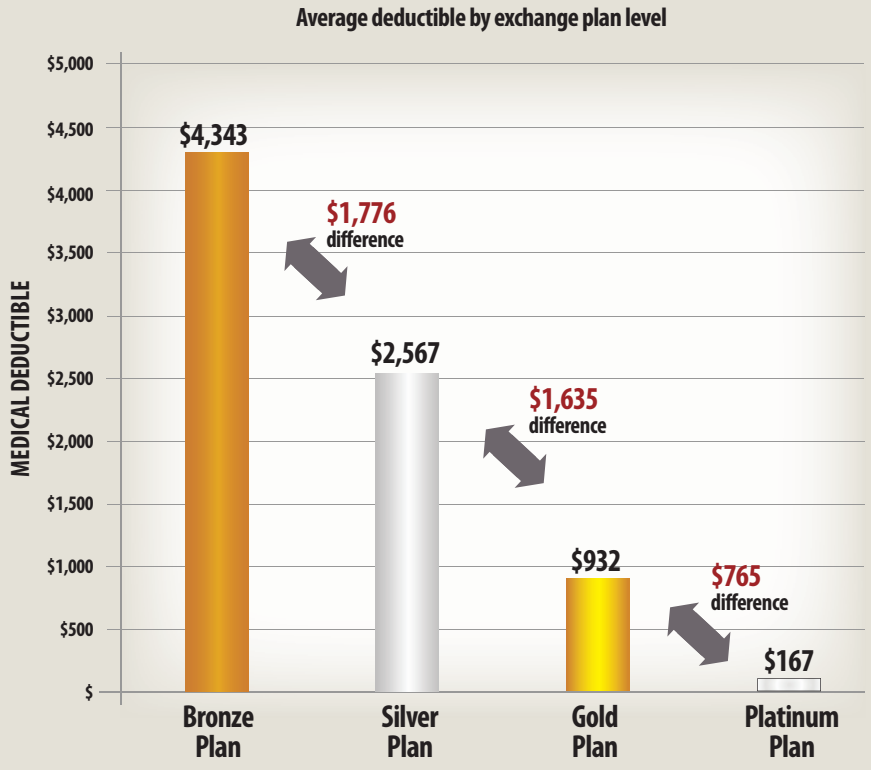
Medical groups including the American Medical Association (AMA) and the Medical Group Management Association (MGMA) have taken issue with the grace period rules, arguing that insurers should be on the hook for those payments, not providers.

At the very least, medical organizations say, payers must give providers notice about patients who have entered the grace period and are in danger of non-payment of their premiums.

"A certain amount of people are not going to pay," says Gray Tuttle, CHBC, a principal at Rehmann Healthcare Advisors in Lansing, Michigan, and a *Medical Economics* editorial consultant. "Some physicians are going to have to repay insurance companies. It's going to sting, particularly when the insurance companies start demanding repayments."

Physicians have limited options for dealing with the grace period, which could last until mid-2014 for patients who buy coverage before open enrollment ends March 31.

HIGH DEDUCTIBLES: OUT-OF-POCKET COSTS FOR ACA PLANS



Source: Avalere Health

Tuttle says physicians can ask patients upon registration whether their coverage is paid for. Another option is to set up credit card authorizations for future payment, so that once an insurance claim is adjudicated, the patient's remaining balance can be put on the credit card.

The major caution, Tuttle advises, is to make sure physicians stick with the requirements of a patient's health plan when asking for payment up front.

Tuttle says he does not anticipate too many issues resulting from the grace period, but as with other ACA changes, "It's another area for cautious preparation."

3/ High-deductible patients

More patients are expected to use high-deductible health plans in the future, a trend only exacerbated by the ACA's insurance exchange. The cheapest "bronze" plan often can have deductibles above $4,000, according to an analysis from Avalere Health.

The best way to handle patients that may owe your practice is to communicate with patients, experts say. Practices should have a policy in place, and payment expectations and options need to be discussed with patients before care is received.

"There needs to be internal training and education with staff about how to communicate upfront payments," says Nate Davis, a product manager with ZirMed, a healthcare information technology and management solutions company in Louisville, Kentucky. "There are plenty of payment plans possible that will work with patients with high-deductible plans."

Adds Tuttle: "If practices know [their patients] are in high-deductible plans, they should be collecting copays and deductibles all along."

Coding Insights

PREPARING FOR ICD-10: SPLIT CLAIMS, CMS TESTING, AND MORE SOLUTIONS

Q: We understand that, at this point, the October 1, 2014, deadline for ICD-10 transition is firm. If we have a date of service in September 2014, but the claim isn't billed until October 2014, which codes do we use, ICD-9 or ICD-10?

YOUR DATE OF SERVICE determines which code set to use. In your example, even if you submit your claim on or after October 1, 2014, if the date of service is before the October 1, 2014, deadline, you will use the ICD-9 Clinical Modification (ICD-9-CM) diagnosis code set for the claim.

On the other hand, for dates of service on or after the October 1, 2014, deadline, you will use the ICD-10 codes. If you have multiple line items on one claim, with dates of service that are before and after the October 1, 2014, deadline, you may have to split those into two claims: one claim utilizing ICD-9 diagnosis codes for dates of service provided before October 1, 2014, and another claim using ICD-10 diagnosis codes for dates of service on or after October 1, 2014. You should check with each of your payers and understand their specific instructions.

Some trading partners may request that ICD-9 and ICD-10 codes be submitted on the same claim when dates of service span the compliance date. Trading partner agreements will determine the need for split claims.

Example of a split claim

Here's an example of a split claim: A patient has an appointment on September 27, 2014, and is diagnosed with simple chronic bronchitis. He returns for a follow-up appointment on October 3, 2014. In this case, a practice will submit a claim based on documentation as follows:

- **September 27, 2014: Use ICD-9 (491.0 Simple chronic bronchitis)**
- **October 3, 2014: Use ICD-10 (J41.0 Simple chronic bronchitis)**

Is your vendor prepared?

Since you will be utilizing both ICD-9 and ICD-10 codes until all of your September 2014 claims are submitted, make sure that your systems, third-party vendors, billing services, and clearinghouses can handle both ICD-9 and ICD-10 codes.

Ask your vendors the following questions:

- **What are your instructions in regard to ICD-9 and ICD-10 coding for submitting a claim for dates of service prior to October 1, 2014, and after October 1, 2014?**
- **What are your instructions in regard to ICD-9 and ICD-10 coding for a continued hospital stay where a patient is admitted on September 27, 2014 and discharged on October 3, 2014?**
- **How long will your system accept ICD-9 codes after October 1, 2014?**
- **When reviewing my medical record, will you translate ICD-9 and ICD-10 for appropriate review?**
- **How long will I be able to appeal a record containing an ICD-9 code?**

All offices need to be prepared, as the Centers for Medicare and Medicaid Services has given no indication that they are pushing back the October 1, 2014 deadline. So take appropriate steps now.

Q: WILL THERE BE CURRENT PROCEDURAL TERMINOLOGY (CPT) CODE UPDATES AS A RESULT OF ICD-10 BEING ROLLED OUT THIS YEAR?

We want your questions on coding and ICD-10. Send them to *medec@advanstar.com*.

Coding Insights

A: While there are going to be minimal changes to the ICD-9-CM codes in 2014, there are a number of changes to the Current Procedural Terminology (CPT) codes.

Remember that International Classification of Diseases, 10th edition, Clinical Modification (ICD-10-CM) does not affect CPT codes, so the code "freeze" in 2014 is for ICD-9 codes only.

The 2014 CPT Manual will include a total of 329 changes, including 175 new codes, 107 code descriptor revisions, and 47 CPT code deletions.

CPT Changes

The following are the highlights:

E/M CODES: There will be four new Evaluation and Management (E/M) codes for interprofessional telephonic/internet assessment and management services.

CARDIOLOGY: The cardiology section will include 19 new cardiology procedures, including five new peripheral stenting codes, eight new CPT codes for fenestrated endovascular aorta repair (FEVAR), and four new CPT for vascular embolization or occlusion.

GASTRO: The gastrointestinal section has the most changes, which include 26 new endoscopy codes, more than 40 revisions to code descriptors, and multiple deleted codes.

ELBOW/SHOULDER: The elbow and shoulder prosthesis section is reorganized in the musculoskeletal chapter. Additionally, three new codes are added to distinguish foreign body removal from removal of a prosthesis.

NERVOUS SYSTEM: The Nervous System section includes eight new codes that will replace the chemodenervation codes.

INTEGUMENTARY: In the Integumentary System section, a new code has been added for image guided fluid collection, drainage of a catheter.

This new code will replace several throughout the 2014 CPT book.

BREAST: In addition, 14 codes will be added for new biopsy codes in the Breast section.

Q: WE HEARD MEDICARE WOULD NOT PERFORM ICD-10 CLAIM TESTING, BUT NOW WE HEAR THEY WILL TEST CLAIMS. CAN YOU PROVIDE ANY INFORMATION TO CLEAR UP THIS CONFUSION?

A: Due to the recent issues surrounding the implementation of Healthcare.gov, the Centers for Medicare and Medicaid Services (CMS) has reversed its decision to test claims. According to MLN Matters® MM8465, CMS will conduct a national ICD-10 code set testing week, March 3 through March 7, 2014, for current direct submitters (providers and clearinghouses).

CMS HAS REVERSED ITS DECISION TO TEST CLAIMS. CMS WILL CONDUCT NATIONAL ICD-10 CODE SET TESTING FROM MARCH 3 THROUGH MARCH 7 FOR DIRECT SUBMITTERS.

The testing week will help you prepare for the ICD-10 transition by giving trading partners access to the Medicare Administrative Contractors (MACs) and Common Electronic Data Interchange (CEDI) for testing with real-time help desk support.

The event will be conducted virtually, and registration is required. You should contact your local carrier for specific information regarding registration.

Breaking down the process of claims testing

Here's what you can expect during testing:

- **Test claims with ICD-10 codes must be submitted with current dates of service (i.e. October 1, 2013 through March 3, 2014), since testing does not support future dated claims;**
- **Test claims will receive the 277CA or 999 acknowledgement as appropriate, to confirm that the claim was accepted or rejected in the system;**
- **Testing will not confirm claim payment or produce remittance advice; and**
- **MACs and CEDI will be staffed to handle increased call volume during this week.**

Contact your vendors to ensure that they will be ready for CMSs testing week.

*Answers to readers' questions were provided by **Renee Stantz**, a billing and coding consultant with VEI Consulting Services in Indianapolis, Indiana. Send your ICD-10 and coding questions to **medec@advanstar.com**.*

Practical Matters

PATIENT FEEDBACK CAN HELP IMPROVE HEALTHCARE DELIVERY

by **JUDY BEE** *Contributing author*

Businesses are obsessed with gathering customer feedback to improve the experience. It's the new norm, and medical practices are no exception. Remember that collecting patient opinions about your practice is the first step, and using the information to improve your service is another matter entirely.

FEEDBACK about your practice can come from many sources. The trick is to create processes to gather and assess these comments regardless of whether it came from an internal survey or an online review.

One of the simplest ways to start gathering this kind of information is by interviewing your front desk and phone staff. After all, they typically are the first to hear the praise and the complaints about the practice.

Patient surveys are another excellent instrument to gather information. We use a simple, short survey that can be given out in the office and returned by mail or dropped in a locked box in the reception area.

The categories of topics fall into Availability (on the phone, for appointments, and email) and Affability (how easy are you to deal with?). We picked up a few tips that help the return and the quality of information.

Keep the survey simple: Ask no more than 10 questions. Pay close attention to the survey that has all excellent marks except one. It tells you that the question hit a nerve, and that the patient stopped to think before responding.

Ask the physicians to hand out the survey to patients, color-coded by physician seen.

If you know you have a problem—long waits on hold, robot phone answering that confuses people, long waits in the office for an appointment—work to find a solution, and don't repeatedly ask for feedback.

For example, if the problem is patients on hold too long, take the robot off the first line of answering, and hire another operator who can handle two lines at a time. Use the robot only when all the incoming lines and operators are engaged. One person can handle two lines and give reasonable service.

Track the number of calls answered by the robot, and the number of call backs required because the patients gave up. Then survey the patients to ask how its going, how long they have to wait on the phone and how courteous the operators are.

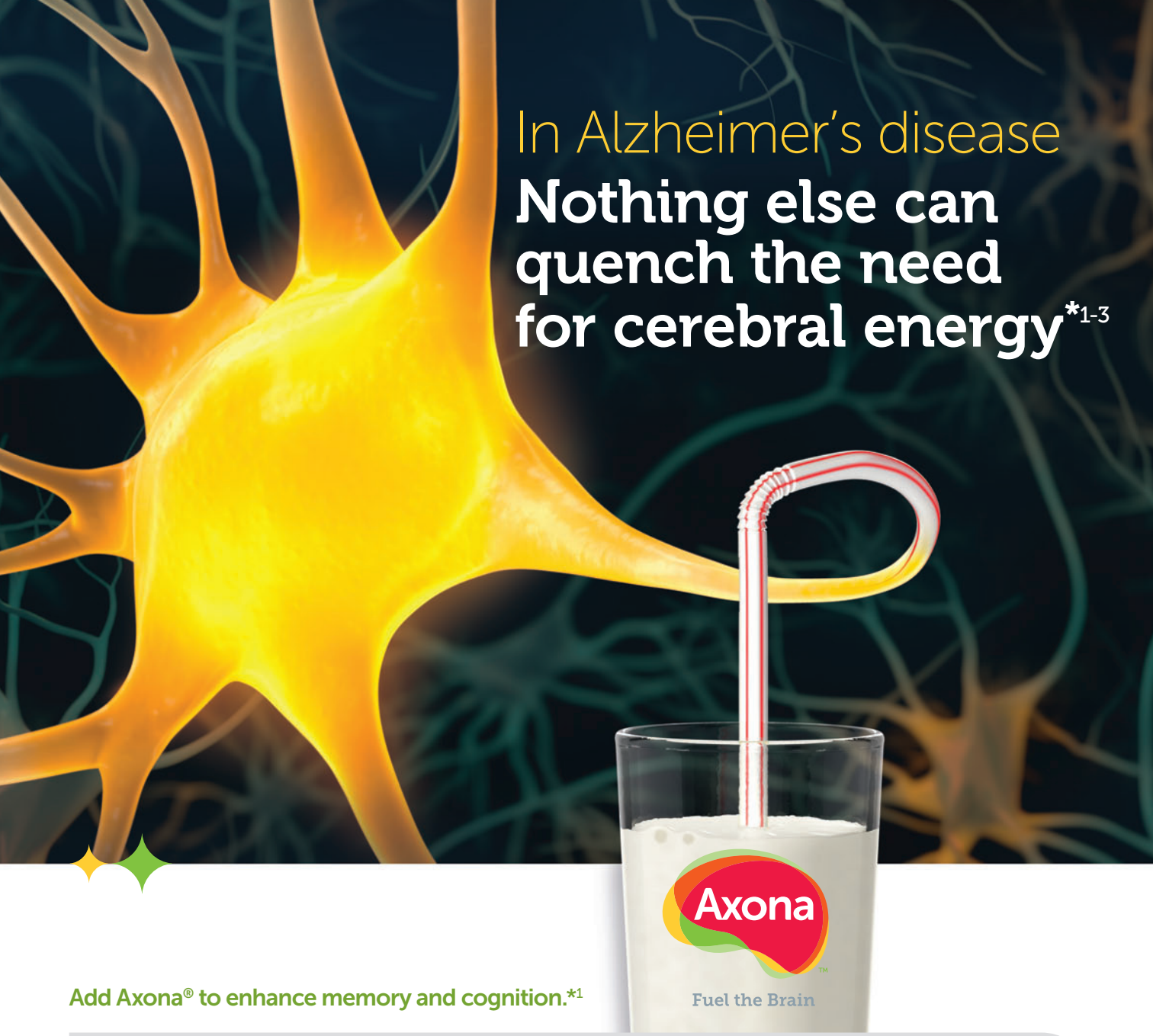
The most consistent complaint about office practice is waiting too long in the office. Our gold standard is that you see the patient in the exam room within 20 minutes of the appointment time 80% of the time. So, tell patients that they should plan on spending about an hour in the office or, even better, when they can expect to leave. Track the time-in and time-out for every patient and measure your performance all the time.

Improving service, communication, and satisfaction takes more than asking, "How are we doing?" Asking about service with no evident attempt to improve it just irritates patients and sends the wrong message. The goal of gathering feedback is to improve your delivery and efficiency, so focus on ways it can help your practice. ◘

@ DOWNLOADABLE RESOURCES

Download a sample patient survey at:
medicaleconomics.com/patientsatisfaction

Judy Bee *is a practice management consultant with Practice Performance Group in La Jolla, California. Send your practice management questions to* ***medec@advanstar.com****.*



In Alzheimer's disease
Nothing else can quench the need for cerebral energy*[1-3]

Add Axona® to enhance memory and cognition.*[1]

- Only Axona addresses diminished cerebral glucose metabolism (DCGM) — a crucial aspect of AD[1-3]
- Only Axona safely supplies effective levels of ketone bodies to target DCGM*[1,3]
- **Add what's been missing from Alzheimer's disease therapy**

Find out more about Axona and how you can help your patients today at www.about-axona.com/hcp.

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

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

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

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

References: 1. Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond).* 2009;6:31. **2.** Cunnane S, Nugent S, Roy M, et al. Brain fuel metabolism, aging, and Alzheimer's disease. *Nutrition.* 2011;27(1):3-20. **3.** National Institute on Aging. Alzheimer's disease [fact sheet]. http://www.nia.nih.gov/sites/default/files/alzheimers_disease_fact_sheet_0.pdf. Reprinted September 2012. Accessed June 4, 2013.

Accera

Legally Speaking

FIRING A PATIENT: WHEN IT'S NEEDED AND HOW TO HANDLE IT CORRECTLY

by **BARRY B. CEPELEWICZ, MD, JD** *Contributing author*

Most physicians have run into troublesome patients they would like to remove from their patient panels. They might be combative, unrealistic in their demands, or just unwilling to adhere to any of your health recommendations. While your patients are free to terminate their relationship with your practice at any time, with or without notice, and for any reason, you cannot necessarily do the same. Why?

PHYSICIANS HAVE an ethical duty to promote the continuity of their patients' care. So you need to follow some basic guidelines when terminating a patient, or you risk the patient filing a complaint against you for abandonment or medical malpractice; the state department of health finding you guilty of professional misconduct; and/or a third-party payer alleging that you breached its participating provider agreement.

While the guidelines discussed below are relatively straightforward, it is surprising to see how many physicians fail to follow them and subsequently find themselves embroiled in audits, investigations or litigation that consume significant time and financial resources.

What reasons justify termination?

For the most part, any reason is justified, as long as it is legal. You cannot terminate a patient for reasons based on age, color, disability, gender, national origin, religion, sexual orientation, or any other discriminatory reason; but typical reasons include the patient being non-compliant (such as for not following your treatment plans and recommendations); being verbally or physically abusive; or not paying his or her bills.

When do you terminate the patient?

The decision to terminate should be the physician's, and it should be determined on a case-by-case basis. If the patient is in stable condition and any reasonable delay caused by the transfer of care would not adversely impact the patient's care, then termination is appropriate. However, if the patient is in an acute or critical stage of his or her care or requires continuous treatment, then you may have to delay the termination.

For example, if you are in the middle of working up the patient, or the patient underwent an operation a few days earlier, or if the patient is in her last trimester of pregnancy or has a complicated pregnancy, or you are the only physician within a reasonable driving distance who can treat the condition, then you may need to wait until a more suitable time when the patient can be transferred (provided that another provider is available to accept the patient). Moreover, if you are a participating provider with a third-party payer, you should review the agreement and the payer's policies to determine what process, if any, must be followed when terminating a patient.

Should you discuss termination with the patient?

If the patient is verbally or physically abusive, you may need to terminate the patient immediately. However, for other situations, a meeting could be beneficial.

First, it should reduce the patient's ability to legitimately claim that he or she was surprised by the termination notice. Second, you need to discuss the termination process and the need for the patient to seek continued care and treatment (including medications). Third, perhaps when you inform the patient that you are considering termination it will motivate the patient

Legally Speaking

to become compliant. You might even learn that the non-compliant behavior was based on the patient's misunderstanding regarding the treatment he or she received from you or your staff and such information could prove valuable in terms of how you run the practice.

Any discussions you have with the patient should be witnessed (for example, by the office manager) and memorialized in detail in the medical record. Even if you decide not to have a meeting or a meeting is not possible, you need to memorialize the reasons for termination.

If the patient is non-compliant you should begin recording the non-compliant behavior as soon as possible; do not wait until after you make the decision to terminate.

The termination process

You need to send the patient a written notice of termination.

If the reason for termination is for non-compliance or failure to pay, you could mention those reasons in the letter, but otherwise it's best not to specify the reasons because it might make an already uncomfortable situation even worse (the reasons, however, should be memorialized in the patient's record).

DON'T REFER A TERMINATED PATIENT TO ANOTHER PHYSICIAN. INSTEAD, SEND HIM OR HER TO A STATE MEDICAL SOCIETY FOR A LIST OF PHYSICIANS IN THE AREA.

The letter should provide an effective date of termination and offer the patient at least 30 days to find an alternate provider during which time you will continue to treat the patient for urgent issues. This time period may need to be extended depending on the patient's condition or availability of alternate care, or if a third-party payer contract requires otherwise.

The patient should be advised to seek continued care and informed of the consequences if he or she fails to follow your directions. You should also offer to provide a copy of the record (not the original) to the new physician and include with your termination notice an authorization form for the patient to sign. While it's up to you whether you charge the patient for copying the records (many providers choose not to bill the patient), under no circumstance should you withhold the patient's records because the patient owes you an outstanding balance.

Referring the patient to specific physicians is generally not a good idea. Why would you refer a problematic patient to a colleague of yours?

Also, if the patient is not satisfied with your referral, the patient could blame you. Instead, refer the patient to the county or state medical society for a list of physicians in the patient's geographic area. If you are part of a larger practice, the termination notice must be clear that the patient is being terminated from the practice, not just you (if that's the case).

The letter should be sent by certified mail, return receipt requested, and a copy of the letter as well as the return receipt should be placed in the patient's record. If the patient refuses to accept the certified mail and it is returned to you, you should retain the original mailing as part of the record.

Keep staff informed about termination decisions

Lastly, make sure you notify your staff about the termination so they don't inadvertently schedule the patient for another appointment after the effective date of termination, because that could result in a determination that the physician-patient relationship was extended.

While it's never easy to terminate a patient, following these guidelines in a consistent manner should enable you to do what's best for you, your practice, and even your patient.

@ MORE RESOURCES

Explore more legal topics that can benefit your practice at MedicalEconomics.com:

Severing payer contracts: How to leave a health plan
http://bit.ly/1hZ0ot4

Barry B. Cepelewicz, MD, JD, *is a partner at Garfunkel Wild, P.C. in Great Neck, New York. Send your practice management questions to* ***medec@advanstar.com****.*

Patient Safety Organizations can help providers improve performance and results

by **ALICE G. GOSFIELD, JD** *Contributing author*

HIGHLIGHTS

01 Patient safety data provided to Patient Safety Organizations (PSOs) is protected by law from legal discovery and publication.

02 While PSOs have been focused on hospitals, physician practices can benefit from using PSOs to scrutinize the quality of care they provide in a legally protected setting.

All physicians will have to change some aspects of their clinical processes within their practices to demonstrate improved value. The first step toward change is to generate internal performance data. This data is essential to improving clinical processes to deliver safer, better, and more valuable medical care. But providers who engage in this self-scrutiny will have to generate highly sensitive data about their own performance, data that may reveal instances of sub-optimal care.

That's where Patient Safety Organizations (PSOs) can benefit your practice. Providers can report safety and quality data to PSOs that is protected from legal discovery and publication. In return, PSOs can be a source of confidential advice and data analysis for physicians seeking to understand and improve their healthcare delivery.

Congress passed the Patient Safety and Quality Improvement Act (PSQIA) in 2005 in response to the Institute of Medicine study, "To Err Is Human," which provided a comprehensive look at ways the healthcare system can reduce preventable medical errors. The law provides two sweeping protections to "patient safety work product" reported to and analyzed by PSOs.

LEGAL PROTECTIONS FOR PATIENT SAFETY DATA

The law creates a privilege to protect information created during the reporting and analysis of patient safety events, which is produced within a provider's patient safety evaluation system and reported to a PSO.

The definition of a provider covered by the PSQIA is broad, including virtually all clinicians licensed under state law to deliver healthcare services. Although the law imposes no obligation on the PSO to analyze the data reported to it, a purpose of the law was for PSOs to analyze and report back to providers on what could be learned from the submitted data. The two protections apply even if no analysis is reported to the submitters.

Under the privilege, protected information cannot be introduced in any federal, state, local, or tribal civil, criminal, or administrative proceeding, and cannot be subject to disclosure under the Freedom of Information Act or similar laws or admitted as evidence in any proceeding. There are very limited exceptions.

Data developed within a patient safety evaluation system and reported to a PSO must be kept confidential. It may not be disclosed except within the PSO system in accordance with specified conditions and sub-

Are your patients making frequent stops to re-dose for OA pain relief?

BAYER

OA=osteoarthritis.

Only* *ALEVE*® offers the route to 24-hour relief with just 2 doses

Because OA pain can last many hours and days, patients using Extra Strength Tylenol® or Advil® have to re-dose more often if pain persists.

Compare the dosing advantage of *ALEVE* with other OTC brands†

	HOUR 0	HOUR 6	HOUR 12	HOUR 18	HOUR 24
ALEVE (naproxen sodium) 220 mg/tablet	1st dose		2nd dose		
Extra Strength Tylenol (acetaminophen) 500 mg/tablet		1st dose	2nd dose	3rd dose	X‡
Advil (ibuprofen) 200 mg/tablet		1st dose	2nd dose	3rd dose	4th dose

Used according to label directions, *ALEVE* is safe and well tolerated

To order *ALEVE* samples and learn more about naproxen sodium, visit www.alevepro.com.

OTC=over-the-counter.

*Among OTC brands.

†Based on minimum label dosing for 24 hours if pain persists.

‡Reflects latest OTC label dosing for Extra Strength Tylenol for adults and children 12 years and older—maximum daily dose reduced from 8 pills (4 grams) to 6 pills (3 grams) with a dosing interval change from every 4-6 hours to every 6 hours unless directed by a doctor.

Tylenol is a registered trademark of The Tylenol Company.
Advil is a registered trademark of Wyeth LLC.

RECOMMEND *ALEVE*
Strong on pain.
Long on relief.

BAYER

> "Providers can report safety and quality data to PSOs that is protected from legal discovery and publication. In return, PSOs can be a source of confidential advice and data analysis for physicians seeking to understand and improve their healthcare delivery."

ject to some extremely limited exceptions. The privilege is enforced by tribunals engaged in proceedings where a provider asserts the protection. The confidentiality provisions are enforced by the Office of Civil Rights of the Department of Health and Human Services, which also enforces Health Insurance Portability and Accountability Act violations. Compliance with the PSO rules is enforced by the Agency for Health Care Research and Quality (AHRQ).

Almost all of the literature to date about PSOs and their implementation has been focused on hospitals. The value of this law to physician practices has been underappreciated.

Here are five steps physicians should take to protect themselves while also working to improve the quality of care they provide.

1/ Develop a patient safety evaluation system

A Patient Safety Evaluation System (PSES) is defined as the collection, management or analysis of information for reporting to or by a PSO. It is a provider-specific creation. There is no required format.

To claim the protections of the law, data must be developed specifically within the identified system and must be reported to a PSO. Although the protections apply whenever data is managed within the evaluation system, it would be hard to have a system without a policy that identifies the processes, activities, physical space, and equipment (e.g., storage, electronic directories) which comprise the system.

The policy should identify which categories of personnel need access to Patient Safety Work Product (PSWP), these include:

- any data, reports, records, memoranda, analyses (such as root cause analyses), or
- written or oral statements (or copies of this material) that could improve patient safety, healthcare quality or healthcare outcomes.

The definitions of patient safety work product and patient safety activities are broad. They include almost everything a physician practice would undertake to improve its performance.

The policy should identify how reports will be made to a PSO and how PSWP will be managed, marked and isolated from other business records. This is similar to how hospitals identify and manage peer review data, but the protections in this system are far broader and easier to assert, and they trump state laws.

2/ Identify and contract with a PSO

There are 77 'listed' PSOs on the AHRQ website. Some are components of providers. Others have a specific focus, such as on medication practices, emergency medicine, anesthesia, breast cancer, or behavioral health. Some are offshoots of state hospital associations. Others have a broader focus. The American College of Physicians has a listed PSO.

PSOs are private organizations. Typically, they charge providers for their services. Because most of their interactions have been with hospitals, their fees to physicians will likely be negotiable. They become business associates to the providers who report to them. AHRQ is supposed to develop common formats for reporting to facilitate further reporting by PSOs to a national clearinghouse of data, but so far they have common formats only for hospitals and skilled nursing facilities.

This should not deter physicians from pushing for protection of their information by reporting to a PSO. The contracts can be

relatively simple, customized yet straightforward.

3/ Learn about physician activities that generate patient safety problems

While more is known about hospital patient safety issues, there is increasing data that demonstrates that physician practices are a source of patient safety concerns as well. Missed diagnoses, unreported abnormal laboratory studies, medication management—particularly for patients taking more than five drugs—and patient misunderstanding of instructions have all been cited.

The Medical Group Management Association, with the Institute for Safe Medication Practices and the Health Research and Education Trust, developed a "Physician Practice Patient Safety Self Assessment Tool" that focuses on some of these issues (www.mgma.com/pppsa/).

AHRQ has also published a Toolkit for Improving Office Testing Processes (www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/ambulatory-care/office-testing-toolkit/) because 40% of physician/patient encounters entail diagnostic testing.

Many of these problem areas are part of the value proposition ➔48

States with Patient Safety Organizations

There are **77** listed PSOs in **29 states** and the **District of Columbia**. Some states have more than one PSO.

- **Alabama:** Healthcare Improvement PSO, Inc.
- **Arizona:** QA STATS LLC
- **Arkansas:** American Data Network PSO
- **California:** California Hospital Patient Safety Organization (CHPSO); Quantros Patient Safety Center
- **Connecticut:** Patient Safety Services, LLC; QA to QI, LLC
- **District of Columbia:** American College of Physicians Patient Safety Organization; Open Safety Foundation; Pascal Metrics Inc.; and Safe Pediatric Healthcare PSO
- **Florida:** Baptist Health Patient Safety Partnership; Medical Peer Review Resource, LLC; MEDNAX PSO, LLC; Patient Safety Organization of Florida (PSOFlorida); Quality Circle Heathcare Inc.; Strategic Radiology Patient Safety Organization, LLC; UM-JMH Center for Patient Safety PSO
- **Georgia:** Piedmont Clinic, Inc.
- **Illinois:** Anesthesia Quality Institute; Chicago Breast Cancer Quality Consortium; Clarity PSO; Society for Vascular Surgery Patient Safety Organization, LLC; Symbria SAFE; The Midwest Alliance for Patient Safety; The Patient Safety Research Foundation, Inc.; and UHC Safety Intelligence
- **Kansas:** Child Health Patient Safety Organization, Inc. (Child Health PSO)
- **Kentucky:** Kentucky Institute for Patient Safety & Quality
- **Louisiana:** Schumacher Group Patient Safety Organization, Inc.
- **Maine:** ABG Anesthesia Data Group, LLC; Fides, LLC; and Specialty Benchmarks PSO
- **Maryland:** AABB Center for Patient Safety; Maryland Patient Safety Center, Inc.
- **Massachusetts:** Academic Medical Center (AMC) PSO; Fresenius Medical Care PSO, LLC
- **Michigan:** Emergency Consultants PSO, LCC; MHA Patient Safety Organization; and Michigan Surgical Quality Collaborative
- **Minnesota:** Emergency Medical Error Reduction Group
- **Missouri:** Ascension Health Patient Safety Organization; Missouri Center for Patient Safety
- **Nebraska:** Nebraska Coalition for Patient Safety
- **New Jersey:** New Jersey Hospital Association Health, Research & Educational Trust Institute for Quality & Patient Safety
- **New York:** MCIC Vermont, Inc. PSO
- **North Carolina:** Carolinas HealthCare System Patient Safety Organization; Carolinas Rehabilitation—Patient Safety Organization; NC Quality Center PSO
- **Ohio:** EMP Patient Safety Organization; Ohio Patient Safety Institute
- **Pennsylvania:** American Medical Foundation Patient Safety Organization; Cassatt Patient Safety Organization; Chart Institute LLC; Close Care Gap, PSO; ECRI Institute PSO; Institute for Safe Medication Practices (ISMP); McGuckin Methods International, Inc.; Society of Hospital Medicine PSO
- **Rhode Island:** The PSO Advisory, LLC
- **South Carolina:** Verge Patient Safety Organization
- **Tennessee:** CHS PSO, LLC; Premerus PSO, LLC; PsychSafe; TeamHealth Patient Safety Organization; Tennessee Center for Patient Safety
- **Texas:** PSO Services Group; Texas Center for Quality & Patient Safety; Texas Patient Safety Organization, Inc.; The Texas A&M Health Science Center Rural and Community Health Institute; WiMED, Inc.
- **Virginia:** Alliance for Patient Medication Safety; Virginia PSO; Wake up Safe
- **Wisconsin:** Center for the Assessment of Radiological Sciences PSO

Source: Agency for Healthcare Research and Quality

Work fast, easy and smart – with less hassle. Ranked #1 by Medical Economics, Cerner Ambulatory offers solutions that fit your balance sheet, from one of the world's leading health companies. The power and simplicity of Cerner's pioneering new practice management solution, fueled by the *same* data set as the EHR, means clinical and financial information about the person are unified. No interfaces, less data reconciliation. Work how you want, where you want. That means more quality time with your patients and family. A healthy life.

Engage with other physicians, providers and staff like you at HIMSS, Booth #6965 or visit us anytime at

www.cernerambulatory.com/why

Cerner

cernerambulatory@cerner.com | 800.927.1024

"If more physicians engaged in reporting to a PSO on similar topics, the PSO would be in a position to receive more meaningful data and produce more significant analysis. In essence, the PSO can become the vehicle for an informal network for sharing important patient safety information that will remain protected even as it is made available within the network."

➔46 as well, since failures of patient safety inevitably lead to increased costs as well as diminished quality.

4/ Think about information that can support clinical integration within your practice

For many physician groups, the work of clinical integration has been difficult because of an inability to envision what their end result might be. In a "Clinical Integration Self Assessment Tool v 2.0" (www.uft-a.com/CISAT.pdf) 17 attributes of a clinically integrated practice context have been identified and three scenarios for each—along a continuum of evolution to fully committed and capable of producing measured value with improved quality—are described. That tool can be a starting point for thinking about what to change to demonstrate more value.

Standardization is a strong theme among the attributes, including standardizing clinical processes in accordance with guidelines and measuring conformity with those guidelines. The selection and adoption of the guidelines, and the results of measurement and actions taken in response, all qualify as patient safety activities, and the data the activities produce are PSWP.

Adopting compensation models in the group to support and motivate improved quality and efficient use of resources, then measuring performance to determine if incentive payments will be awarded, also meet the standards to qualify as patient safety activities.

The point is that while patient safety challenges in the form of avoiding mishaps ought to be addressed by physician groups, far broader initiatives will also merit the protections that the PSQIA has made available.

5/ Encourage peers to report to the same PSO on the same issues

For small physician groups, the work of clinical integration is daunting and the ability to analyze and make changes is difficult because of the lack of resources.

If more physicians engaged in reporting to a PSO on similar topics, the PSO would be in a position to receive more meaningful data and produce more significant analysis. In essence, the PSO can become the vehicle for an informal network for sharing important patient safety information that will remain protected even as it is made available within the network.

There is no protection for any of the data that will be generated to do the hard work of clinical integration and improvement under any other laws. Almost no state peer review protection act protects data within a physician practice, and there is no other federal confidentiality law or pre-emptive privilege as exists in the PSQIA.

IMPROVING PERFORMANCE

The PSQIA was enacted to bolster efforts to improve the quality and safety of health care. The passage of the Affordable Care Act and other reform efforts has only bolstered the mandate to do so, while saving money in the process.

Physicians are principal actors in deciding whether healthcare is good, safe, and efficient, but the work of improving performance is difficult and demanding. By developing and using their own patient safety evaluation systems to report to PSOs, physicians can enhance their position by feeling comfortable in developing robust, actionable information on they can use to improve their performance. ■

PERSPECTIVE

MOC must go: One physician's viewpoint

A critic of Maintenance of Certification explains why the costly program burdens physicians

by **PAUL M. KEMPEN, MD, PHD**

The Maintenance of Certifcation (MOC) program's expense and time commitments continue to grow, producing greater complexity and more headaches for the nation's physicians.

The American Board of Medical Specialties (ABMS) lobbied Congress to pass legislation linking Board Certification to Medicare and Medicaid reimbursement payment. The Physician Quality Reporting System (PQRS) led the American Board of Anesthesiology (ABA) to become a "provider" in 2013, even though in 2011 the ABA publicly stated that "The ABA does not believe that the additional requirements for the MOC bonus will have a sufficient impact on patient care, nor will the reimbursement bonus justify the additional time and resource burden on its diplomates. Accordingly, the ABA does not intend to submit an application for CMS [Centers for Medicare and Medicaid Services] approval of an ABA MOC-PQRS program in 2011."

Just weeks ago the ABA gave notice that it will become a new PQRS-MOC provider, under multiple pressures including the impending requirement for providers to register by the end of 2013 so that diplomates can avoid the 1.5% and 2% penalties looming in 2014 and 2015, respectively.

As a concerned physician, I have followed the multiple requirements for this MOC program and clearly noted that leaders of the ABMS certification industrial complex themselves have been reluctant to subscribe to the corporate policy of certification they propose, except under duress.

Simulation training has been dictated as a core and primary MOC requirement in my specialty. All anesthesiology certifications have become "limited" to 10-year intervals since 2000, mandating absolution of simulation for the 1,500 anesthesiology resident graduates each year since 2010.

The leadership in anesthesiology recently disclosed in the ASA newsletter that although these 4,500 "new millennium" graduates are all due to recertify and must have completed simulation by 2010, in the first two years of the MOC-Anesthesiology (MOCA) simulation requirement, only 583 ABA diplomates completed courses at 27 ASA centers. By the end of 2013, only 1,600 had done so.

With over 50,000 ASA members, and

Speak Out

Do you support MOC? Do you oppose the program? Medical Economics wants to hear from physicians about this controversial issue.

Share your thoughts by e-mailing them to:

medec@advanstar.com

> Does the American public really want to see physicians priced out of the market due to arbitrary constraints by corporations offering nothing of real value or improvement in care, thus further facilitating healthcare provided by the least educated midlevel providers to contain costs?

35,000 practicing anesthesiologist in the United States, the fact that only 583 physicians submitted to MOCA simulation in the first two "mandatory years", reaching only 1,600 after the years (0.1% participation,) is hardly a resounding vote of approval for MOCA.

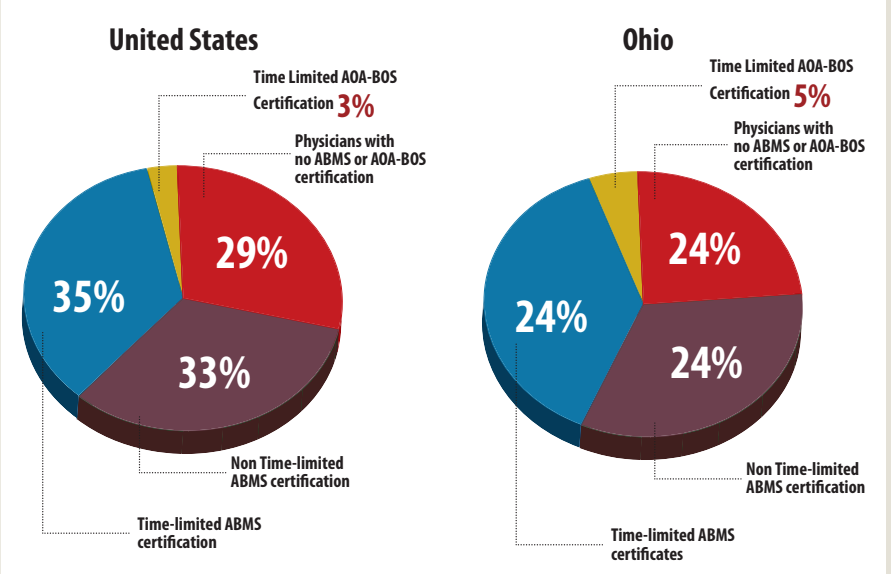
Recently, four of my colleagues underwent this simulation training. None indicated there was reasonable value regarding the six CME credits at a discounted cost of $1,200 (the typical cost is $2,000) to our department's membership. They were required to respond in the exit survey indicating three things they had learned, and would only receive these MOCA® credits after an interval to affirm that the chosen "practice improvements" had been instituted.

The "survey process" itself appears geared to reaffirm the "value" of this simulation as just one more coercive technique.

MOC PARTICIPATION STATISTICS

In December 2012 I requested from CMS, via the Freedom of Information Act, a summary of all payments for the PQRS-MOC program (see table on page 55.) It was revealing to see that in 2011, only 1,683 physicians signed up for the program, and that only 964 were actually paid a cumulative $959,042.94 in a total of 458 payments. This amounts to an average payment per physician of $994.86, with multiple phy- ➔52

ABMS and AOA Re-Certification Estimates



Source: State Medical Board of Ohio, 2011

GET READY FOR ICD-10
OCT 1, 2014

2014 COMPLIANCE DEADLINE FOR ICD-10

The ICD-10 transition is coming **October 1, 2014**. The ICD-10 transition will change every part of how you provide care, from software upgrades, to patient registration and referrals, to clinical documentation and billing. Work with your software vendor and billing service now to ensure you are ready when the time comes. ICD-10 is closer than it seems.

CMS can help. Visit the CMS website at **www.cms.gov/ICD10** for resources to get your practice ready.

CMS ICD-10
Official CMS Industry Resources for the ICD-10 Transition
www.cms.gov/ICD10

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

sicians paid together under some corporate collaboration. ➔50

Given that there are more than 850,000 physicians in the country, state data obtained from the Ohio Medical Association (see graphs on page 50) shows that roughly one-fourth of all physicians have never become board certified, and PQRS-MOC participation is almost non-existent. The federal government is looking forward to a significant windfall reduction in payments to physicians under these conditions, once the penalty phase begins in 2015. The reduction in physician payments at 1.5% and 2% "penalties" for non-participation may total between $2.5 billion and $3.3 billion in 2015 and 2016, respectively.

'REGULATORY CAPTURE'

The PQRS-MOC program was conceived by the ABMS to secure enrollment of all physicians in the ABMS' MOC programs via "regulatory capture," which occurs when special interests co-opt ➔55

The components of maintaining certification

American Board of Medical Specialties

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

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

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

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

Osteopathic continuous certification

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

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

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

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

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

Report includes claims data for services rendered between 1/1/2011 and 12/31/2011, and processed into National Claims History by 2/24/2012. Report also includes final action data submitted via Registry and EHR for the 2011 PQRS program year.

MOC Physician incentive statistics

Number of participating Eligible Professionals (EP)	Number of EPs who earned MOC incentive	Total amount of MOC incentive	Number of payments
1,683	964	$959,042.94	458

Source: Centers for Medicare and Medicaid Services, December 2011 data

"It is time to stop the multiple ABMS "legacy organizations" from repackaging their products into an unproven, wasteful, unnecessary, and expensive yearly subscription payment requirement of all physicians. Taxpayers, as patients, will ultimately pay for this increased cost of doing business for physicians or simply suffer quality decline by receiving care from "cheaper" midlevel providers."

→52 policymakers or political bodies—regulatory agencies, in particular—to further their own ends.

Due to the increasing employment of physicians by hospitals, this regulatory capture may undermine the already tenuous fiscal stability of community hospitals, in particular.

The increased costs to physicians' practices will be carried by employer hospitals, facilitating the "dumbing down" of medical care via replacement of physicians with less expensive and less-educated midlevel providers, who for now are not required to undergo MOC, but are reimbursed by CMS.

Does the American public really want to see physicians priced out of the market due to arbitrary constraints by corporations offering nothing of real value or improvement in care, thus further facilitating healthcare provided by the least educated midlevel providers to contain costs?

The board certification process has never been validated as improving healthcare by outcome-based studies, serving instead more as an exclusive guild, yielding benefits to only those already enrolled. The ABMS recertification program is a multimillion dollar yearly expenditure of questionable value.

The fallacy of certification was openly admitted recently by the ABMS on its website: "FACT: ABMS recognizes that regardless of the profession—whether it is healthcare, law enforcement, education or accounting—there is no certification that guarantees performance or positive outcomes."

It is time to stop the multiple ABMS "legacy organizations" from repackaging their products into an unproven, wasteful, unnecessary, and expensive yearly subscription payment requirement of all physicians. Taxpayers, as patients, will ultimately pay for this increased cost of doing business for physicians or simply suffer quality decline by receiving care from "cheaper" midlevel providers.

Paul M. Kempen, MD, PhD, is an anesthesiologist at the Cleveland Clinic, in Cleveland, Ohio.

Money

When will Medicaid pay more?

While some states have raised Medicaid payments to physicians to match Medicare reimbursements, others lag behind

by **SCOTT BALTIC,** *Contributing author*

HIGHLIGHTS

01 Reports show Medicaid managed-care programs lagging behind enhanced fee-for-service payments.

02 Physician advocate groups are pushing to extend Medicaid parity for another two years beyond its planned expiration at the end of 2014.

The rationale behind the Affordable Care Act's mandate that Medicaid reimbursements for certain primary care services be increased to Medicare levels is simple: To help patients covered by Medicaid get better access to primary care by **boosting the payments to the physicians who provide it**. Research shows that Medicaid's low rates are a major reason why patients find it hard to see a physician.

WHILE PARITY'S purpose is simple, actually making it happen has been much more challenging. With the parity adjustment now past the halfway point in its current projected lifespan, it's fair to ask where things stand and what might happen when parity expires—if it actually does—at the end of this year.

The two biggest factors in health outcomes, says Reid Blackwelder, MD, FAAFP, president of the American Academy of Family Physicians (AAFP), are whether an individual has healthcare coverage and whether they receive regular medical care, typically from a primary care physician.

But a big obstacle for Medicaid patients has always been the Medicaid program's lower-than-Medicare reimbursements. Blackwelder points out that on average Medicaid pays only about two-thirds of what Medicare pays, though this varies from pre-existing parity in a

➔58

*Source: Carbonview Research – Employee Morale Survey

Brew a better workday.

Employees love Keurig. In fact, when offered Keurig Brewed® beverages, 87% of employees are more likely to be satisfied with their coffee at work.* After all, they'll be getting a gourmet cup of coffee at the touch of a button, with over 200 beverage varieties to choose from.

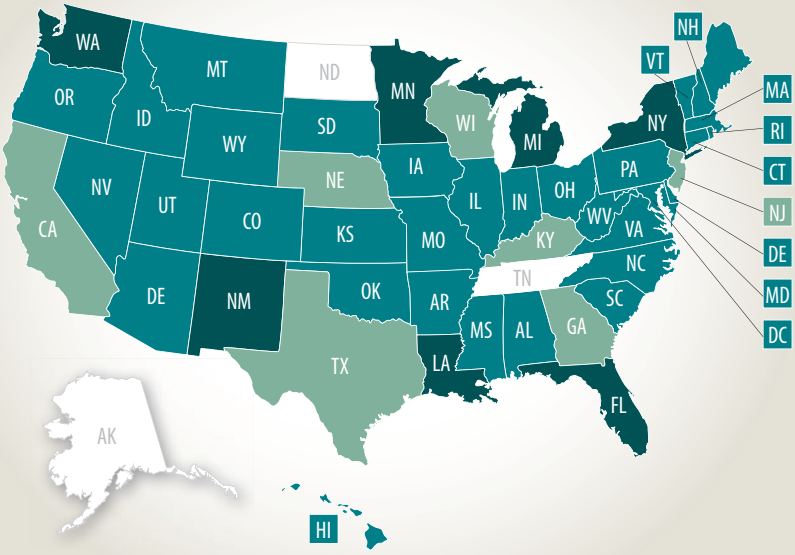
And that means a job well done.

Learn more
Keurig.com/healthcare

Brew the Love.™

KEURIG

Where Medicaid-Medicare parity stands: A breakdown of the 50 states



No managed care payments have started, but paying fee-for-service

No payment yet

Paying Fee-for-service

Note : **Alaska** is not participating.
North Dakota will experience a nominal increase.
Tennessee has no Medicaid fee-for-service program; the parity will affect managed care.

* Current as of 10/1/2013 AMA/AAFP Chapter survey.

Source: American Academy of Family Physicians, November 2013

➔56 couple of states (Alaska and Wyoming) to as little as one-third as much, in Rhode Island.

An August 2012 article in *Health Affairs*, by Sandra L. Decker of the Center for Disease Control and Prevention's National Center for Health Statistics, reported that in a 2011 survey, nearly one-third of office-based physicians said they were unwilling to accept new Medicaid patients. The survey also found that "Higher state Medicaid-to-Medicare fee ratios were correlated with greater acceptance of new Medicaid patients."

Other studies have also shown that reimbursement increases—along with other fixes, such as reducing administrative hassles—also increases physician participation and patient access in Medicaid, says Bob Doherty, senior vice president/governmental affairs and public policy at the American College of Physicians. He points to a September 2013 article in *Health Affairs*, which reported that despite concerns about Medicaid reimbursement rates, many of the physicians surveyed viewed caring for Medicaid patients as an important part of their mission.

As a result, these physicians said they struggled with serving the Medicaid population while keeping their own practices financially viable. One physician was quoted as saying, "We would accept more Medicaid patients if we could afford to do so."

Given what's at stake for both physicians and Medicaid patients, it's no surprise that the implementation of parity has been closely monitored by the medical profession.

Since pediatricians are so reliant on Medicaid and the Children's Health Insurance Program, Doherty says, the American Academy of Pediatrics (AAP) is closely tracking parity implementation.

> "What will happen if primary care physicians accept new Medicaid patients and parity ends? This worry is common among family practitioners with whom he has spoken, says Reid Blackwelder, MD, FAAFP, president of the American Academy of Family Physicians. "In a sense, they're doing this on trust."

And in September, the American Medical Association's Advocacy Resource Center polled its state societies about the implementation of the pay parity bump, he adds. At that time, several states (including California, Georgia, New Jersey, and Texas) had yet to begin payments, and in several others (including Florida, Michigan, New York and Washington) enhanced payments had started in fee-for-service, but not in Medicaid managed care.

A few states apparently were struggling with applying enhanced payments retroactively, while others appeared to be retroactively applying the enhancement in stages.

In early November, an AAFP report, based on a survey of the group's chapters, similarly found that Medicaid managed care programs were lagging behind enhanced fee-for-service payments. (See "Where Medicaid-Medicare parity stands: A breakdown of all 50 states," page 58.)

WHY DID IT TAKE SO LONG?

There are reasons, it turns out, why the rollout of Medicare-Medicaid parity has been delayed and why fee-for-service parity is well ahead of enhanced payments to Medicaid managed-care organizations.

For one, although parity became effective by law at the start of 2013, the CMS implementing regulations weren't finished until November 2012, much later than planned, "so even after the program starts, we're already behind," explains Kathleen Nolan, director of state policy and programs at the National Association of Medicaid Directors.

The rate increase sounds pretty straightforward in concept, but from a technical standpoint, "it's an incredibly complicated piece of legislation to implement," adds Tricia McGinnis, director of delivery system reform at the Center for Health Care Strategies.

Medicaid-Medicare parity, by the numbers

- Section 1202 of the Affordable Care Act mandates (essentially) that Medicaid reimbursements for primary-care services provided by a primary-care physician be paid at the rate for Medicare Part B. The increase applies to E&M and vaccination codes and is paid entirely from the federal budget.
- The adjustment is effective for calendar years 2013 and 2014, with retroactive payments to Jan. 1, 2013, as needed.
- Over the program's two years, the total amount estimated to be paid (all of it to physicians, the ACA specifies) is $11.8 billion, according to the Center for Health Care Strategies.

"WE WANT MORE PRIMARY CARE DELIVERED THROUGH MEDICAID. THE JURY IS STILL OUT ON WHETHER WE'RE GOING TO BE ABLE TO DO THAT."

— KATHLEEN NOLAN, DIRECTOR OF STATE POLICY AND PROGRAMS, NATIONAL ASSOCIATION OF MEDICAID DIRECTORS

"For a state, this has been an iterative process," says Nolan. She explains that first, a state had to submit its State Plan Amendment (SPA) relating to parity by March 31, 2013, a deadline that every state met. Then CMS had to review and approve all of the SPAs, after which the states paying Medicaid as fee-for-service could start to check physicians's self-attestations regarding their primary care qualifications.

That was the easy part.

It's no surprise that the managed-care side of Medicaid has been giving administrators fits, Nolan and McGinnis agree. Indeed, from their descriptions of how tricky it is for states to calculate equivalence between Medicare and Medicaid payments, it sounds like trying to figure out how many apples it takes to equal a dozen tomatoes.

Calculating the translation from Medicare fee-for-service dollars into capitated Medicaid dollars has been "a very complex process," McGinnis says.

And it only adds more complications, Nolan explains, that Medicaid managed-care organizations generally consist of a mix of for-profit, nonprofit, and Medicaid-only providers and major health insurers, with multiple plans and contracts.

The bottom line, she says, is that "We have to get the money out the door, but we have to put an effective, useful program in place."

In general, Nolan says, some of the initial delays were intentional, because the states did not want to move forward on their own in handling Medicaid parity until CMS issued the necessary regulations. It might have cost some time, she concedes, but it prevented the possibility that a state might issue administrative requirements, then have to change them and subject physicians and practices to additional paperwork.

WILL PARITY BE EXTENDED?

Now that the implementation of parity seems to finally be in its home stretch, attention is likely to focus on its results, not just in helping primary care physicians stay financially solvent, but in increasing Medicaid patients' access to primary care.

The states are generally optimistic that primary care physicians will indeed either take on Medicaid patients, or take on more of them, says McGinnis.

Blackwelder, however, expresses concern over what will happen if primary care physicians accept new Medicaid patients and parity ends. This worry is common among family practitioners with whom he has spoken, Blackwelder says. "In a sense, they're doing this on trust."

The potential answer is to maintain parity for at least a while longer.

In late November, the AAFP, AAP, American College of Physicians, American Congress of Obstetricians and Gynecologists, and American Osteopathic Association wrote to the chairs and ranking members of the U.S. Senate Committee on Finance and the U.S. House of Representatives Committee on Energy and Commerce. The associations urged that parity be extended for at least another 2 years, noting that the slow start-up of the parity adjustment, "combined with a lack of assurance that it will be extended beyond 2014[,] has not allowed ... enough time to demonstrate the program's effectiveness in improving access" to physician services.

The letter also prodded Congressional leaders to include ob-gyns in the parity extension. It pointed out that as of 2010, "Medicaid programs in 30 states and the District of Columbia recognized ob-gyns as primary care providers in their managed care organizations" and noted that nearly half of births in the United States are currently financed by Medicaid.

With all the complications and delays, and uncertainty about parity's future, says Nolan, it's easy to lose sight of that simple goal that Section 1202 of the ACA aims at: "We want more primary care delivered through Medicaid," by getting physicians to treat, or treat more, Medicaid patients.

But, she cautions, "The jury is still out on whether we're going to be able to do that."

@ MORE RESOURCES

Payment outlook for 2014: The good, the bad, and the unknown
http://bit.ly/1eAudej

More delays expected for Medicaid parity reimbursements
http://bit.ly/1dqs0d0

INVOKANA™ is the #1 branded therapy prescribed by endocrinologists when adding or switching non-insulin type 2 diabetes medications*

ENVISION NEW **POSSIBILITIES**

Invokana™
canagliflozin tablets

*Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data through 9/20/13.

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

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

IMPORTANT SAFETY INFORMATION

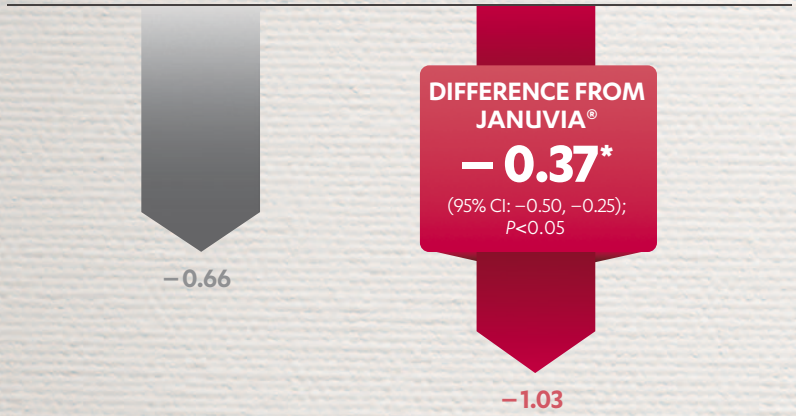
CONTRAINDICATIONS

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

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

INVOKANA™ 300 mg demonstrated greater reductions in A1C vs Januvia® 100 mg at 52 weeks...

Adjusted Mean Change in A1C From Baseline (%): INVOKANA™ 300 mg vs Januvia® 100 mg, Each in Combination With Metformin + a Sulfonylurea[1]



Incidence of Hypoglycemia

With metformin + a sulfonylurea over 52 weeks: INVOKANA™ (canagliflozin) 300 mg: **43.2%**; Januvia® 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[1]

Convenient Once-Daily Oral Dosing[1]

- Recommended starting dose: INVOKANA™ 100 mg
- Dose can be increased to 300 mg in patients tolerating 100 mg who have an eGFR ≥60 mL/min/1.73 m^2 and require additional glycemic control

*INVOKANA™ + metformin is considered noninferior to Januvia® + metformin because the upper limit of the 95% confidence interval is less than the prespecified noninferiority margin of 0.3%.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS and PRECAUTIONS

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

COVERED FOR >**75%** OF COMMERCIALLY INSURED PATIENTS WITHOUT PRIOR AUTHORIZATION[3]

...as well as greater reductions in body weight† and systolic blood pressure (SBP)†

Change in Body Weight†

Significant reductions in body weight at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[1]

»Difference from Januvia®‡:
300 mg: **–2.8%**

Change in SBP†

Significant lowering of SBP at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[2]

»Difference from Januvia®‡:
300 mg: **–5.9 mm Hg**

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

†Prespecified secondary endpoint.

‡Adjusted mean.

INVOKANA™ provides SGLT2 inhibition, reducing renal glucose reabsorption and increasing urinary glucose excretion.[1]

Adverse Reactions

In 4 pooled placebo-controlled trials, the most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.[1§]

References: 1. INVOKANA™ [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2013. **2.** Schernthaner G, Gross JL, Rosenstock J, et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. *Diabetes Care*. 2013;36(9):2508-2515. **3.** Data on file. Janssen Pharmaceuticals, Inc., Titusville, NJ. Data as of 9/17/13.

SGLT2 = sodium glucose co-transporter-2.

§Included 1 monotherapy and 3 add-on combination trials with metformin, metformin + a sulfonylurea, or metformin + pioglitazone.

Learn more at **INVOKANAhcp.com/journal**

»**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.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

ENVISION NEW
POSSIBILITIES

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION (cont'd)

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, 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 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.

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

November 2013 004991-131021

» **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 pruritus, thirst, nausea, and constipation.

K02CAN13149

Please see brief summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

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.

INVOKANA™ (canagliflozin) tablets

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.

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

INVOKANA™ (canagliflozin) tablets

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

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

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

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

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

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

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

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

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

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

DRUG INTERACTIONS

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

INVOKANA™ (canagliflozin) tablets

OVERDOSAGE

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

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

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

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

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

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

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

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

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

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

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

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

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

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

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

Active ingredient made in Belgium

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

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

Licensed from Mitsubishi Tanabe Pharma Corporation

10282400

K02CAN13080B

janssen

Cosmetic procedures: The possibilities and pitfalls

Botox injections and skin procedures may help your bottom line, but use caution when adding them to your practice

by **SUSAN KREIMER** *Contributing author*

HIGHLIGHTS

01 Primary care physicians who want to consider cosmetic procedures should select one procedure, such as Botox injections, and determine if you can handle the demands of cash-paying patients who may want perfect results.

02 If the economics are right, it may be more feasible to hire other health professionals to perform ancillary dermatology services in your practice.

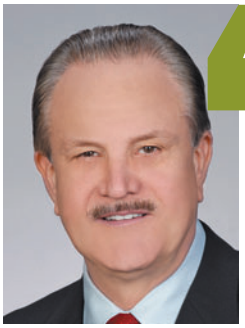
Cosmetic dermatology is a growing market, one that some primary care physicians can use as an ancillary revenue stream to boost their income. But before adding these services, experts say, it's vital to first take a hard look at your practice and patient mix to see if the fit is right. Entering the highly competitive cosmetic dermatology market means training, upfront costs, and dealing with a different kind of patient.

THE PROSPECT OF boosting a primary care practice's income by catering to baby boomers' quest to look more youthful is alluring.

But experts advise primary care physicians (PCPs) to weigh a number of factors—such as fit with your practice and how much training you would be willing to take on—in deciding whether to offer cosmetic dermatology in their practices.

Americans spent nearly $11 billion on cosmetic procedures in 2012, ranging from injections to skin rejuvenation and laser hair removal or treatment of leg veins. Botulinum toxin type A injections (including Botox and Dysport) ranked as the most popular nonsurgical procedure, according to the latest statistics from the American Society for Aesthetic Plastic Surgery.

"Yes, cosmetic procedures are a potential additional line of revenue," says Neil Alan Fenske, MD, FACP, founder and director of "Derm for Non-Derms," an annual dermatology course for non-dermatologists. "Let me tell you, however, that it's an extraordinarily competitive business with enormous overhead.



> Cosmetic patients have very different expectations than patients who are ill. See if you can deal with those kinds of patients because they are challenging. Don't buy a bunch of lasers and go in over your head because you will go bankrupt."
>
> — NEIL ALAN FENSKE, MD, FACP, PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF DERMATOLOGY AND CUTANEOUS SURGERY, UNIVERSITY OF SOUTH FLORIDA COLLEGE OF MEDICINE, TAMPA ,AND FOUNDER AND DIRECTOR OF "DERM FOR NON-DERMS."

"Cosmetic patients have very different expectations than patients who are ill," adds Fenske, who is also professor and chairman of the department of dermatology and cutaneous surgery at the University of South Florida's College of Medicine in Tampa. "See if you can deal with those kinds of patients, because they are challenging. Don't buy a bunch of lasers and go in over your head because you will go bankrupt."

DETERMINING THE FINANCIAL VIABILITY

So how do you determine if adding cosmetic procedures will be financially viable in your practice? Reed Tinsley, CPA, a Houston, Texas-based medical practice adviser, suggests starting with the following questions:

- Is there a demand for the procedure?
- Is someone else in the community providing the procedure?
- Can I perform the procedure better than the competition?
- How will it affect my current patients and staff?
- How will it affect my time?
- How much will I be reimbursed?
- Where is my break-even point?

Fenske advises starting small, by selecting one procedure, such as Botox injections, and determining if you can handle the demands of cash-paying patients who may expect perfect results.

If the procedure you're considering will require adding equipment, you need to figure out how whether the additional revenue will pay for the equipment, and in how long. (See "Equipment cost analysis," page 63.)

Buying lasers poses the most significant risk, because they can cost $100,000 or more, and cost up to $10,000 per year to maintain, Fenske says.

TYPICAL PRICES FOR COMMON COSMETIC PROCEDURES

Physicians generally charge $300 to $600 for a Botox treatment ($10 to $15 per unit), averaging 30 to 50 units per session. They tend to collect about $500 to $700 per dermal filler treatment. Cosmetic laser sessions range from $300 to $1,000 each, depending on the size of the area being treated, says John P. Bryan, CPA, a partner in the White Plains, New York, office of Citrin Cooperman, an accounting, tax and consulting firm.

"A practice that is committed to adding the services and appropriate marketing could add $50,000 to $100,000 in revenues without too much trouble," Bryan says.

Remember, though, that the return on your investment is a key component.

THE MARKETING COMPONENT

Next, you'll need to make sure potential customers know about your new service. Marketing to existing patients has the

COMMON COSMETIC PROCEDURES PRIMARY CARE PHYSICIANS CAN CONSIDER

These five minimally-invasive procedures were the most frequently performed, according to data from 2012:

botulinum toxin type A :	3,257,913
hyaluronic acid :	1,423,705
laser hair removal:	883,893
microdermabrasion:	498,821
chemical peel:	443,824

Source: American Society for Aesthetic Plastic Surgery

best chance of success, says Joshua A. Teplitzky, JD, CPA, MBA, an accountant in Woodbridge, Connecticut, with healthcare expertise. This approach could consist of e-mail blasts announcing the new services with discounts and introductory programs, mailed advertising included with a patient's regular bill, and promotional posters displayed in the office.

Depending on the extent of the promotions, the cost could range anywhere from a few thousand dollars to $25,000, while a campaign that includes print media, television, and radio advertising "could run into the hundreds of thousands of dollars," Teplitzky says.

A better sales plan may reside within the staff, displays, and a provider making suggestions to patients, says Owen J. Dahl, MBA, FACHE, a Houston-area healthcare consultant specializing in the business of medicine. "Word of mouth is the key," he says. "It would be beneficial to include these products on the website and track the sales that might come from that."

SEEK TRAINING OPPORTUNITIES

For those inclined to take the risk, proper training is key. Practitioners will need more than one course spanning a few days and a demonstration or tutorial from the product's manufacturer. And be sure to inquire with your state's licensing board about the laws governing cosmetic procedures, says Tamella Buss Cassis, MD, FAAD, a dermatologist in Louisville, Kentucky, and a member of the Women's Dermatologic Society.

"If you feel that you can offer great quality cosmetic procedures, and there is demand in your area, then always take procedures very slowly," says Cassis, who also serves on the American Academy of Dermatology's safety committee. "Cosmetics companies really try to lure primary care physicians to the land of cosmetics with the idea that they will make money. Buyer beware."

The real challenge is figuring out how to obtain the additional education and how to determine if it's adequate. That answer "has to reside within the conscience of the individual," Fenske says. "They have to search their soul, 'Have I had enough training or will I harm anybody?' "

EQUIPMENT COST ANALYSIS

Use the following formula to calculate whether an instrument will pay for itself in time saved.

Formula

	Purchase price ÷ estimated useful life in years	=
+	Annual cost of supplies and maintenance	+_____
=	New instrument's annual cost	=
÷	Days/times used per year	÷_____
=	**Cost per day/time used**	=

Staff Labor:

	Wage per hour	
+	Benefits per hour	+_____
=	Labor cost per hour	=
÷	60 (minutes per hour)	÷_____
=	**Staff labor cost per minute**	=

Doctor labor:

	Annual receipts	
÷	Hours worked per year	÷_____
=	Gross receipts per hour	=
÷	60 (minutes per hour)	÷_____
=	**Doctor labor cost per minute**	=

Time savings needed:

	Doctor or staff cost per day
÷	Labor cost per minute
=	**Minimum # of minutes needed to be saved per day/times used to justify cost**

Use this formula to calculate additional profit potential:

	Reimbursement for service
–	Reimbursement w/o new equipment
=	Increased reimbursement per procedure
–	Additional labor per procedure
–	Other (remodel, training, space used)
–	Cost per time used (above)_____
=	Profit per procedure
X	Estimated procedures per year_____
=	**Profit per year**

"Is it something that truly complements their practice, or is it something that's inconsistent with what they're doing?" A physician should think long and hard before adding ancillaries to their practice."

—HAYDEN S. WOOL, A HEALTHCARE COMPLIANCE LAWYER AT GARFUNKEL WILD P.C. IN GREAT NECK, N.Y.

DOES COSMETIC DERMATOLOGY SUIT YOUR PRACTICE?

Patients may question why the scope of a doctor's practice has widened beyond medically necessary procedures. That's why practitioners should ask themselves, "Is it something that truly complements their practice, or is it something that's inconsistent with what they're doing?" says Hayden S. Wool, a healthcare compliance lawyer at Garfunkel Wild P.C. in Great Neck, New York "A patient may find it odd that his cardiologist is now doing cosmetics, so a physician should think long and hard before adding unrelated ancillaries to their practice."

Says Dahl: "The other 'cost' is whether or not the patient population served by the practice would look at this as a service, or if it is just the doctor trying to make a few more dollars."

The economics of medicine may be driving some practitioners to pursue ways of generating income outside the traditional realm. Amid declining reimbursement rates and rising malpractice insurance costs, physicians often express a desire to expand their practices, Wool observes, while cautioning, "There is a broad array of compliance issues that need to be looked at when adding any specialties or activities in a practice."

Federal and state laws may limit a physician's ability to provide certain ancillary services.

It may be more feasible to hire other health professionals to perform ancillary services in your office while you're busy seeing patients. "You can have other people working for you, and presumably, at a profit," Wool says, after accounting for the initial costs and maintenance of equipment, wages of qualified personnel, and advertising to draw new patients.

A sound business model may entail PCPs joining forces in a clinic with dermatologists, keeping referrals "in house" for everyone's financial benefit, says Mary P. Lupo, MD, a board-certified dermatologist in New Orleans, Louisiana, and a clinical professor of dermatology at Tulane University School of Medicine.

"This would be the most ethical model, as long as they refer to the qualified plastic surgeon nearby when the situation and clinical presentation warrants," says Lupo, founding co-director of the Cosmetic Boot Camp, a continuing medical education course aimed at the "core" aesthetics specialists.

The vast majority of complications that Lupo retreats are from "non-core" practitioners. Injectable fillers and laser procedures pose the greatest likelihood of serious complications.

Lupo recommends that PCPs interested in providing cosmetic procedures take a sabbatical to pursue residency training.

"If you feel that you can offer great quality cosmetic procedures, and there is demand in your area, then always take procedures very slowly. Cosmetics companies really try to lure primary care physicians to the land of cosmetics with the idea that they will make money. Buyer beware."

—TAMELLA BUSS CASSIS, MD, FAAD, BOARD-CERTIFIED DERMATOLOGIST IN LOUISVILLE, KENTUCKY, MEMBER OF THE AMERICAN ACADEMY OF DERMATOLOGY'S SAFETY COMMITTEE, AND MEMBER OF THE WOMEN'S DERMATOLOGIC SOCIETY.

Preparing for 2014 tax changes

Major tax changes for 2013 will continue to hit physician's wallets in 2014. Here's what to look out for.

by **REED TINSLEY, CPA** *Contributing author*

HIGHLIGHTS

01 Gift appreciated securities to IRS-approved charities instead of cash. That way, the gains won't be included on the donor's return.

02 Sell loser securities held in taxable brokerage firm accounts to offset earlier gains from such accounts.

In 2013, we saw major tax changes, including 55 tax breaks that expired, that will continue to impact physicians into 2014.

Higher-income physicians will be in for a big surprise when they finally tally up their 2013 tax bill before April 15th. The higher amount of taxes that may be owed will be the result of the combination of several factors, the cumulative effect of which will be significant for many.

These factors include a higher income tax rate, a higher capital gains rate, a new net investment income tax, and a new Medicare surcharge on earned income, as well as a significantly reduced benefit from personal exemptions and itemized deductions for those in the higher income tax brackets. Since most of these changes will cause significant changes to physicians in 2014, let's take another look at them.

1/ Higher top income tax rate

The American Taxpayer Relief Act of 2012 made permanent for 2013 and beyond the lower Bush-era income tax rates for all.

The exceptions are for taxpayers with taxable income above $400,000 ($450,000 for married taxpayers filing jointly, $425,000 for heads of households).

Income above these levels has now been taxed at a 39.6% rate rather than at the top 35% rate since January 1, 2013. Those amounts are adjusted for inflation after 2013 (for 2014, those threshold levels are $432,200, $457,600, and $406,750, respectively. Taxpayers with $150,000 of income above the threshold amounts, for example, must pay an additional $6,900 in tax in 2013 because of the additional tax rate of 4.6%).

2/ Capital gains and dividends

The American Taxpayer Relief Act also raised the top rate for long-term capital gains and dividends to 20%, up from the Bush-era maximum 15% rate—again, applicable to all net long-term capital gains from transactions made on or after January 1, 2013.

That top rate will apply to the extent that a taxpayer's income exceeds the thresholds set for the 39.6% rate ($400,000 for single filers; $450,000 for joint filers and $425,000 for heads of households).

Especially applicable to those investors who have been riding the recent stock market rally, a jump in the rate from 15% to 20% represents a 33.33% tax increase.

3/ ACA impact on Medicare taxes

Set into motion on January 1, 2013 by the Affordable Care Act of 2010, higher-in-

come taxpayers have been required to pay an additional 3.8% on net investment income as well as a 0.9% Additional Medicare Tax on earned income.

In both cases, the income threshold levels for being subject to these new taxes are considerably lower than the 39.6% bracket and 20% capital gain rates. The threshold amount is $200,000 in the case of a single individual, head of household (with qualifying person) and qualifying widow(er) with dependent child. The threshold amount is $250,000 in the case of a married couple filing jointly and $125,000 in the case of a married couple filing separately.

For the 3.8 percent net investment income tax, the threshold is adjusted gross income (modified for certain foreign-based income). For the 0.9% Additional Medicare Tax, the threshold is measured against compensation earned for the year (including self-employment income):

Net investment income tax:

This is one of the most important changes impacting physicians. The 3.8% tax not only covers capital gains and dividends, but also passive-type income flowing from real estate, investments in businesses, and the like. The rules are complex, and many taxpayers will struggle with the extent to which income on their 2013 tax returns will be subject to the new net investment income tax.

For income subject to this tax, the effective rate will increase to 23.8% on net capital gain and dividends and 43.4% on short-term capital gain and all other passive-type income.

Additional Medicare Tax:

For tax years beginning after December 31, 2012, the 0.9% Additional Medicare Tax applies to employee compensation and self-employment income above the threshold amounts noted above.

An employer's withholding obligation for the Additional Medicare Tax applies only to the extent the employee's wages are in excess of $200,000 in a calendar year.

For some dual-income couples with combined earned income above the $250,000 threshold but with no one earning more than $200,000, they may find themselves under withheld and subject to an estimated tax penalty as a result.

Couples should remember that to prevent a reoccurrence in the future, an employee may request additional income tax withholding, which will be applied against all taxes shown on the individual's return, including any liability for the Additional Medical Tax.

4/ Itemized deductions limitation

The American Taxpayer Relief Act officially the "Pease" limitation on itemized deductions.

The new thresholds, first applied in 2013, are $300,000 for married couples and surviving spouses; $275,000 for heads of households; $250,000 for unmarried taxpayers; and $150,000 for married taxpayers filing separately.

The Pease limitation reduces the total amount of a higher-income taxpayer's otherwise allowable itemized deductions by three percent of the amount by which the taxpayer's adjusted gross income exceeds this applicable threshold.

The amount of itemized deductions may be reduced up to 80% under this formula.

Four ways to reduce net investment income:

1. **Selling loser securities held in taxable brokerage firm accounts to offset earlier gains from such accounts.**
2. **Gifting soon-to-be-sold appreciated securities to children and letting them sell them to avoid including the gains on the parent's return. But beware of the Kiddie Tax, which can potentially cause children under age 24 to pay taxes at their parent's higher rates. However, as long as the investment income is reported on the child's return (i.e., the parents don't elect to include it on their return), it won't be subject to this additional tax unless the child's modified adjusted gross income exceeds his or her applicable threshold.**
3. **Utilizing an installment sale to spread a big investment gain over several years. (This will also reduce AGI.)**
4. **Instead of cash, gifting appreciated securities to IRS-approved charities. That way, the gains won't be included on the donor's return.**

Certain items, such as medical expenses, investment interest, and casualty, theft or wagering losses, are excluded.

5/ Personal Exemption Phase-out rules

The American Taxpayer Relief Act also revived the personal exemption phaseout rules, at the same levels of adjusted gross income revived for the Pease limitation.

Under the phaseout, the total amount of exemptions that may be claimed by a taxpayer is reduced by two percent for each $2,500, or portion thereof (two percent for each $1,250 for married couples filing separate returns) by which the taxpayer's adjusted gross income exceeds the applicable threshold level.

At the full phase out level, therefore, a family with four personal exemptions in 2013 will lose $15,600 in exemptions, creating $6,178 in additional tax at the 39.6% bracket.

6/ Federal estate and gift tax strategies

One bright spot for higher-income taxpayers is the change that took place starting in 2013 directly applicable to estate planning strategies.

The American Taxpayer Relief Act permanently provided for a maximum federal estate tax rate of 40% with an annual inflation-adjusted $5 million exclusion for estates of decedents dying after December 31, 2012.

Couples can combine exclusions and effectively exempt $10 million from estate tax (for 2013, the inflation-adjusted level is $10.5 million, rising to $10.68 million in 2014).

@ MORE RESOURCES

Strategies for reducing the tax bite

http://bit.ly/1a1fREo

Reed Tinsley, CPA, is a healthcare consultant in Houston, Texas, and a Medical Economics editorial consultant.

Financial Strategies

EFFECTIVE SUCCESSION PLANNING: STARTING EARLY CAN REAP BENEFITS

by **ROBERT C. SCROGGINS, JD, CPA, CHBC** *contributing author*

Nearly half of all physicians are older than 50, and approaching retirement. Early retirement planning and open communication can help you find a buyer for your practice, ease your transition to retirement, ensures your practice thrives and provides effective care coordination for your patients.

YOU'VE WORKED HARD to build a successful medical practice and you are beginning to see the retirement light at the end of the tunnel.

So now what? Who will care for your patients? Will you be able to find a buyer who is the right fit? How do you make sure you go into the transition with the best chance for success?

Whether you have a solo practice or are part of a group, the main ingredients for a successful transition are advanced planning and good communication.

This may seem obvious, but as practice management consultants, our firm has encountered situations where a failure to address these fundamentals resulted in a failure of succession.

Here are some of the essentials to a successful transition when you approach the end of your career.

The importance of advanced planning

A practice has much less value at the "last minute," and the last minute will sneak up on you faster than you suspect.

This is true in any case, but particularly if you are in solo practice. An abrupt retirement will drive your patients to another doctor in short order. The astute type of successor, the kind of person you want to attract, will look for a well thought out transition plan, because risking a loss of patients is counterproductive.

Having a good transition plan is an indication of a well-run practice and sends the right message to your potential buyer.

Even in a group setting, a quick departure will impact value since much of the overhead will continue. Ongoing overhead without related production takes money right off the bottom line. Patients will typically hang in longer with a group, but if they can't get an appointment with those who remain or don't have a good opportunity to build rapport with their new doctor, they will leave.

Good advanced planning ensures that all stakeholders (you, your partners, and the new doctor coming in) are all on the same page. Planning before a transition is on the horizon is beneficial because it helps avoids decision making based on individual agendas and instead causes everyone to think in terms of what is best for the practice.

In order to facilitate a smooth transition and establish expectations, here are important topics to address and questions to answer within your group.

How early should you start?

How much notice is required to retire with full value (i.e. stock value, account receivable payout, etc.)?

We recommend a minimum of a year, and to have the notice and timing well-coordinated with the recruiting time table for doctors completing training.

For example, if a one year notice is required but is given at year-end, you may miss out on the doctors available the next summer.

What about partial retirement?

Is semi-retirement, dropping call, etc. allowed? If this is not decided in advance, some doctors will assume that going part time is naturally permitted.

But, a part-time practice still requires space and overhead and can limit

➔71

Financial Strategies

➔68 capacity necessary for a new doctor to build a practice. Economically, accommodating a part-time doctor is difficult without a significant reduction to compensation.

A semi-retirement arrangement should ideally have a defined duration only long enough for the transition to be successful, and it should be allowed only if it is good for the practice as a whole.

Required retirement age?

Should you have a required retirement age for physician owners? This can be helpful. Age 65 is typical for practices that have such a stipulation. It is also a good idea to have senior doctors exit management responsibilities in advance of actual retirement, such as at age 60.

An important caveat: Make sure you establish a provision like this with the guidance of legal counsel so it complies with relevant age discrimination exceptions, and be consistent by applying the same requirement to all similarly situated physician owners.

Transparency, communication is key

More transparency is better. It is important to make sure that expectations are the same for the doctor leaving and the doctor coming in.

HAVING A GOOD TRANSITION PLAN IS AN INDICATION OF A WELL-RUN PRACTICE AND SENDS THE RIGHT MESSAGE TO YOUR POTENTIAL BUYER.

As you recruit for your replacement be proactive with sharing detailed information about the practice culture and financials. As part of the interview process have the new doctor spend time at the practice to get a feel for how it operates.

Without open communication we find that the failure rate is around 50% simply because assumptions surrounding important matters will be different in the mind of each party.

If you are leery about being an open book, particularly with financials, then do so under a non-disclosure agreement with your prospective successor agreeing to keep the information you share confidential.

And keep in mind that culture trumps everything else. You can find the most technically skilled successor, but if that person doesn't fit the culture of your practice, what you worked hard to build will not last for long.

Seek out good advice

Finally, work with advisers who are practical and understand how medical practices work. Transition planning and execution does not need to be complicated.

If you pick a good practice management consultant, accountant and/or attorney, they will be valuable to you in planning for and facilitating the process and can bring insights from other engagements in order to anticipate and resolve issues before they become problems.

Stick with the plan

It is bittersweet to retire from a rewarding career of serving your patients so it can be difficult to let go.

If you go through a careful process to pick the right person, you should feel confident about the ongoing care of your patients and actually enjoy watching a younger physician embark on the journey that you once took yourself. ■

@ MORE RESOURCES

Find more financial planning resources at MedicalEconomics.com

Theft in a medical practice: Why it happens and how to stop it
http://bit.ly/Jlg71t

Thinking outside the box about practice profitability
http://bit.ly/1ervnJd

Examing costs of payer relationships
http://bit.ly/1aloLDG

Electronic check-in saves time and money
http://bit.ly/KyJN14

Robert C. Scroggins, JD, CPA, CHBC, *is a management consultant and principal with ScrogginsGrear, Inc., in Cincinnati, Ohio. Send your practice management questions to* ***medec@advanstar.com****.*

Technology

Assessing the payoff from Meaningful Use of EHRs

More physicians are using electronic health records, but opinions are mixed over the value of digitization

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

HIGHLIGHTS

01 Due in large part to the federal government's Meaningful Use program, the percentage of physicians using electronic health records rose from 17% in 2009 to more than 50% in 2013.

02 Many of today's physicians are frustrated by the complexity of EHRs but experts believe later versions of the technology will become more user-friendly.

The Health Information Technology for Economic and Clinical Health Act of 2009 included $27 billion to help doctors, hospitals, and other healthcare providers buy and install electronic health record (EHR) systems. Through November of 2013, about $5.8 billion of that had been paid to physicians who had successfully attested to the first stage of the meaningful use program (MU1).

WITH THE start of 2014, physicians can begin attesting to MU2, the program's second stage, making this an opportune time to pause and ask what physicians—and the healthcare system generally—have gotten for that money.

As is often the case, the answer depends on whom you ask. For many primary care physicians (PCPs), especially those in solo or small independent practices, the answer would be "very little"—unless you count frustration, lost productivity, and sleepless nights.

Many policy analysts, however, and even some practicing physicians, say that it's still too soon to know what the payoff from adopting EHRs will be, or in what form it will occur. They point out that in other sectors of the economy, such as manufacturing or banking, it took many years for widespread computerization to begin paying substantial dividends.

→74

CLEAR THE AIR ON CONTRACTS.

Medical Economics EHR Web Seminar Series
Managing Payer & Network Contracts to Improve Your Bottom Line

IN THIS WEB SEMINAR: Payer and network agreements are the foundation of the bottom line and yet, over the years, contract terms have become elusive and confusing. Payer contracting and credentialing expert Penny Noyes takes away the mystery and fear, walking you through the steps to find contracts and rates, analyze the impact of current and offered fee schedules on your bottom line, model an offer or counter-offer, and determine when/how/why to initiate a contract negotiation.

REGISTER TO LEARN ABOUT:

- Gathering your fully executed agreements & rates
- Determining when and with which payers/networks to negotiate & initiate
- Analyzing & achieving your aggregate financial goal for a given contract negotiation

WHO SHOULD ATTEND: Practice owners/managers, billing managers and staff, and others involved with payer and network contracts.

MARCH 5, 2014. **REGISTER TODAY.**
medicaleconomics.com/ehrwebseminars

Presented by Medical Economics

Provided by kareo Go Practice

➔72

One thing that is certain is that the number of doctors using EHRs has increased—from about 17% in 2009 to about 50% through the first half of 2013, according to the U.S. Department of Health and Human Services, which administers the Meaningful Use program through the Centers for Medicare and Medicaid Services.

DOCTORS VOCAL IN THEIR UNHAPPINESS

Practitioners' unhappiness with EHRs was expressed throughout *Medical Economics*' 2-year "EHR best practices study." Daniel Goodman, MD, a solo internal medicine practitioner near Atlanta, Georgia, spoke for many when he said: "I can't believe this is what I've been going through. I've been feeling this depression because I'm spending my time staring at a computer and trying to get it right to achieve meaningful use." Andrew Garner, MD, a solo family practitioner in Glen Falls, New York, likened the time and effort required for installing his EHR to returning to medical school.

More broadly, a 2013 RAND Corporation study of factors affecting physicians' professional satisfaction found that although many doctors recognize EHRs' potential for improving healthcare delivery, the technology reduces professional satisfaction due to factors such as poor usability, time-consuming data entry, interference with face-to-face patient care, lack of interoperability among different systems, and degradation of clinical documentation. "Few other service industries are exposed to universal and substantial incentives to adopt such a specific, highly regulated form of technology, one that our findings suggest has not yet matured," the report notes.

Ironically, another RAND study, from 2005, was one of the catalysts for the Meaningful Use program. The study estimated that widespread EHR use could reduce overall medical spending by $81 billion annually. But an editorial published in the January 2013 issue of *Health Affairs* noted that healthcare spending had grown from $2 trillion to about $2.8 trillion in the 8 years between the two studies, and that EHRs have yet to fulfill their promises of greater efficiency and lower costs.

The belief that EHRs could dramatically improve the quality and efficiency of healthcare rests on healthcare policymakers' faith in the transformative power of collecting and managing large quantities of data, says Jason Mitchell, MD, director of the Center for Health Information Technology for the American Academy of Family Physicians.

"We work from the theory base that many of the key problems occurring with healthcare quality and efficiency are related to data management, Mitchell says. "And managing data in paper charts has been a key problem in why we haven't been more efficient and able to monitor quality more effectively." Consequently, the thinking went, doctors only need to digitize their patients' records for the healthcare system to begin reaping the same rewards.

BARRIERS TO COMPUTERIZATION

But healthcare has some unique traits that make computerization especially tricky, says Bob Rudin, PhD, an associate researcher with the RAND Corporation. One is the complexity of clinical workflows. "Medical offices have their own, customized way of doing things, and they all want the technology to fit into it exactly. It presents a very challenging technical design problem [for EHR vendors]," he says.

"Some practices just don't have the capacity for change, or for focused quality improvement," adds Mitchell. "So they install an EHR and expect it will make their lives

MEANINGFUL USE INCENTIVE PAYMENTS TO PHYSICIANS THROUGH NOVEMBER 2013

Medicare eligible professionals

- Doctors of medicine or osteopathy: **$3,633,201,174**

Medicaid eligible professionals

- Physicians: **$1,776,395,371**

Medicare advantage organizations for eligible professionals: $315,704,786

Source: Centers for Medicare and Medicaid Services

better, when in fact it's just a tool and they need the skills to adjust and manipulate the application of that tool so it can work effectively in their practice."

Another challenge, notes Rudin, is the disconnect between those who perform the additional work EHRs require—physicians and their staffs—and those who reap the benefits, which are patients (in terms of better outcomes) and third-party payers (in terms of lower costs. "For a market to work successfully, the people who buy the product are the ones who should benefit from it," he says.

He cites the example of e-prescribing, where EHRs include quality and safety tools such as dosage checking and clinical decision support. But taking advantage of these tools requires doctors to enter a great deal of data and clicking numerous buttons, "whereas before the doctor could scribble some note on a piece of paper, hand it to the patient, and move on to the next patient," Rudin says.

THE BENEFITS EHRS CAN BRING

Despite the frustrations EHRs have caused, it's far too early to declare the meaningful use program a failure, experts say. For one thing, there is growing evidence of EHRs' ability to improve patient outcomes. For example, a study published in the September, 2011 *New England Journal of Medicine* compared achievement of and improvement in quality standards for diabetes care among a group of paper-based and EHR-based practices in Ohio. It found that the achievement of composite standards for care and composite standards for outcomes were 35 percentage points and 15 percentage points higher, respectively, at the EHR sites than at the paper-based sites.

Doctors' complaints about EHRs have to be viewed with some historical perspective, says Pat Wise, RN, MS, vice president of healthcare information systems for the Health Information Management Systems Society. Wise notes that practices had been using EHRs for many years before the Meaningful Use program began.

"The practices that moved to EHRs in the 1990s and early 2000s were most likely the practices that saw the power of the technology and recognized they needed to move for the business model of their practices, that it was the only way they were going to become more efficient," she says. "So these practices already were motivated to make [EHRs] a success."

Moreover, at least some of the practices adopting EHRs in the last few years are doing so to avoid incurring financial penalties starting in 2015. "These practices are on a shortened timeline, and they probably feel a lot more stress than the practices that did it at their own pace," Wise says.

THE 'PRODUCTIVITY PARADOX'

It's also possible that EHRs are already affecting the healthcare system in ways that we don't even realize, because we aren't measuring them. Such was the case in the 1970s and 1980s, according to "Unraveling the IT Productivity Paradox—Lessons for Healthcare," an editorial Rudin coauthored in *NEJM* in June 2012.

> "Medical offices have their own, customized way of doing things, and they all want the technology to fit into it exactly. It presents a very challenging technical design problem [for EHR vendors]."
>
> —BOB RUDIN, PH.D., ASSOCIATE RESEARCHER, RAND CORPORATION

Rudin and his fellow researchers noted that during those earlier decades the economy's overall computing capacity dramatically increased, even as the rate of productivity growth appeared to be declining. Later research showed that the "productivity paradox" occurred in part because of limitations in the data and methods used to evaluate productivity.

The same phenomenon could be occurring now in healthcare, the authors say. They cite the example of a physician who communicates with patients via telephone or e-mail, rather than face-to-face in office visits. These doctors "will all appear less productive on measures of productivity, even if they are actually delivering more convenient, accessible, and effective care."

The article goes on to point out that significant productivity gains from information technology in other parts of the economy came only after investments in training and process redesign, and that a comparable process of re-engineering healthcare delivery is only now getting started.

EHRs will almost certainly become more user-friendly as vendors incorporate feedback from customers into newer versions, says Mark Snyder, MD, a specialist leader in the Health Care and Life Sciences area of Deloitte Consulting.

Snyder compares the current versions of most EHR systems to early e-mail programs and Internet search engines. "Those didn't just spring to life as useful as they are now," he says. "But that doesn't mean we abandoned them. They continued to evolve, and now it's hard to imagine how we ever got along without them."

THE PROMISE OF POPULATION HEALTH MANAGEMENT

Taking a longer perspective, it may be that the biggest payoffs of widespread EHR use will take more time to accomplish. One of these is integrating individual patient care and population health management.

The AAFP's Mitchell calls caring for an individual patient an "anecdote" of care. "But when we look across populations, EHRs help us aggregate those individual anecdotes into algorithms on how we are caring for patients, and what gaps in care are there," Mitchell says.

"With the improved information management EHRs make possible, we get better methods for monitoring conditions, and applying the best available evidence to an individual patient's specific circumstances. Then we can create a comprehensive care plan with the patient and other members of the care team that meets the patient's needs and expectations."

Finally, the data aggregation and improved communication EHRs make possible are essential for creating a system that rewards quality rather than volume through models such as the accountable care organization and Patient-Centered Medical Home. "When clinical data is on paper, you don't have a prayer of using it for quality measurement in any efficient fashion," says Rudin. "Whereas if it's in electronic form, you can start to make those measures better, and start to create standards for them. The value-based models all need to be measuring the quality of their care. And the better the quality measurements we get, the better those programs will be.

"This is a huge undertaking, wiring the whole healthcare system," Rudin adds. "And as much as we want a return on our investment right away, it really should be viewed as a long-term investment for which we're just now laying the foundation." ◻

Transition of care calls for primary care quarterback

While coordination between providers is critical to quality outcomes, the question remains if incentives for practices are realistic

by **DONNA MARBURY, MS** *Content specialist*

HIGHLIGHTS

01 EHRs and telemedicine can help coordinate transition of care, but don't rely on them to fix all your communication problems.

02 There are several transition of care models that work for solo and small practices of all types that utilize community resources and non-medical assistants to coordinate care.

Imagine you have a patient who was recently hospitalized because of a stroke. After weeks in the hospital, with rehabilitation, she is being discharged on a Friday afternoon. She lives alone, but her son comes to the hospital to take her home. The physical therapist's notes state that the patient can only safely maneuver four steps. Her son works full time and has a wife and children of his own.

IT BECOMES clear that this patient may have issues with taking medications on time, and getting around her home safely. But who should be at the discharge planning meeting—the hospital physician, her primary care physician? Does her son know all he needs to know to ensure her care? Who is accountable for following up with the patient?

Mona Sweeney, RN, assistant director of accreditation services—primary care for the Accreditation Association of Ambulatory Health Care (AAAHC), says that at a recent discharge planning meeting, she was surprised that no one was asking the patient, or her family, critical questions about her life outside of the hospital.

"A number of hospital discharges happen on Fridays or on the weekends, and no one asked how many stairs were in the house—there were 15," Sweeney says. "We need practitioners to look at

the whole piece, and not just doing a good job at what they do. This includes an assessment of family and home situations."

There are a number of programs being developed that aim to address transition of care issues, many coupling primary care and Patient-Centered Medical Homes (PCMH). And though research suggests that medical communities can provide the most comprehensive care to those moving from one healthcare situation to another, many of these programs have limited funding.

"The system does not incentivize physicians," says Sweeney, adding that AAAHC has accredited 371 satellites as PCMHs, which branch out to include several more individual sites. "It is very difficult for a small practice to be a team. If they are hiring people, they need to be working at the top of their degree. Many of these practices are overwhelmed with patients, overwhelmed with paperwork. But a big piece of successful transition of care is the medical home, which helps address and sustain patients to prevent readmissions."

The Centers for Medicaid and Medicare Services estimated that it will pay $600 million to practices after implementing five new codes that support care coordination in 2013. For 2015, new codes reimbursing practitioners for non face-to-face visits and telemedicine have been approved. But experts agree that it is difficult to track and bill for meetings with other physicians, and conversations with caregivers.

Also, getting physicians from different disciplines, nurses, health coaches, family and patients all on one page seems like a colossal task for an already busy primary care physician.

Young adults are having difficulties transitioning from pediatric to adult care

Though the Affordable Care Act (ACA) has allowed millions of young adults to stay on their parents' insurance until they are 26, many fall through the cracks after they have to establish their own insurance, according to a recent study by the National Collaborative on Workforce and Disability (NCWD).

Some young adults are experiencing a gap in coverage for illnesses that need chronic care, including asthma, diabetes, heart disease, HIV/AIDS; and physical, intellectual, and emotional disabilities that are episodic and more unpredictable.

Mona Sweeney, RN, assistant director of accreditation services—primary care for the Accreditation Association of Ambulatory Health Care, says that the organization is starting to focus on young adults in college. "In student health, there is a lot of transition between leaving home and learning to become a consumer. Universities are considering becoming accredited medical homes. They teach people so many ways to be adults, and this is a captive audience that needs to be informed healthcare consumers," she says.

"In college, they may not qualify for school-based health insurance because of difficulty in maintaining full-time status because of their medical issues. They have difficulty obtaining employment-based insurance coverage because they cannot obtain full-time employment in mid- to large-size companies and, about 74% who met childhood Medicaid's eligibility criteria fail to meet Social Security income (SSI) disability criteria, which is necessary for adult Medicaid eligibility. Thus, they are forced into low-income jobs or unemployment to qualify for and maintain SSI eligibility," the study points out.

Even those who can secure Medicaid assistance have difficulty finding physicians who can help them transition from pediatric to adult care. Also, Medicaid is often drastically more restrictive when it comes to providing medically necessary care compared with high-tech and attentive pediatric healthcare systems. Many young adults continue seeing pediatricians well into adulthood.

"Medicaid pays for services that enable young people with significant disabilities to live in the community, but it favors paying for institutionalization," the study finds. "Waiting lists in 38 states for community-based services can force young adults to wait more than 2-½ years; some of these young people are forced to move into institutions because they no longer receive the personal services they had as children to maintain basic function, e.g., to eat, dress, bathe, etc."

The NCWD is recommending that pediatric medical homes are a good place for pediatric doctors to work with young people and their families to provide comprehensive medical care that extends into adulthood. The organization also states that accurate data collection, healthcare professional development, and stronger federal oversight are among several policy issues being discussed to assist more young people into a smoother transition into being productive adults.

"The medical community needs education on healthcare transition and quality healthcare, so young people with childhood-onset chronic conditions and disabilities can thrive, learn, work, earn, and participate in community life," NCWD states.

"We put a lot of emphasis on relationships, which may sound soft. But that's the piece that leads the other pieces. Patients become partners in their own care and doctors are in charge of knowing the neighborhood," Sweeney says.

CHALLENGES FOR PRIMARY CARE

Practitioners are being urged to become more patient-centered, which has been proven to help patients transition between providers. Many models encourage primary care and family physicians to be "quarterbacks" in patient care, but how practical is it for busy practices to implement this idea?

"In general terms of transition of care, it doesn't always include primary care. Sometimes there are elderly patients who are bouncing between sites. Doctors are left out when patients are bounced between specialists," says Harbrecht. "With PPO [Preferred Provider Organization] plans, patients can be bounced around a lot, and primary care doctors can be out of the loop. Someone needs to be the coordinator, the quarterback for the patient. Without it, it is more likely to lose focus in patient care."

Lattimer says that cost barriers such as adopting new technologies and hiring additional advanced-level nurses and practitioners are also issues that face small practices. However, in some communities there are other resources that practices can utilize to communicate with patients better, she says.

Though it is hard to estimate how much it costs to launch a PCMH, the American Academy of Family Physicians estimates that it can cost up to $100,000 per fulltime physician, including technology costs. In order for the model to work, practices are going to have to find affordable ways to coordinate care.

"A lot of what we see with primary care physicians is that they are trying to identify health coaches and care coordinators within their community to provide support. These people can understand resources beyond hospitals and specialists," Lattimer says. "In rural areas there is a tremendous challenge because community resources could be very limited and physicians just don't have the same choices. But many of those doctors use non-medical home entities to help coordinate transition of care coordination with patients."

MODELS THAT WORK

Cheri Lattimer, executive director of the National Transition of Care Coalition (NTOCC) says that there are several working models being used across different populations. The NTOCC has information on their website (http://www.ntocc.org/WhoWeServe/HealthCareProfessionals.aspx) that help you evaluate plans and put together transition of care checklists. Visit the websites below for more information on these working models to find out if they would work for your practice.

- **Guided Care**
  http://www.guidedcare.org/program-history-results.asp
- **Better Outcomes by Optimizing Safe Transitions (BOOST) Care Transitions**
  http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_CareTransitions/CT_Home.cfm
- **Project Re-engineered Discharge (RED)**
  http://www.bu.edu/fammed/projectred/components.html
- **Rush Memorial Hospital**
  http://www.rush.edu/rumc/page-1298330101593.html
- **Tallahassee Memorial Hospital**
  http://tmh.org/TransitionCenter

IS TECHNOLOGY THE SOLUTION?

The implementation of electronic health records (EHRs) and more acceptance of telemedicine are often viewed as a big step in care coordination, but there are still glaring technology difficulties. Interoperability between EHR systems inhibits solo practitioners from easily communicating, with can slow up transition of care.

"It is very challenging because practitioners are not on the same EHRs, and are often very busy in their own offices, the payment system doesn't reward for it at all and attempts at communication is not always mutual, Harbrecht says.

Unfortunately, technology can sometimes do more to slow the transition of care process. Half of the patient records primary care physicians send to specialists never reach them, according to statistics published in the Journal of the American Medical Association. The study also found that 48% of hospital discharge letters contain incorrect information about patients' medical history.

Lattimer says that there are still security issues surrounding the management of patients via video and telephone. In addition, one of the requirements for primary care practices to be reimbursed for non-face-to-face care is that they have a nurse practitioner or physician assistant on staff. This may be a challenge for a solo practitioner.

"There is still a lot of concern when you talk about telemedicine and the patient-centered medical record switching several hands and remaining confidential," Lattimer says. "I am a strong believer in technology as a tool and a resource, but it is not an end all answer."

WHICH PATIENTS NEED THE MOST TRANSITION OF CARE HELP?

Elderly patients aren't the only ones dealing with transition of care issues. In fact, our experts encourage practitioners to stop looking at transition of care as an old age problem.

According to the Center for Healthcare Quality and Payment Reform, preventable readmissions occur because of surgical site infections; patients and caregivers not receiving clear instructions about medications and lifestyle adjustments; and recurring chronic conditions.

"Anyone who has a transition of care is affected by the challenges of care coordination," says Marjie Grazi Harbrecht, MD, chief executive officer of HealthTeamWorks, a long-term support organization for practices and organizations adopting patient-centered care.

Cheri Lattimer, executive director of the National Transition of Care Coalition (NTOCC), agrees that any patient moving from one medical setting to another, or facing significant rehabilitation, needs a transition of care plan. "It is more dangerous in poor transition of care with someone who is 20 years old with a knee replacement, than a 40-year-old who has better care options," she says.

Patients with mental disabilities, multiple handicaps, complex chronic or reoccurring medical problems, and who don't speak English often have the most issues with care coordination between providers.

"It's not about procedures or ailments. Specific populations are at a higher risk of being out of the loop—seniors, pediatrics, homeless, and the under-insured or those with no insurance," Lattimer says.

MAKE TRANSITION OF CARE WORK FOR YOUR PRACTICE

At the end of the day, implementing a plan to make transition of care coordination a priority in your practice is more about what patients need and not what is easiest for practitioners.

"If we focus on the patients and what the patients need, as opposed to each individual entity or practitioner and their needs, we can have greater success," Harbrecht says. "The biggest things are engaging and empowering the patient. Second is making sure there is a quarterback with medical knowledge to fight for the patient. Lastly, communication between all the entities providing care."

After evaluating transition of care models for years across different populations, from rural to big cities, NTOCC has identified seven key interventions that all models have in common:

1. **Medications management**
2. **Transition planning**
3. **Patient and family engagement/education**
4. **Information transfer**
5. **Follow-up care**
6. **Healthcare provider engagement**
7. **Shared accountability across providers and organizations**

Visit www.MedicalEconomics.com to download a PDF with more information about how to fit these interventions into your practice. Lattimer notes that models that implemented these seven key interventions showed better engagement and adherence and were better able to use technology to communicate with patients.

Ultimately, any strategy must include a strong communication component. Lattimer says that providers need to understand the language they use among each other is not the same language they can use with patients. When patients feel they aren't being heard, or don't understand what needs to be done, the risk rises for readmission.

"There needs to be more than written instructions. Everybody can raise the bar and attempt to approve. Providers can't point fingers at patients because there is a lot of room for all of us to improve," Lattimer says.

FINANCIAL ADVISERS FOR DOCTORS

Those companies listed in *Medical Economics 2012 Best Financial Advisers for Doctors* display this symbol in their ads.

Medical Economics 2012 Best Financial Advisers for Doctors

PRODUCTS & SERVICES

MEDICAL EQUIPMENT

RECRUITMENT

NATIONAL

RECRUITMENT

NORTH DAKOTA

Trinity Health

One of the region's premier healthcare providers.

Currently Seeking BC/BE

- Ambulatory Internal Medicine
- General Surgery
- Psychiatry
- Urology
- Neurology
- Otolaryngology

Contact us for a complete list of openings.

Based in Minot, the trade center for Northern and Western North Dakota, Trinity Health offers the opportunity to work within a dramatically growing community that offers more than just a high quality of life.

Comprised of a network of nearly 200 physicians in hospitals, clinics and nursing homes, Trinity Health hosts a Level II Trauma Center, Critical Care Helicopter Ambulance, Rehab Center, Open Heart and Lung Program, Joint Replacement Center and Cancer Care Center.

Physicians are offered a generous guaranteed base salary. Benefits also include a health and dental plan, life and disability insurance, 401(k), paid vacation, continuing medical education allowance and relocation assistance.

TRINITY HEALTH
Reinventing Health
www.trinityhealth.org

For immediate confidential consideration, or to learn more, please contact

Shar Grigsby
Health Center - East
20 Burdick Expressway
Minot ND 58702
Ph: (800) 598-1205, Ext 7860
Pager #0318
Email: shar.grigsby@trinityhealth.org

Advertiser Index

* Indicates a demographic advertisement.

The Last Word

STUDY: EXPANDED MEDICAID LEADS TO MORE EMERGENCY DEPARTMENT USE

by **ALISON RITCHIE** *Content associate*

Proponents of expanding Medicaid have long argued that better access to primary care would decrease the use of Emergency Departments (ED) for non-emergent care and would eventually lead to a reduction in overall healthcare costs. But a recent study from Oregon is casting doubt on that assumption.

THE STUDY, published in the journal of ***Science***, found a significant increase in the number of ED visits among the newly insured.

The data used in the study was collected from the Oregon Health Insurance Experiment, which presented a unique opportunity for researchers to examine the impact of Medicaid from a randomized sample. In 2008, the state used a lottery drawing to provide Medicaid coverage to about 25,000 low-income adults from a wait list of about 90,000 people.

The study found that ED use was about 40% higher for the newly insured, and the authors estimate the increase in annual Medicaid spending in the ED to be about $120 per insured person.

This is the third report that researchers have compiled from the Oregon Health Insurance Experiment. The first report, which examined the impact of the first two years of Medicaid coverage, showed some positive results. It found that coverage improved overall health and lowered depression.

> "We find that expanding Medicaid coverage increases emergency department use across a broad range of visit types, including visits that may be most readily treatable in other outpatient settings."

The second report found that Medicaid coverage increased the use of healthcare.

But this most recent study is raising the question: How will Medicaid expansion affect healthcare use and cost nationwide? The Affordable Care Act (ACA) allowed for the expansion of Medicaid eligibility to adults with incomes up to 138% of the federal poverty level. Twenty-three states chose to opt-out of the expansion. About 3.9 million new enrollees have gained coverage through Medicaid and the Children's Health Insurance Program expansion.

The study's authors acknowledge the limitations of their sample populations and how it may be applied to the general population.

"Ours is disproportionately white and urban-dwelling. It is also a population who voluntarily signed up for coverage; effects may differ in a population covered by an insurance mandate," the authors wrote.

The authors say that their study provides new insight into the debate over Medicaid expansion.

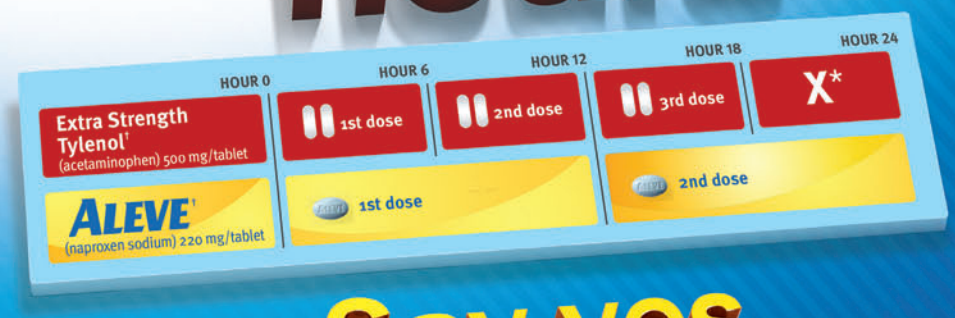
"Our study is able to make use of a randomized design that is rarely available in the evaluation of social insurance programs to estimate the causal effects of Medicaid on emergency department care," they wrote. "We find that expanding Medicaid coverage increases [ED] use across a broad range of visit types, including visits that may be most readily treatable in other outpatient settings. These findings speak to one cost of expanding Medicaid, as well as its net effect on the efficiency of care delivered."

@ Do you believe the Medicaid expansion and the Affordable Care Act in general will increase healthcare costs? Send your thoughts to medec@advanstar.com. Your comments could be included in the next issue of *Medical Economics*.

Based on latest OTC labeling, Tylenol® patients may go with...

Extra Strength Tylenol®

pain reliever for 6 hours*



Say yes to ALEVE.®

24-hour dosing regimen without a gap

*Reflects latest OTC label dosing for Extra Strength Tylenol for adults and children 12 years and older — maximum daily dose reduced from 8 pills (4 grams) to 6 pills (3 grams) with a dosing interval change from every 4-6 hours to every 6 hours unless directed by a doctor.

†Based on minimum label dosing if pain persists.

ALL DAY STRONG®
ALEVE®

BAYER