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Obamacare's Broken Promise

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PLUS

How doctors and patients can FIGHT BACK

ADVANSTAR

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.

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ONLINE EXCLUSIVE

INTEROPERABILITY: HEALTH IT'S NEXT CHALLENGE

Ensuring the easy exchange of electronic health among providers—interoperability—is now a national priority, says Karen DeSalvo, MD, MPH, the new National Coordinator for Health Information Technology. DeSalvo outlined steps the government is taking to help create a national health information network when she addressed the 2014 meeting of the Health Information Management Systems Society (HIMSS). Find more details at **MedicalEconomics.com/DeSalvo**

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#2 AMA CALLS FOR ICD-10 BACKUP PLAN
The American Medical Association wants a contingency plan in place if ICD-10 testing goes awry. Details at
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—Keith Borglum, CHBC
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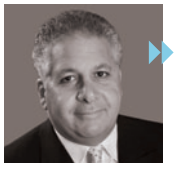

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from the Trenches

> Like many physicians in the country I strongly feel that MOC and taking the test for recertification is outrageous and ridiculous. It is emotionally and socially torturing to prepare for the test. The questions are absurd. They rarely have any value in day-to-day practice.
>
> **Raj Patel, MD, FAAC,** LYCOMING COUNTY, PENNSYLVANIA

MOC EXAM HAS LITTLE VALUE

Regarding the article on maintenance of certification (MOC): ("MOC must go: One physician's view," January 25, 2014) I took my MOC American Board of Internal Medicine test in October 2013 and passed it.

Like many physicians in the country I strongly feel that MOC and taking the test for recertification is outrageous and ridiculous. It is emotionally and socially torturing to prepare for the test. The questions are absurd. They rarely have any value in day-to-day practice.

I think MOC should be voluntary, not mandatory. I know that expressing my concern may not do anything, but I am doing this hoping that it may hit some deaf ears or blind eyes. It is sad to see that almost all doctors complain about MOC but there is no collective voice making an actionable and powerful picture against the ABIM and MOC.

Raj Patel, MD, FAAC
LYCOMING COUNTY, PENNSYLVANIA

MOC REQUIREMENTS ARE ONEROUS AND EXPENSIVE

I am totally against maintenance of certification (MOC.) It's yet another way to extract money from physicians. I'm board certified in both general surgery and plastic surgery and the combined MOC requirements are both onerous and expensive.

If a sizable group of physicians would simply boycott MOC, we could do away with this nonsense. Oh wait, I forgot, doctors have no spine...

David Allison, MD
GAINESVILLE, VIRGINIA

HEALTHCARE DELIVERY SYSTEM MUST BE SIMPLIFIED

I was just on a cruise with the most well-travelled and educated group of people with whom I have ever associated, but their ignorance of the healthcare system was staggering. Their belief that physicians have the time to be fully aware of everything that happens to them everywhere and at any time shows zero understanding of the 60 daily notes from pharmacy benefit managers and insurers, the fact that progress notes from a 20-minute visit would take a minimum of 15 minutes to read, digest, and summarize, the time to properly review labs and other reports, and the complexity of disability forms, etc.

On my first day back I spent four hours reviewing the papers generated by a week away, and I won't pretend that I actually read all the emergency department notes, the entire consults, the notes indicating patients hadn't used enough medication to indicate they are compliant, and

> While virtually any intelligent person can find inefficiencies and friction in all aspects of providing and getting paid for healthcare services, unless and until there is a commitment to finding less involved and simpler provision of services there is no hope of achieving a truly cost-effective, value-driven healthcare system.
>
> **Jim Maher, MD, FACP,** MARSHALL, MICHIGAN

so many other notes that if I read everything I would not see my first patient for another week.

Focusing on the price paid, or even the number of services provided, is irrelevant if 50% of the resources consumed don't benefit the patient as much as they cost. A system like Kaiser or the Veterans Administration may have less administrative overhead, but I see nothing in the future that is going to reduce the administrative load on medical practices.

While virtually any intelligent person can find inefficiencies and friction in all aspects of providing and getting paid for healthcare services, unless and until there is a commitment to finding less involved and simpler provision of services there is no hope of achieving a truly cost-effective, value-driven healthcare system.

Jim Maher, MD, FACP
MARSHALL, MICHIGAN

BEING A 'STAR' CAN TAKE MANY FORMS FOR DOCTORS

In his December 25 letter, "Being A Star Isn't Needed To Help Patients" John Giannone, MD described how he no longer admits to the ICU and doesn't do obstetrics and sigmoidoscopies and no longer serves on committees and boards. But he gets satisfaction from providing broad coordinated care.

His story is similar to that of many primary care doctors. The rapid advances of medical science and the time-consuming strain of administrative tasks that primary care doctors have to deal with has made it necessary for most primary care doctors to limit their practices.

I have been in practice almost 40 years and I no longer admit to the hospital. I use hospitalists for my in-patients, delegate care of my nursing home patients, no longer do pediatrics, and have limited my committee participation (although I remain active in my state and county medical societies' political activities.)

Like Giannone, although my practice is limited I derive great satisfaction from delivering the comprehensive coordination of care that my patients need.

Perhaps physicians need to be in practice for several years to understand that they can no longer live up to the "do it all" model that they learned in residency.

Be this as it may, it seems that there are many ways that a primary care physician can be a "star." It depends on how long they have been in practice, what their financial goals are, how important the life-work balance is to them, and the aptitude they have for personal contact with their patients.

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AMA: CMS NEEDS ICD-10 'BACKUP PLAN'

The American Medical Association (AMA) says it's "deeply concerned" that a contingency plan is not in place if issues occur during International Classification of Diseases—10th Revision (ICD-10) testing this month.

"The slightest glitch in the ICD-10 rollout could potentially cause a billion dollar back-log of medical claims that jeopardizes physician practices and disrupts patients' access to care," Ardis Dee Hoven, MD, president of the AMA, said in a written statement. "At the end of the day sticking hard and fast to the ICD-10 deadline without a back-up plan to address disruptions in medical claims processing will hurt doctors and their patients."

The Centers for Medicare and Medicaid Services (CMS) conducted front-end testing in early March for claims submitted using the ICD-10 code set. In addition, CMS will conduct end-to-end testing of more than 25,000 claims with a limited number of providers.

CMS Administrator Marilyn Tavenner has said there would be no more delays.

OBAMA'S 2015 BUDGET CALLS FOR FUNDING BOOST TO TRAIN, PAY PRIMARY CARE DOCTORS

TRAIN PRIMARY CARE PHYSICIANS

13,000
DOCTORS

13,000 doctors: The president's budget proposal seeks increase the physician workforce by 13,000 by adding $5.23 billion over 10 years to train primary care residents in underserved areas.

EXTEND MEDICAID PARITY

$5.44
BILLION

A one year extension on Medicaid parity payments for primary care physicians would cost $5.44 billion. The parity is set to expire at the end of the year.

LOAN FORGIVENESS

$3.95
BILLION

The president is requesting $3.95 billion to increase the National Health Service Corps, which gives scholarships and loan forgiveness to primary care physicians who work in underserved communities.

FUNDING CUTS

$15
BILLION

Obama proposes to cut $15 billion in funding to teaching hospitals. In addition, the Health and Human Services budget would be cut by 7.6%, down to $73.7 billion, in order to cut $402 billion from Medicaid and Medicare in the next decade.

PRESIDENT BARACK OBAMA is proposing increased funding toward medical school programs for internal medicine, pediatrics, and family medicine in his 2015 budget proposal.

The funding would add ➔ 14

Getty Images/E+/Floortje

STUDY: STROKE PREVENTION FOR ELDERLY PATIENTS MAY BE 'EXCESSIVE'

Patients more than 80 years old are being "over-treated" for stroke prevention and doctors need to actively rethink their priorities and beliefs about stroke prevention, according to a new study published in Evidence Based Medicine.

Individuals in their 80s are often prescribed drugs to prevent a stroke when the risk of a stroke is not that high and the drugs have other side effects, according to the study's author Kit Byatt of the Department of Geriatric Medicine, The County Hospital in Hereford, United Kingdom.

Byatt pointed out that the largest trials of antihypertensive therapy and statins for people in this age group have shown only a marginal reduction in stroke and very modest reductions in other cardiovascular events.

Statins and antihypertensive drugs are widely prescribed to patients in their 80s to ward off stroke. Millions of dollars are spent annually on medications to prevent stroke and significant savings can be found, says Byatt.

He advised physicians to perform a risk/benefit assessment for each patient.

➔13

$5.23 billion over 10 years to train primary care residents in underserved areas.

The American College of Physicians (ACP) released a statement requesting that Congress cooperate with Obama in order to decrease the growing need for primary care physicians in the United States.

"The proposal shows an understanding of the important role that primary care places in ensuring access to high quality and cost-conscious care. Studies show that the United States will need at least 40,000 more primary care physicians for adults by the end of the decade to meet current and anticipated demand," says Molly Cooke, MD, FACP, president of ACP.

Obama's proposal also aims to extend Medicaid parity payments for primary care physicians for another year at the cost of $5.44 billion. The president is also requesting $3.95 billion to increase the National Health Service Corps, which give scholarships and loan forgiveness to primary care physicians who commit to working in underserved communities.

Some organizations are critical of cuts to teaching hospitals for training and complex care. The proposal includes almost $15 billion in cuts to the programs.

Mobile health devices can increase patient adherence

HOW CAN physicians begin to leverage the 247 million Americans who using healthcare mobile applications?

A new study finds that the increase in people using their mobile devices to monitor their health can also help them adhere to a physician's advice.

According to a study by Mobile Future and Infield Health, the wireless pill bottle, a device that digitally monitors the amount of pills in a bottle and can send Health Information Portability and Accountability Act (HIPAA) -compliant, text or phone reminders to patients to take their medicine, increases adherence to 95%.

Also, medical text message reminders can increase medication adherence by 10%, double smoking cessation, and save diabetes patients more than $800 a year.

"Consumer demand for wireless digital health tools is dramatically improving medical outcomes and reducing health costs," says Mobile Future member Infield Health CEO Doug Naegele.

The study finds that by 2018, the mobile health industry's ability to connect with patients has the potential to save the United States $36 billion in healthcare costs. There is already an increasing number of seniors using smartphones (77%) and 42% of hospitals are already using digital health technology to treat patients.

According to the study, 247 million Americans hae downloaded a health app. The student estimates that remote patient monitoring using mobile devices will save the United States $36 billion in healthcare costs by 2018.

THE POWER OF A TEXT

A study by Mobile Future and Infield Health finds that medical text message reminders to patients can:

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Double the quit rate for smokers

SAVE $812 per diabetes patient

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- How to improve poor adherence and better engage patients in your practice.
- Strategies to ease prior authorization headaches
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- Team strategies that improve efficiency
- Negotiating with payers
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The Medical Economics Fighting Back Essay Contest (the "Contest") starts on March 3, 2014 at 12:00 a.m. Eastern Time ("ET") and ends on to May 10, 2014 at 11:59 p.m. ET ("Contest Period"). **ELIGIBILITY:** The Contest is open to [licensed?] physicians who are legal residents of the fifty (50) United States or the District of Columbia, of legal age of majority in their jurisdictions of residence (and at least 18). Employees, temporary workers, freelancers and independent contractors, and their immediate families (spouse and parents, children, siblings and their respective spouses, regardless of where they reside) and those persons living in their same households, whether or not related, of Medical Economics ("Sponsor") and its parents, affiliates, subsidiaries, participating vendors, promotion or advertising agencies are ineligible to enter or win the Contest. By participating, entrants agree to be bound by these Official Rules and the decisions of the judges and/or Sponsor, which are binding and final on matters relating to this Contest. Void where prohibited by law. Contest is subject to all applicable federal, state and local laws. **HOW TO ENTER:** During the Contest Period, write an 800 to 1,200 word essay on how your medical practice has addressed the challenges of running a economically viable medical practice and send to medec@advanstar.com or Medical Economics Fighting Back Contest, 24950 Country Club Blvd., North Olmstead, OH 44070, along with your full name, contact email address, mailing address and telephone number (collectively, an "Entry"). All Entries must be received on or before May 10, 2014. Limit one (1) Entry per person. Entries received in excess of the stated limitation will be void. If handwritten, Entries must be legible. All Entries become the sole property of the Sponsor and will not be returned. Entry must (i) be your own original work, (ii) be in English, (iii) cannot be previously published or submitted in connection with any other contest, (iv) be in keeping with the Sponsor's image and (v) not be offensive or inappropriate, as determined by the Sponsor in its sole discretion, nor can it defame or invade publicity rights or privacy of any person, living or deceased, or otherwise infringe upon any person's personal or property rights or any other third party rights (including, without limitation, copyright). Without limiting the foregoing, Entries must not contain any confidential or personally-identifying patient information. Sponsor reserves the right to disqualify any Entry that it determines, in its sole discretion, does not comply with the above requirements or that is otherwise not in compliance with these Official Rules. **JUDGING:** All eligible Entries received by Sponsor will be judged by a panel of qualified judges based equally on the following criteria: Practicality of solutions offered, clarity and quality of writing, and level of detail to enable other physicians to apply your solution to their practices. The five (5) Entries with the highest scores, as determined by Sponsor in its sole discretion, will be deemed the potential winners. In the event of a tie, an additional, "tie-breaking" judge will determine the winner(s) based on the criteria listed herein. Sponsor reserves the right not to award all prizes if, in its sole discretion, it does not receive a sufficient number of eligible and qualified Entries. Prize awards are subject to verification of eligibility and compliance with these Official Rules. Judges' and Sponsor's decisions are final and binding on all matters relating to this Contest. **WINNER NOTIFICATION:** Potential winners will be notified by telephone, mail and/or email on or about July 10, 2014 and may be required to complete an Affidavit of Eligibility, Liability and Publicity Release (unless prohibited by law), which must be returned within a time period specified by Sponsor. Return of prize or prize notification as undeliverable, failure to sign and return requested documentation within the specified time period, the inability of Sponsor to contact a potential winner within a reasonable time period or noncompliance with these Official Rules by any potential winner will result in disqualification and, at Sponsor's sole discretion, the prize may be awarded to a runner-up. **LICENSE/USE OF ENTRIES:** By submitting an Entry, each entrant agrees that Sponsor and its designees shall have the worldwide perpetual right to exploit, edit, modify, and distribute such Entry, and all elements of such Entry, including entrant's name and likeness, in any and all media now known or not currently known, and for any legal reason, without compensation, permission or notification to entrant. **PRIZES:** Five (5) VISA $500 Gift Cards, one per winner, and publication of the Entry essay in a future edition of Medical Economics Magazine and/or on MedicalEconomics.com with attribution to winner. Approximate Retail Value ("ARV") of each prize is $500. Gift cards are subject to terms and conditions specified thereon. All prize details are at Sponsor's sole discretion. Sponsor may substitute a prize of comparable or greater value at Sponsor's sole discretion. Prizes are non-transferable with no substitutions or cash redemptions except at Sponsor's sole discretion. Additional restrictions may apply, subject to gift card terms and conditions available on the back of the gift card and in included literature. Winners are responsible for all applicable federal, state and local taxes, if any. Limit one (1) prize per person. In the event that Sponsor is unable to publish a winning essay, that part of prize will be forfeited and winner will receive a Visa Gift Card only. Sponsor makes no guarantee as to date of publication of each winning Essay. **GENERAL:** By participating, each entrant agrees: (a) to abide by these rules and decisions of Sponsor and judges, which shall be final in all respects relating to this Contest; (b) to release, discharge and hold harmless Sponsor, its parents, affiliates, subsidiaries, and advertising and promotion agencies, and all of the officers, directors, shareholders, employees, agents and representatives of the forgoing (collectively, "Released Parties") from any and all injuries, liability, losses and damages of any kind to persons, including death, or property resulting, in whole or in part, directly or indirectly, from entrant's participation in the Contest or any Contest-related activity, or the acceptance, possession, use or misuse of the awarded prize or the use by Released Parties' of any rights granted herein; and (c) to the use by Sponsor and its designees of his/her name, entry, biographical information, photograph, image and/or likeness for trade, advertising, publicity and promotional purposes in any and all media, now or hereafter known, worldwide and on the Internet, and in perpetuity, without compensation (unless prohibited by law), notification or permission, unless prohibited by law, and to execute specific consent to such use if asked to do so. Released Parties are not responsible for late, lost, damaged, delayed, inaccurate, misdirected, incomplete, illegible, undeliverable, destroyed, mutilated, stolen or postage-due entries, entry fees, or for errors or problems of any kind whether electronic, network, technical, typographical, printing, human or otherwise relating to or in connection with this Contest, including, without limitation, errors which may occur in connection with the administration of the Contest, the processing or judging of entries, or the announcement of the prizes or in any Contest-related materials. Persons who tamper with or abuse any aspect of the Contest, who act in an unsportsmanlike or disruptive manner or who are in violation of these Official Rules, as solely determined by Sponsor, will be disqualified and all associated Entries will be void. Should any portion of the Contest be, in Sponsor's sole opinion, compromised by non-authorized human intervention or other causes which, in the sole opinion of the Sponsor, corrupt or impair the administration, security, fairness or proper play, or submission of Entries, Sponsor reserves the right at its sole discretion to suspend, modify or terminate the Contest and, if terminated, at its discretion, select the potential winners from all eligible, non-suspect Entries received prior to action taken using the judging procedure outlined above. . ANY ATTEMPT TO DELIBERATELY UNDERMINE THE LEGITIMATE OPERATION OF THE CONTEST MAY BE IN VIOLATION OF CRIMINAL AND CIVIL LAWS AND SHOULD SUCH AN ATTEMPT BE MADE, SPONSOR RESERVES THE RIGHT TO SEEK DAMAGES AND OTHER REMEDIES (INCLUDING ATTORNEYS' FEES) FROM ANY SUCH INDIVIDUAL TO THE FULLEST EXTENT OF THE LAW, INCLUDING CRIMINAL PROSECUTION. Sponsor reserves the right in its sole discretion to cancel or suspend any portion of the Contest for any reason. **REQUEST FOR WINNERS LIST:** For the names of the Winners (available after July 10, 2014), send a self-addressed, stamped, envelope to: Attn: Daniel R. Verdon, Advanstar Communications, 24950 Country Club Blvd., North Olmstead, OH 44070.

NARROW NETWORKS

Obamacare's broken promise, and how doctors and patients can fight back

by **KEITH GRIFFIN,** *Contributing author*

This fight is about money, and it's about patient choice. In the aftermath of a lawsuit targeting UnitedHealthcare after it dropped thousands of physicians from its Medicare Advantage network—despite a public pledge by President Barack Obama that patients could keep their doctors—insurance companies are reportedly using healthcare reform to tighten their physician networks. While the goal, payers say, is to rein in healthcare costs, the consequences will impact all practicing physicians as they scramble to implement provisions of Affordable Care Act (ACA) and guide patients through an increasingly complex payment maze.

HIGHLIGHTS

01 Several states are considering variations on "any willing provider" laws that would make payers accept broader provider networks.

NARROW PROVIDER networks—which allow insurance companies to keep premiums down by including physicians they see as providing less-costly, more value-based care—are not a new phenomenon.

The trend, however, has accelerated since enactment of the ACA, under which payers are using narrow networks to keep premiums lower in the federal and state health insurance exchanges.

In October 2013, narrow networks' impact on physicians was highlighted when UnitedHealthcare targeted 2,200 Connecticut doctors for removal from its Medicare Advantage network. That move is now embroiled in a legal battle.

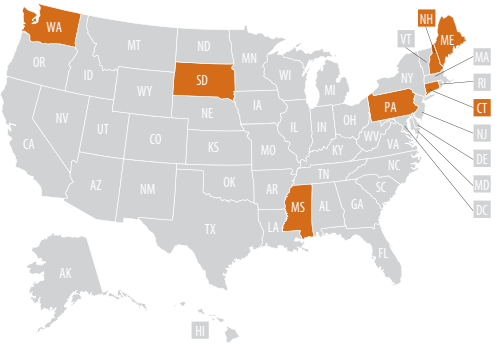
Experts in the healthcare field say that this trend is not going away as the nation's healthcare system attempts to evolve from one that pays for volume to one that tight-

ens costs and delivers value. But if insurance companies want to avoid a rerun of the managed care battles of the 1980s and 1990s—when they were seen as opponents of patient choice—they must negotiate a treacherous political landscape and balance the needs and wants of physicians and patients against their widespread mandate to tamp down costs.

Physicians are paying attention, and are fighting back. In addition to the legal battle being waged in New England, the American Medical Association is pushing legislation on the state level and hoping to influence changes in federal policies. Several states are considering variations on "any willing provider" laws requiring payers to accept broader provider networks. The federal government announced in February that it is exploring rules that, starting in 2015, would require insurers to submit their network lists for review before being approved for the

Narrow Network battleground

Snapshots of skirmishes across the United States



Maine

State regulators prohibited Anthem BlueCross BlueShield from switching some patients to a network sold through the Affordable Care Act's marketplace that excluded six of the state's hospitals. The insurer argued that narrowing its network would provide more affordable but high-quality care.

Washington

Several health plans were banned from the online insurance exchange for what the state insurance commissioner deemed "inadequate caregiver networks." Since then some plans have broadened their networks, while others remain disputed.

New Hampshire

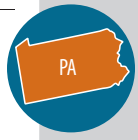
Anthem's 2014 marketplace plans exclude more than a third of the state's hospitals. Lawmakers have written legislation that would force insurers to expand physician choice.

Connecticut

Physicians associations are fighting in court to prevent UnitedHealthCare from dropping thousands of physicians from its Medicare Advantage network. In February, a federal appeals rejected the insurers request to toss out a preliminary injunction stopping the insurance company from dropping doctors.

Mississippi

BlueCross Blue Shield of Mississippi cancelled in-network contracts in summer 2013 with Health Management Associates, which includes 10 hospitals in the state. Now state legislators are considering an "any-willing-provider law", which typically requires insurers to take any hospital, clinic or doctor under terms accepted by other participants.



Pennsylvania

A bill in the state legislature would curb "inappropriate use of market power" by insurers to control consumer choice of healthcare providers.

South Dakota

A proposal making on the statewide ballot in 2014 would prohibit insurance companies from restricting their customers from choosing physicians who aren't included in company networks.

The proposal would allow any health provider to participate in a health insurer's network as long as the provider is willing to meet the terms and conditions of the insurance company and practices within the geographic boundaries of the company's coverage area.

federal health insurance exchange.

"Doctors can't afford to be passive," says Valora Gurganious, senior consultant for DoctorsManagement LLC, a medical practice consulting firm in Knoxville, Tennessee. "Their patients are being ripped away from them and that's not right. They're not being allowed to practice their craft. We're in a major transition, and it's going to be bumpy."

TAKING COVER

While narrow networks are a long-time trend, experts say the ACA was the break in the dam that has allowed insurance companies to quicken the move to narrower provider networks.

"The ACA may give insurers cover for what they wanted to do anyway," says David E. Williams, MBA, co-founder of the Health Business Group, a healthcare consulting firm, based in Boston, Mass.

The ACA makes it difficult for insurance companies to drop costly patients, so "the only opportunity they have is to drop the physician" and hope the patients leave too, Gurganious says.

She expects UnitedHealthcare and other payers to drop physicians when and where they can. She says the company picked the markets and targeted providers with costly patients to drive them to other networks with a goal of negotiating better rates.

"It's putting more downward pressure on remaining carriers," she says, adding it sets a precedent with a lower bar. She says it wouldn't be surprising if other insurers soon followed suit. "It's an unfortunate consequence we could see in the coming months," Gurganious says.

Jeff Hoffman, a senior partner with healthcare consulting firm Kurt Salmon, says the ACA is partly responsible for the narrow networks, but even on the commercial side costs were too high and employers wanted to lower them.

"The day of a premium price model is coming to an end. These changes take time," Hoffman says. "The Affordable Care Act influenced it but it was going to happen eventually. Insurers are looking at how to do better and how to manage."

Insurers are investing in technology and processes to build narrow networks, track the most expensive diseases, and find better treatment management instead of "lurching from crisis to crisis," Hoffman says. The goal is to achieve lower costs while increasing quality of life.

Jeff Moffat, of Blue & Co., a public accounting firm in Indianapolis, Indiana with a large healthcare consulting business, says that even before passage of the ACA there was pressure to contain costs, because insurance companies were lowering reimbursements.

"Physicians feel it most as small employers. It's ironic all these changes are affecting the providers," he says.

Barbara Bergin, MD, an orthopedic surgeon in Austin, Texas, and founding partner of a 27-physician orthopedic group, says, "Doctors have a great feeling of instability and no ability to predict the future. This process has been going on for 20 years. ACA is the straw that broke the camel's back."

THE PAYER BALANCING ACT

One of the reasons payers push narrow networks is to gain leverage over providers by forcing prices down and increasing competition between physicians. Taken to their end point, narrow networks mean providers who meet the value and cost targets will be kept in the network. Those who do not will be removed.

"Welcome to the world of competition in healthcare, because that is what narrow networks are about," David Blumenthal, MD, MPP, president of The Commonwealth Fund writes in a commentary on the Huffington Post website.

Tammy D. Arnold, a clinical and network communications spokeswoman for Aetna, says that patient access to affordable health plans requires affordable provider services.

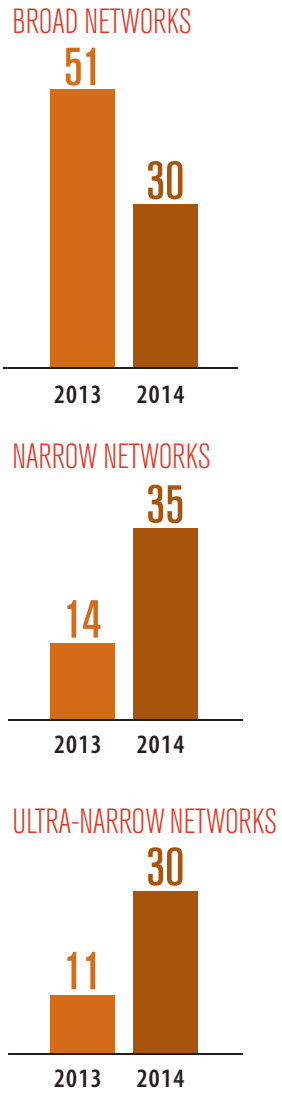
"Under the healthcare reform law, there are a number of new benefits and new costs for consumers, employers, and seniors," she says. "Given these new costs, as well as the wide variation in the cost and quality of services provided by doctors and hospitals, insurers are developing high-value provider networks to help keep health care affordable for millions of Americans."

But insurers must strike a balance between achieving cost savings and customer convenience, says Reid Rasmussen, owner of freshbenies, a subscription

The rise of Narrow Networks

McKinsey & Company analyzed network configurations on the individual market in 2013, prior to the ACA, and compared them to the the networks on insurance exchange in 2014, based on whether the networks are considered broad, narrow, or ultra-narrow based on McKinsey's criteria.

They found:



service for concierge-like medical services in McKinney, Texas, with decades of experience in the healthcare industry.

"There's a high cost to the convenience we've had in medical care," Rasmussen says. "Narrow networks are the future, but it's in flux as companies determine what patients want. Insurers don't want to lose their customers."

Narrowing networks is essentially the same strategy as that used by Walmart, Rasmussen says: push prices lower in order to leverage better prices from suppliers, in this case the physician. The downside to insurers squeezing physicians is that the physicians eventually will stop working with insurance companies if the companies squeeze too hard.

> "Welcome to the world of competition in healthcare, because that is what narrow networks are about."
>
> —DAVID BLUMENTHAL, PRESIDENT, COMMONWEALTH FUND IN THE *HUFFINGTON POST.*

"There will be times when insurance companies push too hard, and during the time of flux is when it will be most ugly," he says.

Donald J. Rebhun, MD, an internist and corporate medical director of HealthCare Partners Medical Group and Affiliated Physicians in Southern California, says he has seen narrow networks based solely on cost, which is a mistaken approach.

"The focus must first be on quality and then cost," he says. "There have been clear outcomes that you can combine quality with cost savings to get a superb system."

HealthCare Partners has had that focus for years, Rebhun says. The practice, which is described as the largest medical group in the United States, is more focused on patient management. "There's a transition in America from volume to value," he says.

Jessica Ogden, an associate principal at McKinsey & Company consultants in New Jersey, and coauthor of the McKinsey Center for U.S. Health System Reform report, "Hospital networks: Configuration on the exchanges and their impacts on premiums," says narrowing networks is one of the way insurers are best able to lower their premiums. According to her research, insurance companies are offering almost three times as many ultra-narrow and narrow networks for hospitals as they offered in the same markets prior to the creation of exchanges under the ACA.

Both Rasmussen and Williams say that narrow networks will be the right choice for many Americans, while others will prefer to pay more and have available a broader selection of providers. In fact, a February poll from the Kaiser Family Foundation found that patients newly insured by exchange plans "are more likely to prefer less costly plans with narrow networks over more expensive plans with broader networks."

In addition, research by McKinsey shows that patients don't mind narrow networks for hospitals. McKinsey reviewed Centers for Medicare and Medicaid Services' (CMS) records of readmissions and its composite score (value-based purchasing) of 20 other quality and patient satisfaction measures and found no discernible differences in performance on these scores among the hospitals participating in ultra-narrow, narrow, and broad networks. There was also no meaningful difference when it compared lowest-price to higher-price products.

FIGHTING BACK

Still, many physicians and their patients have sounded the alarm regarding narrow networks, and powerful forces are lining up to support physicians who say insurers are harming healthcare by coming between doctors and their patients.

In Connecticut, where physicians are battling UnitedHealthcare's Medicare Advantage cuts, the Fairfield and Hartford county medical associations have successfully fought the elimination of more than 2,200 physicians thanks to a federal Court of Appeals ➔23

➔22 decision that forced UnitedHealthcare to grant the physicians arbitration hearings.

"It was positive for us," says Robin Oshman, MD, PhD, a dermatologist practicing in Westport and New Canaan, Connecticut and president of the Fairfield County Medical Association. "We won the initial battle so doctors could remain in the plans and patients could remain with their doctors."

Oshman says she hopes other medical associations across the country will follow their lead and seek injunctive relief.

Ardis Dee Hoven, MD, president of the American Medical Association (AMA), says the association is concerned about the creation of more narrow networks on the healthcare exchanges, and that they are "going to have to monitor them for adequacy of care."

The most immediate concern, Hoven says, is making sure that payers are open with providers about the reasons for the cuts.

"It's how they're doing it," she says. "It needs to be transparent to patients and doctors so the healthcare community can help determine standards."

Along those lines, the AMA is pushing new legislation on the state level and hoping to affect changes in federal policies. Hoven says state insurance departments will provide better oversight on the continuity of care issue and provide better monitoring and measurement of care.

The new federal proposal will force insurers to submit plan details, including lists of providers to CMS by June 27, 2014, for products they wish to sell during the 2015 enrollment period so that CMS can determine network adequacy. Federal officials will review the plans over the summer and notify insurers about any deficiencies so fixes can be made by mid-October.

"As consumer interest grows and puts pressure on the companies to say 'we want broader networks,' there will be a new filing for Qualified Health Plans for 2015," U.S. Health and Human Services Secretary Kathleen Sebelius told *Medical Economics* during a February visit to Cleveland. "And I think insurance companies are hearing that from a lot of their customers. They want more choice. They're willing to pay more money for broad access to a network, and I think we'll begin to see that."

Bob Doherty, senior vice president,

DROPPED BY A PAYER? WHAT TO DO NEXT

Notify patients

While payers are legally obligated to contact patients to inform them that their physician is no longer in the network, physicians should call patients themselves to inform them of their options.

"You should take it upon yourself to notify the patients yourself, especially if they are on the schedule for the next three to four weeks. You need to know whether the patient still wants to see you," says David Zetter, consultant with Zetter Healthcare Management Consultants in Mechanicsburg, Pennsylvania

Zetter also suggests writing a script to explain the situation and the options for patients, so whoever is calling patients will be prepared for their questions.

Get answers

Contact provider and contract representatives within the payer organization to get concrete answers on why you were dropped.

"If you find out a few other doctors you know were dropped, you can try to call the payer and get answers," Zetter says. "But you may not get far."

Reach out

An untapped resource for many physicians is local medical societies and organizations. County medical associations have led the charge in the fight against UnitedHealthcare in Connecticut, and have won short-term legal victories for physicians. Physicians should use these groups as a way to make their voices heard.

Create payment policies

Decide on a standard self-pay policy to offer to patients who still want to see a physician who is no longer in their insurance network. Your fees should be equal to the highest reimbursement you received from your third-party payers.

"I don't recommend a standard percentage cash discount," Zetter says. "Your cash policy should be in writing because if you are charging people different prices, it could raise some issues with payers."

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>
> — VALORA GURGANIOUS, SENIOR CONSULTANT, DOCTORSMANAGEMENT LLC, KNOXVILLE, TENNESSEE.

governmental affairs and public policy for the American College of Physicians (ACP), says the ACP was pleased with the proposal to strengthen network adequacy requirements. But the ACP would like to see the federal government improve the current network adequacy standards by taking into account additional criteria, including patient-to-physician ratios, use of out-of-network clinicians and hospitals, and urban, suburban, and rural area-relevant standards as indicators of access. It also wants compliance and complaint information from network adequacy monitoring be made available to the public, Doherty says.

Payer transparency is key, Hoven says. "Insurance companies need to standardize this," Hoven says, adding that the system should be evaluated regularly to make sure it is running smoothly.

"I think that includes CMS, the federal government, and everybody involved. This is something that is doable. It all goes back to transparency. If we invoke the rule of transparency, we can make better decisions," Hoven says.

OPTIONS FOR PHYSICIANS

One way for physicians to avoid the stress that comes from being dropped by payers is to create a business model that minimizes the importance of insurance. Enter models such as direct pay.

Rachot Vacharothone, MD, an internist in South Jordan, Utah, created a medical membership plan for his seven After Hours Medical urgent care clinics. Members pay $25 per month and a $10 flat fee per visit that includes testing, x-rays and other treatments. Members also have 24-hour access to providers through telemedicine services.

Vacharothone says he believes the future of physician payment lies in flat fees and higher reimbursement for good patient outcomes.

"I believe 10 years from now, accountable care organizations are going to be the way for reimbursing providers," Vacharothone says, adding that the current fee-for-service method is not sustainable. "Now you do more and get paid more, regardless of the outcome. The answer is capitation. Insurers should do that so costs are not going out of control and doctors get rewarded for good outcomes."

Rebhun agrees that some form of capitation or integrated care involving payment per patient should be part of any future solution. In the past, Rebhun has seen patients change doctors because employers have switched insurance carriers. But when employers switch from pre-paid insurance to high-deductible preferred provider organizations, almost all of his patients have stayed with HealthCare Partners.

Hoffman, from the healthcare consulting firm Kurt Salmon, advises physicians not to get caught up in shared savings offered by insurers where they are responsible for patient management and investing in new technology to change the care model. Doctors should seek something more long-term for creating this new value for the insurers and become partners with them. Payments for shared savings will dry up as goals change annually and become more difficult to attain as more efficiencies are created and costs drop.

"Just getting a percent of savings is not enough value for bearing the risks," Hoffman says.

Bergin, the Texas orthopedic surgeon, says doctors can quit insurance companies. In the past they have terminated relationships because the offices couldn't afford the fees. "Insurance companies aren't afraid of that any more. They are always going to be able to find somebody to accept their fees," Bergin says.

Another alternative is the Patient-Centered Medical Home (PCMH) model. Moffat says PCMHs almost always focus on primary care, internal care, and pediatrics.

"They're getting paid to keep [patients] well," he says. They leverage mid-level providers like nurse practitioners supervised by doctors. Nurse practitioners do the follow-ups doctors used to do. But medical homes can be difficult because it involves changing the way a practice operates at a fundamental level.

Advocacy is going to be an important step for physicians to take. Gurganious says physicians need to become more involved in their local medical associations and encourage more advocacy and negotiation. "They need to be as massive a force as the other side," she says. "There is always strength in numbers." ◻

Avoiding landmines when signing a hospital contract

Look closely at compensation, impacts of new payment models, termination clauses, and restrictive covenants

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

HIGHLIGHTS

01 Many hospital employment agreements include restrictive covenants prohibiting three types of behavior: working for a competitor, soliciting employees to leave, or soliciting patients to leave their practice.

02 Many hospitals base their employed physician compensation on work relative value units (wRVUs), which is the essence of a volume driven payment.

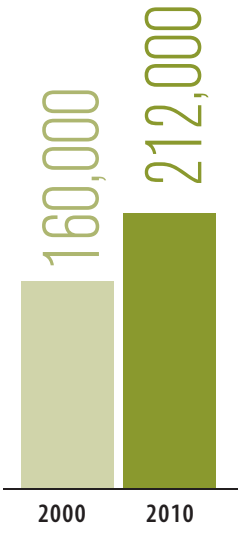
Physician employment contracts with hospitals or healthcare systems can be unpredictable. Mergers and layoffs are all often overlooked realities for employed physicians, especially during a time when so much emphasis is on reducing healthcare costs. If you are negotiating an employment contract, take a close look at the compensation arrangement, termination clauses, and non-compete agreements.

BECAUSE THINGS may not work out as anticipated for either the physician or the employing hospital or health system, it is important to address at the outset some of the potential issues that may arise upon termination of the relationship. This article examines typical issues that should be addressed in a hospital employment contract and suggests post-termination matters that should be brought up before signing.

THE BASIC RELATIONSHIP

Many health systems have practice entities that are separate corporations through which they employ physicians. In other

PHYSICIANS EMPLOYED BY HOSPITALS



Source: American Hospital Association

While the physician ranks in hospitals have been growing, some systems have adopted compensation ceiling policies that won't go above the 75th percentile.

circumstances, the physician is employed directly by the same entity that holds the hospital license and hospital tax identification number.

Where the employment is directly by the hospital or the same entity holding the hospital license, there are some additional restrictions that apply under Medicare rules, such as the prohibition under the Stark statute against compensating physicians for "incident to" services provided by hospital personnel. In a separate practice of the hospital, "incident to" revenues could be allocated to the employed physicians within the hospital group, as part of their productivity.

No matter which entity is the employer, the relationship is a one-to-one proposition. Under common law, the employment relationship is that of master-servant, which means the employer has the right to tell the employee how, when, and where to perform services. Many hospital employment contracts contain these strong control features.

If you were previously in a group, and even if all the members of your group become employees of the hospital, unless you are in a separate corporate structure (which can happen but is unusual), you should understand that you are an individual in relationship to your employer. Your group cohesion will mean very little.

Familiarize yourself with the policies and rules you are expected to comply with as of the start date, and that the hospital will notify you regularly of changes during the term.

COMPENSATION

Many physicians seek hospital employment for financial security. The sustainability of many apparently lucrative employment relationships is eroding. However, this makes the compensation clauses extremely important.

Many hospitals base their employed physician compensation on work relative value units (wRVUs), which is the essence of a volume-driven payment. Some have adopted policies that they will not compensate a physician above the 75th percentile of relevant compensation surveys so as to be certain they are paying fair market value, even if the physician is significantly more productive than his or her peers.

Being clear on the expectations of productivity and that wRVU targets are realistic is important. The opportunity to earn a bonus above a base salary will often be an issue.

Often these contracts do not address the fact that over the three years of the contract, for example, new payment models including case rates, bundled payment, and global capitation may be introduced, so that wRVUs are no longer an appropriate sole measure of performance for compensation.

How these changes will be accommodated going forward, and the extent to which the employed physician has any say in their construction is also important. Being certain on what basis the compensation can change over time will be critical, especially because hospitals have begun to be assessed Stark and false claims settlements, where excessive compensation was paid.

Many hospital employment contracts assign to the hospital Meaningful Use and Physician Quality Reporting System (PQRS) bonuses and do not pass those payments through to physicians. Few have yet addressed what will happen when penalties kick in for PQRS reporting failures.

In addition, beginning in 2015 the value-based payment modifier for the Medicare physician fee schedule will apply to groups of 100 or more physicians reporting through the same tax identification number based on 2013 performance. How will that be handled?

In the last analysis, the question to ask when entering an employment situation with a hospital that is facing its own challenges from fewer readmissions, the effects of their value based payment modifier, and lower volumes of admissions, is what happens when the hospital believes it cannot financially sustain what it agreed to. Sometimes you can negotiate that if the hospital proposes a compensation change that is more than a certain percentage lower than the original compensation, you can walk away with no restrictive covenant.

This raises the issue of bases for termination.

TERMINATION

One of the first issues is whether the loss of productivity, which may not be in the physician's control, is grounds for outright termination or for renegotiating the compensation. Parsing out the distinctions between lower performance from lack of effort versus loss of productivity from a shift in utilization can be thorny, but it can be addressed in contract language.

The hospital employer will ➔27

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Advil (ibuprofen) 200 mg/tablet		1st dose	2nd dose	3rd dose	4th dose

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➔26 typically document a litany of bases for immediate termination (e.g., loss of license, loss of insurability, violation of alcohol or drug policies) with no opportunity to save employment.

There are typically other grounds for termination for cause (e.g., violation of a policy) with a cure period. For termination without cause, there are pros and cons to the length of time for notice. If termination without cause is only available on 180 days notice, this gives both parties the opportunity to make other arrangements, but if the physician is unhappy he or she is stuck for six months. If the hospital is unhappy with the physician, they have six months of service from a disgruntled employee.

If, however, the notice period is only 60 or 90 days, then there is little security in the arrangement. In addition, if the hospital can terminate the physician without cause, it is fair to ask that any restrictive covenants not apply, but not all hospitals will concur.

Another issue is whether the physician has the right to terminate for breach of contract. Surprisingly to many physicians, many employment agreements do not allow this. If the physician terminates for breach, the restrictive covenants should not apply, but not all hospitals will agree to that. In the last analysis, these decisions are sometimes made on the front end with little appreciation of what they will mean on the back end.

The parties can always agree later to something not in the contract. The likelihood of that depends entirely on context.

RESTRICTIVE COVENANTS

Many hospital employment agreements include restrictive covenants prohibiting behavior of three types: working for a competitor, soliciting employees to leave, or soliciting patients to leave their practice.

These are almost always in place during the term of the employment, but often are also in place post-termination, sometimes for longer than a year. The enforceability of these clauses and their reasonableness in terms of geographic scope and length of time is determined by state law. As systems increasingly consolidate, hospitals are often more concerned about their employees fleeing to a competitor than going back into private practice.

As a result, it is sometimes possible to negotiate permission to be in independent practice—even with a group—as long as the practice is not managed, affiliated with or owned by a competitor.

Non-solicitation clauses sometimes prohibit a terminating physician from taking hospital employees with him or her. Usually the prohibition is on active solicitation, but if someone leaves voluntarily, the provision is not triggered. Careful drafting can be important.

Solicitation of patients post-termination

PHYSICIANS AND HOSPITAL ADMINISTRATORS

Breaking down cultural differences

Physicians and hospitals must co-exist for the success of the U.S. healthcare system, but both physicians and the executives who run hospitals have very different philosophies, and this dichotomy can lead to conflict.

Physician culture	Hospital administration culture
Values autonomy, trained to work independently	Trained to delegate and work in groups, embraces the collective mission
The need for quick decision-making	Deliberate decision-making
Resistant to hierarchy	Hierarchy is key to success
Trained in biomedical sciences, clinical expertise	Trained in management, social sciences
Seeks consensus in group decisions	Respects top-down hierarchy when making decisions

Source: Nathan Laufer, MD, "The employment of doctors by hospitals—indentured servitude or practice salvation?"

Many hospital employment contracts assign to the hospital the Meaningful Use and Physician Quality Reporting System (PQRS) bonuses that have been available and do not pass those payments through to physicians. Others do. Few have yet addressed what will happen when penalties kick in for PQRS reporting failures.

is often prohibited, but depending on how the relationship unfolds, if employment is terminated by either party after a short time, it is sometimes possible to bargain for the ability to take back the patients that you brought. When employment situations fall apart early, usually both parties are unhappy.

In anticipation of potential termination, some hospital employers are willing to specify in the agreement what steps they will take to notify patients of the physician's whereabouts when he or she leaves. Some state laws have requirements regarding notices and whether the patients belong to the hospital or the physician.

These issues also relate to patient records and what happens with them.

MEDICAL RECORDS

Physicians typically bring medical records with them when they become employed. Hospitals usually integrate the records into the system's electronic health record (EHR).

While physicians have the right of access to records of patients they are treating, in some states, such as South Carolina, the law says the records themselves belong to the physicians. The hospital is then the custodian of the records.

Upon termination, the issue is whether the physician can take back what he or she brought. Patients can always direct that a copy of a record be made available to their physician post-termination, but with EHRs it can be important to specify in the contract the format in which the records will be provided, the process for that to happen, and who pays the expense, if any.

In addition, the question of how access to records will be made available to the physician for legitimate reasons post termination should be addressed.

BILLING RECORDS AND POST-PAYMENT AUDITS

In virtually all hospital employment contracts, the hospital handles the billing and collection for the physicians.

Medicare law requires that during the term of employment, the physician have access to all claims submitted on his or her behalf, but it is important to include that in the contract. And the right should extend to post-termination access, as well for audits and other reasons.

In addition, since the hospital will control the claims submission process, it should indemnify the physician for negligence in claims submission, including post-termination. The hospital often will have a provision that says that the physician indemnifies them for negligence in documentation.

If the hospital will not agree to indemnify, an alternative approach is to have it warrant that it will submit claims in accordance with the standards of the industry. In turn, the physician can agree to submit claims in accordance with legal and payor requirements.

Increasingly hospital employers use contract provisions that provide for financial responsibility, including post-termination, for the physician whose documentation has led to audits, investigations, settlements, or penalties which the hospital must pay.

If these clauses are presented, it is important for the physician to have access to the basic data on which the determination has been made; that the hospital be obligated to pursue the defense of such claims and involve the physician, and even that they jointly select the lawyers to manage the case, if any.

The physician will need legal representation in these circumstances; and the hospital should be obligated to respond to that need and any issues the attorney raises during the resolution of the matter. It is important to provide the foundation for these concerns in the employment agreement.

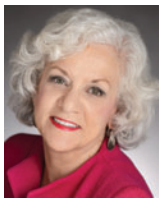
CONCLUSION

The healthcare landscape is changing rapidly, and hospital employment is a pathway

physicians are increasingly pursuing. But it is fraught with pitfalls. The contract is where those issues can first be confronted. The ability to do so, however, will depend entirely on context.

The more important the potential employee is to the hospital or system, the greater the likelihood these issues can be negotiated. On the other hand, some systems have their requirements and will not change them.

Indications of potential problem areas can be gleaned in the negotiation process. These issues should inform the decision about whether to sign at all.



Alice G. Gosfield, JD, is principal of Alice G. Gosfield and Associates, P.C., a healthcare law firm in Philadelphia, Pennsylvania.

MUST WATCH

KEY POINTS OF AN EMPLOYMENT CONTRACT

by Scott Baltic

Physicians considering an employment agreement with a hospital have many decisions to make. Hospitals have learned from previous cycles of buying practices and hiring large numbers of physicians, says H. Christopher Zaenger, president of Z Management Group in Elgin, Illinois. Here is what physicians need to know to succeed in the current climate:

Next contract is key

"The hammer that hasn't fallen yet" for many physicians who've sold their practices, Zaenger warns, is that a typical hospital employment contract runs for two or three years, after which the hospital has the unilateral right to adjust the physician's compensation.

Read the contract

Whether contracts are for partnerships, hospital employment, or insurance, "physicians don't read contracts, they just sign them," Zaenger says. "Some doctors just hate paying lawyers."

When joining a hospital or a larger practice, "Go in with your eyes wide open," he says, and if you don't talk to a lawyer, at least talk to your accountant.

Magnifying contract details

- Realize that employment contracts typically specify that the hospital's interest is assignable in the event of a merger, says Alice G. Gosfield, JD, of Alice G. Gosfield and Associates, Philadelphia, Pennsylvania.
- Be sure to read the survivorship provision to see if it gives you an out in the event of a hospital merger, agrees William J. DeMarco, MA, CMC, president/chief executive officer of Pendulum HealthCare Development Corp. And if the hospital's expectations change following a merger, "You need to reopen negotiations," he advises.
- Bear in mind that non-competition provisions are highly variable, says DeMarco, so they warrant substantial attention. (Zaenger knows one family practitioner who wound up having to move from the Chicago area to Wisconsin because of a non-compete.)
- Recognize that non-competition provisions can be renegotiated if the hospital wants to keep the physician as a source of admissions, Zaenger says. "It is all about money," he says.
- Examine whether the physician has the right to contract directly with a managed-care organization or other third parties, advises DeMarco.
- Specify in the contract that if the physician is terminated without cause, the restrictive covenants do not apply, Gosfield says.

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Improving cash flow through accounts receivable financing

Access to credit can help physicians get through tough times, but use diligence before accepting terms

by **CHRISTINA VAN VORT, JD,** *Contributing author*

HIGHLIGHTS

01 Accounts receivable financings are generally structured as lines of credit, where the provider can borrow, repay the loan, and re-borrow as new receivables are generated.

02 By its nature, accounts receivable financing is structured so that the provider is continuously dependent upon the lender for capital, as the provider borrows and its collections are applied to pay down the existing loan.

Cash flow is the lifeblood of any business. Financing the provider's patient accounts receivable is one way to generate needed capital. Instead of waiting to receive reimbursement from third-party payers for healthcare services or goods provided, receivables financing allows providers to get a portion of that money sooner, thus accelerating cash flow.

Providers considering receivables financing should become familiar with the structure and how it might impact their cash flow. This article will provide an overview of receivables financing for healthcare providers.

Accounts receivable financings are secured by the provider's patient accounts receivable. In a loan secured by equipment or real property, with which providers may be more familiar, the provider usually borrows a set amount of money in one lump sum. So long as the provider repays the loan as required, the lender takes a relatively hands-off approach and does not closely monitor the provider's business. Accounts receivable financings generally function differently.

Since the lender's collateral is constantly changing as receivables are collected and new receivables are generated, the provider's ability to borrow adjusts accordingly.

For this reason, these financings are generally structured as lines of credit, where the provider can borrow, repay the loan, and re-borrow as new receivables are generated. In order for the lender to determine the borrowing availability continually, the lender must have access to up-to-date receivables information.

THE BORROWING BASE

Usually providers are able to borrow up to the lesser of the maximum amount of the facility and the "borrowing base."

The borrowing base is the lender's calculation of the provider's borrowing ability based on the amount the provider is expected to collect on its eligible receivables, which amount is discounted to provide a cushion for the lender.

For example, a lender may consider all patient receivables that are

less than 90 days old and that are owed by third-party payers (for example, managed care organizations, Medicare, and Medicaid) to be eligible for purposes of the borrowing base calculation. The provider would be able to borrow a percentage, such as 80%, of the amount the provider is expected to collect on these receivables.

Understanding the borrowing base calculation is important for several reasons. First, the provider should be aware that despite the maximum value of a facility, it will only be allowed to borrow up to its borrowing base.

Second, lenders commonly charge a fee for the "unused" portion of a facility, or the difference between the maximum amount and the borrowing base.

Therefore, a provider should negotiate a maximum facility amount that does not significantly exceed its projected borrowing base.

Third, because the borrowing base is a percentage of eligible receivables, the provider should focus on the eligibility criteria.

While it is expected that lenders will reserve some discretion in loan documents, wide discretion in this area could result in the provider's borrowing availability being substantially lower than the provider expected.

CASH MANAGEMENT

Another crucial aspect of an accounts receivable financing is cash management. Since the lender's main collateral is cash collections, which is easily disposable, the lender may want to monitor its collateral.

Lenders will often require the provider to have its third-party payers send payments on receivables directly to the lender. The lender then automatically retains monies owed to it, and returns any excess cash to the provider. As the provider needs additional cash it re-borrows and the cycle continues.

Implementing this cash management system allows the lender to exercise control over its collateral. If the provider defaults under the loan documents and a balance is outstanding, the lender may repay itself without the provider's cooperation. However, there is one important limitation on this system.

Payments from Medicare and Medicaid must be made directly to the provider of ser-

LENDERS WILL OFTEN REQUIRE THE PROVIDER TO HAVE ITS THIRD-PARTY PAYERS SEND PAYMENTS ON RECEIVABLES DIRECTLY TO THE LENDER.

Accounts receivable financing worksheet

- ☐ **Setting the borrowing base**
  A lender will consider patient receivables that meet certain criteria to formulate the borrowing base. For example, the lender may include all receivables less than 90 days old owed by third-party payers.

- ☐ **Borrowing ability**
  The provider would be able to borrow a percentage, such as 80%, of the amount the provider is expected to collect on these receivables.

- ☐ **Receivables expected to be collected**
  Of the eligible amount determined by the borrowing base, the lender will determine the amount the provider is expected to collect.

- ☐ **Liabilities**
  The lender may impose reserves against the financing amount based on the provider's liabilities.

- ☐ **Calculating the line of credit**
  A practice with $1 million in outstanding patient receivables is seeking financing. The lender determines that the borrowing base is $800,000, and of that amount the provider is expected to collect $700,000.

  The provider may borrow 80% of the $700,000, or $560,000, even if this amount is lower than the maximum amount of the facility. If the provider has a potential $50,000 liability to Medicare, the lender may subtract this amount from the provider's availability, reducing it to $510,000.

Accounts receivable financing is structured so that the provider is continuously dependent upon the lender for capital, as the provider borrows and its collections are applied to pay down the existing loan.

vices, except in limited circumstances. Thus, a healthcare provider may not direct these payments to be sent directly to a bank account that is controlled by the lender.

This limitation is designed to prevent fraudulent billing practices. Because of this limitation, lenders generally require that payments from governmental entities be sent to a lockbox controlled by the provider.

The provider then instructs the bank to sweep all of the funds to the lender periodically. These instructions must be revocable; however, the provider can agree in the loan documents not to change or revoke the instructions. If the provider does redirect the funds, it is considered an event of default under the loan documents.

A cash management system of this type gives the lender the maximum permissible control over the provider's cash collections.

HIPAA COMPLIANCE

Another issue that both providers and lenders need to focus on when healthcare receivables are involved is the confidentiality of patient information.

In the course of reviewing information about the provider's accounts receivable, a lender typically will have access to patient health information. The federal law dealing with patient confidentiality is the Health Insurance Portability and Accountability Act (HIPAA) of 1996. HIPAA limits uses and disclosures of patient information by the provider.

Under HIPAA, the lender is likely to be viewed as a "business associate" of the provider. Providers may disclose patient information to business associates so long as a HIPAA-compliant business associate agreement exists between the provider and the business associate.

Business associate agreements must contain certain provisions designed to ensure that the business associates maintains the confidentiality and security of the patient information disclosed to them by the provider. State confidentiality laws may also apply to this situation.

DIFFICULT TO GET OUT

In addition to the foregoing transactional issues, providers should be aware that it may be difficult to get out of an accounts receivable financing.

By its nature, accounts receivable financing is structured so that the provider is continuously dependent upon the lender for capital, as the provider borrows and its collections are applied to pay down the existing loan.

Thus, if a provider consistently borrows the full availability under its loan facility and spends substantially all of the proceeds, the provider may not have sufficient funds to satisfy all outstanding obligations, either at the maturity of the loan or earlier.

If feasible, the provider could try to wean itself off the facility by gradually decreasing its borrowings. By doing so, cash collections may accumulate to fund all or a portion of a payoff. Alternatively, the provider will need to refinance the debt.

Accounts receivable financings are a viable alternative for healthcare providers to raise capital, but it is essential for a provider to understand how these financings function in order to evaluate both the financial benefits and the impact on the provider's cash flow. ◘

Christina Van Vort, JD, is a partner at Garfunkel Wild, P.C. in Great Neck, New York. She specializes in areas of healthcare law including regulation, HIPAA compliance, and financing.

@ MORE RESOURCES

More coverage at *MedicalEconomics.com*

Credit line can be lifeline for your practice *http://bit.ly/NUtdKN*

Examining accounting and finances can illuminate ways to save, bring in revenue *http://bit.ly/1q6POTo*

When it's time to grow, where do you find the money? *http://bit.ly/MNLmZZ*

Leasing medical office space: Negotiate for the long-term, but plan for change

by **GERALD H. MORGANSTERN, JD** *Contributing author*

HIGHLIGHTS

01 A single practitioner obtaining a long lease may want a cancellation clause in the event of death or disability.

02 Relocation clauses are becoming more common in leases. If a landlord customarily includes a right to relocate a tenant to another location, you should make sure the provisions cover the extra time and expense involved to relocate a medical facility.

As medical practices move to traditional retail and office spaces, and as urgent care centers continue to grow, understanding the complexities of lease arrangements and spelling out the needs of a busy and changing medical practice take on even greater financial importance for physicians.

It's important to note that leases and the leasing process for medical practices are largely similar to leases for non-medical retail or office space, but there are far more patient safety and regulatory requirements to consider. Leasing medical space involves certain risks too. It is best to plan for the long term to avoid surprises, but the lease agreements have to be flexible enough to accommodate for change as the practice evolves and grows.

While it is important to work with an attorney on such matters, this article details some of the most significant real estate and operational issues that you and your landlord must understand when initiating a medical lease.

SPECIAL NEEDS OF MEDICAL PRACTICE

If your practice will occupy previously non-medical space, there may be a requirement for physical changes in the building. This must be made clear in the process of negotiating your lease.

It is important that the landlord understand the nature of a medical practice. Consider the possibility of emergency care or performance of outpatient surgery and the possible need for ambulance services to the premises. Late-night visits are not a problem for a retail location, but may be for an office or apartment building.

Make sure your landlord spells out any rules and charges for needed after-hours usage of the property in the lease agreement.

Since medical practices usually require installation of extensive and expensive equipment, short-term leases are not practical. Your practice may need at least a 10-year lease and you should also seek exten-

LEASE NEGOTIATION CHECKLIST

Whatever the condition of your local real estate market, you still can take steps to get a better deal.

- ☐ **Measure the space.** Don't just accept the square-footage amount (or approximation) the landlord provides. Catching even a 1% error will gain you 3 free weeks of rent in a 5-year lease.
- ☐ **Get representation.** Using your building's (or affiliated hospital's) broker to negotiate a lease for you is asking to be bamboozled. Have your own broker, consultant, or attorney on your side of the table. Spending a few hundred dollars could knock thousands off your cost of occupancy. More important, you could avoid being handcuffed to provisions that make your tenancy unbearable for years to come.
- ☐ **Put a cap on rent increases.** If you are willing to protect the landlord from inflation at all, then tie rent increases to some real-world index such as the local consumer price index. And bargain for only a portion of the increase as a pass-along. Let the landlord take some of the risk along with you.
- ☐ **Get an "out" clause.** Your landlord wants a 5-year lease, but your situation could change. So include a clause that gives you the right to cancel the lease any time after 3 years if you pay for unamortized improvements.
- ☐ **But keep the option to renew.** Try to lock in the renewal rate, too. If you find that the market is soft when your lease is up, you can always renegotiate.
- ☐ **Keep the right to sublease.** "Standard" leases forbid your assignment of the lease or subletting. Replace this language with your own clause requiring the landlord to approve a reasonable subtenant. And keep the "use" clause as vague as possible, too.

sion options. A single practitioner obtaining a long lease may want a cancellation clause in the event of death or disability. A typical provision says the election can be made within 60 days after the event or appointment of the person's legal representatives.

Another choice is to allow sale of the practice upon death or disability without recapture or other impediments.

MEDICAL EQUIPMENT

Certain equipment may be strictly regulated. X-ray, computed tomography (CT) scan or other radiation producing machines need lead shielding.

Both parties will want to be sure they are operating safely and the lease should provide for plans, certified by your architect, designed to avoid the possibility of damage to the premises and individuals in or near the premises. In addition to obtaining required governmental approvals or certificates of compliance, be sure you understand what you need to do to comply with all rules mandated by the landlord's or your own insurance company regarding the elimination or amelioration of risk posed by X-rays or electromagnetic rays and/or fields.

If available, you should have an endorsement in your liability policy providing protection against claims of injury from exposure to X-rays, etc., making sure to name the landlord as an additional insured.

MEDICAL WASTE

Most medical offices have medical waste which cannot be combined with normal rubbish. You should expressly agree to properly dispose of any contaminated material, medical waste, or other articles which may be contagious or radioactive. Such waste must be in a secure place so that unauthorized persons or children cannot open or take the containers.

ADA REQUIREMENTS

Some medical patients may have issues that make them prone to injury.

Careful compliance with the Americans with Disabilities Act is necessary from both landlord and tenant so no claim of injury can be based on a failure to comply with the act. Curb cuts must be in the right places, ramps must be angled correctly, and doors must be wide enough.

MEDICAL RECORDS

You will have to give your landlord timely access to your premises as needed to make repairs and show prospective lenders, purchasers, and tenants.

Medical personnel are required to keep confidential medical records either in paper or electronic files. Thus, you need the right to have any landlord representative accompanied by you or a member of your practice. If the lease ends and files and computers are abandoned, or

➔40

➔34 for some other reason, such as eviction, are not taken, there should be specific requirements for storage and eventual destruction of such records.

END OF LEASE

The lease should clearly spell out your responsibilities to remove any alterations to your space at the end of the lease term.

You will want to specify in the lease that you need not remove lead shielding or other special installations. The landlord will probably want you to remove these installations or will want to make that determination shortly before the lease ends, in case he finds another medical tenant.

Relocation clauses are becoming more common in leases. If a landlord customarily includes a right to relocate a tenant to another location, you should make sure the provisions cover the extra time and expense involved to relocate a medical facility.

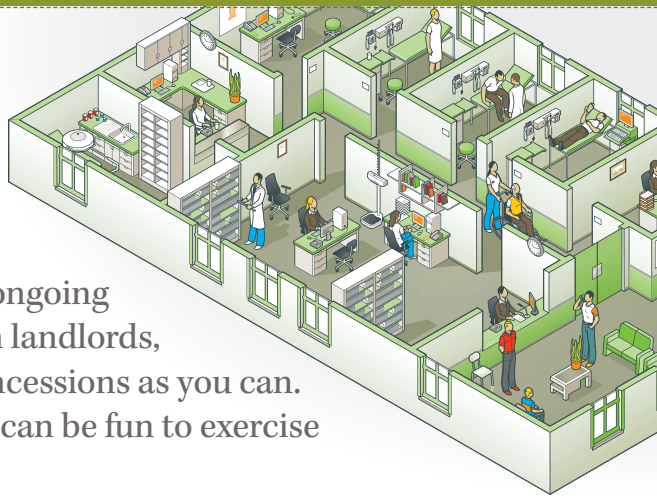
LIABILITY, INDEMNITY, AND INSURANCE

While landlords are responsible for providing services, they generally state they have no liability, especially if the lack of service is caused by a utility company or is the result of natural causes or other reasons beyond landlord control.

Landlords may seek an indemnity from the tenant against claims of injury or damage caused by the tenant's patients. In some states there is a strict liability statute that may hold the landlord liable if his actions

5 strategies for improving your leasing arrangement

By Judy Bee



In most negotiations, it's possible to spoil your ongoing relationship by being too hard a bargainer. With landlords, however, it's worth trying to obtain as many concessions as you can. Most landlords are excellent negotiators, and it can be fun to exercise your bargaining skills with the pros.

KNOW YOUR COMMUNITY

Knowing what's going on in your community could be your ticket to big rent savings. Property owners looking to salvage a bad investment may be willing to cut a deal. Paying attention to the commercial real estate market in your area can pay dividends.

DON'T LIMIT YOURSELF TO MEDICAL BUILDINGS

There was a time when management consultants uniformly advised physicians to "be where the doctors are. "That's still smart in some specialties. But if you have a solid marketing plan and the self-confidence that comes with a successful practice, moving into nontraditional quarters can save you money. Medical buildings are more expensive because they are designed with special amenities, but you may not need them.

RENT SHOULDN'T GO UP

When your lease is about to expire, you may become anxious, wondering just how much the rent will increase with your new lease. Many leases even contain clauses that cause the rent to increase each year during the term of the lease. Usually, the rent is indexed to some cost of living escalator with a minimum figure.

We don't understand what causes rent to increase at all. At the end of a 5-year lease, the building is 5 years older, the suite of offices 5 years more shopworn, and the parking lot 5 years more pot-holed.

Getty Images/Vetta/Peter Williams

Interested in buying instead? The pros and cons of investing in real estate: http://bit.ly/1i4Nsk5

or failure to act contributes to the problem.

A smart landlord will ask you to indemnify him against any such claims. The protection, of course, is insurance. In addition to your professional liability insurance covering X-ray exposure claims, consider general liability insurance (with the landlord as an additional insured) that would cover any claim due to building failures not covered under your malpractice policy.

EXCLUSIVES AND AMENITIES

Should you have an exclusive right to provide your medical specialty in the building or center? It may not be beneficial, and insistence on exclusivity could prevent you from being in a great location. Patients generally would not shop for services by walking from one office to another. More medical services at a location may give more credibility to those services.

The biggest benefit may be having a landlord familiar with medical needs and who has provided amenities for such needs. This could include better elevator service, extra facilities for the handicapped, or building-wide back-up generators.

In addition, a medical-use building providing many similar services could have in it a radiology lab or blood lab, making it convenient for patients to get tests and convenient for you to get results. ◘

Gerald H. Morganstern, JD, is managing partner of Hofheimer Gartlir & Gross, LLP,, a real estate and general practice law firm in New York, New York.

In many areas, new office spaces are available, with more modern facilities and (sometimes) more competitive offers.

Rent should decrease each time you renegotiate a lease, as the building deteriorates. If used at all, cost-of-living escalators should be applied only to the portion of your rent that reflects actual costs to the landlord: Taxes, insurance, utilities, and maintenance.

LANDLORDS HAVE A TURNOVER BUDGET

Chances are, if you move out, the landlord will have to refurbish your suite before he or she can rent it to someone else. Refurbishment, at a minimum, will involve new wall and floor coverings, but extensive renovations may be necessary.

The cost associated with space turnover gives you some bargaining edge. Why not have the same money spent on your suite for you?

If your suite doesn't need extensive refurbishing, why not negotiate for some free rent, just as a potential new tenant would? Every month an office remains vacant represents lost revenue to a building owner.

Rent should decrease each time you renegotiate a lease.

Landlords often are generous with improvement allowances, rent subsidies, and free parking to attract new tenants. Why should your landlord's willingness to spend be any different to keep an existing tenant?

MAKE DO WITH LESS

You may want to rethink how much office space you actually need. Most practices feel cramped, and you may be considering a move to larger quarters or expansion into adjacent space.Your landlord will be delighted to accommodate your needs if he or she can do so, but often, a much less costly solution exists.

By scheduling longer office hours, for instance, you may be able to increase the productivity of your office significantly without adding square footage. This "cubic day" scheduling technique involves opening the office for 10 or 12 hours each day instead of the usual 7 or 8 hours. Doing so gives physicians in a group practice the opportunity to work single office sessions of 5 to 6 hours each day, retaining large blocs of time in the morning or afternoon for other work activities. Frequently, it's possible to raise the production of a physician by 50% to 100% and add doctors to a group without increasing the office space.

Another option is to secure storage space for inactive medical records and bulk storage of supplies, as many practices do. Why use expensive medical office space to store toilet paper? Even better, throw away junk on a regular basis to free up space for storage. And consider securing other, less expensive office space in a commercial building for business office functions such as billing, transcription, and bookkeeping—a measure some practices take.

Realize the tax benefits of owning your office: http://bit.ly/1bOpYji

PATIENT-CENTERED MEDICAL HOMES
A new study casts doubt on the ability of medical homes to achieve their promise of lowering costs, improving outcomes [63]

Policy

MOC changes aim to lessen burden on physicians, but debate continues

by **BETH THOMAS HERTZ** *Contributing author*

HIGHLIGHTS

01 Maintenance of certification (MOC) standards have been updated to reduce redundancy and allow a more patient-centered perspective.

02 MOC critics say that member boards won't allow comments and suggestions that question the validity of certification.

Despite new standards designed to address time and cost pressures associated with participation in maintenance of certification (MOC), some **physicians believe the program represents one more expensive and redundant obstacle** as they attempt to climb a mountain of other bureaucratic and compliance mandates associated with Obamacare, International Classification of Diseases—10th revision (ICD-10), Health Insurance Portability and Accountability Act (HIPAA) compliance, use of electronic health records, billing and reimbursement challenges, and much more.

IN FEBRUARY the American Board of Medical Specialties (ABMS) announced new standards for maintenance of certification (MOC) programs that were designed to address objections about the time and cost required by the process.

The updated guidelines, which were developed over ➔44

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Lois A. Bowers, Editor-in-Chief, Medical Economics

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> As a group, physicians are lifelong learners. It's just in our DNA. The language in the new standards that calls for flexibility in the construct of activities, innovation in self-assessment and education, and working with specialty societies to develop practice and specialty-relevant activities, all may drum more people into participating."
>
> – MIRA IRONS, MD, SENIOR VICE PRESIDENT OF ACADEMIC AFFAIRS, AMERICAN BOARD OF MEDICAL SPECIALTIES

➔42

two years, are a framework for ABMS' 24 member boards to use when implementing their MOC program. Set to take effect in 2015, they are designed to reduce redundancy between physicians' MOC work and improvement projects in their practices.

The new standards also allow more innovation, have a more patient-centered perspective, and emphasize professionalism, patient safety, and performance improvement, says Mira Irons, MD, senior vice president of academic affairs at ABMS.

"Continuing certification and maintenance of certification are part of a physician's continuing professional development, and like any educational program, it requires re-evaluation and updating to remain current and relevant," Irons says.

The leaders of the American Board of Internal Medicine (ABIM) and American Board of Family Medicine (ABFM) both say that recent changes they have made in their MOC programs mean they are in alignment with the new guidelines. Some physicians who are vocal opponents of recertification and MOC, meanwhile, say the changes do not go far enough.

AN EVOLVING ARGUMENT

There is little doubt that MOC is a hot-button issue among physicians. And while substantial changes have occurred in the way certification has been granted historically, arguments against MOC run much deeper.

Some physicians say they do not find the educational activities and testing requirements relevant to their patients or practice. Although obtaining board certification is voluntary, critics charge there is growing pressure for physicians to participate because it is being increasingly linked to hospital privileges, insurance reimbursements, and network participation. In addition, a public awareness campaign by ABMS encourages patients to choose board-certified physicians, and lets them look up their physicians' status by visiting www.certificationmatters.org.

Physician resistance has come in many forms, too. For example, resolutions against MOC have been enacted recently by the American Medical Association and the state medical societies of New Jersey, Michigan, Ohio, Oklahoma, New York, and North Carolina, says Howard Mandel, MD, an Ob/Gyn in private practice in the Los Angeles area and MOC opponent.

The Association of American Physicians & Surgeons (AAPS) filed a lawsuit in April in federal court against ABMS, saying it restrains trade and reduces patients' access to their physicians. ABMS denies those allegations, and has filed a request to have the case dismissed or moved from Trenton, New Jersey, to its home base of Chicago.

Both sides point to studies that support their arguments, that MOC either enhances physician knowledge and quality, or that it has no such value.

Despite the polarizing debate, more than 450,000 physicians participate in the process. Irons says the recent changes may encourage even more to do so.

"As a group, physicians are lifelong learners," she says. "It's just in our DNA. The language in the new standards that calls for flexibility in the construct of activities, innovation in self-assessment and education, and working with specialty societies to develop practice and specialty-relevant activities, all may drum more people into participating."

THE CHANGES

ABMS had two main reasons to update its standards, Irons says. "Physician practice, knowledge, and skills continue to evolve over time and the standards need to reflect

that changing medical environment. Also, advances in self-assessment and learning activities and how we gather information have evolved as well."

ABMS did not acknowledge the resistance from physicians as influencing these most recent changes. The updates are expected to address the changes that have happened both in medicine and education since they were last reviewed in 2009, and address some of the comments ABMS has heard from physicians about making sure the standards are relevant and not overly burdensome.

Irons says the new standards encourage more innovation in terms of the types of activities that the member boards can accept for MOC credit.

"An example of innovation would be to develop MOC activities that reflect the latest adult learning principles and also reflect how physicians practice," she says. "For example, instead of physicians attending a lecture, which is often difficult for them to schedule, to offer more online activities.

"Also, there is language in the standards that allows the member boards to consider alternative ways of administering the high stakes exam, perhaps even to allow some resource information or open-book format, using the resources that are available for physicians in their practice settings today," she adds.

Efforts to enhance professionalism are evident in activities designed to help members be more sensitive to diverse patient populations, such as cultural competency activities that are specific to the cultural groups in physicians' practices, Irons says.

"Another example of the professionalism standard is to talk about the diplomates practicing wellness for themselves because when physicians are ill, they can't take care of their patients. It's an area we don't often think about but it's important to address," she says.

The Maintenance of Certification (MOC) debate

Argument for	Issue	Argument against
Obtaining board certification is strictly voluntary.	Participation	While it may be voluntary, MOC participation is being linked to hospital privileges, reimbursement, and network participation.
Maintaining board certification has helped some physicians improve their work and knowledge of the medical field.	MOC helps physicians	Other physicians say they do not find the educational activities and tests relevant to their patient bases, so the requirements do not help improve patient outcomes.
The new MOC standards will reduce redundancy between physicians' MOC work and improvement projects they are already doing in their practice, thus allowing more physician education that directly improves their practices.	Physician education	Physicians already engage in lifelong learning through CME requirements, so MOC requirements are redundant.
The ABIM has recently changed its policies to allow diplomates to pay their 10-year fee in annual installments instead of all at once.	Cost	MOC is a "money making scheme" by the boards, and any payment is an excessive burden on physicians who already are struggling to cope with government mandates and payer pressures.

Getty Images/Photolibrary/Adam Blasberg

THE 24 MEDICAL SPECIALTY BOARDS affected by recent MOC CHANGES:

- Allergy and Immunology
- Anesthesiology
- Colon and Rectal Surgery
- Dermatology
- Emergency Medicine
- Family Medicine
- Internal Medicine
- Medical Genetics
- Neurological Surgery
- Nuclear Medicine
- Obstetrics and Gynecology
- Ophthalmology
- Orthopaedic Surgery
- Otolaryngology
- Pathology
- Pediatrics
- Physical Medicine and Rehabilitation
- Plastic Surgery
- Preventive Medicine
- Psychiatry and Neurology
- Radiology
- Surgery
- Thoracic Surgery
- Urology

Source: ABMS

Most graduate medical education courses today incorporate didactic teaching and experiential learning in patient safety, and the updated standards seek to continue that, Irons says.

She says performance-improvement modules were heavily used in the past because that was the main way practice data were gathered. The new standards allow data to be gathered in more ways, such as through registries, patient logs, patient and peer surveys, or performance-improvement CME activities.

"The goal is to focus on improving patient outcomes, the patient experience, and the value of the healthcare experience," Irons says.

The updated standards also encourage physicians to be involved in practice improvement activities that are multidisciplinary and possibly aligned with other care-related quality improvement programs.

"We know that diplomates work across medical specialties as part of multi-professional healthcare teams and within complex healthcare systems," she says. "If physicians are doing performance-improvement and quality-improvement activities in their healthcare settings, we are asking member boards to allow them to get MOC credit for it."

Many healthcare settings didn't have robust performance-improvement or quality-improvement programs until recently, she adds. "Times are different," Irons says. "In the past 5 years, physicians have become more involved in these types of programs in their practice settings and the two have come together."

ABIM: PROGRAM IN COMPLIANCE

Richard J. Baron, MD, president and chief executive officer of ABIM, the largest of the ABMS member boards, says his organization was involved in revising the standards, and the new program ABIM rolled out in January is in full compliance.

"We are an active participant in ABMS and they communicated very carefully and consistently with us so we knew where our program stood relative to the evolving standards. It has been a coordinated effort on both sides," he says. "We had both been planning these updates for a while and there were multiple conversations across the organizations."

One example of recent change is to allow diplomates to pay their 10-year fee in annual installments, instead of all at once. Also, ABIM has added a variety of pathways that physicians can use to satisfy its requirements through activities they are performing within their health systems or professional societies, he says.

"There are lots of ways in which it has become easier to fulfill program requirements. We are deploying a more flexible program and we continue to evolve it and improve it," Baron says.

ABFM: AMBIGUITY IS CLARIFIED

The ABFM leadership also supports the new standards. "We feel they go a long way toward streamlining the MOC process and clarifying many of the aspects of the old standards that were ambiguous," says James C. Puffer, MD, ABFM president and chief executive officer.

For example, he says, previously there were developmental standards in the areas of patient safety, patient experience of care, and peer surveys.

"It was the expectation that between 2009 and 2013 ABMS member boards would experiment with developing and piloting tools for assessing each of those three areas. What is quite clear in the new standards is that while there is obviously considerable emphasis on the whole area of patient safety, the other two developmental standards, specifically around patient experience of care and peer surveys, resulted in the new guidelines being somewhat agnostic. There's no specific requirement for patient experience of care surveys, nor peer surveys. However, certainly member boards that wish to explore those areas are can do so," he says.

"We have gone to great lengths to continuously improve our program since it began in 2003 and have a very dynamic process that looks at every aspect of each of the four components of our program and attempts to improve every aspect of the tools we utilize to assess our diplomates in each of those areas," Puffer says.

Specifically, ABFM has sought to avoid making its physicians engage in redundant activities.

"A perfect example was our initiation of the Multi-Specialty Portfolio Approval Program that was jointly developed by ourselves and the boards of internal medicine and pediatrics," he says.

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CMS' Tavenner at HIMSS: No delays for ICD-10

THERE will be no more delays to the October 1 deadline to implement the International Classification of Diseases-10th revision (ICD-10) coding system.

That was the message from Centers for Medicare and Medicaid Services (CMS) Administrator Marilyn Tavenner during Thursday's keynote presentation to the Health Information and Management Systems Society (HIMSS) 2014 Annual Conference and Exhibition in Orlando, Florida.

Tavenner made the remarks to thousands of attendees during the Thursday morning session, addressing a range of topics from fee-for-service to the progress made following last fall's faulty rollout of HealthCare.gov.

In addressing the ICD-10 implementation timeline, Tavenner says, "Let's face it, we have delayed this more than once, and it is time to move on. We have already delayed the adoption standard, a standard the rest of the world has adopted many years ago, and we have delayed it several times, most recently last year. There will be no change in the deadline for ICD-10."

Earlier this month, the American Medical Association (AMA) petitioned CMS for a delay in ICD-10, due to financial and administrative costs that they say medical practices aren't ready for. According to the AMA, small practices can expect costs ranging from $56,639 to $226,105 to implement ICD-10. According to a February survey by the Medical Management Group Association, 79% of physicians report that they haven't begun ICD-10 implementation, or were only "somewhat ready."

Despite media reports questioning whether electronic health records (EHR) vendors and public and commercial payers will even be ready for the ICD-10 conversion, Tavenner says CMS will be.

In 2011, CMS began installing and testing system changes to support ICD-10. As of October 2013, the service systems at CMS were ready and a range of testing will ensue.

CMS ADDS QUALITY SCORES TO PHYSICIAN COMPARE WEBSITE

The Centers for Medicare and Medicaid Services (CMS) has added physician quality measures for diabetes and heart disease treatments to Physician Compare, the website designed to help patients select providers.

The website was launched in 2010 as a requirement of the Affordable Care Act. This year, quality measures will be reported for 66 group practices that participated in the Physician Quality Reporting System Group Practice Reporting Option, and 141 accountable care organizations that participated in the Medicare Shared Savings Program. The quality ratings are displayed using a five-star scale.

Right now, information for individual providers includes their name, education, and contact information. Eventually, the website will include patient experience data.

"This is an important first step in publicly reporting quality measures on Physician Compare," said Patrick Conway, MD, CMS chief medical officer and deputy administrator for Innovation and Quality in a press release.

➔46 "The program, which has just successfully been transferred to the ABMS, provides an opportunity for diplomates who are doing quality improvement work within their institution or within their medical group or professional societies to be appropriately recognized and for individual diplomates to receive appropriate credit for the work they have undertaken along with their colleagues."

Physicians who participate in boards that are not as far along in the evolution of their MOC process as ABIM and ABFM will most likely see greater changes, Puffer adds. "The good news is that before they move too much further in maturing their programs, they will be able to adopt and comport with these new guidelines that streamline and make the entire MOC process more efficient."

AAFP: MAXIMIZE QUALITY, MINIMIZE BURDEN

Mindi K. McKenna, PhD, MBA, director of the continuing medical education division of the American Academy of Family Physicians, agrees with Puffer that family medicine has already made many improvements over the years that some other specialties are just now making.

"For instance, tightening up the frequency in which practice assessment and performance improvement kinds of endeavors are undertaken and reported, having a secure exam, having that kind of ongoing approach to maintaining your competency and effectiveness," she says.

She says a lot of thought went into the nuances of the details of the revisions. "ABMS' communications indicated that they were working really hard to find that balance of enough stability and consistency over time that it doesn't put an undue administrative burden or cost on physicians," she says. "We provided comments and encouraged ABMS to continue to be cognizant of trying to find ways to maximize the value for patient care to ensure that patients are getting the best possible care while minimizing the burden on physicians."

DISSENTERS

Despite the optimism expressed by these leaders, some physicians say the latest changes do not address the real problem.

"The fact that they are calling these 'new rules' is somewhat preposterous considering how long this has all been in effect," says Ron Benbassat, MD, who has been in practice in California for 20 years and is certified and recertified by ABIM. He is a leader in the organization Change Board Recertification.

"All board certificates must be converted to lifetime status. Only then will MOC be voluntary," Benbassat says. "We already engage in lifelong learning through CME requirements to keep our licenses. MOC is nothing more than a money-making scheme by the boards."

> All board certificates must be converted to lifetime status. Only then will MOC be voluntary. We already engage in lifelong learning through CME requirements to keep our licenses. MOC is nothing more than a money-making scheme by the boards."
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> — RON BENBASSAT, MD, ABIM CERTIFIED PHYSICIAN, LEADER OF CHANGE BOARD RECERTIFICATION GROUP

The combined revenue of all the boards in the United States is more than $350 million, Benbassat says. "Who benefits from these tests? I would argue that it is the 450 board members, not the 800,000 private physicians in the United States," he says.

Benbassat also objects to the boards' statements that they accepted comments online during the revision period. Several opponents of MOC provided *Medical Economics* with e-mails they received stating that their comments were not being posted because they did not meet the criteria set by the moderator. "Many people tried to submit statistics and information about MOC and they were rejected," Benbassat says.

Baron readily acknowledges that some dissenters' comments were not allowed on the ABIM forum.

"It's not an open forum. It's a moderated forum, and it is moderated according to principles that are posted on the site," he says. "We welcome input on the program, but if people are going to take a subject area and post comments that say there shouldn't be any program, people will not bother to read the comments or engage in the conversation."

"When people say all we care about is money and that the program should be done away with, we simply don't regard that as a comment that is engaged with how to make MOC better. We know there are people think there should not be MOC and they have lots of places on the Internet where they make that point. We are trying to manage a civil discourse on a subject on which there is a range of opinion," he says.

He points out that many comments critical of MOC were allowed past the moderator. "It is one thing to offer specific criticisms of the program, but another to say there shouldn't be a program and we don't see the role of this conversation to be to give a platform to that," Baron says. ◻

EHRs' interoperability challenge

HIE expansion aimed at helping providers exchange health information safely, but not all services created equally

by **DEBRA BEAULIEU-VOLK** *Contributing author*

HIGHLIGHTS

01 The upside of health information exchanges—which eliminate the need to print, scan, and fax documents—can boost productivity in your office by exchanging information directly with specialists, subspecialists or hospital systems.

02 Meaningful use requires that EHRs support electronic exchange of information, but 2014 certified systems have not yet been widely deployed.

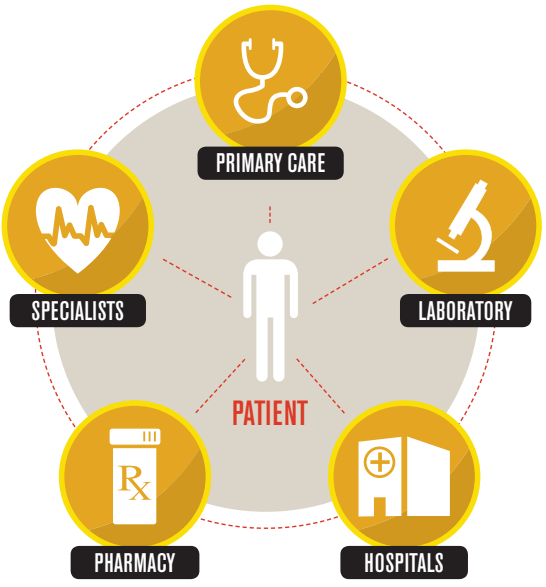
Most adults can access their cash anywhere, and few banking customers would tolerate it any other way. Health information, however, is still largely walled off from one institution to another. Experts say that **fewer than 40% of physician's offices** have the ability to share that information with other providers via a health information exchange (HIE), and many physicians don't know what HIEs provide.

ALTHOUGH MOST physicians recognize the clinical benefits of efficient electronic exchange of health information—for example, an emergency department being able to access a patient's medications, allergies and problem lists—the incentives have yet to outweigh the challenges of widespread interoperability, according to Joseph C. Kvedar, MD, founder and director of the Center for Connected Health, a division of Partners HealthCare; a board-certified dermatologist; and associate professor of dermatology at Harvard Medical School.

"Sadly, in healthcare, the business model to reward participants for making those data streams interoperable hasn't been figured out yet," he says. "The federal government is saying that you have to be on an exchange—it's a regulation—and people are complying. But from a financial perspective it hasn't really

How Health Information Exchanges (HIEs) work

HIEs allow healthcare providers to share clinical information among different systems to facilitate access to and retrieval of clinical data to provide safer and more timely, efficient, effective, and equitable patient-centered care.



Source: HealthIT.gov

become clear to anyone why that would be a good idea."

WHAT IS AN HIE?

Another reason for the low participation is confusion, says Rosemarie Nelson, a principal at Medical Group Management Association Health Care Consulting Group and a *Medical Economics* editorial consultant.

For starters, the acronym 'HIE' could be misunderstood to stand for 'health insurance exchange,' which is actually abbreviated as 'HIX.' And even in the correct realm, 'health information exchange' is also frequently used as a verb referring to the movement of the data. For clarity (which may unintentionally make matters worse), some organizations refer to the noun form as a 'health information organization,' or HIO.

"Some people don't even know that this concept of health information exchange exists," Nelson says. "It's nebulous—more nebulous than the cloud. And here's a mechanism that would use the cloud to share information, but it's even more esoteric."

HIEs VS. RECs

To help address knowledge gaps, the American Medical Association (AMA) has published a list of physicians' frequently asked questions about HIEs. Aiming to sort out even more alphabet soup, the authors explain the distinction between HIEs and regional extension centers (RECs).

RECs are entities funded by the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) to assist physicians—and small practices in particular—implement and maintain electronic health records (EHRs).

When looking to learn more about joining an HIE, your local REC is a great place to start. In Massachusetts, however, the Massachusetts eHealth Institute (MeHi) is both the ONC award grantee for health information exchange and the REC, notes Laurance Stuntz, MeHi executive director. Nationally, many HIEs are leveraging RECs to help sign up providers, he says. "Extension centers, as part of their ongoing sustainability, are trying to figure out how to deliver value-added services to keep themselves in business and help keep the knowledge base that they've developed. Many of them are offering some HIE connections," Stuntz says.

HIE QUALITY VARIES

Also potentially slowing HIE enrollment is a perceived lack of availability of HIEs to join in some areas, notes Nelson.

"Even in New York, we have only a couple of initiatives," she says. "We have one that's driven more upstate and another more driv-

> "What we see is that organizations that start to use health information exchange don't stop."
>
> — LAURANCE STUNTZ, EXECUTIVE DIRECTOR, MASSACHUSETTS EHEALTH INSTITUTE

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en in the New York City area. It offers great access to information, but it's not always easy to import and download data into your EHR, which takes us back to the whole integration issue and easy sharing across disparate vendors."

Estimates vary, but there are as many as 280 HIEs in the United States that enable the electronic sharing of health-related information, according to the Agency for Healthcare Research and Quality.

"So it's not that there aren't that many HIEs, because they seem to be pretty widely dispersed and every state has at least some activity in HIE," Stuntz says. "To me, the challenge is really integration with the EHR. We've really not seen good integration with EHRs or HIEs."

Meaningful Use 2 requires that EHRs support electronic exchange of information,

Questions to ask an HIE vendor before signing a contract

Q: What are other practices and healthcare organizations in my community doing in terms of HIE participation, and how will this impact my business?

Q: How will joining the HIE disrupt or delay the work flow of my office during implementation?

Q: Will my data be used for evaluating my performance or other analysis? If so, is there transparency surrounding the methodology used?

Q: Is there physician representation on the HIE's governing board?

Q: Who owns the clinical data transmitted by the HIE?

Q: What patient populations, referral networks, hospitals, and physicians does the HIE include? Does the HIE connect with the facilities, labs, and providers with whom I need to interact, or will I need to participate in multiple HIEs to access all of the necessary entities?

Q: Does the contract hold the physician liable for the accuracy and completeness of the data provided to the HIE and any adverse outcomes that result from the use of HIE data?

Q: Are stakeholders across the HIE using the same standard terminology and format for data exchange?

Q: How can the physician get out of the HIE contract?

Q: What types of user testing and training will be provided to physicians joining the HIE?

Q: How much will it cost to participate, and how will I be charged (by transaction, monthly, or annually)?

Q: What are the risks involved with participating in an HIE, and who assumes liability for those risks?

Source: American Medical Association

Thinkstock/iStock/KeremYucel

he explains, but 2014 certified EHR systems are not yet widely deployed.

THE CASE TO CONNECT

Once a practice adopts an EHR system, the additional expense to connect to an HIE typically is minor. In Massachusetts, for example, MeHi enrollment costs $5 per doctor per month, Stuntz says, adding that many EHR vendors charge similar rates to connect to their HIEs.

And in theory, that investment should pay for itself in increased efficiencies. For example, offices can save time and money by avoiding the manual printing, scanning and faxing of documents; not having to physically mail or fax records and follow up by phone to verify delivery; and less need to recover missing information or conduct duplicate tests.

"What we see is that organizations that start to use health information exchange don't stop," Stuntz says.

To aid in evaluating HIE contracts, the AMA has published a worksheet delineating key questions for physicians to ask before going into an agreement. One of many important considerations, for example, is how the HIE handles and guarantees privacy of patient information. Because patients' explicit consent is required before sharing their medical information over an HIE, you want to be able to confidently assure their records are safe.

BIGGER DRIVERS TO COME

Perhaps the biggest barrier to wider HIE enrollment is not so much driven by objection, but by the myriad competing priorities physician practices are facing today. Stuntz and Nelson agree that the looming deadline to convert to the International Classification of Diseases—10th Revision (ICD-10) coding system is taking up a lot of practices' focus at the moment.

But as the healthcare industry increasingly moves away from fee-for-service reimbursement and more practices begin to enter quality and risk-based contracts, interest in HIEs will likely build, Stuntz predicts. "I think there were limited direct incentives for HIE in the past, but as HIE becomes a critical piece of supporting alternative payment arrangements, I expect a change over the next couple of years," he says.

HIPAA COMPLIANCE REQUIRES INFORMING PATIENTS OF PRIVACY RIGHTS

By Jeffrey Bendix, senior editor

Being able to exchange patient health information electronically with other providers will greatly benefit patients. But it also comes with legal obligations you need to be aware of.

The rules regarding privacy safeguards for patient health information are part of the Health Insurance Portability and Accountability Act (HIPAA). First passed in 1996, HIPAA has been updated to keep pace with changes in technology, especially the use of e-mail and other forms of electronic communication, and the widespread adoption of electronic health records.

The most recent update occurred in 2013 with the adoption of an Omnibus Rule that supplemented HIPAA's rules governing the privacy, security, and breach notification for patient health information. In terms of health information exchange, a crucial requirement for medical practices is ensuring that patients are aware of their privacy rights, says Daniel Shay, JD, a healthcare attorney with Alice G. Gosfield and Associates in Philadelphia, Pennsylvania.

The reason, Shay explains, is that although the HIPAA Omnibus Rule requires obtaining a patient's consent for certain disclosures of health information, it makes exceptions for purposes of treatment, payment, and operations. But patients still must be made aware of their privacy rights, Shay says, a requirement practices must meet by distributing and/or posting a notice of privacy practices (NPP).

"Providers should have updated their NPPs after this most recent (Omnibus) rule was published," says Shay. "In that (update) should be a statement that 'we may disclose your information to other providers who are treating you,' or similar language. As long as they provide that, they've basically met their requirement to inform patients about disclosures for treatment purposes."

For purposes of exchanging health information, it's not necessary to get the patient's consent to all the provisions of the NPP, but only the acknowledgment that the patient has seen it, says Lisa Gallagher, BSEE, CISM, vice president for technology solutions for the Health Information Management Systems Society.

"It (the NPP) is informing the patient that what the provider is doing is normal practice under the law to care for the patient adequately," she says. "The patient doesn't have to agree to it, they just have to see it, and the doctor can make a note that the patient was presented with it and proceed as usual."

Of course, informing patients of their privacy rights does not relieve doctors of the obligation to use HIPAA-compliant methods to exchange protected health information (PHI), says Kenneth Rashbaum, principal with the law firm Rashbaum Associates LLC in New York, New York. "This has been a significant concern, because even though they've been advised to the contrary, a lot of physicians only use commercial e-mail, and that's not a secure way to exchange patient information," he says.

Much PHI exchange now takes place via private applications such as a cloud site or virtual private network. Rashbaum advises clients to get specific consent from patients when using those methods. "I often recommend that doctors get patient consent that their information may be sent over a secure third-party site to share with other caregivers participating in their treatment, or something along those lines," he says. "The transparency is helpful."

Another consideration is how much of the patient's medical history the receiving provider should get. The HIPAA Privacy Rule says providers must make "reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request."

The law allows providers some discretion in deciding what constitutes the "minimum necessary," says Gallagher. Even so, "the sending provider should at least ask, 'do I need to send the patient's entire medical history? Or is there a portion I can send that will be sufficient for this purpose?'"

Practical Matters

FIVE WAYS TO OPTIMIZE YOUR PATIENT SCHEDULE FOR EFFICIENCY

by **KEITH BORGLUM, CHBC** *Contributing author*

Patient scheduling is one of the most important operational systems in your practice for the delivery of care; for physician, patient, and staff satisfaction; and for practice profitability. Often it does not receive the attention it needs, to the detriment of the practice. Here are five tips to improve your scheduling process.

Prioritize complex visits

Each patient visit has different levels of complexity. Assign weight to the different visits and list them for reference by your schedulers. Manage uncomplicated issues outside the office visit by phone, email, and group visits.

While this may not be directly reimbursed, it can provide indirect financial rewards by increasing the complexity of office visits. The average reimbursement per visit should go up, offsetting the loss of simple visits.

Focus on maximizing work relative value units (wRVUs) per visit rather than office visit counts. If your days still overflow, hire other providers to treat the lower levels of acuity.

Create organized triage

Providers often get interrupted by schedulers about working in patients. Create a triage chart for the scheduler to use. The chart should rate your top 20 symptoms by a series of criteria. The criteria should include the symptom, appointment urgency, and appointment length. Create codes for urgency and for appointment length.

This results in a grid that will allow you to assign appointments to physicians or midlevels depending on the urgency, complexity, and anticipated length of an appointment.

Manage calls

Processing phone calls intrudes on schedule flow. Calls need a system of controls set up by physicians beyond phone message slips or apps. Create a guide for staff on processing calls. Distribute it to nurses, medical assistants, office managers, and billers.

Each has a structure of what calls to put through immediately, which calls will be returned, and when they will be returned.

Work toward open access

The goal of open access scheduling is to do today's work today, and see patients on the day they call when possible.

This is not always possible, and is often impractical outside of urgent care or emergency settings. It can take months to achieve for practices already scheduled weeks ahead.

Gradually reduce the pre-appointed visits to no more than 70% of the day, with even fewer on Mondays and after holidays, when urgent-access visits are in high demand. Maintain a list of patients who want to be seen sooner, and call them to in-fill or "compress" the schedule on the same day.

Use quick huddles

Keep patient scheduling on the agenda for monthly office meetings.

A highly effective technique is when the provider arrives and is ready to see patients, have a standup, one-minute huddle with the provider, the scheduler, and the medical assistant to look at the upcoming bloc of patients for a discussion about how to manage it.

Keith Borglum, CHBC, *is a practice management consultant with Professional Management and Consulting, Santa Rosa, California. Send your practice management questions to* ***medec@advanstar.com****.*

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

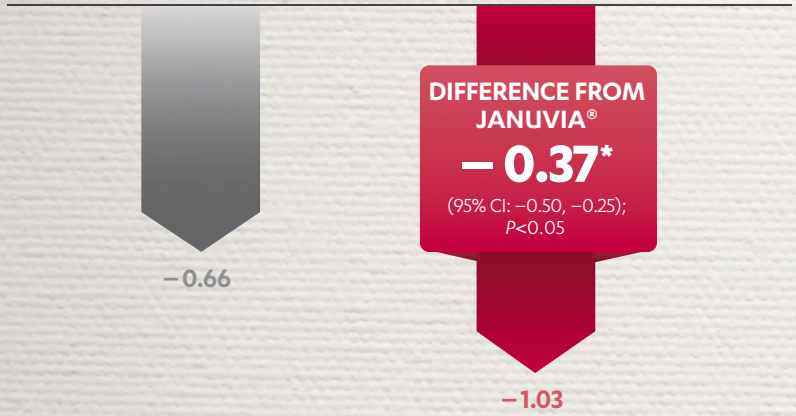
CONTRAINDICATIONS

- 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.

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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

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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

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Coding Insights

HOW TO CODE LABORATORY TESTS WAIVED BY FEDERAL REGULATIONS

Q Our office is Clinical Laboratory Improvement Amendments (CLIA)-certified. Can you provide an update on which tests are CLIA-waived?

ACCORDING TO CLIA regulations, a facility is required to be appropriately certified for each test performed.

According to the Centers for Medicare and Medicaid Services, (CMS), laboratory claims are currently being edited at the CLIA certificate level in order to ensure that the Medicare and Medicaid programs only pay for laboratory tests categorized as waived complexity for those entities that hold a CLIA certificate of waiver.

Listed in the chart to the right are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. Modifier QW (CLIA waived test) needs to be appended to the CPT codes for the listed tests with the exception of 82962 (Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use).

CLIA-waived tests are those that are cleared by the FDA for home use. Waived tests must be simple and have a low risk for erroneous results, though the tests are not error-proof. ◘

*The answer to the reader's question was provided by **Renee Stantz**, a billing and coding consultant with VEI Consulting Services in Indianapolis, Indiana. Send your practice management questions to **medec@advanstar.com**.*

G0434QW Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

Effective date	Description
May 29, 2013	"SCI International Inc. New Choice At Home Drug Test: Marijuana (Strip Format)"
July 29, 2013	Alere iCup DX 14 (Cassette Dip Card format)
September 25, 2013	American Screening Corporation, Inc. Discover Drug Test Cards
September 25, 2013	American Screening Corporation, Inc. Discover Multi-Panel Drug Test Cups

82465QW Cholesterol, serum or whole blood, total

83718QW Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)

84478QW Triglycerides

82962 Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

Effective date	Description
July 1, 2013	Infopia USA, LipidPro® Professional Lipid Profile and Glucose Measuring System
November 12, 2013	Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System

Legally Speaking

PREVENTING UNAUTHORIZED RECORDING AT YOUR PRACTICE

by **STACEY L. GULICK, JD** *Contributing author*

We all know audio, video, and photography capabilities are standard on smartphones and tablets, allowing anyone to record anywhere, including physician offices. For healthcare, these features have caused troubling incidents related to the unauthorized dissemination of information about patients and practices. While it's impossible to completely prevent unapproved recordings, steps can be taken to minimize the risks. Here's how:

ALL PRACTICE staff should be instructed to never record patients unless they have approval of both the patient and the practice. This should be included in written policies.

The actual recording of patients is not prohibited by law. However, the use and disclosure of such recordings are strictly regulated by numerous federal and state laws and accreditation standards. Except in very limited circumstances, the patient's authorization is required before using or disclosing recordings.

Patient authorization

There are different requirements for authorizations depending on the purposes of the recording and its use.

In all circumstances, the patient's authorization for the practice and its staff to record and use or disclose such recordings should be in writing. If the recording is for treatment purposes, a general consent form is typically sufficient.

If the recording is for the practice's external purposes such as research or marketing, a separate authorization that complies with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) must be used.

If the patient requests the recording for his or her own purposes—such as to document before and after images for certain procedures, or to participate in a television documentary—the authorization should be accompanied by language that releases the practice from liability for subsequent use of the recording. Having the written approval of the patient for the recording is a strong defense against any future allegations by the patient or a regulatory or accreditation agency.

Staff violations

If it is determined that a staff member has violated the practice policies regarding unauthorized use or disclosure of recordings (e.g., a technician takes a picture of an unusual skin condition and texts it to a friend or posts it on Facebook), immediate action needs to be taken.

First, steps must be taken as quickly as possible to mitigate any harm (e.g., any unauthorized posts must be taken down). Then the practice needs to evaluate whether the incident constitutes a "breach" under HIPAA, and follow its breach notification policy.

The practice could face significant financial consequences with potential HIPAA penalties of up to $1.5 million per year for the same type of violation as well as exposure to state regulatory penalties.

Less control of patient recordings

The practice has less liability for the actions of its patients and visitors, but the practice also has less control over the actions of those groups.

Once again, a good starting point is a policy that prohibits recording without approval.

This can be best communicated by signs

Legally Speaking

in the waiting and public areas.

If the practice becomes aware that a patient or visitor has captured another patient on a recording, the practice may not have a legal obligation to inform the affected patient, but should consider doing so to allow the affected patient an opportunity to protect against harm.

Depending on the facts and circumstances, it may not be permissible to inform the affected patient of the identity of the person who made the recording because the confidentiality of the person who made the recording may also be protected. Navigating these areas of confidentiality and transparency with your patients is important for gaining their trust.

Dealing with noncompliance

Another difficult question is how to respond if a patient refuses to stop recording, particularly during treatment.

In some circumstances, the practitioner may be comfortable with the recording, but practitioners should be aware that such recordings can be used for subsequent legal action, including malpractice claims, even if the practitioner believes that the care was appropriate.

If the patient who refuses to stop recording is capturing the images of other patients, it is within the purview of the practice to require the patient to leave the premises. If there is a health-related reason that the patient cannot be removed from the premises, he or she can be seated in a treatment room away from others.

If a patient refuses to cease recording during treatment, practitioners can refuse to treat the patient or discharge the patient from the practice, especially if a clear policy prohibits recording. Refer to laws and regulations on discharging a patient in your state first.

It may seem like a solution to simply prohibit recording devices, but that is practically impossible.

Instead, the practice must be aware of the risks, and implement the strategies discussed herein and other identified safeguards to protect the practice and the confidentiality of its patients. ◘

Stacey L. Gulick, JD, *is a partner at Garfunkel Wild, P.C. in Great Neck, new York. Send your legal questions to* ***medec@advanstar.com****.*

Use these FIVE STRATEGIES to protect your practice against unauthorized recording

Create clear policies for staff

Recording patients is not against the law, but there are rules about consent and what can be disclosed. Make sure your practice has clear policies about video and audio recording, and photography.

Obtain patient consent

There are different requirements for patient authorization depending on the purpose of the recording, but it is good practice to require patients to authorize any video, audio or photography.

Publicize the recording policy

Make sure patients and staff members in your practice know about your recording policy. Pass out information sheets to new patients and post signs in the waiting room and throughout the practice.

Create consequences for policy violations

There must be consequences for patients and staff members who violate your recording policy. Physicians can refuse to treat a patient who violates the policy. Staff members should be disciplined in accordance with your practice's personnel policy.

Notify patients about breaches

A video of a patient that goes public may be a HIPAA breach. You should notify the patient, even if your practice does not have a legal obligation to inform. Notification provides the affected patient an opportunity to protect against harm.

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Our current economic climate is very scary at best. Today **70% of physicians' main concern is future compensation.** Concerns include Obamacare, Medicare, Medicaid, reduced insurance reimbursements, malpractice insurance, compliance, practice management, overhead, kids, family, college, aging parents, retirement and oh, taxes. **How do you make a living safely and insure the long term value of your retirement without risking a dime?**

The safest and most secure move you can make is to build a portfolio of Antique Guns that is buried in your safe. In my humble opinion, in 20 to 25 years when you retire, a portfolio of Antique Guns will be worth more than the same money in stocks, bonds, an IRA or 401K. **Some stocks and bonds have gone to zero, right?** You think Antique Guns will ever go to zero? John Williams from Shadow Stats, for 30 years, has been exposing the hidden truth in government economic data, minus Wall Street & political hype, simply the bitter U.S. economic reality.

Williams thinks the **U.S. systemic solvency crisis of the last 5 years is accelerating unabated.** Resulting in an inevitable economic meltdown, and hyperinflationary great depression. Creating a complete loss in the purchasing power of the U.S. and a collapse in the U.S. financial system. **Mr. William's timing on hyperinflation is 2015.** All instigated by Ben Bernanke's plan to debase the dollar since 2010, QE 1, 2, 3.

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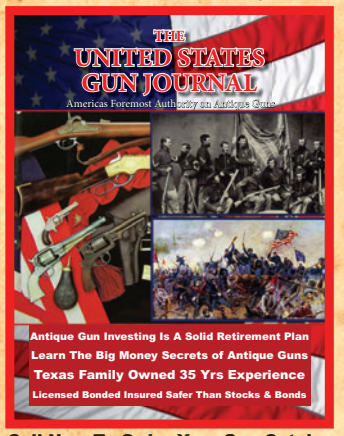

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The U.S. is at a first ever 2+ years of a lower AA+ credit rating, from a perfect AAA, of U.S. Treasury debt rated by Standard & Poor's. **The uncertainty is multiplied by a $16 trillion dollar national debt.** The budget deficit hit a record $6.6 trillion in 2012, or 42% of GDP, highest in history, forcing the U.S. into a certain mortal long term solvency crisis. Williams warns **"Hyperinflation remains a virtual certainty."** What should you do?

You must secure financial catastrophe insurance on the value of your money. **You can't buy flood insurance after the flood, can you? You insure every part of your life; why not insure the value of your money? You are safer to err on the side of caution than to weather this financial hurricane uninsured.** You wouldn't drive your car without insurance, or not have home owners insurance, or not renew your malpractice insurance, would you? Then doesn't it make sense to insure the value of your money with a portfolio of Antique Guns? Call now, you will be glad you did!

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The Last Word

PATIENT-CENTERED MEDICAL HOMES: NOT YET DELIVERING ON PROMISE

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

A new study of one of the nation's largest Patient-Centered Medical Homes (PCMH) pilots shows that the model has yet to deliver on its promise of lowering medical costs and improving outcomes for chronically ill patients.

A TEAM OF researchers from the RAND Corporation, Harvard Medical School, the University of Pennsylvania, and others studied changes in the quality, utilization, and cost of care provided by 32 small and medium-sized medical practices in a pilot PCMH in southeastern Pennsylvania. They examined performance data on 11 quality measures for diabetes, asthma, and preventive care, as well as changes in hospital and emergency department use, and costs of care.

After examining three years of data—from June 2008 through May 2011—the researchers found improvement in one quality measure—nephropathy screening in diabetes. They found no changes in hospital or emergency department usage or the cost of care.

"We were a little surprised by the findings, mainly because expectations of the medical home concept have been very high," Mark W. Friedberg, MD, MPP, a scientist at RAND and the study's lead researcher tells *Medical Economics*. "Based on the strength of evidence of how important primary care is to overall patient health and the quality and efficiency of care, we expected to see more of an effect than we did at this particular pilot."

The research team also compared data from the PCMH practices with data from 29 similarly sized practices in the region that were not part of the pilot. They found no significant differences between the two groups in any of the areas measured.

Friedberg cautions that the study's findings shouldn't be interpreted to mean that the PCMH model can't work. "It's really just to say there's not guarantee that all attempts to implement the model are going to meet the high expectations for it," he says.

Other studies have shown improvements in outcome and lowered costs in PCMH settings. In July 2013 Independence Blue Cross (IBC) announced results of a series of studies of PCMHs in Pennsylvania. The studies found significant reductions in medical costs for patients with chronic conditions treated in primary care practices that had been transformed into medical homes, especially among patients with diabetes. Those patients saw a 44% reduction in hospital costs and a 21% reduction in overall medical costs.

Diabetic patients treated in the studied PCMHs also saw a 60% improvement in getting their low-density lipoprotein levels under adequate control. Overall, the number of patients with poorly controlled diabetes declined by 45%, according to IBC.

Friedberg notes that research on PCMHs is continuing, both by his team and others. "Once we have results from these (studies) we'll be able to look at those that performed better and those that performed less well, and deduce in a quantitative way what seems to make a difference," he says.

Results of the study were published in the February 26, 2014 issue of the *Journal of the American Medical Association*.

@ Do you believe that the Patient-Centered Medical Home is the future of primary care, or another failing model? Send your thoughts to medec@advanstar.com. Your comments could be included in the next issue of *Medical Economics*.

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